PROCEEDINGS

NINETY-NINTH
ANNUAL MEETING

UNITED STATES ANIMAL
HEALTH ASSOCIATION

JOHN ASCUAGA'S NUGGET HOTEL
RENO, NEVADA

October 28-November 3, 1995
This book is dedicated in memory to the members on USAHA who passed away in 1995.

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CONTENTS

Officers and Committees ................................................................. ix
Record of Previous Meetings ......................................................... xxviii
Invocation and Memorial Service - M. R. Marshall ......................... xxxi
Welcome to Nevada - Mr. Paul Iverson, Administrator, Division of Agriculture, Reno, NV ................................................... xxxii
Response to Welcome - C. E. Starkey ........................................... xxxiii
A Message from the Under Secretary of Agriculture for Food Safety - Mr. Michael R. Taylor, Washington, DC. .................. xxxiv
Remarks of the President of USAHA - H. W. Towers, Jr. ................ xliii
Remarks of the President of AAVLD - D. H. Lein ........................... xlvi
National Assembly Award - F. Y. Rogers ..................................... I
APHIS Animal Health Award - L. J. King ................................... li

ANIMAL DISEASE SURVEILLANCE AND ANIMAL HEALTH INFORMATION SYSTEMS

Animal Health Information - A National Portfolio - N. Wineland .......... 1
Experience with Animal Health Monitoring and Surveillance Programs in Switzerland - K. Stark ................................. 6
Identification and Consolidation of Existing Data Sources and Standardization of Disease Definitions and Reporting - Workshop Report - F. Elvinger ........................................ 15

ANIMAL WELFARE


AQUACULTURE

Taura Syndrome: An Economically Important Viral Disease Impacting the Shrimp Farming Industries of the Americas Including the United States - D. Lightner ........................................ 36
An Introduction to the Salmonid Eggs Industry - M. Jansen ............... 53

BIOLOGICS & BIOTECHNOLOGY

Evaluation of a Potential Swine Influenza Vaccine - P. Foley, B. Moss, R. Levings, L. Wyatt, D. Saari and S. Hanson .................. 61
BLUETONGUE AND BOVINE RETROVIRUS


The Implications of Genetic Variability of Viruses in Bluetongue Virus Infection - B. I. Osburn, C. A. de Mattos, C. C. de Mattos and N. J. Maclachlan ............................................................................... 81

Report of the Committee on Bluetongue and Bovine Retrovirus - L. D. Miller, et al. .................................................................................................................. 95

BRUCELLOSIS

Placentitis Induced by Brucella Abortus Strain RB51 in Pregnant Cattle - M. V. Palmer, S. C. Olsen, M. G. Stevens and N. F. Cheville ........................................................................... 104

Efficacy of Brucella Abortus Strain RB51 to Protect Cattle Against Brucellosis - S. C. Olsen, M. Stevens, M. Palmer and N. F. Cheville .................................................................................. 108

Identifying Candidate Genes for Natural Resistance to Brucellosis - L. G. Adams and J. W. Templeton .................................................................................. 111


Current Brucellosis Situation in the Greater Yellowstone Area - Bob Hillman ........................................................................................................... 144

CAPTIVE WILDLIFE AND ALTERNATIVE LIVESTOCK

Report of the Committee on Captive Wildlife and Alternative Livestock - C. W. S. Lum, et al. .................................................................................. 148

ENVIRONMENTAL RESIDUES


EPIZOOTIC ATTACK


Report of the Committee on Epizootic Attack - J. P. Huntley, et al. ........ 158


National Perspective on Avian Influenza - K. Preston. .................................................................................. 163

Veterinary Service - Emergency Programs-Foreign Animal Disease
Surveillance Activities in FY 1995 - J. Williams .................. 165
Bovine Spongiform Encephalophthy (BSE) - J. Williams .................. 171

FEED SAFETY


FOOD SAFETY

Report of the Committee on Food Safety - J. L. Blair, et al. .............. 182

FOREIGN ANIMAL DISEASES

The Contribution of Exandis to AAHC to the Evolution of Animal Health Services in Australia - S. Hoare ........................................ 187
Report of the Committee on Foreign Animal Diseases -
C. Gale Wagner, et al. ................................................................. 193
Joint Session: The Committee on Epizootic Attack and the Committee on Foreign Animal Diseases - C. J. Maré, et al. ...... 209

GOVERNMENT RELATIONS

Report of the Committee on Government Relations -

HEMOPARASITIC DISEASES

Report of the Committee on Hemoparasitic Diseases -
R. Harrington, et al. ................................................................ 229
Equine Granulocytic Ehrlichiosis: Epidemiologic and Zoonotic Implications - M. Ristic, C. J. Holland and L. Wanduragala ...... 231

IMPORT/EXPORT

Report of the Committee on Import/Export - J. C. Lemmermen, et al. 246
Minutes on Embryo Movement Subcommittee - S. V. Timberlake. ...... 251
National Center for Import and Export - R. F. Kahrs. ....................... 257

INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA

Potentiation of Bovine Respiratory Syncytial Virus Infection in Calves by Bovine Viral Diarrhea Virus - C. L. Kelling,
B. W. Brodersen, L. J. Perino, V. L. Cooper, A. R. Doster
and J. A. Pollreisz. ..................................................................... 273
Report of the Committee on Cattle, Bison and Llama - C. S. Card, et al. 279
Diagnosis of Mycobacterium Bovis Infections in Llamas -
M. Essey, J. Rhyan .................................................................... 293
INFECTIONOUS DISEASES OF HORSES

Report of the Committee on Infectious Diseases of Horses - R. C. Knowles, et al. .......................................................... 294

JOHNE'S DISEASE

Ongoing Johne's Research at National Animal Disease Center - J. Stabel .......................................................... 311
Johne’s Disease-The International Perspective - M. T. Collins and J. B. Manning .......................................................... 313
Report of the Committee on Johne's Disease - R. H. Whitlock, et al. ....... 317

LEPTOSPIROSIS


LIVESTOCK IDENTIFICATION

Report of the Committee on Livestock Identification - J. L. Lindstrom, et al. .......................................................... 328

NOMINATIONS AND RESOLUTIONS

Report of the Committee on Nominations and Resolutions - T. J. Hagerty, et al. .......................................................... 353

PARASITIC DISEASES AND PARASITICIDES

Report of the Committee on Parasitic Diseases and Parasiticides - W. E. Pace, et al. .......................................................... 363

PHARMACEUTICALS

The Center for Veterinary Medicine:Outside Looking In - R. H. McCapes 367

PROFESSIONAL OVERSIGHT


PSEUDORABIES

International Pseudorabies Symposium Summary and European Pseudorabies Update - A. C. Taft .......................................................... 427
Report of the Committee on Pseudorabies - D. D. Gingerich, et al. ....... 429
United States Pseudorabies Eradication Program Report - A. C. Taft .......................................................... 432
Pseudorabies Program Work Conference Summary - G. N. Slack 441
Minnesota Pseudorabies Report - P. L. Anderson ......................... 443
Illinois Pseudorabies Update - R. D. Hull ........................................ 446
Iowa Pseudorabies Advisory Committee Comments - P. Armbrecht ............................................. 448
North Carolina Pseudorabies Update - T. J. McGinn, III ........................................................ 453
Minutes National Pseudorabies Control Board - P. E. Bradshaw .......... 456
National Premises Identification for Cull Breeding Swine -
J. F. Wiemers .................................................................................................................. 457
Pennsylvania PRV Eradication Progress Report -
M. A. Van Buskirk ........................................................................................................ 460
Update on the Major Issues that are Central to the Successful Implementation of PRV Differential Vaccines - F. A. Osorio .............. 465

PUBLIC HEALTH AND ENVIRONMENTAL QUALITY

Report of the Committee on Public Health and Environmental Quality -
J. C. New, et al. ............................................................................................................. 471

PUBLIC RELATIONS


RABIES

Report of the Committee on Rabies - Deborah J. Briggs, et al. .............. 483

SALMONELLA

Antimicrobial Susceptibility Monitoring of Salmonella Organisms -
L. Tollefson and G. A. Mitchell .................................................................................. 499
Selected Risk Reduction Factors From the Salmonella Enteritidis Pilot Project for Consideration in Food Safety Programs in the Egg Industry - D. J. Henzler ................................................................. 502
Report of the Committee on Salmonella - B. P. Smith, et al. ................. 506
Salmonella Serotypes From Animals and Related Sources Reported During July 1994-June 1995 - K. E. Ferris and L. A. Thomas. ... 510
Epidemiologic Study of an Occurrence of Salmonella Enteriditis, phage type 4 in a Commercial Layer Flock in Southern California - Willoughby, Kinde, Kerr, Little, Tarbell, Bickford, Reed ................................................................. 525

SHEEP AND GOATS

Report of the Committee on Sheep and Goats - C. V. Kimberling, et al. 527
Comparative Evaluation of the Agar Gel Immunodiffusion Test and Recombinant ELISA tests for the Diagnosis of Ovin Progressive Pneumonia - R. A. Juste, J. Kwang, A. de la Concha-Bermejillo ................................................................. 536

TRANSMISSIBLE DISEASES OF POULTRY


TRANSMISSIBLE DISEASES OF SWINE

Report of the Committee on Transmissible Diseases of Swine - Beth Lautner, et al. ...................................................................................... 589

TUBERCULOSIS

Comparison of North American PPD's IN VIVO: Caudal Fold Testing - B. S. Goff, et al. ...................................................................................... 593
Report on Reviews of Mexican State's Tuberculosis Programs - C. Gaborick ............................................................................................... 597
Report of the Committee on Tuberculosis - B. R. Hillman, et al. ....... 602
Status of the State Federal Bovine Tuberculosis Eradication Program: Fiscal Year 1995 - M. A. Essey and J. S. VanTiem ... 615

WILDLIFE DISEASES


Constitution and Bylaws ........................................................................ 649
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<table>
<thead>
<tr>
<th>Date</th>
<th>Place of Meeting</th>
<th>President</th>
<th>Secretary</th>
</tr>
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<tbody>
<tr>
<td>1. Sept. 27-28, 1897†</td>
<td>Fort Worth, TX</td>
<td>Mr. C. P. Johnston, Springfield, IL</td>
<td>Mr. D. O. Lively, Fort Worth, TX</td>
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<tr>
<td>2. Oct. 11-12, 1898</td>
<td>Omaha, NE</td>
<td>Mr. C. P. Johnston, Springfield, IL</td>
<td>Mr. Taylor Riddle, KS</td>
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<tr>
<td>3. Oct. 11-12, 1899†</td>
<td>Chicago, IL</td>
<td>Mr. C. P. Johnston, Springfield, IL</td>
<td>Mr. Mortimer Levering, Lafayette, IN</td>
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<tr>
<td>4. Oct. 2-3, 1900</td>
<td>Louisville, KY</td>
<td>Mr. C. P. Johnston, Springfield, IL</td>
<td>*Dr. E. T. Eisenman, Louisville, KY</td>
</tr>
<tr>
<td>5. Oct. 8-9, 1901</td>
<td>Buffalo, NY</td>
<td>Dr. E. P. Niles, VA</td>
<td>*Dr. E. T. Eisenman, Louisville, KY</td>
</tr>
<tr>
<td>6. Sept. 23-24, 1902</td>
<td>Wichita, KS</td>
<td>Mr. W. H. Dunn, TN</td>
<td>Mr. Wm. P. Smith, Monticello, IL</td>
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<tr>
<td>7. Sept. 22-23, 1903</td>
<td>Denver, CO</td>
<td>Mr. W. E. Bolton, Woodward, OK</td>
<td>Mr. Wm. P. Smith, Monticello, IL</td>
</tr>
<tr>
<td>8. Aug. 23-24, 1904</td>
<td>St. Louis, MO</td>
<td>Dr. J. C. Norton, AZ</td>
<td>Mr. Wm. P. Smith, Monticello, IL</td>
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<tr>
<td>9. Aug. 15-16, 1905</td>
<td>Guthrie, OK</td>
<td>Mr. Wm. P. Smith, Monticello, IL</td>
<td>*Dr. S. H. Ward, St. Paul, MN</td>
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<tr>
<td>10. Aug. 15-16, 1906</td>
<td>Springfield, IL</td>
<td>Mr. M. M. Hanks, Quanah, TX</td>
<td>*Dr. S. H. Ward, St. Paul, MN</td>
</tr>
<tr>
<td>11. Sept. 16-17, 1907</td>
<td>Richmond, VA</td>
<td>Dr. D. F. Luckey, Columbia, MD</td>
<td>*Dr. S. H. Ward, St. Paul, MN</td>
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<tr>
<td>13. Sept. 13-15, 1909</td>
<td>Chicago, IL</td>
<td>Dr. W. H. Dalrymple, Baton Rouge, LA</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>14. Dec. 5-7, 1910</td>
<td>Chicago, IL</td>
<td>Dr. C. E. Cotton, St. Paul, MN</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>15. Dec. 5-6, 1911</td>
<td>Chicago, IL</td>
<td>Dr. John F. Devine, Goshen, NY</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>16. Dec. 3-5, 1912</td>
<td>Chicago, IL</td>
<td>Dr. Macycop P. Ravener, Madison, IL</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
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<tr>
<td>17. Dec. 2-4, 1913</td>
<td>Chicago, IL</td>
<td>Peter F. Bahnsen, Atlanta, GA</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
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<tr>
<td>18. Feb. 16-18, 1914</td>
<td>Chicago, IL</td>
<td>Dr. S. H. Ward, St. Paul, MN</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
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<tr>
<td>19. Dec. 2-3, 1915</td>
<td>Chicago, IL</td>
<td>Dr. J. L. Gibson, Des Moines, IA</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
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<tr>
<td>20. Dec. 5-7, 1916</td>
<td>Chicago, IL</td>
<td>Dr. O. E. Dyson, Springfield, IL</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>21. Dec. 3-5, 1917</td>
<td>Chicago, IL</td>
<td>Dr. J. G. Wills, Albany, NY</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>22. Dec. 2-4, 1918</td>
<td>Chicago, IL</td>
<td>Dr. M. Jacob, Knoxville, TN</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>23. Dec. 1-3, 1919</td>
<td>Chicago, IL</td>
<td>Dr. G. W. Dumphy, Lansing, MI</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>24. Nov. 29-Dec. 1, 1920</td>
<td>Chicago, IL</td>
<td>Dr. S. F. Musselman, Franfort, KY</td>
<td>*Mr. J. J. Ferguson, Chicago, IL</td>
</tr>
<tr>
<td>25. Nov. 28-30, 1921</td>
<td>Chicago, IL</td>
<td>W. F. Crewe, Bismarck, MD</td>
<td>*Mr. J. J. Ferguson, Columbus, OH</td>
</tr>
<tr>
<td>26. Dec. 6-8, 1922</td>
<td>Chicago, IL</td>
<td>Dr. T. E. M. Munce, Harrisburg, PA</td>
<td>*Mr. Theo. Burnett, Columbus, OH</td>
</tr>
<tr>
<td>27. Dec. 5-7, 1923</td>
<td>Chicago, IL</td>
<td>Dr. W. J. Butler, Henena, MT</td>
<td>*Mr. Theo. Burnett, Columbus, OH</td>
</tr>
<tr>
<td>28. Dec. 3-5, 1924</td>
<td>Chicago, IL</td>
<td>Dr. J. G. Femeyhough, Richmond, VA</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>29. Dec. 2-4, 1925</td>
<td>Chicago, IL</td>
<td>Dr. J. H. McNeil, Trenton, NJ</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>30. Dec. 1-3, 1926</td>
<td>Chicago, IL</td>
<td>Dr. John R. Mohler, Washington, DC</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>31. Nov. 30-Dec. 2, 1927</td>
<td>Chicago, IL</td>
<td>Dr. L. Van Es, Lincoln, NE</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>32. Dec. 5-7, 1928</td>
<td>Chicago, IL</td>
<td>Dr. C. A. Cary, Auburn, AL</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>33. Dec. 4-6, 1929</td>
<td>Chicago, IL</td>
<td>Dr. Chas. O. Lamb, Denver, CO</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>34. Dec. 3-5, 1930</td>
<td>Chicago, IL</td>
<td>Dr. A. E. Wright, Washington, DC</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>Date</td>
<td>Place of Meeting</td>
<td>President</td>
<td>Secretary</td>
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<tr>
<td>35. Dec. 2-4, 1931</td>
<td>Chicago, IL</td>
<td>*Dr. J. W. Connaway, Columbia, MD</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>36. Nov. 30-Dec. 2, 1932</td>
<td>Chicago, IL</td>
<td>*Dr. Peter Malcolm, Des Moines, IA</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>37. Dec. 6-8, 1933</td>
<td>Chicago, IL</td>
<td>*E. T. Faulder, Albany, NY</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>38. Dec. 5-7, 1934</td>
<td>Chicago, IL</td>
<td>*Dr. T. E. Robinson, Providence, RI</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>39. Dec. 4-6, 1935</td>
<td>Chicago, IL</td>
<td>*Dr. Edward Records, Reno, NV</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>40. Dec. 2-4, 1936</td>
<td>Chicago, IL</td>
<td>*Dr. Walter Wisnicky, Madison, WI</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>41. Dec. 1-3, 1937</td>
<td>Chicago, IL</td>
<td>*Dr. R. W. Smith, Concord, NH</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>42. Nov. 30-Dec. 2, 1938</td>
<td>Chicago, IL</td>
<td>*Dr. D. E. Westmoreland, Frankfort, KY</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>43. Dec. 6-8, 1939</td>
<td>Chicago, IL</td>
<td>*Dr. J. L. Axby, Indianapolis, IN</td>
<td>*Dr. O. E. Dyson, Kansas City, MO</td>
</tr>
<tr>
<td>44. Dec. 4-6, 1940</td>
<td>Chicago, IL</td>
<td>*Dr. H. D. Port, Cheyenne, WY</td>
<td>Dr. Mark Welsh, College Park, MD</td>
</tr>
<tr>
<td>45. Dec. 3-5, 1941</td>
<td>Chicago, IL</td>
<td>*Dr. E. A. Crossman, Boston, MA</td>
<td>Dr. Mark Welsh, College Park, MD</td>
</tr>
<tr>
<td>46. Dec. 2-4, 1942</td>
<td>Chicago, IL</td>
<td>Dr. I. S. McAdory, Auburn, AL</td>
<td>Dr. Mark Welsh, College Park, MD</td>
</tr>
<tr>
<td>47. Dec. 1-3, 1943</td>
<td>Chicago, IL</td>
<td>Dr. W. H. Hendricks, Salt Lake City, UT</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>48. Dec. 6-8, 1944</td>
<td>Chicago, IL</td>
<td>Dr. J. M. Sutton, Atlanta, GA</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>49. Dec. 5-7, 1945</td>
<td>Chicago, IL</td>
<td>Dr. C. U. Duckwork, Sacramento, CA</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>50. Dec. 4-6, 1946</td>
<td>Chicago, IL</td>
<td>Dr. William Moore, Raleigh, NC</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>51. Dec. 3-5, 1947</td>
<td>Chicago, IL</td>
<td>*Dr. Will J. Miller, Topeka, KS</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>53. Oct. 12-14, 1949</td>
<td>Columbus, OH</td>
<td>*Dr. T. O. Brandenburg, Bismarck, ND</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>54. Nov. 1-3, 1951</td>
<td>Phoenix, AZ</td>
<td>*Dr. C. P. Bishop, Harrisburg, PA</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>55. Nov. 14-16, 1951</td>
<td>Kansas City, KS</td>
<td>*Mr. F. E. Mollin, Denver, CO</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>57. Sept. 23-25, 1953</td>
<td>Atlantic City, NJ</td>
<td>*Dr. T. Childs, Ottawa, Canada</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>58. Nov. 10-12, 1954</td>
<td>Omaha, NE</td>
<td>*Dr. T. C. Green, Charleston, WV</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>59. Nov. 16-18, 1955</td>
<td>New Orleans, LA</td>
<td>Dr. H. E. Wilkins, Helena, MT</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
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<tr>
<td>60. Nov. 28-30, 1956</td>
<td>Chicago, IL</td>
<td>Dr. A. L. Brueckner, Baltimore, MD</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>61. Nov. 13-15, 1957</td>
<td>St. Louis, MO</td>
<td>Dr. G. H. Good, Cheyenne, WY</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>62. Nov. 4-6, 1958</td>
<td>Miami Beach, FL</td>
<td>Dr. John G. Milligan, Montgomery, AL</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>63. Nov. 15-18, 1959</td>
<td>San Francisco, CA</td>
<td>Mr. F. G. Buzzell, Augusta, ME</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>64. Oct. 17-21, 1960</td>
<td>Charleston, WV</td>
<td>*Dr. J. R. Hay, Chicago, IL</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>65. Oct. 30-Nov. 3, 1961</td>
<td>Minneapolis, MN</td>
<td>Dr. A. P. Schneider, Boise, ID</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>67. Oct. 15-18, 1963</td>
<td>Albuquerque, NM</td>
<td>*Dr. T. J. Grennan, Jr. Providence, RI</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>Date</td>
<td>Place of Meeting</td>
<td>President</td>
<td>Secretary</td>
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<tr>
<td>70. Oct. 10-14, 1966</td>
<td>Buffalo, NY</td>
<td>Dr. C. L. Campbell, Tallahassee, FL</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>71. Oct. 16-20, 1967</td>
<td>Phoenix, AZ</td>
<td>Dr. Grant S. Kaley, Albany, NY</td>
<td>*Dr. R. A. Hendershott, Trenton, NJ</td>
</tr>
<tr>
<td>72. Oct. 6-11, 1968</td>
<td>New Orleans, LA</td>
<td>Dr. John F. Quinn, Lansing, MI</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>73. Oct. 12-19, 1969</td>
<td>Milwaukee, WI</td>
<td>*Dr. John L. O'Hara, Reno, NV</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>75. Oct. 24-29, 1971</td>
<td>Oklahoma City, OK</td>
<td>*Dr. M. D. Mitchell, Pierre, SD</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>76. Nov. 5-10, 1972</td>
<td>Miami Beach, FL</td>
<td>Dr. J. C. Shook Mechanicsburg, PA</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>77. Oct. 14-19, 1973</td>
<td>St. Louis, MO</td>
<td>*Dr. W. C. Tobin, Denver, CO</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>79. Nov. 2-7, 1975</td>
<td>Portland, OR</td>
<td>*Dr. J. E. Andrews, GA</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>80. Nov. 7-12, 1976</td>
<td>Miami Beach, FL</td>
<td>*Dr. H. E. Goldstein, Columbus, OH</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>81. Oct. 16-21, 1977</td>
<td>Minneapolis, MN</td>
<td>*Dr. A. E. Janawicz, Montpelier, VT</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>82. Oct. 21-Nov. 3, 1978</td>
<td>Buffalo, NY</td>
<td>**Dr. L. E. Bartell, Sacramento, CA</td>
<td>*Dr. W. L. Bendix, Richmond, VA</td>
</tr>
<tr>
<td>83. Oct. 28-Nov. 2, 1979</td>
<td>San Diego, CA</td>
<td>Dr. T. F. Zweigart, Raleigh, NC</td>
<td>Dr. J. C. Shook, Hyattsville, MD</td>
</tr>
<tr>
<td>84. Nov. 2-7, 1980</td>
<td>Louisville, KY</td>
<td>*Mr. B. W. Hawkins, Ontario, OR</td>
<td>Dr. J. C. Shook, Hyattsville, MD</td>
</tr>
<tr>
<td>85. Oct. 11-16, 1981</td>
<td>St. Louis, MO</td>
<td>*Dr. L. W. Hinchman, Indianapolis, IN</td>
<td>Dr. J. C. Shook, Hyattsville, MD</td>
</tr>
<tr>
<td>86. Nov. 7-12, 1982</td>
<td>Nashville, TN</td>
<td>Dr. G. B. Rea, Salem, OR</td>
<td>Dr. J. C. Shook, Annapolis, MD</td>
</tr>
<tr>
<td>87. Oct. 16-21, 1983</td>
<td>Las Vegas, NV</td>
<td>Dr. J. R. Ragan, Nashville, TN</td>
<td>Dr. J. C. Shook, Annapolis, MD</td>
</tr>
<tr>
<td>88. Oct. 21-26, 1984</td>
<td>Ft. Worth, TX</td>
<td>Mr. J. O. Pearce, Jr. Okeechobee, FL</td>
<td>Dr. J. C. Shook, Annapolis, MD</td>
</tr>
<tr>
<td>89. Oct. 27-Nov. 1, 1985</td>
<td>Milwaukee, WI</td>
<td>*Dr. David U. Walker, Montpelier, VT</td>
<td>Dr. J. C. Shook, Annapolis, MD</td>
</tr>
<tr>
<td>90. Oct. 19-14, 1986</td>
<td>Louisville, KY</td>
<td>*Dr. N. W. Kruse, Lincoln, NE</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>91. Oct. 25-30, 1987</td>
<td>Salt Lake City, UT</td>
<td>Dr. J. F. Hudelson, Denver, CO</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>92. Oct. 16-21, 1988</td>
<td>Little Rock, AR</td>
<td>Dr. J. A. Cobb, Atlanta, GA</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
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<tr>
<td>93. Oct. 28-Nov. 3, 1989</td>
<td>Las Vegas, NV</td>
<td>Dr. P. E. Bradshaw, Griggsville, IL</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
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<tr>
<td>94. Oct. 6-12, 1990</td>
<td>Denver, CO</td>
<td>Dr. M. A. Van Buskirk, Harrisburg, PA</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>95. Oct. 26-Nov. 1, 1991</td>
<td>San Diego, CA</td>
<td>Dr. P. L. Smith, Sacramento, CA</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>96. Oct. 31-Nov. 6, 1992</td>
<td>Louisville, KY</td>
<td>Dr. J. Lee Alley, Montgomery, AL</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>97. Oct. 23-29, 1993</td>
<td>Las Vegas, NV</td>
<td>Dr. T. J. Hagerty, St. Paul, MN</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>98. Oct. 29-Nov. 4, 1994</td>
<td>Grand Rapids, MI</td>
<td>Mr. J. B. Finley, Jr., Encinal, TX</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
<tr>
<td>99. Oct. 28-Nov. 3, 1995</td>
<td>Reno, NV</td>
<td>Dr. H. Wesley Towers, Dover, DE</td>
<td>Dr. J. C. Shook, Mechanicsburg, PA</td>
</tr>
</tbody>
</table>

+This was the last meeting of the Interstate Association of Livestock Sanitary Boards
INVOCATION

Michael R. Marshall, D.V.M.
Salt Lake City, Utah

Our Eternal Father In Heaven:

We are most grateful to be Thy children and to be here upon the earth in this day and age when so many marvelous things are happening all over the world. We are grateful to be part of this animal kingdom and to be stewards over animal health within that kingdom.

We are grateful for our families who are at home and give us so much support and encouragement in all of the things that we do. We are very grateful for the opportunity that is ours to increase our knowledge and our minds and then to use that knowledge in the service of people and animals.

We humbly pray that Thou might bless those who are ill and afflicted, that they might receive a blessing especially designed for them. We ask Thy blessings upon the world leaders that they might have Thy spirit to be with them, and be led in the proper ways to help mankind the world over.

We are very grateful to be gathered in this great free land of America and to be able to participate in open, free dialogue and exchange of ideas here at this meeting. Now we ask for Thy blessings upon us all and we say this in the name of Jesus Christ.

Amen.

MEMORIAL SERVICE

Mr. President, members of USAHA, AAVLD, Ladies and Gentlemen, it is our privilege at this time to pause for a moment of Silent Prayer and Personal Meditation to pay tribute and honor to our colleagues and friends who have passed away since our last meeting.

They are:

Dr. E. V. Morse - Life Member - W. Lafayette, IN - Deceased February 7, 1995.
Dr. John G. Milligan - President of USAHA, 1958 - Montgomery, AL - Deceased February 27, 1995.
Dr. Robert J. Velure - Former State Veterinarian of North Dakota - Mandan, ND - Deceased September 1, 1995.
Dr. C. S. McCain - USAHA Member - Pike Road, AL - Deceased 1995.
Dr. I. Howard Kahan - USAHA Member - Hudson, FL - Deceased 1995.
We extend a warm welcome to the great "Silver State" of Nevada. Nevada is one of the most urban in terms of population and also the most rural states. The statewide population is approximately 1.5 million people and is growing at a rate of about 4,000 people monthly. Nevada is one of the fastest growing states in the nation.

Two major basic industries, which are a cornerstone of Nevada progressive economy, are Mining and Agriculture. Nevada produces approximately 500,000 head of cattle; 107,000 head of sheep and 9,000 swine. Cash receipts from the marketing of livestock is $189,425,000 and from farm commodities is $109,696,000 annually.

Nevada is a major producer of alfalfa hay and alfalfa seed, potatoes, onions and is rapidly becoming the major garlic and garlic see producer.

The goal of the Division of Agriculture is to promote the welfare of all people of Nevada, and to promote the efficient, orderly, and economical conduct of various activities for the encouragement, advancement, and protection of the livestock and agriculture industries in Nevada.

Best wishes for a successful and productive meeting. May your stay in Nevada be pleasurable. Thank you for being here.
RESPONSE TO WELCOME

Charles E. Starkey, D.V.M.
Little Rock, Arkansas

On behalf of the United States Animal Health Association and the American Association of Veterinary Laboratory Diagnosticians, we wish to thank you, Mr. Iverson, for your warm and gracious welcome to the "Silver State" of Nevada, and to the exciting city of Reno.

We look forward to enjoying all the sights this famous city is known for, besides all the exciting amenities of the John Ascuaga's Nugget Hotel. I am sure this will be a memorable meeting for each of us, and hopefully, we will be returning to our homelands with our pockets-full of silver.

Next year we are looking forward to all of you coming to the "Natural State" of Arkansas. Remember you will be in "Razorback Country," so be prepared to call the HOGS! Arkansas is a word from the Quapaw Indian tribe that means "downstream people." Our State Capitol was patterned after the U.S. Capitol in Washington, D.C., and our State's population is 2.4 million. In Little Rock you will be surrounded by many fine restaurants, excellent golf courses, lots of great shopping areas, flea markets, and antique malls. New to the Little Rock area is the IMAX Theater with its six-story high screen, featuring aviation and space exploration at present.

Arkansas produces all crops normally grown in the temperate zone and, with the exception of citrus fruits, grows practically every crop produced in the U.S. Arkansas leads the nation in the production of rice and broilers, and ranks high in egg and turkey production. Arkansas ranks 12th among states in harvested acreage with a total of 8,095,000 harvested acres. Our brucellosis program continues to progress. We now have only 1(one) known infected herd, and feel we are on target to reach class-free status by the end of 1998.

We are proud of our State and we hope you will come to Little Rock next year to help us celebrate the 100th annual USAHA meeting in the "Land of Opportunity." We will try to provide plenty of down-home southern hospitality.

Although we don't have silver mines, we do have bauxite mines, and as far as I know, the only diamond mine in the United States which is at Murfreesboro where you can dig for diamonds.
I appreciate the opportunity to speak before you at a time of enormous interest and activity in food safety. This has been a significant year, both in terms of progress made in food safety and in terms of the level of public debate we have seen in the halls of Congress, in government offices, and reported in the media. We have seen the subject of food safety elevated to new levels of public awareness.

Through all of the public debate and activity, there is one thing on which everyone seems to agree—and that is on the need for real change to improve food safety. And I believe everyone recognizes that there is no silver bullet solution to today's food safety problems. It will take a concerted and long-term effort on the part of all of us—producers, processors, the retail industry, government, the scientific community, and consumers—to meet our objective of significantly reducing the risk of foodborne illness and to meet the public's expectation that industry and government are doing everything it is reasonably possible for them to do to improve food safety.

Today, I want to update you on the progress we have made so far in making significant changes along the farm to table chain to improve food safety. Specifically, I want to discuss what the Food safety and Inspection service (FSIS) is doing to establish a system to regulations and oversight in federally inspected meat and poultry plants that focuses on preventing hazards and reducing microbial pathogens in meat and poultry products.

I also want to discuss some of the positive steps the meat and poultry industries have taken to focus on pathogen reduction, particularly in the area of technology development. The industry is responding not just with words, but with real action. They are making substantive changes in how they do business that I believe will lead to real improvements in the safety of the meat and poultry supply.

I also want to talk to you about the type of change we believe is needed at the beginning of the farm to table chain, at the animal production level, to improve food safety. We recognize that the approach we take to improve food safety at the animal production level is different from the approach we can take in federally inspected plants. We have not reached the same level of scientific knowledge when it comes to knowing how to prevent contamination with harmful pathogens at the animal production stage. And we know
that a regulatory approach to food safety is neither practical nor feasible in this area of the farm-to-table continuum.

But there are still important similarities in what it will take to make real progress. Solving food safety problems at the animal production level will require the same ingenuity and hard work that is required at the in-plant level. It will require commitment and investment on the part of industry to find solutions and implement them. And it will require constructive collaboration among industry, government, and the scientific community to meet the public's demand for a safer food supply.

**FSIS's Strategy for Change**

FSIS bears an important share of the responsibility for preventing food safety problems and reducing foodborne illness. And we have a lot of work to do before we can say that we are fully meeting our responsibility.

Clearly, our regulatory activities must be focused at the in-plant and post-plant level. This is where our regulatory authority lies, and it is where we have a clear mandate from Congress to implement change.

Our food safety strategy and the system of inspection we envision for the future are based on a number of key principles. For instance, we know that science-based, systematic prevention of food safety hazards must guide the efforts of both government and industry. The current system relies too heavily on FSIS inspectors to detect and correct problems after they have occurred. A system of preventive controls operated by plant management and overseen by FSIS inspectors will work better to produce safe food.

We also must better target the most significant risks in the food supply—that is, the risks to human health posed by pathogenic microorganisms. Unless we address the most significant risks in the food supply, we cannot truly say we are doing all it is reasonably possible to do to improve food safety.

We must clearly define, and respect, the industry's responsibility for systematically preventing hazards and achieving an acceptable level of food safety performance. FSIS must develop objective measures of accountability--performance standards—to verify that meat and poultry plants are meeting their food safety responsibility.

We also must design and operate a system of government oversight that ensures the most efficient and effective use of its resources to improve food safety. FSIS must have the flexibility to target its resources and change the allocation of its resources in a manner that allows it to address significant and emerging food safety problems all along the farm-to-table chain.

Our strategy starts with the rulemaking initiative we began in February to reduce pathogenic microorganisms and implement HACCP (Hazard Analysis and Critical Control Points) in all meat and poultry plants.

The proposals provide the regulatory framework for our program—a framework that will enable us to act on many of the principles I just de-
HACCP establishes for both industry and government a systematic, science-based framework for preventing food safety hazards.

The proposals would enable both industry and government to better target the most significant risks in the food safety hazards.

The proposals clarify that industry is responsible for systematically preventing food safety hazards and achieving an acceptable level of food safety performance.

And, by establishing targets for pathogen reduction and other performance standards, they would provide FSIS with an objective means of verifying that meat and poultry plants are meeting their food safety responsibility.

We have learned a great deal during the extensive public comment process, including the six days of interactive public meetings we held in September. We will take full advantage of this input in shaping the final rules.

**Technological Development**

One of the important objectives of our plan to rely more heavily on food safety performance standards is to provide an added incentive for industry to develop new technologies to improve food safety. We believe the development of new technology can contribute significantly to improving the safety of the food supply, especially with regard to reducing the threat posed by pathogenic microorganisms.

And we are doing our part by streamlining the approval process for new technology so we do not stand in the way of progress. In November 1994, we announced we would not longer require prior approval for plants to use accepted antimicrobial rinses and hot water rinses after beef carcasses pass inspection.

We are now reviewing all of our systems for prior approval—such as those for facility blueprints, processing equipment, quality control programs, and product labels. We intend to eliminate, streamline, or modify them to ensure that our legitimate oversight obligations are in place without unduly delaying the introduction of new technologies or imposing unnecessary burdens on industry.

We also have established a single point of contact within the agency regarding technology assessment—the Technology Assessment and Research Coordination Division in the Science and Technology Program. This office is encouraging new technology directed at food safety improvements by facilitating the experimentation under commercial conditions that is needed to successfully introduce new technologies and procedures in plants.

For instance, we recently announced our approval of commercial trials for an innovative process to remove hair and external contamination from cattle in slaughter plants. Preliminary data suggest that this technology may contribute to producing meat with reduced bacterial counts.
ogy will not be itself solve the public health problems posed by harmful bac-
teria—no single technology can—but it is an important example of the kind of
serious innovation and commitment to improvement that is needed to re-
duce risk and achieve our food safety goals.

Industry Accomplishments

I want to be very clear. Technological innovation by industry to improve
food safety is welcomed and appreciated at FSIS. It will play a key role in
achieving the food safety goals we share. And we are especially pleased
that industry is investing resources in finding ways to control pathogenic
bacteria. We are receiving as many as five requests each week for review
of scientific data supporting the use of technical equipment, products, and
processes to reduce bacteria.

Let me cite a few more examples.

—FSIS has approved trial testing of a hot water steam vacuum system
that kills bacteria and loosens contamination such as fecal material, which is
then vacuumed off carcasses.

—The agency has approved trial testing of a patented process using
pressurized steam to reduce bacteria on meat and poultry carcasses.

—We have approved trial tests of chlorine dioxide as a poultry rinse and
a trisodium phosphate rinse for beef.

These are just a few examples of the kind of new food safety technolo-
gies that we foresee being incorporated by innovative companies into the
HACCP systems of the future.

Food Safety Goals at the Animal Production Level

These investments in new technology will help to reduce contamination
in the plant environment. But we must also address the potential hazards
that arise throughout the food production and delivery system, including be-
fore animals enter FSIS-inspected plants and after meat and poultry prod-
ucts leave those plants.

We cannot afford to have any weak links in our food safety chain, nor
can we afford to debate who is most responsible for food safety. It is clear
that all of us—producers, processors, government, transporters, retailers,
and consumers—must do whatever we can at each step of the process to
make food safer.

Last year, Congress transferred the responsibility for animal production
food safety from USDA’s Animal and Plant Health Inspection Service(APHIS)
to FSIS. As a result, we established at FSIS and Animal Production Food
Safety staff headed by Dr. Bonnie Buntain, who previously handled pre-har-
vest food safety at APHIS. Dr. Buntain and her group are doing an outstand-
ing job managing this transition and planning for the future.

Congressional action on our budget for fiscal year 1996 is forcing us to
make difficult decisions on how we use our very scarce resources to ad-
dress animal production food safety. In one area, our program addressing *Salmonella enteritidis* in eggs, Congress explicitly precluded continued funding.

But I want to make it very clear to you tonight that we are committed to maintaining a viable animal production food safety program. We cannot achieve our food safety goals—we cannot meet the public’s expectations—unless we are addressing food safety from farm to table.

I also think it is important for all of us to be very clear regarding roles and responsibilities in the animal production food safety arena. That is why I want to spend the remainder of my time talking about how we see our role and the industry’s role and about the opportunities that I believe the U. S. Animal Health Association has to exert leadership from the private sector.

**FSIS Role in Animal Production Food Safety**

First, as I have emphasized many times, we at FSIS do not have, and we do not seek, the kind of direct regulatory relationship with animal producers that we have with packers and processors. Rather, as a public health agency, we see ourselves in a leadership role, in a catalyst role, guiding research and other activities toward the greatest public health risks. It is clear that practices at the animal production level can influence the levels of pathogenic microorganisms in animals brought to slaughter, which may in turn affect the safety of products that reach consumers. We consider it our obligation to encourage research, data collection, and interventions at the animal production level that address these public health risks and will improve the safety of meat and poultry products coming out of federally inspected plants.

In some cases, we will support key data collection ourselves. For example, I can tell you that we have decided to continue our collaboration with APHIS to build some human pathogen data collection into the National Adult Dairy Cow Survey and to finish the National Swine Survey.

We also plan to continue some support for data collection that will help resolve whether management and transportation practices for culled dairy cows may be related to the prevalence of pathogenic *E. coli* 0157:H7 in ground beef. It is our responsibility to focus on potential high-risk animal populations and encourage sound scientific resolution of whether improved industry management practices are needed and can be developed and implemented to address food safety problems. In this regard, we greatly appreciate the cooperation and collaboration of the National Milk Producers Federation, the Food Animal Production Medicine Consortium, the National Veterinary Services Laboratory, and many academic and state colleagues.

Beyond data collection, we also believe we have a role in ensuring a smooth connection between the various links in the farm-to-table chain. Changes that are made in one segment of the farm-to-table chain can reverberate all along the chain. For instance, as we require HACCP systems in
slaughter plants, these slaughter plants may require their suppliers to have HACCP programs or take other preventive measures to address safety outcomes. We intend to explore what we can do to ensure that standards or expectations established all along the farm-to-table chain, including at the animal production level, are based on science.

Another role for FSIS is to coordinate with other Federal agencies that have a role in animal production food safety, including APHIS; the Agricultural Research Service; the Cooperative State Research, Education and Extension Service; and the Packers and Stockyards Administration, as well as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Good coordination will help ensure that the government’s efforts and limited resources are being well used to improve food safety at the animal production level. This coordination includes assisting other governmental agencies in emergency situations involving contaminated products when assistance is requested.

**Salmonella Enteritidis**

As I mentioned, Congress specifically precluded FSIS from spending funds to control *Salmonella enteritidis* in shell eggs. Our hands are tied in a real way, and we are concerned that this leaves us with no immediate capacity to address this food safety problem at the production level. We intend to resolve the issue of what constitutes safe shipping practices for shell eggs. In addition, we are now actively working with FDA, which has the primary statutory authority over shell eggs, to determine what the appropriate next step might be at the federal level to address shell egg safety from farm to table. We certainly support the efforts of U.S. Animal Health Association’s *Salmonella enteritidis* task force in developing standardized guidelines for producer-implemented quality assurance programs. Such programs are a necessary part of an effective food safety strategy for shell eggs and are a prime example of steps the industry can take to meet their responsibility for food safety.

**Industry Role in Animal Production Food Safety**

If the government’s role is to provide leadership—guiding research and activities toward public health risks—what, then, is the industry role and responsibility in animal production food safety? The bottom line is simple: developing and implementing improved food safety practices at the farm level is—and certainly for the foreseeable future will remain—a private sector responsibility. This was true before Congressional action on our 1996 budget, but this reality is certainly underscored by the fiscal constraints under which we operate.

Experiences of the past show that we can realistically expect the industry to meet its responsibility. By taking responsibility and investing real effort and resources, the animal production industry has made great strides in
controlling animal diseases. It also has had much success in implementing preventive programs at the animal production level to address the problem of chemical residues. Similar efforts are needed to address food safety at the production level.

Of course, the control of microbial pathogens at the animal production level is, in many ways, unknown territory. There are many things we just don’t know about the ecology of microbial pathogens and about how management practices can be changed or introduced to reduce pathogens. But just as the slaughtering and processing industry is finding new ways to reduce pathogens in the plant environment, the animal production sector has a responsibility to seek similar solutions in live animals before they reach the federally inspected plant. I recognize that must research is ongoing already, and I applaud these efforts. My investment in research and program development must grow.

National Forum on Animal Production Food Safety

One of our roles in government can be to foster agreement on how best to target both public and private investment in food safety. In May, FSIS sponsored a National Forum on Animal Production Food Safety that brought together the producer community, academic scientists, government representatives, consumer groups, and others to work toward a national consensus on a science-based strategy for animal production food safety. I was very pleased with the substantive discussions that took place on important issues such as research priorities and the roles and responsibilities of the various stakeholders, and I appreciate the U. S. Animal Health Association’s participation in that process. We believe such discussions involving a wide range of constituencies are necessary to develop a focused research agenda and to work together to craft strategies and practical action plans to yield real progress on food safety.

Copies of the forum proceedings are available here today, and I encourage you to consider the information contained in the document as you plan your activities. This document pulls together much of the best information we have today on where we are and where we need to go.

I cannot discuss all of the valuable insights that came out of the forum, but I would like to point out a few of the more significant areas of consensus. For instance, there was strong support for the formation of partnerships between industry, government agencies, academic institutions, foundations and consortia to accomplish needed food safety research, with government playing a leadership role to develop a consensus research agenda and stimulate private sector investment in that agenda.

Participants also agreed that there is a real need to determine whether changes in animal production practices translate to decreased public health risks for the consumer. It is not enough to reduce pathogens; we must be able to show a link to public health. FSIS recently began a new foodborne
disease surveillance project in conjunction with CDC, FDA, and state health departments at five locations nationwide to identify more accurately the incidence of foodborne illness. The project will for the first time provide more precise national data to use in evaluating the effectiveness of current and future food safety programs.

The need for cost-effective, standardized and accurate diagnostic tests to evaluate pre-harvest food safety interventions was a recurring theme. The development of such tests obviously is a research priority. We should have some way of evaluating strategies before time and money is spent to implement them.

Participants at the forum also agreed that it is primarily the animal production industry's responsibility to develop, implement, and maintain food safety assurance programs. With their emphasis on industry responsibility and creative collaboration between government and all elements of the private sector, the forum proceedings provide a guide to much of what should happen and I believe will happen in animal production food safety in coming years.

Role of the U.S. Animal Health Association

I believe the U.S. Animal Health Association and its members can play an important leadership role and help shape the future of animal production food safety. I see that leadership occurring on two levels.

First, as professionals involved in animal production, you and your fellow USAHA members can be food safety leaders in your local areas. Much work can be done at the local level to encourage preventive programs to improve public health. You have the professional and scientific expertise and the practical experience to know what the problems are and what will work and won't work in your own areas. I urge you as individuals to take a leadership role to guide activities in the right direction.

The U.S. Animal Health Association, as an organization, can provide leadership as well. The successful development, implementation, and evaluation of effective, industry animal production food safety programs will require regular, ongoing discussions between all stakeholders—industry, state and federal government agencies, the scientific community, and consumers. It is important that research conducted to fill our knowledge gaps be coordinated so that precious research dollars are not wasted. It is important that research be focused on food safety risks. And it is important that industry quality assurance programs be validated before they are implemented.

We believe the U.S. Animal Health Association can play a key convening and leadership role in these areas. You can play a vital bridging role, bring together producers, scientists, and the public health community to push private sector food safety efforts ahead. I am pleased your organization has indicated its interest in assuming this important role. I understand that you have decided to form an animal production food safety steering committee.
and that you plan to hold an annual forum to encourage open discussion and facilitate coordination of activities in the animal production area.

We believe your organization is well suited to these tasks because of its track record in addressing a variety of animal production issues, from feed safety to animal diseases to food safety. Your membership already includes a wide array of producers and professionals involved in animal production, including local and state government representatives who can help to implement change at the grassroots level. I urge you to build new coalitions that reflect the entire farm-to-table chain. It is important that stakeholders at the other end of the food safety chain—retailers and consumers, for instance—be represented in this important process. And we at USDA want to work closely with you to assist in any way we can and to ensure that activities at the animal production level are focused on public health concerns.

FSIS will also be holding meetings to explore specific issues in animal production that relate to public health concerns. During this fiscal year, we plan to hold three regional meetings and will work closely with USAHA and other groups in the planning and implementation of these meetings.

Conclusion

A leadership role for USAHA on food safety would reflect your recognition that food safety is everyone’s responsibility, from animal producer to processor, to retailer, to consumer. We must all forge partnerships and develop strategies that work throughout the chain of production, processing, distribution, and sale to prevent hazards and reduce the risk of foodborne illness.

If we all assume our proper responsibility for food safety and invest the resources necessary to find solutions to today’s food safety problems, I believe we can make real progress toward reducing foodborne illness and building a food safety system that can earn and maintain public confidence.

We look forward to working with you.
REMARKS BY THE PRESIDENT OF USAHA
DR. H. WESLEY TOWERS, JR.

Let me begin by saying that it has been a great honor and a tremendous pleasure for me to have served this year as president of the United States Animal Health Association. It has been a real learning experience for me. One of the most important things that it has given me is a sincere appreciation of the many talented and unselfish people, especially the committee chairmen, who make possible an organization such as ours. This organization certainly could not function in the way that it does if it were not for the competent work of Linda and Beverley in the Richmond office and Dr. John Shook, our treasurer. I would like to thank my wife for being supportive of me as I worked on association projects at home and took time away from home to attend various meetings throughout the year. I also want to publicly thank my bosses, the Secretary and Assistant Secretary of Agriculture, who not only allowed me to be away from the office for meetings, but also added some extra money to my travel budget. I would also be remiss if I did not thank my secretary for the extra work she has done for me this year.

Being president this year has also provided me with the opportunity to broaden both my perspectives and my horizons. Being from a state small in size, such as Delaware, one tends to focus on the problems and concerns generated within its borders and to have only a narrow view of many other things. One of the first functions in which I was asked to participate was the APHIS Future Search Conference which had as its objective to re-think and re-shape the direction the agency and its employees would be taking in the next ten to fifteen years. This conference made me realize that the way things had been approached in the past was not necessarily the way they should continue. Even though our organization has had a very successful track record in the past does not mean that innovative approaches to old practices and new, emerging challengers cannot be brought forward, evaluated, and acted upon. Someone once said, "It is better to invent the future rather than trying to redesign the past." We also need to be open and ready to re-examine and fine-tune our relationship with AAVLD, and we need to explore the possibility of ways to achieve mutual benefits from partnering with other similar organizations such as LCI. At Saturday’s Board of Directors’ meeting, we heard a proposal of how USAHA could have a whole new relationship with FSIS and the people that it serves. I am not saying that the organization should go off on a tangent every time a new idea comes along. What I am saying is that we should at least be open to exploration and evaluation of fresh, relevant suggestions that are made to us.

I hope you will agree with me that there have been some beneficial changes and improvements in the operation of our organization during this year. I am very proud that our Richmond office now has a significant computer upgrade in place. The 1994 proceedings were in the mail by early February, earlier than ever before in the history of our organization. With the continued help of committee chairmen and program speakers, we hope to maintain or even surpass last year’s mail-out date. I know all of you are as thrilled and as
impressed as I am with the new look, style, and timely contents of our newsletter these days. Dr. Dick McCapes, our third vice president, has really done a tremendous job as editor this year. During the year, we have strengthened an old alliance with APHIS as evidenced by the fact that I was invited to their Future Search Conference as a major stakeholder. I was asked to co-host two regional meetings with Veterinary Services' Emergency Diseases staff to inform the U.S. poultry industry of the very serious avian influenza outbreak in Mexico. In February, the Governmental Relations Committee was also invited to participate in Veterinary Services' NAFTA-GATT Free Trade Workshop.

During this year, we have established a new alliance with the FSIS Animal Production Food Safety Group. To help address some of this group's objectives, our newly appointed Animal Production Food Safety Working Group will meet and work with FSIS personnel. This group will be a source of expertise and guidance for FSIS as they develop their plan of action for this important new initiative. Our Salmonella enteritidis Task Force has been re-activated to also work with the Animal Production Food Safety Group in establishing uniform quality assurance standards for the table egg industry. We look forward to developing a full partnership alliance with FSIS in the Animal Production Food Safety area. As evidence of this new relationship, we are very pleased that Mr. Taylor has taken time from his busy schedule to be our keynote speaker here tonight.

Other new initiatives this year include the establishment of a Johnes-Chrones Disease Working Group, an ad hoc poultry products export committee, and an investigative/regulatory enforcement officers' forum. Also, this year for the first time, we are prepared to give continuing education credits for attending the meeting. In addition, the Board will also continue to explore and pursue extra funding sources and other alternatives.

Of course, we have not thrown the baby out with the bath water, so to speak, in pursuing these new ideas and initiatives. We have continued to work with, streamline, combine where possible, and strengthen our existing committees, which are the backbone of this organization. We have continued to partially fund expenses for our member of the bi-national TB committee, and we remain committed to working toward the eradication of that disease as well as other pathogens.

This has been an exciting and rewarding year for me. I hope that I have been able to transfer some of that excitement that I have for our organization to you through the newsletter and through my visits with you at the various meetings I have attended throughout the year. President Elect Mike Marshall is already preparing for next year's historic centennial meeting. I truly believe the United States Animal Health Association is on the brink of embarking on some new ideas and initiatives that our founding fathers would not have dreamed of pursuing nearly one hundred years ago. Mike, I challenge you as you lead our organization in 1996 to prepare it to step boldly into its second century of serving animal agriculture and the consuming public. Remember, Robert Theobold once said, "Those who mill around the crossroads of history do so at their own peril". Thank you.
Dr. Michael R. Marshall, President-Elect of USAHA, presents plaque, tie tack and life member badge to outgoing USAHA President, Dr. H. Wesley Towers, Jr.
MESSAGE FROM THE AAVLD PRESIDENT
DONALD H. LEIN, D.M.V.
ITHACA, NEW YORK

It is indeed a pleasure and honor to welcome all members of USAHA/AAVLD and guests to the 38th Annual Meeting of the AAVLD. It has been a privilege and honor to serve the AAVLD as President for 1995.

I was very impressed with the scientific session of the 38th Annual Meeting of the AAVLD and want to thank the Program Chairman, Dr. Alex Ardans, Director of the California Laboratory System, his committee and presenters for the excellent scientific session they have provided. I would like to take a few seconds to just read the titles and subjects of the opening Plenary Session. I believe it shows the great diversity that our diagnostic laboratories deal with and also their international interest in emerging diseases, wildlife and exotic animal diseases, zoonotic diseases, forensic diagnosis, toxicology, epidemiology and biotechnology and molecular diagnostics. The first paper reported on the pathologic finding of the new equine morbillivirus that was diagnosed in an Australian outbreak this year that caused illness and death in both horses and humans that attended the sick horses. This was followed by a report on "Forensic Medicine in veterinary diagnostics: Necropsy of a mountain lion suspect in a fatal human attack." The third paper dealt with the pathology and toxicokinetics of locoweed poisoning in livestock. Following were papers on bovine herpesviral encephalitis; granulocytic ehrlichiosis in Minnesota and Wisconsin dogs, a parasitic disease that is closely related or possibly the same as the recently discovered human granulocytic ehrlichiosis; chlamydiosis in rattites and imported Mauritius pink pigeons; toe grubs and rim shoes as possible risk factors for fatal musculoskeletal injuries of Thoroughbred racehorses in California, an issue and concern for the safety of horses and jockeys; hemorrhagic septicemia (Pasteurella multocida types B3 and B4) in domestic South Dakota bison; the epidemiology of eastern encephalomyelitis virus infection in swine, an interesting paper that incriminates the pig as a possible carrier of this zoonotic disease; and the last papers of the opening session, characterization of Helicobacter pylori gastritis in cats and its public health implications. I believe this array of scientific papers demonstrates the scientific sophistication and broad scope of our laboratories and the association.

The program also had split session today on Avian diseases, Pathology, Microbiology and Toxicology. The final Plenary Session tomorrow will deal with the concepts and examples of studies in diagnostic epidemiology and emerging diseases. This session will be of great interest to all the attendees of USAHA and AAVLD.

The AAVLD continues to grow, mature and change to meet the needs of the diagnosticians and veterinarians, regulatory medicine, producers, public and the animals they serve. Our membership is in the 900s and we will soon reach the 1,000 mark. The association offers services and educational fo-
rums for all aspects of the diagnostic laboratory operation including the professional, technical, administrative, clerical, data and business staff.

The scientific Journal of Veterinary Diagnostic Investigation keeps growing in stature and worldwide recognition. Special thanks to the editor, Dr. Lenn Harrison and his wife, Sandra, associate editors, reviewers and authors for the excellent journal.

The accreditation of diagnostics state and university laboratories by AAVLD continues to increase the credibility of all laboratories in the association. To date, 34 laboratories are accredited. The Guelph Ontario Ministry of Agriculture and Food Veterinary Laboratory Services is the first Canadian laboratory to be accredited.

The most recent accomplishment is the formation of the AAVLD Foundation, a tax-free foundation that will develop funding for the advancement of veterinary diagnostics through research, scholarship and education funds. The Foundation Board is just being formed and instituted and we are looking forward to a successful future of the very worthwhile cause.

The members of the association continue to work on minimal requirements for Quality Assurance, Quality Control, Standardization and Laboratory Safety for all the disciplines within the diagnostic laboratory. These practices are so important to the credibility of our laboratories and are imperative to the diagnostic and surveillance testing that is required for global trade, prevention and eradication of diseases and the epidemiology of emerging diseases.

The co-existence of the USAHA and AAVLD is so important to the success of the health of our animal industry. The ability to interact with regulatory veterinary medicine, state, federal and international, the animal producers, support industry and veterinarians who serve them and diagnostic laboratories is paramount to the well-being of our animal industry. We must continue to keep this coalition strong and healthy.

In closing, I want to thank our AAVLD Secretary/Treasurer, Dr. Harvey Gosser and his staff, the Executive Board and the several Committee Chairman and their committee members for their much appreciated support. They are the backbone of AAVLD and what makes it great.
REMARKS BY THE PRESIDENT-ELECT OF AVMA
DR. MARY BETH LEININGER

It is indeed an honor to be here at the 99th annual meeting of the United States Animal Health Association.

I bring you greetings from the more than 56,000 members of the American Veterinary Medical Association, the professional colleagues of many of you here in this room.

As you approach your second century of service to American animal agriculture, and the people all over the world who are fed by that industry, the members of USAHA certainly have reason to celebrate. Not only is this a milestone, it is also a time to reflect on the successes which you and your predecessors have had in controlling or eradicating animal diseases in the U.S. Most of you can recite quicker than I can, the dozen or so diseases that no longer exist in our animal populations: diseases such as hog cholera, foot and mouth disease, Texas fever, contagious bovine pleuropneumonia, glanders.

Disease control in our food animals is the primary reason our nation enjoys such abundant and wholesome food.

A statistic I recently learned gives special meaning to this statement. The U.S. holds approximately 8% of the world’s animal population, yet our animal agriculture provides 70% of all the meat and milk produced worldwide. That remarkable achievement is certainly a reason to applaud your organization.

Why has USAHA had such an impact on animal agriculture? From my perspective, I believe it was because almost 100 years ago and for the years since, you and your predecessors have built COALITIONS among all the STAKEHOLDERS long before those two buzzwords even existed. When I read the organization’s background I see phrases used as: “a forum for study, a national plan, drawing together from all walks of life and from all industries affected by animal health problems.” By focusing on planning and including the concerns of everyone - animal producers, food animal veterinarians, laboratory diagnostic workers, state and federal regulatory people, researchers, animal shippers and processors - USAHA has made a difference in improving animal and human health in our country.

The mission of USAHA is clear and simple: to provide the forum which helps eradicate, or at least control, transmissible animal disease. Where does AVMA fit into this mission? I have two examples that demonstrate that “fit”.

1) The extra-label initiative that resulted in a legislative change to the Food, Drug and Cosmetic Act will allow veterinarians to make therapeutic choices based on their professional judgement and will result in healthier animals going to market.

2) The Memorandum of Understanding signed last year which makes AVMA’s fledgling Emergency Response Force available to help USDA-APHIS combat animal disease outbreaks when the Secretary of Agriculture declares a national emergency.

And what about the future? The members of the veterinary profession,
whether we wear the hat of USAHA or AVMA, face interesting challenges. For example:

1) Our federal government’s decision to lower trade barriers will cause us to shift our focus from national disease control programs to international ones.

2) Our profession needs veterinarians with a high degree of specialization in food animal practice and needs veterinarians with a greater understanding of epidemiology and zoonoses control in regulatory work, yet our student population is more and more urban.

3) And what about the shrinking pool of animal research dollars? This certainly slows our ability to solve disease problems.

We have so many common concerns, yet the relationship between our two organizations could be stronger, the communication links could be more direct, we could be working together more consistently to “get the job done”. Certainly the need today is urgent: financial resources everywhere are limited; manpower is stretched; the challenges continue to multiply.

My presence here tonight is an indication of the importance with which AVMA views this need for closer ties. My request to you is that when the Executive Committee of USAHA meets later this week, will you discuss with the AVMA liaison representative the steps we can take to forge those closer links?

More than 30 years ago John F. Kennedy pointed out that the Chinese character for “change” is made up of two parts - one represents crisis; the other, opportunity. Our success as organizations of the future will depend on where we choose to focus. I hope it’s opportunity ................. opportunity that leads to our continued success in the next 100 years.

Dr. H. Wesley Towers, President of USAHA, shaking hands with Dr. Mary Beth Leininger, President-Elect of AVMA.
NATIONAL ASSEMBLY AWARD

F. Y. Rogers, D.V.M.
Jackson, Mississippi

Each year the National Assembly of Chief Livestock Health Officials gives an award to an individual who is still active in the field of animal health and has made significant contributions.

This year the award is given to Dr. Lewis P. Thomas of Charleston, West Virginia. Dr. Thomas was born in Atterbury, Illinois. He was involved in farming as a young man and attended the University of Illinois. He was an honor student and received his D.V.M. degree in 1971. Dr. Thomas went on to gain an M.P.H. degree from the University of Texas, School of Public Health in 1972. Since that time he has been Director of Animal Health and State veterinarian of West Virginia.

During these 23 years his state has attained status as Bovine Tuberculosis and Brucellosis Free State, U. S. Pullorum-Typhoid Free State, U. S. Mycoplasma Gallisepticum Clean State for Turkeys and is in Status III of the Pseudorabies Eradication Program.

He has received numerous awards from various agricultural organizations. It gives me a great deal of pride and pleasure to present this year's annual award to Dr. Lewis P. Thomas for his outstanding and dedicated contributions to programs related to animal and human health.
Dr. Frank Y. Rogers, President of the National Assembly of Chief Livestock Health Officials, presented the seventh National Assembly Award to Dr. Lewis P. Thomas, State Veterinarian of West Virginia. The award is given to an active regulatory official or an industry representative for outstanding service in animal health regulatory programs.
PRESENTATION OF THE APHIS ADMINISTRATOR'S
AWARD FOR USAHA

Lonnie J. King
Administrator, APHIS, VS, USDA
Washington, DC

Good evening. Tonight I have the great pleasure of presenting this year's Administrator's Award to Mr. Philip Bradshaw.

I'd like to begin by telling you a story about Phil. As I'm sure many of you know, he's a midwesterner, an Illinois native. Now some years ago, Illinois was constructing a highway east-west across the middle of the State. As construction proceeded, that highway passed through Champaign, on to Decatur and Springfield, and nearly up to the edge of the Illinois River. At that point, the road came to an abrupt end. Federal funding had dried up, and there was no money to build a bridge across the river. Some people believe that Highway 36 would probably still end there, cutting off the western part of the State, if it hadn't been for the efforts of Phil Bradshaw. But Phil knew how much that road would benefit the area residents, their agriculture and industry. So he assembled a committee of interested local citizens and began lobbying the State government for funding. Not too much later, a bridge went up across the river, and soon Highway 36 became Interstate 72, traveling through the western part of the State and on into neighboring Missouri.

I think this story illustrates the kind of person Phil Bradshaw is. A bridge builder. A road paver. A man who is always willing to step in and lend a hand when he sees a need. It's been said that "the measure of a man is in the number of people whom he serves." In working to extend that road, Phil assisted a great many people in his State and his community. And as I looked over his extensive biography, I was reminded that he's served a great many people, in a great number of capacities, during his career. Certainly, Phil has always been ready and willing to serve American agriculture.

Phil's involvement in agricultural advocacy goes back decades, when he was instrumental in organizing his local and State producers' organizations. As President of the Illinois Pork Producers Association in the early 1970's, he mobilized hog farmers to achieve common goals. He has long been a friend of APHIS, particularly in the area of swine health. As a member of the Secretary's Swine Health Protection Committee for nearly a decade, Phil advised APHIS on carrying out this major disease prevention program concerning waste fed to swine. From 1985 to 1987, he was involved in work to survey animal diseases as Chairman of the Board of the Livestock Conservation Institute. While serving on the APHIS-sponsored National Animal Health Monitoring System Working Group, he helped spearhead the development of the first comprehensive system to track livestock and poultry diseases at State, regional, and national levels. I also had the opportunity a few years back to serve with Phil on the Secretary's Foreign Animal and Poultry Dis-
eases Committee.

As many of you will remember, we were lucky to have Phil serve a term as President of this organization in 1988 and '89. When he was elected, he became the first practicing producer to serve in that position. He hired a manager for his farm and came East to volunteer his time and skills to work—without pay, I might add—toward our collective goals. And as many people can tell you, Phil brought with him a large endowment of common sense, a quick grasp of situations, and keen people skills. But most of all, he brought an immediate, first-hand knowledge of what the farmer can and would do.

In the 1970’s, when Phil was emerging as an industry leader and organizer, pseudorabies was first diagnosed in Illinois. And undoubtedly Phil’s biggest contribution to American agriculture has been his work with the pseudorabies eradication program. He’s served as chairman of the National Pseudorabies Control Board since 1986, when the program first began, and he’s still serving in that capacity today. Along with Don Gingrich and Neil Black, the recipient of last year’s Administrator’s Award, Phil is largely responsible for making the national pseudorabies program as successful as it is today. I’m proud, as he should be, that in the past 4 years, we’ve been able to cut the number of infected herds in half. We’re making great strides toward our goal of eradicating pseudorabies from the Nation by the year 2000.

With the help and support of his wife, Linda, and their three children—Cindy, Lisa, and Todd—Phil has accomplished much—far too many achievements for me to mention tonight. And Phil managed all this while operating his 900-acre general grain and livestock farm, with a 200 sow farrow-to-finish confinement operation. I’ve been told that Phil has said repeatedly that he doesn’t want to quit farming because he’s afraid of missing the good year that comes around about 1 out of every 10. While I can’t speak for his farming, I can certainly say that Phil’s had more than a few good years in his service to farmers, and many, many high points in his distinguished career. And now—in what I hope is another high point—it is my privilege to present Phil with the 1995 USAHA Animal Health Award. Please join me in recognizing him.
Dr. Lonnie J. King, Administrator, presents the APHIS Administrator's Award to Mr. Philip E. Bradshaw.
Information relevant to animal health is in high demand by a wide range of entities today. Their needs range from specific details of a rare disorder to general descriptions of husbandry practices. The information is used for everything from the daily, detailed decisions of an individual producer to industry-wide campaign efforts.

To be useful, information to meet these needs must be timely and factual. In the absence of reliable information, decisions are guided by individual perceptions which may not reflect reality. The Animal Industry Act of 1864 charged the Bureau of Animal Industry (the USDA:Animal Plant Health Inspection Service’s predecessor) to investigate and report upon the condition of the domestic animals and live poultry of the United States and to collect such information on these subjects to benefit the country’s agricultural and commercial interests. Interpretation of this charge has led APHIS to develop various monitoring and surveillance schemes in the United States.

Animal health monitoring and animal disease surveillance activities in the United States have been handled in different ways over the last several decades. Historically, USDA:APHIS:Veterinary Services has handled livestock health activities on a disease-by-disease basis. The information gathered as a result of individual disease control and eradication efforts has been geared to each specific disease. Some states have also created disease control and eradication efforts unique to their particular situations and needs. Data gathered in support of specific disease control or eradication efforts are often referred to as surveillance data, since they are gathered as part of an effort to detect particular diseases.

National Studies

In addition to traditional disease eradication and control programs, Veterinary Services has initiated an animal health monitoring program which focuses on increasing knowledge about interactions among animal health, welfare, production, product wholesomeness, and the environment. The National Animal Health Monitoring System (NAHMS) began in the early 1980’s in the form of individual state pilot projects with university initiatives. These projects did not allow inferences beyond the sample itself, and uniformity between states was lacking.
By 1990, the NAHMS program had developed into a nationally-driven initiative to generate statistically-valid and scientifically-sound national and regional estimates of various on-farm, health-related practices for specific animal commodities. NAHMS studies are geared to provide a limited amount of 'core' trend information across years and to target critical issues for major U.S. livestock industries. NAHMS studies generally include on-farm interviews and biological or environmental specimen collection. Producers are selected at random from sampling frames provided by the USDA's National Agricultural Statistics Service (NASS) and are first contacted by NASS representatives. Producers agreeing to participate in NAHMS studies are guaranteed confidentiality and receive national study results and laboratory test results for their operation.

Results of these national studies are in high demand. Reports, ranging from one-page fact sheets describing specific production management activities, such as branding practices, to descriptive data tabulations and scientific articles in refereed journals, are produced to share study results. Baseline information gathered as part of the national studies is used for a wide variety of analyses and further studies. Data are also used to address emerging situations such as the 1993 *Cryptosporidium parvum* outbreak in Milwaukee and a 1994 peracute bovine diarrhea disease (BVD) situation. Most of the biologic samples collected as part of the national studies are banked for future use and are useful in retrospective evaluations of new conditions and further work on endemic conditions.

These national monitoring efforts require considerable resources to design and develop each project, train data collectors, implement data collection, and analyze and disseminate results. Due to costs, the frequency and nature of NAHMS studies are limited, and only a few scientifically-worthy issues can be addressed. To date, resource constraints have limited study of any particular commodity, such as dairy cattle, to once every five years. Certainly this system is less than ideal to monitor trends which fluctuate more frequently than five year cycles.

Given these constraints, the relative merits and costs associated with other options for filling the information gaps not addressed by NAHMS national studies are useful to consider. To date, several ongoing monitoring activities have been investigated, and a few are employed in a 'portfolio' of monitoring and surveillance activities. These activities are relatively low-cost, and wherever possible, use existing data sources. They are often restricted to a limited inference base.

**Ongoing Monitoring**

**Diagnostic Laboratory Disease Reporting:** The present Veterinary Diagnostic Laboratory Reporting System (VDLRS) reports test results from 28 voluntarily participating laboratories. The VDLRS includes five disease conditions for which standardized case definitions have been agreed upon by the
American Association of Veterinary Laboratory Diagnosticians' subcommittee on Animal Disease Reporting. These data and limited interpretations are reported quarterly in the DxMonitor Animal Health Report. Veterinary diagnostic laboratories present an admittedly biased sample, and the present reporting system does little to address the bias other than utilizing standardized case definitions. This type of monitoring is useful, however, in describing the geographic distribution of actively monitored diseases and relative changes in prevalence of certain diseases. Participating laboratories are also encouraged to report unusual patterns in laboratory accessions in an attempt to gather information on emerging animal pathogens and conditions. In addition, the VDLRS provides a framework/network for conducting surveys when an emerging trend is thought to be developing such as the BVD situation. Data gathered through the VDLRS has been requested by pharmaceutical companies interested in developing new products.

Sentinel Cattle Feedlot Reporting: This voluntary system involves monthly death loss reporting by consultant veterinarians working in cattle feedlots. Currently seven consultants report on 55-60 feedlots which account for roughly 1.5 million head of cattle on feed (approximately 12% of the total U.S. cattle on feed population). Participants submit confidential monthly reports of death loss for each of their operations and, in turn, receive a report on trends in their operations and overall trends for all participating operations. This reporting scheme allows limited monitoring for the emergence of feedlot death loss trends. The scheme itself is relatively low-cost and, similar to the VDLRS, sets up a network of contacts for more targeted monitoring and specific studies when an emerging trend is identified.

NASS Inventory Information: This information is generated semiannually for cattle and quarterly for sheep and swine and is used as an estimate of the total population of each species of livestock. Inventory information is most useful as a current, maximum figure for the population at risk and gives national- and state-level estimates on livestock location (for both individual animals and herds). In general, figures are available by animal weight class and numbers of producers. The NASS livestock inventory information is available to the general public at no cost.

NASS Death Loss Studies: NASS has agreed to ask additional questions on some quarterly and semiannual surveys on behalf of NAHMS. To date, these questions have focused on death losses and causes of death.

National Poultry Improvement Plan (NPIP) Breeder Pathogen Information: Information compiled through NPIP on the prevalence of certain Salmonella and Mycoplasma species in breeder flocks is graphed to follow trends in the number of flocks monitored, the number of birds monitored, and the flock prevalence of these diseases.

Somatic Cell Count (SCC) Information from the Dairy Herd Improvement Association (DHIA) and the USDA's Agricultural Marketing Service (AMS): DHIA has provided annual summary milk somatic cell count information while
AMS supplies monthly producer-level information. The AMS oversees use of SCC information in milk pricing schemes in some parts of the country. Bulk tank samples of milk are laboratory tested, and averages will be evaluated over time by herd size and geographic area. SCC monitoring provides a gauge of dairy udder health and milk quality and may allow the detection of emerging conditions.

Food Safety Inspection Service (FSIS) Slaughter Condemnation Data: FSIS routinely records carcass condemnation information for cattle, swine, sheep, and poultry which is useful in evaluating trends surrounding recorded conditions. In response to a request from the National Cattleman's Association in 1991, trends in condemnations due to eosinophilic myositis were evaluated to determine if the rate of condemnation for this condition was cause for concern. Condemantion rates were examined for the previous three years by class of cattle and it was determined that the rates were constant within each class of cattle, but heifers had a significantly higher rate than other classes of cattle. As part of the needs assessment for the broiler industry, FSIS condemnation data from 1980 through 1995 were examined. Condemnations due to Marek's Disease increased during this time period and as a result, the 1996 NAHMS broiler study will focus on determining potential risk factors for within flock spread.

Future areas under consideration: Due to declining budgets in the face of demands for continued and, in some cases, increased services, the NAHMS program is constantly evaluating ways to streamline efforts. These efforts entail low-cost ways of utilizing existing data or data gathering mechanisms to monitor the health of the nation's livestock and poultry. One largely un-tapped area which is getting increasing attention involves utilizing the existing surveillance programs in a more coordinated and integrated manner. Disease surveillance and health monitoring activities have not been linked, but with a few procedural modifications, data gathered in support of disease programs can be used as part of the monitoring portfolio.

**Targeted Studies**

In many cases, it is enough to monitor and report trends observed and detected through various means. Often, however, these trends raise further questions about relevance, cause and effect, pertinent risk factors, and a myriad of other topics which can only be adequately addressed through careful followup studies aimed at answering specific questions. National probability-based, cross sectional studies, and ongoing monitoring schemes are used to identify trends, detect potential risk factors, and generate hypotheses which cannot be proven without further study. On the other hand, further study could be prohibitively expensive if initial information about possible risk factors generated through major national studies and ongoing monitoring efforts were not available.

Many targeted followup studies born out of national study or ongoing
monitoring findings are conducted in controlled, experimental conditions. Universities and other research institutions, both public and private, conduct smaller scale field studies to further test hypotheses generated through national study and ongoing monitoring activities. USDA:APHIS:VS conducts a limited number of these followup studies when such studies are within the scope of agency missions and goals. An example of a VS targeted study which grew out of a national survey involved risk factors for *Escherichia coli* 0157:H7 shedding in dairy heifers, inspired by the existence of related data from the 1991 NAHMS National Dairy Heifer Evaluation Project.

**Summary**

Given the high demands for scientifically accurate and timely animal health information, the portfolio strategy of combining national studies; ongoing monitoring; and limited, targeted studies is anticipated to provide modern agriculture with the most complete and economical approach to information needs possible. While national studies provide statistically-valid estimates of a wide range of potential risk factors and practices at specific points in time, ongoing monitoring is a useful tool for keeping a watchful eye on trends that might be developing in selected areas and provides the framework and network on which to build targeted studies. In turn, targeted studies allow further evaluation of specific hypothesized relationships (such as cause and effect) between health outcomes and suspected risk factors. National studies, ongoing monitoring, and targeted studies combined are helping paint a more complete picture of animal health in the United States.

**Acknowledgements:** The author thanks Ms. Nina Rothenberger and Drs. Donna Carver, Dave Dargatz, Ann Seitzinger, Marty Smith, and Scott Wells for their thoughtful suggestions and review.
EXPERIENCES WITH ANIMAL HEALTH MONITORING AND SURVEILLANCE PROGRAMS IN SWITZERLAND

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Summary

Switzerland has traditionally used a passive disease reporting system for all notifiable diseases. This type of system is not suitable for the documentation of very low prevalences (‘freedom from disease’ status), sub-clinical cases, and non-notifiable diseases. In order to meet the high international standards for animal health surveillance and to fulfill the general need for sound animal health data, Switzerland has evaluated the feasibility of modern monitoring and surveillance concepts.

In general, the principle of active surveillance has been adopted and is now being applied whenever possible. In this paper, several examples of Swiss surveillance systems are presented and discussed. They include systematic testing of random population samples, carcass surveillance at abattoirs and sentinel herd monitoring.

Introduction

As a consequence of animal disease control and eradication programs, Switzerland has reached a favorable animal health status. Many infectious diseases of livestock have been eradicated. Yet, when it comes to the scientific documentation of a disease free status, systematic data collection is needed. Animal health surveillance holds a key position in providing such data. The Office International des Epizooties (OIE) has started to publish guidelines for the declaration of a disease-free status (Anonymous, 1989, 1993). In any case, the basis for such declarations will be data recorded by a modern, active surveillance system.

Endemic disease problems form a second area, in which animal health information is needed. Chronic and degenerative disorders are still causing substantial losses in Swiss animal production. The planning and evaluation of possible control measures need to be based on reliable epidemiological and economic data derived from a representative population. For this reason, the need for sound animal health information has increased markedly over the last years.

In order to meet the demand for animal health data, the current monitoring and surveillance programs in Switzerland have been systematically evaluated and new or additional concepts have been elaborated (Stärk et al., in press). This paper will present some examples featuring the new elements.

Laboratory screening

The systematic testing of entire livestock populations has been a central
ANIMAL HEALTH MONITORING IN SWITZERLAND

element of various disease eradication programs in Switzerland. Over the last years, it was mainly applied to the cattle population in order to screen for infectious bovine rhinotracheitis (IBR) and enzootic bovine leukemia (EBL).

During the eradication process the prevalence of IBR and EBL dropped dramatically (Stärk and Hauser, 1993). When it fell considerably below a prevalence of 1% it was decided to switch from a yearly complete population survey to a random sample testing procedure.

For this survey, the farms were selected with the help of the Federal Office of Statistics using a farm register. This register is updated after each nation-wide business census. It contains the farmer's address, farm size and number of large livestock equivalent units (computing unit for administrative purposes) but no detailed information on herd size and livestock species. The required sample size for the survey was calculated such that an infected farm could be detected with a 99% probability if the prevalence of infected farms had risen above 0.1% (Cannon and Roe, 1982). A 20% increase of the sample size was made and eventually 5'576 farms were selected. All these herds were visited by practitioners and either blood or milk samples were collected from all bovines older than 24 months.

This method was first used in 1994. The evaluation of the reports that were written by the veterinarians collecting the samples demonstrated that the goal of collecting data on at least 4'600 farms was obtained (Siréjols, 1995). With help of this data the IBR- and EBL-free status of Switzerland on a 0.1% prevalence level could be documented.

The main problem with this approach was the outdated farm register, in which many farmers were not producing cattle any more but were still listed. An other drawback was the lack of livestock information in the register, i.e. it was not possible to discriminate dairy cow farms from swine farms. These problems will be solved as soon as the new agricultural data base AGIS is available. It will include all data that are collected during the annual agricultural census, e.g. detailed herd size data for all species and farm characteristics. This data will also be geo-referenced for the use in geographic information systems. The new data base is a joint project of several Swiss Federal Offices and the Cantons (Swiss administrative units, similar to states).

The experience with random sample testing has shown that it is a reliable, feasible and cost-efficient tool for health status documentation purposes. It is planned to expand this program in the near future. For example, the milk samples taken for IBR/EBL antibody screening could be used for Brucella abortus testing as well. In the long term, similar national surveys are planned for health monitoring of the national swine population. Diseases of interest are classical swine fever, Aujeszky's disease and brucellosis.

If serum samples are taken from representative samples of the population these could also be stored in a national serum bank and used for future investigations.
Slaughterhouse surveillance

Meat inspection data can also contribute substantially to animal health information systems. For some subclinical diseases such as contagious bovine pleuropneumonia (CBPP) it is not just the easiest but the only way to identify suspect animals (Anonymous, 1993). Although CBPP was eradicated in Switzerland in the 19th century, several cattle exported to Italy were tested sero-positive for anti-CBPP-antibodies in 1992. Subsequently, Switzerland developed an active surveillance system for this disease based on OIE standards (Stärk et al., in press).

In Switzerland, all carcasses of cattle are routinely screened for lesions of notifiable diseases. In 1993, a specific awareness campaign for CBPP lesions was organized. The meat inspectors were encouraged to take samples from all suspect lungs of cattle older than 2 years and to send them to the reference laboratory for microbiological analysis. So far, more than 100 suspect lesions were submitted and yet Mycoplasma mycoides sp. mycoides SC has not been isolated. As a conclusion of this study, the lesions occurring in CBPP-infected animals can no longer be called pathognomonic for the disease, and Switzerland has documented to be a CBPP-free country.

Such an abattoir surveillance system includes active elements of data collection. It is therefore more reliable than a passive reporting system although it requires constant information and motivation of the meat inspectors. This can only be obtained by feeding information gathered by the system back to them. Also, data recording at the abattoir particularly requires technical considerations in order not to interfere with routine slaughter and processing. It is planned to intensify data collection in the slaughterhouse in the future and to link it with pre-harvest herd health information. Although the latter programs are still in their infancy in Switzerland, they are likely to gain increasing importance in the future in both the beef and pork industry. If health certificates are going to create a market advantage they need to be based on reliable data.

Health profiles

In 1993, a pilot study was initiated to investigate the health profile of Swiss dairy cows. The goal was to follow a representative sample of farms during a defined time period, and to record all occurring health events along with treatment information and management characteristics. With the help of the Federal Office of Statistics a stratified random sample of 284 dairy farms was selected out of the total of 60'000 farms. The farmers were contacted and asked to participate. Finally, 113 (42%) of the farms were enrolled in the study (Stärk et al., 1994). All the farmers collaborated on a contract basis.

During a 15 month period, all health events were recorded on pre-printed sheets and returned to the investigators every second week. Additionally, the farms were visited regularly, and blood and feces samples were collected for laboratory analyses. The results of this pilot study will provide information on both clinical disease incidence and sub-clinical agent and/or antibody preva-
ANIMAL HEALTH MONITORING IN SWITZERLAND

A short summary of the incidence measures for different disease categories in cows and calves are presented in TABLE 1. Further analyses are currently being done to estimate the expenses associated with these health problems.

**TABLE 1**: Incidence measures of disease by category, expressed as incidence density (ID) per 100 animal-years or as cumulative incidence (CI) per 100 calvings and statistics on farm level

<table>
<thead>
<tr>
<th>Disease category</th>
<th>ID</th>
<th>Mean of ID*</th>
<th>Median of ID*</th>
<th>95% C.I. of the Median***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive disorders</td>
<td>1316</td>
<td>152.2</td>
<td>117.3</td>
<td>91.7-151.8</td>
</tr>
<tr>
<td>Diseases of the udder</td>
<td>419</td>
<td>40.5</td>
<td>36.7</td>
<td>30.8-43.0</td>
</tr>
<tr>
<td>Calving disorders</td>
<td>24.7*</td>
<td>25.4**</td>
<td>20.0***</td>
<td>15.4-23.1***</td>
</tr>
<tr>
<td>Lameness</td>
<td>160</td>
<td>16.4</td>
<td>10.0</td>
<td>5.9-13.6</td>
</tr>
<tr>
<td>Metabolic disorders</td>
<td>114</td>
<td>11.6</td>
<td>9.7</td>
<td>7.1-12.2</td>
</tr>
<tr>
<td>Disease of the digestive tract</td>
<td>58</td>
<td>7.2</td>
<td>0.0</td>
<td>0.0-3.5</td>
</tr>
<tr>
<td>Diseases of calves</td>
<td>921</td>
<td>87.6</td>
<td>53.4</td>
<td>0.0-76.7</td>
</tr>
</tbody>
</table>

* calculated on a farm level (n=113)
** CI
*** Mean of CI

This program is particularly helpful for the monitoring of non-notifiable diseases. Priorities for further research can be set with the help of the supplied information for example in intervention studies. The experience from working with the farmers with respect to data collection is encouraging and high data quality can be obtained, provided that there is a straightforward documentation of the data recording protocol and feedback between the study coordinators and the farmers.

Similar programs in different production sectors such as swine production and a repetition of the health profile in the dairy industry are planned in the future.

**Conclusions**

An evaluation of the Swiss animal health monitoring and surveillance system has shown a need for new concepts in order to meet industry demands as well as international standards. The latter are a prerequisite for access to the international market of livestock and animal products. As a consequence of the current trade liberation all supplemental health requirements made by any country will need to be based on scientifically sound data.

Key issues identified when implementing the described monitoring and
surveillance programs are:
- need for up-to-date and readily accessible sampling frames for livestock farms
- recruiting and motivation of professional and non-professional people for data recording
- good data quality
- prompt data analysis and feedback of information to data source

A new, integrated system to obtain and evaluate animal health data has since been proposed for future use (Stärk et al., in press). It will consist of different modules each covering a certain source of animal health data, i.e. data from diagnostic laboratories or abattoir data. All of these modules will emphasize active surveillance principles. Data exchange between the modules will be facilitated by common disease codes and standardized data fields. Farm and animal identification will also have to be guaranteed. An animal health information center will coordinate collection, transfer and analyses of the data, and make them accessible to both the decision makers as well as the public. For this purpose an information server providing on-line access is currently in development.

This system will be an important support for decision making in animal health issues and optimize the distribution of scarce resources by setting realistic priorities.

Acknowledgments
I thank Dr. Christian Griot, Director of the Institute of Virology and Immunoprophylaxis, and Prof. Dr. Ueli Kihm, Swiss Chief Veterinary Officer, for their critical review of this manuscript.

References
The Committee met for two sessions. A total of 84 individuals attended the two sessions. The first session was a workshop and discussion session with the theme "Identification and Consolidation of Existing Data Sources and Standardization of Disease Definition and Reporting". The session was moderated by Dr. Francois Elvinger. A companion paper is the final report from this workshop.

Several speakers presented their papers during the second session of the Committee meeting. Dr. Josie Traub-Dargatz, Colorado State University, discussed the equine data sets available in state veterinary diagnostic laboratories that could be used in a national equine disease reporting system. She summarized a study conducted in cooperation with the APHIS:Centers of Epidemiology and Animal Health (CEAH) on 17 equine data sources. Among these sources are the veterinary teaching hospitals, state diagnostic laboratories, and abattoirs. She presented the advantages and disadvantages for some of these data sources. She focused on two sources: veterinary teaching hospitals and state diagnostic laboratories. Examples were given from a study which was performed using data from both of these sources. The findings from a survey which was conducted by APHIS:CEAH and Dr. Traub-Dargatz was presented. The survey included the 26 state diagnostic labora-
REPORT OF THE COMMITTEE

In the report, the committee highlighted the importance of electronic data recording in laboratories. Twenty-three laboratories responded to the survey, with the most significant concern being the electronic recording of data. Only half of these laboratories could link the results of two different serological tests submitted at different times. The results of the survey were published in the Dx Monitor in the winter 1994 issue.

Dr. Katharina Staerk, Institute of Virology and Immunoprophylaxis - Switzerland, discussed the Swiss approach to animal disease surveillance programs. Dr. Staerk's presentation is in a companion paper to this report. The study focused on dairy herds which were selected randomly as sentinel herds for animal health information. Several issues related to the Swiss' approach to animal health information were discussed during the questions and answers round. Some of the issues discussed are the importance of sampling frame, recruitment, data validity, motivation, contact time, analysis, and feedback system.

Dr. Theresa Bernardo, Inter-American Institute for Cooperation in Agriculture (IICA) in Costa Rica, presented a paper entitled “Future of International Disease Reporting”. Dr. Bernardo reviewed the current international animal health reporting systems. She gave the history and the description of the software for data collection HandiSTATUS: Help with World Animal Disease Status. This software is a public domain program that requires no computer experience and minimal requirements for computers space. The program allows selection of a group of diseases based on various classifications includes risk identification for import/export. Several countries have already used this software as their reporting system to both OIE and FAO. The program is available through the Internet via FTP. Currently the 1993 and 1994 animal health data are included and the 1995 data will be available in first half of 1996. The Chief Veterinary Officers (CVOs) should be able to send in their own data through this program. Dr. Bernardo circulated several copies of the program to the audience.

Dr. Jim Case, University of California - Davis, presented a summary of the symposium entitled “Electronic Dissemination of Information”. The Symposium was held Friday October 27, 1995. The symposium was well attended. Topics presented during the symposium were the Internet and how it is used to disseminate information, value of teaching veterinarians and the public through Internet, filtering of information through electronic tools, tools for dissemination, e-mail, listservs, newsgroups, file transfer protocol (FTP), NOAH, TelNet remote log-in, gopher, and World Wide Web.

Dr. Nora Wineland, USDA:APHIS:VS; CEAH, presented a paper entitled “Animal Health Information - A National Portfolio”. Dr. Wineland summarized the history of the current Animal Health Monitoring System (NAHMS) and its future. A companion paper has the complete report of Dr. Wineland's presentation. Questions such as source of funding, source of focus groups, time frame for the studies, personnel resources and costs, and use of external funding were generated during the discussion.
Dr. Francois Elvinger gave a summary of the meeting outcomes from the AAVLD Animal Disease Reporting subcommittee. The main emphasis of the subcommittee meeting was on the direction and redirection of the Veterinary Diagnostic Laboratory Reporting System (VDLRS). This subcommittee felt that VDLRS was stagnant and a revival of the effort was necessary in order to include additional species and conditions and retain or recruit additional laboratories. Following discussion it was conceived that reporting of conditions by laboratories should be done in 4 different formats:

1) determine a list of conditions to be reported with a great level of detail, i.e. number of tests performed and positive, or number of accessions tested and positive, or number of premises tested and positive. These conditions should be reported as is presently done on a monthly/quarterly basis. The list of diseases reported under this format should be based on recommendations by the USAHA committee on Animal Disease Surveillance and Animal Health Information.

2) determine a list of conditions to be reported with a low level of detail, i.e. detection/lack of detection of a condition on a monthly or quarterly basis. The list of diseases reported under this format should be based on recommendations by the USAHA committee on Animal Disease Surveillance and Animal Health Information or recommendations from other sources.

3) request contributions to LabNotes from laboratory directors or liaison people at laboratories. This request should be mailed quarterly in a format to be worked out prior to information requests for the next DxMonitor.

4) determine conditions of interest and invite contributions from laboratory directors or liaison people with each request for information for DxMonitor. Conditions should be broadly defined (i.e. enteric diseases in cattle, abortion in pigs) and the format of reporting by laboratories should be left open.

These issues were presented to the AAVLD Committee of Laboratory Directors. They agreed to support our efforts and suggested to us to request from all labs that produce monthly, bimonthly, quarterly or bi-annual newsletters or reports to be included on mailing list to obtain relevant information. The directors also did not see a problem with addition of State Veterinarians animal health information to the VDLRS.

Finally at the end of the session the Committee members discussed the future role of the USAHA in the animal health reporting system. It was decided that the Committee should initiate a national animal health reporting system in which both animal health and disease records from state diagnostic laboratories and state veterinarian offices will be merged under a quarterly based reporting bulletin such as Dxmonitor. A subcommittee consisting of Drs. Akey, Case, Elvinger, Park, Salman, and Wineland will develop and implement the report form. This subcommittee will be responsible to evaluate the
reporting system. The subcommittee will report its findings during the meeting next year.

It was decided that this committee will not join the AAVLD disease reporting subcommittees at this time. Each of these two Committees has a different mandate and responsibilities. However, the two Committee will continue working together toward a better animal health information system. "Identification and Consolidation of Existing Data Sources and Standardization of Disease Definitions and Reporting" - Workshop Report.
"IDENTIFICATION AND CONSOLIDATION OF EXISTING DATA SOURCES AND STANDARDIZATION OF DISEASE DEFINITIONS AND REPORTING"
WORKSHOP REPORT

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This workshop was co-sponsored by the USAHA Committee on Animal Disease Surveillance and Animal Health Information Systems and the AAVLD Subcommittee on Animal Disease Reporting. The workshop was held in a question-answer format following a brief and informal presentation to lead off into the 4 items on the agenda:

1) Objectives of a reporting system
2) Present reporting activities
3) Reporting Standards
4) Trade and public health aspects

Objectives of a reporting system were established in a brainstorming session moderated by Dr. François Elvinger, Dr. Mo Salman from Colorado State University and Dr. Bruce Akey introduced present reporting activities, Dr. Jim Case and Dr. Will Hueston elaborated disease definition and reporting standards, and Dr. Cristobal Zepeda-Sein presented trade and public health aspects of reporting systems.

Presently there is no unified system for reporting animal health/diseases in the U.S. However, several reports on various conditions/agents/diseases are published with varying levels of detail from different sources. Consolidation, enhancement and expansion of these reports should be a prime objective for the activities of USAHA and AAVLD committees.

Objectives of a national animal health reporting system
Why report?

Prevention of national and international spread of disease, identification of emerging diseases, estimation of disease prevalences, incidences and trends, determination and evaluation of risk factors, monitoring of eradication programs, protection of the food supply and the economic viability of the ani-
STANDARDIZATION OF DISEASE DEFINITIONS AND REPORTING

mal food and fiber industries, estimation of the health status of animal populations in the country for reasons of international trade and public health protection were the reasons mentioned for establishing a national animal health reporting system. Adequate and accurate information has to be available for decision making at all levels (regulatory, trade, ...) affected by the health status of animal populations.

Who are clients for information reported in a national system?

First of all, ourselves, the people and groups involved with animal production and maintenance in the United States. These include state and federal governments including public health authorities, producers and commodity groups, research entities, pharmaceutical and other allied industries, professional organizations, veterinary practitioners, diagnostic laboratories, the press and consumers and users of animals and animal products. In addition trade partners and national and international regulatory authorities have an interest in a unified United States Animal Health Reporting System.

What conditions/agents/diseases should be included in a national reporting system?

Conditions to be included can be classified according to the needs of the clients receiving the information, the quality of the available data and the impact that reporting could have on affected industry groups. Several possible classifications were considered: specific conditions/agents/disease must be reported and a reporting system already is in place, while many other conditions may be reported. Diseases that must be reported are likely to have a high economic and trade impact, often are considered exotic, as opposed to indigenous and frequently endemic conditions that at the present time do not require rapid and timely reporting or reporting at all. Depending on conditions and audience there are advantages to report raw data, while in other cases composite reports or information based on data analysis and interpretation is requested. Conditions to be reported can in general be classified as conditions with international trade impact and conditions with impact on national production, although there often is no clear-cut delimitation. The choice of reporting conditions with no regulatory requirements has to be based on feasibility/sustainability and support for reporting, and costs and benefits considerations are warranted.

The points determined in this session can be used to create a matrix for inclusion of conditions/agents/diseases to be reported that can help in establishing priorities in the reporting system.

Present Reporting Systems/Capabilities

Dr. Mo Salman reported results of a mail-survey of 49 USAHA and AAVLD committee chairmen. Twenty-six chairmen or their representatives returned filled-out questionnaires. Questions and responses are following: Does your committee deal with a specific disease? yes 13, no 12. / Does your committee deal with the reporting of health events? yes 5, no 18, occasionally 3. /
ELVINGER

What are the best criteria to define the diseases your committee considers? Responses included complete definitions (n=7), partial definitions (n=4), no definition (n=2), not applicable (n=11), no answer (n=2). Is there a need for a national or regional reporting system? Yes 9, no 1, is already in place (n=2), not applicable (n=13). Various responses were received to the question on what would be the best system to inform producers, public and other interested parties about these diseases. Responses included tabulation and dissemination via reporting systems like the Veterinary Diagnostic Laboratory Reporting System or an APHIS disease reporting system, computer bulletin boards, articles in producers journals. Responses suggested that standard disease definitions are already or could be established/modified on brucellosis, tuberculosis, equine infectious anemia, equine babesiosis, equine encephalitides, equine viral arteritis, contagious equine metritis, some enteric diseases of swine, bluetongue, rabies, leptospirosis and avian influenza.

Dr. Salman concluded his presentation by reiterating the need for a national and/or regional reporting system, the establishment of a list of diseases to be reported, and the development of disease definitions and reporting standards for many diseases. The Office International des Epizooties has a diagnostic manual of standards for testing that can be used as a guide (protocols and definitions).

Dr. Akey reported results of a mail survey to 50 State Veterinarians and 1076 selected private practitioners in large or mixed animal practice, done in collaboration with Dr. Marty Smith from USDA:APHIS:VS:CEAH:CAHM. Results from 48 (96%) State Veterinarians and 86 (8%) private practitioners were reported. Eighty-three percent of responding states have existing reporting systems with 73% of those requiring reporting of at least some list A diseases. However one fifth of private practitioners responded that they were not aware of a reporting requirement or reporting system in their state when the State Veterinarian indicated that there was. At the present time, 38% of State Veterinarians offices have computing capabilities that could be used for reporting purposes and all State Veterinarians or their representatives indicated willingness to participate in a national animal health reporting system. However, pilot testing of a reporting system is advisable, and it has to be determined if participation should be voluntary or mandatory. Questions of funding and administration of such a system have to be solved. Dr. Akey concluded his presentation assuring that indeed we are ready to start developing an appropriate reporting system.

The discussion following these presentations centered around the step-wise approach to develop a system. The Veterinary Diagnostic Laboratory Reporting System that results in publication of the quarterly DxMonitor is a dynamic system that was initiated in the late 1980's and has undergone several changes since the first issue in 1990. Reporting systems have surveillance and sentinel functions. Any reporting system has to be constantly adapted to the needs of the audience and the capabilities and resources of
the reporting units.

**Standards for Reporting of Animal Health Information**

Dr. Case explained that standards improve content and consistency of animal health information, improve data sharing, provide the means for measuring improvements, improve the speed of delivery of information, reduce the need for redundant procedures, aid in management of resources, improve risk management, provide vendors with defined specifications for performance, content, format, and function, and improve cost recovery. A standard is commonly used and is accepted as an authority. Messaging standards determine format and structure of data and allow capturing of information from different systems for which storage may be physically different (different groupings, different values). These standards reduce errors of omission and transcription, improve accessibility of data and improve ability to integrate data from different sources. Dr. Case cited as examples the American Society for Testing and Materials (ASTM), IEEE-MEDIX, ANSI X-12, ACR-NEMA. Codes and Vocabularies: Messaging does not address content. Statistical analysis however requires standard representation of data (synonyms, eponyms, abbreviations) that is essential for the exchange of information and to realize benefits of computerization. Nomenclature is a set of names or terms, classification is a statistical tool that groups data based on nomenclature. Current nomenclature systems contain a lot of synonyms (up to 60%) but are usually mapped to a single preferred term. There is always concern that a nomenclature system will be restrictive, inflexible or inadequate. Reviews in human medicine have shown this is not the case. You must not only identify the tool (nomenclature) that will be used but it is also critical to give directions on how the tool will be applied. Examples: SNOMED International (limited veterinary terms, READ CODES, LOINC (laboratory information), UMLS (uniform medical language system). Identifiers provide a unique identification of client, patient, site of diagnosis etc. Problems in veterinary medicine include owners with multiple animals, herds and others, however solutions of these problems do not appear to be of high priority at this time. Identifiers are critical to determine discrete occurrences of a disease versus a continuing problem of a previously reported occurrence.

Dr. Hueston presented current developments on OIE standards. The Office International des Epizooties (OIE) was formed after World War I to provide a forum for reporting of national disease status, serve as an international organization to reach consensus on diagnostic standards (Diagnostic Manual) and methods/procedures for prevention of entry of diseases into a country (Animal Health Code). The U.S. has only been a member since 1976. The OIE has a formal role under GATT and NAFTA as an international standards setting organization. GATT and NAFTA are based on the golden rule of “do unto others as you would have them do unto you” and allows more than one way to meet requirements as long as they are scientifically equivalent. The
animal health codes and diagnostic standards are moving ahead much faster than the reporting standards. There are no definitions of reporting terms and no independent verification of what is reported. Risk communication is the emerging area of interest. A mechanism for evaluating the veterinary services and reporting infrastructure and for validating reporting is needed. Zero risk is no longer considered attainable and the statement “free of disease” is not valid. Instead we can classify countries as to level of risk for a particular disease. Surveillance is a dynamic area. A lot of development is still needed.

In the following discussions the warning came up that developers of a national broad spectrum system should not reinvent the wheel and/or use too many wheels. However, since disease definitions, diagnostic and reporting standards are still being developed, it appears that there is flexibility in establishing the criteria best suited for reporting disease in the United States. Cooperation between state, national and international agencies and industry groups will ensure a greater chance for successful implementation of a reporting system.

**Trade and Public Health Aspects**

Dr. Zepeda explained that diseases other than OIE List A diseases should be reported if warranted due to their potential importance and economic impact. For example, non-pathogenic avian influenza is not a List A disease but the virus has the potential to mutate resulting in a disease with severe economic impact. Avian influenza therefore is of sufficient importance to be reported. Any diseases that can affect trade or human health are important and should be reported whether they are on List A or not. Mexico currently has a long list of reportable diseases, many of which are not reported on due to various reasons. The Mexican list needs to be trimmed to a list including exotic diseases, List A diseases, any disease with high mortality, with significant economic impact or that limits international trade and diseases that are potential zoonoses.

The final consensus was that a comprehensive and accurate reporting system for conditions/agents/diseases affecting American animal populations is a necessary tool to allow decision makers and anybody including USAHA and AAVLD specialty committees to allocate resources based on needs established following accurate reporting, not perception. A national animal health reporting system needs to be practical, timely, sustainable, flexible, uniform, transparent and trusted by all parties concerned with the health status of animal populations in the United States.
REPORT OF THE COMMITTEE ON ANIMAL WELFARE

Chairman: Mr. John H. Lang, Stoughton, WI
Vice Chairman: Dr. Carolyn L. Stull, Davis, CA

Ms. JoAnn Alumbaugh, IA; Mr. Fred R. Bauer, CA; Mr. Robert B. Buckler, MN; Dr. Thomas C. Bunting, IL; Mr. Donald C. Christ, OR; Dr. Morley Cook, MD; Dr. Richard L. Crawford, MD; Ms. Amelia J. Donald, TX; Mr. Robert Dykhuis, MI; Dr. Nancy A. Frank, MI; Mr. Daniel M. Goodyear, PA; Dr. Steven L. Halstead, MI; Mr. Del E. Hensel, CO; Dr. Patrick D. Hoctor, IN; Dr. Richard D. Hull, IL; Mr. Tom J. Hunt, MI; Mr. Ralph D. Jones, SD; Mr. Steve L. Kopperud, VA; Dr. Herbert E. Little, CA; Dr. Herbert C. Lloyd, FL; Dr. Calvin W. S. Lum, HI; Mrs. Amy Mann, DC; Dr. Charles E. Massengill, MO; Mr. Marshall Meyers, DC; Dr. Raymond L. Morter, IN; Dr. Victor F. Nettles, GA; Dr. Tomas A. Neuzil, IA; Mr. James E. Rich, WA; Ms. Nancy Robinson, MO; Dr. Dale F. Schwindaman, MD; Dr. Morton S. Silberman, GA; Mr. Alan J. Stern, FL; Mrs. Christine Stevens, DC; Dr. Paul Sundberg, IA; Dr. R. Flint Taylor, NM; Mr. George Teagarden, KS; Dr. Robert M. Temple, OH; Dr. Kenneth L. Thomazin, CA; Mrs. Michele C. Turner, TX; Dr. Charles D. Vall, CO; Dr. Gary M. Weber, DC; Mr. Dave Whittlesey, CO; Dr. Elizabeth S. Williams, WY; Dr. Norman G. Willis, CAN

The meeting of the Animal Welfare Committee of the United States Animal Health Association was called to order by its Chair, John Lang, at 1:30 PM, Tuesday, October 31, 1995. Present were twenty members and 17 non-members and guests.

In his opening remarks, Lang reminded those attending of the need to recognize the interrelationships of animal welfare concerns among all persons who own and raise animals. He said that the day’s agenda would focus on dog, cat and horse issues, but he urged all members to follow the discussion to look for clues to issues they might eventually face and to provide the benefit of their ideas and experiences in responding to challenges and opportunities facing the cat, dog and horse industries.

The first speaker on the program was Dr. Dale Schwindaman, USDA-APHIS-REAC. He reported on activities of REAC in the face of budget declines; emphasis is being placed on quality of inspections as opposed to simply numbers of inspections. Significant attention is being placed on investigation resulting from complaints and to responding questions and concerns voiced by the public.

Next on the program was Dr. Norman Willis, Agriculture Canada reporting of his agency’s efforts to develop humane standards for transporting animals. He defined their goal as being “to develop a shared quality assurance program for animal transportation in Canada.” Agriculture Canada has been very suc-
REPORT OF THE COMMITTEE

cessful in bringing together stakeholders ranging from animal owners to animal protection advocates working together to develop standards for animal care in Canada.

Last year the committee approved a resolution to appoint a task force to develop a model state law regulating the cat and dog industry. At that time, Committee Chair Lang appointed the members of the task force headed by Missouri State Veterinarian Dr. John Hunt to undertake the project. At this meeting, Dr. Hunt reported the results of the efforts of the task force including the major provisions of the model law.

The final presentation of the program was a panel discussion of horse welfare concerns lead by Animal Welfare Committee Vice Chair Dr. Carolyn Stull. She introduced Mr. Norm Lubba, North America Equine Ranching Information Council who presented information on issues surrounding pregnant mare urine ranch practices and facilities. Next, Dr. Morley Cook, USDA-APHIS-REAC highlighted the use of thermography for detecting sores on horses in complying with the Horse Protection Act. Mrs. Amy Mann, American Horse Council, discussed the background and introduction of Senate Bill SB 1283 which focuses on the welfare of horses being commercially transported to slaughter. Finally, Dr. Ted Friend, Texas A&M shared preliminary data from his on-going study examining the water needs of horses transported for 24 hours in hot climatic temperatures.

A resolution approved by the committee affirmed a resolution from the Infectious Diseases of Horses Committee to oppose allowing equine piroplasmosis positive horses from being brought into the United States for the Summer Olympic Games in Atlanta in 1996. Another resolution approved by the committee calls for USDA to make available funds to study welfare concerns of horses being transported to slaughter.

At 6:00 PM Chairman Lang announced that the meeting of the Animal Welfare Committee would resume at 7:30 AM on Thursday November 2.

The meeting of the Animal Welfare Committee was called to order by its chair, John Lang at 7:30 AM on Thursday, November 2.

Silberman moved that the text of The Uniform Dog and Cat Welfare Act be included in the committee report. The motion was Seconded. Discussion followed, the question was called for and the motion was approved.

Lang declared the meeting adjourned at 8:00 AM.

(Note from the Chair: Dr. John Hunt asked that task force members be recognized. They are Mr. George Teagarden, Kansas Livestock Commission, Ms. Christine Stevens, Animal Welfare Institute, Mr. Robert Buckler, APPDI, and Dr. Alan Stern. Others making significant contributions were Mr. John Gleiber, Ms. Debra Duncan, Mr. Roger Lambert, Dr. L. Dale Wood, Ms. Christi Johnson, and Ms. Jo Anne Steene.)
ANIMAL WELFARE

THE UNIFORM DOG AND CAT WELFARE ACT
(model law as proposed by the USAHA Animal Care Task Force)

Preamble: The USAHA appointed an Animal Care Task Force at its 98th annual meeting in October, 1994. The Task Force was charged with preparing a model state law for the fair and reasonable regulation of pet production, distribution, boarding, shelter and pound facilities. It was further resolved "that the model state law shall promote a common, uniform national standard for pet animal welfare and shall discourage conflicting state and local regulation." The Task Force reviewed the laws of all 50 states and prepared the following model law. USAHA recommends that each state legislature recognize this as a model to be used as a guide in enactment of state law.

The purposes of this act are (1) to insure that animals are provided humane care and treatment by regulating the transportation, sale, purchase, housing, care, handling and treatment of such animals; (2) to insure that animals confined in pet shops, kennels, pounds, animal shelters and auction markets are provided humane care and treatment; (3) to reduce the number of homeless animals by insuring that only sterilized animals are released for adoption from pounds and animal shelters; (4) to prohibit the sale, trade or adoption of those animals which show physical signs of infection, communicable disease, or congenital abnormalities that threaten life or health, unless veterinary care is assured subsequent to sale, trade or adoption; (5) to protect the owners of dogs and cats from the theft of such pets; and (6) to prevent the sale or use of stolen pets.

An individual, family, or associations who do not fall within the meaning and definition of an animal breeder, animal distributor, operate an animal shelter, pound, boarding kennel, pet shop, or exhibition facility, shall also reasonably comply with the provisions of this act in the handling, care, and keeping of pet animals under their ownership, care, or custody.

Section 1. Definitions. As used in this act, unless the context otherwise requires:

(A) "Adequate feeding" means supplying at suitable intervals (not to exceed twenty-four (24) hours for adult animals and eight (8) hours for puppies and kittens) of a quantity of a wholesome foodstuff, suitable for the species and age, and sufficient to maintain a reasonable level of nutrition in each animal.

(B) "Adequate veterinary medical care" means:

(1) A documented program of disease control and prevention, routine veterinary care and euthanasia care shall be established and maintained under the supervision of a licensed veterinarian, on a form provided by the [insert reference to proper authority, i.e., commissioner,
REPORT OF THE COMMITTEE
director, etc.], and shall include a documented on-site visit to the premises by the veterinarian at least once each year; and
(2) that diseased, ill, injured, lame or blind animals shall be provided with veterinary care as is needed for the health and well-being of the animal.
(C) “Adequate watering” means a supply of clean, fresh, potable water, supplied in a sanitary manner and either continuously accessible to each animal or supplied at intervals suitable for the animalspecies, not to exceed intervals of eight (8) hours. Continuous potable water must be supplied if the ambient temperature is more than eighty-five degrees (85°).
(D) “Ambient temperature” means the temperature surrounding the animal.
(E) “Animal” means any live dog or cat.
(G) “Animal breeder” means any person who operates an animal breeder premise.
(H) “Animal breeder premise” means any premise or facility at which more than three (3) intact female animals are maintained where dogs or cats, or both, are sold, or offered or maintained for sale.
(F) “Animal control officer” means any person employed by, contracted with or appointed by the state or any political subdivision thereof, for the purpose of aiding in the enforcement of this law, or any other law or ordinance relating to the licensing of animals, control of animals or seizure and impoundment of animals, and includes any state, county or municipal law enforcement officer, animal warden, animal control officer, constable or other employee, whose duties in whole or in part include assignments which involve the seizure or taking into custody of any animal.
(I) “Animal distributor” means any person who operates an animal distributor premise. This term shall also include persons who buy and sell, or mediate the sale of animals at wholesale or retail, including auctions, whether or not an animal distributor premise is maintained.
(J) “Animal distributor premise” means any premise where dogs or cats, or both, are bought and sold, or offered or maintained for sale, primarily at wholesale for resale to another.
(K) “Animal shelter” means a facility which is used or designed for use to house or contain, impound or harbor any seized stray, homeless, relinquished or abandoned animal and which is owned, operated or maintained by a duly incorporated humane society, animal welfare society, society for the prevention of cruelty to animals, animal rescue, or other not for profit organization devoted to the welfare, protection, and humane treatment of such animals, or a person who acts as an animal rescuer, or who collects and cares for unwanted animals or offers them for adoption. Animal shelter also includes a facility of an
ANIMAL WELFARE

individual or organization, profit or nonprofit, maintaining twenty (20) or more dogs or cats, or both, for the purpose of collecting, accumulating, amassing or maintaining, or offering for sale or adoption such animals.

(L) "Auction" means any person selling any consignment of dog(s) or cat(s) to the highest bidder. This shall include any means, procedure or practice in which the ownership of a dog or cat is conveyed from one (1) person to another by any type or method of bidding process. Auction sales shall be considered as animal distributors and must be licensed as such under this act.

(M) "Boarding kennel" means a place or establishment, other than a pound or animal shelter, where animals, not owned by the proprietor, are sheltered, fed, and watered, or trained in return for a consideration; however, boarding kennel shall not include breeders who board intact females for a period of time for the sole purpose of breeding such intact females, and shall not include individuals who temporarily, and not in the normal course of business, board or care for animals owned by other individuals;

(N) "Business hours" means seven o'clock in the morning through seven o'clock in the evening (7:00 a.m.-7:00 p.m.), Monday through Friday (excluding legal holidays), or by written mutual agreement between the licensee and inspecting officials.

(O) "Cat" means any animal which is wholly or in part of the species Felis domesticus.

(P) "Certificate of veterinary inspection" or "health certificate" means a certificate signed by a licensed veterinarian stating that the animals described thereon are free of any sign of visible symptoms of communicable disease.

(Q) "Commissioner [insert proper authority's title]" means the principal state animal official that is responsible for administering this act.

(R) "Dog" means any animal which is wholly or in part of the species Canis familiaris.

(S) "Euthanasia" means the humane destruction of an animal, which may be accomplished by any of those methods currently approved by the American Veterinary Medical Association (AVMA) Panel on Euthanasia.

(T) "Exhibitor" means any person (public or private) exhibiting any animals, to the public for compensation, as determined by the [insert reference to proper authority]. This term includes carnivals, circuses, animal acts, zoos and educational exhibits, exhibiting such animals whether operated for profit or not. This term excludes retail pet stores, dog races, organizations sponsoring and all persons participating in state and county fairs, field trials, coursing events, purebred dog and cat shows and any other fairs or exhibitions intended to advance
agricultural arts and sciences as may be determined by the [insert reference to proper authority].

(U) "Housing facility" means any room, building or area used to contain a primary enclosure or enclosures.

(V) "Intact female" means, with respect to a dog, a female dog between the ages of six (6) months and twelve (12) years of age which has not been surgically sterilized by a licensed veterinarian; and with respect to a cat, refers to a female cat between the ages of six (6) months and ten (10) years which has not been surgically sterilized by a licensed veterinarian. Proof of sterilization must be made available upon request to the [insert reference to proper authority] or the [insert reference to proper authority]'s authorized representative.

(W) "License year" means the twelve (12) month period ending December 31.

(X) "Out-of-state distributor" means any person residing in a state other than [insert state name], who is engaged in the business of buying for resale dogs, or cats, or both as a principal or agent, or who represents such person's self to be so engaged as otherwise classified by the United States Department of Agriculture.

(Y) "Person" means any individual, association, partnership, corporation or other entity.

(Z) "Pet shop" means any premise where dogs or cats, or both, are bought, sold, exchanged or offered or maintained for adoption or retail sale to the public. Pet shop does not include any pound or animal shelter, or any animal breeder or animal distributor premise.

(AA) "Pet shop operator" means any person who operates a pet shop.

(BB) "Pound" means a facility which is used for the purpose of harboring any seized stray, homeless, relinquished or abandoned animals and which is operated:

(1) By the state, or any political subdivision thereof; or
(2) Under contract with the state or any political subdivision thereof.

(CC) "Primary enclosure" means any structure used or designed for use to restrict any animal to a limited amount of space, including but not limited to a room, pen, cage, compartment or hutch.

(DD) "Sale, sell, sold" includes transfers by sale or exchange. Maintaining animals for sale is presumed whenever twenty (20) or more dogs or cats, or both, are maintained by any person.

(EE) "Sanitize" means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.
ANIMAL WELFARE

Section 2. License annually required to operate animal boarding facilities, pet shops, pounds, distributors and breeders.

No person shall act as an animal breeder, animal distributor, operate an animal shelter, pound, boarding kennel, pet shop, or exhibition facility, unless such person has obtained a license for such operations from the [insert reference to proper authority]. An applicant shall obtain a separate license for each separate facility subject to this act which is operated by the applicant. Any person exempt from the licensing requirements of this act may voluntarily apply for a license. Application for such license shall be made in the manner provided by the [insert reference to proper authority]. The license shall expire annually on December 31 unless revoked.

Section 3. Refusal to issue or renew or suspension or revocation of license; grounds; judicial review; seizure and disposition of animals, when.

(A) The [insert reference to proper authority] may refuse to issue or renew or may suspend or revoke any license required under this act and amendments thereto for any one or more of the following reasons:

(1) Material misstatement in the application for the original license, or in the application for any renewal of a license;
(2) disregard of any provision of this act or any regulation [rule] adopted hereunder, or any aiding or abetting of another in the violation of any provision of this act or any regulation [rule] adopted hereunder;
(3) permitting any license issued hereunder to be used by an unlicensed person or transferred to unlicensed premises;
(4) the conviction of any crime relating to the theft of or cruelty to animals;
(5) substantial misrepresentation;
(6) misrepresentation or false promise, made through advertising, salespersons, agents or otherwise, in connection with the operation of business of the licensee;
(7) a fraudulent bill of sale;
(8) the housing facility or the primary enclosure is inadequate; or
(9) the feeding, watering, sanitizing and housing practices at the licensee’s premises are not consistent with this act or the regulations [rules] adopted hereunder.

(B) Any refusal to issue or renew a license, and any suspension or revocation of a license under this section shall be in accordance with the provisions of [insert reference to proper state administrative procedures law] and shall be subject to review in accordance with the act for judicial review and civil enforcement of agency actions.

(C) Whenever the [insert reference to proper authority] denies, suspends or revokes a license under this section, the [insert reference to proper
REPORT OF THE COMMITTEE

authority] or the [insert reference to proper authority]'s authorized, trained representatives shall seize and impound any animals in the possession, custody or care of the person whose license is denied, suspended or revoked if there are reasonable grounds to believe that the animals' health, safety or welfare is endangered. Such animals may be returned to the person owning them if there is satisfactory evidence that the animals will receive adequate care by that person or such animals may be sold, placed or euthanized, at the discretion of the [insert reference to proper authority]. Costs of care and services for such animals while seized and impounded shall be paid by the person from whom the animals were seized and impounded, if that person's license is denied, suspended or revoked. Such funds shall be paid to the [insert reference to proper authority] for reimbursement of care and services provided during seizure and impoundment. If such person's license is not denied, suspended or revoked, the [insert reference to proper authority] shall pay the costs of care and services provided during seizure and impoundment.

Section 4. Administrative civil fine for violations of the act; judicial review; seizure and disposition of animals, when.

(A) In addition to or in lieu of any other civil or criminal penalty provided by law, the [insert reference to proper authority], upon finding that a person has violated or failed to comply with any provision of this act or any regulation [rule] adopted hereunder, may impose on such person a civil fine not exceeding one thousand dollars ($1,000) for each violation.

(B) Any imposition of a civil fine pursuant to this section shall be only upon notice and a hearing conducted in accordance with [insert reference to proper state administrative procedures law] and shall be subject to review in accordance with the act for judicial review and civil enforcement of agency actions.

(C) Whenever the [insert reference to proper authority] has reasonable grounds to believe that a person or premises required to be licensed under this act has failed to comply with or has violated any provision of this act or any regulation [rule] adopted hereunder and that the health, safety or welfare of animals in such person's possession, custody or care is endangered thereby, the [insert reference to proper authority] shall seize and impound such animals using emergency adjudicative proceedings in accordance with the [insert reference to proper state administrative procedures law]. Such animals may be returned to the person owning them if there is satisfactory evidence that the animals will receive adequate care by that person or such animals may be sold, placed or euthanized, at the discretion of the [insert reference to proper authority]. Costs of care and services for
such animals while seized and impounded shall be paid by the person from whom the animals were seized and impounded, if that person is found to be in violation of this act or any regulation [rule] adopted hereunder. Such funds shall be paid to the [insert reference to proper authority] for reimbursement of care and services provided during seizure and impoundment. If such person is not found to be in violation of this act or any regulation [rule] adopted hereunder, the [insert reference to proper authority] shall pay the costs of care and services provided during seizure and impoundment.

Section 5. Judicial review of [insert reference to proper authority]'s actions.

Any action of the [insert reference to proper authority] pursuant to sections [insert reference to seizure sections of this act], and amendments thereto, is subject to review in accordance with the act for judicial review and enforcement of agency actions.

Section 6. Inspections and investigations; confidentiality of complaints; records of inspections.

(A) The [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representatives shall make an inspection of the premises for which an application for an original license is made under this act and amendments thereto, before issuance of such license. The application for a license shall conclusively be deemed to be the consent of the applicant to the right of entry and inspection of the premises sought to be licensed by the [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representatives during business hours with the owner or owner's representative present. Refusal of such entry and inspection shall be grounds for denial of the license. Notice need not be given to any person prior to inspection.

(B) The [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representatives shall make an inspection of each premises for which a license has been issued under this act, and amendments thereto. If such premises are premises of a person licensed under public law 91-579 (7 U.S.C. section 2131 et seq.), such premises shall be inspected at least once each year. Otherwise, the premises shall be inspected at least twice each year. The acceptance of a license shall conclusively be deemed to be the consent of the licensee to the right of entry and inspection of the licensed premises by the [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representatives during business hours with the owner or owner's representative present. Refusal of such entry and inspection shall be grounds for
suspension or revocation of the license. Notice need not be given to any person prior to inspection. [NOTE: USAHA Task Force members recommend implementing regulations [rules] that clearly state that no notice will be given for routine inspections.]

(C) The [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representatives may make inspections of the premises or vehicles used to transport or house animals of a person required to be licensed under this act and amendments thereto, upon a determination by the [insert reference to proper authority] that there are reasonable grounds to believe that the person is violating the provisions of this act, and amendments thereto, or regulations [rules] adopted thereunder or that there are grounds for suspension or revocation of such person's license.

(D) Any complaint filed with the [insert reference to proper authority] shall be confidential and shall not be released to any person other than employees of the [insert reference to proper authority] as necessary to carry out the duties of their employment.

(E) Any person making inspections under this section shall be trained by the [insert reference to proper authority] in reasonable standards of animal care.

(F) The [insert reference to proper authority] may request a licensed veterinarian to assist in any inspection or investigation made by the [insert reference to proper authority] or the [insert reference to proper authority]'s authorized, trained representative under this section.

(G) Any person acting as the [insert reference to proper authority]'s authorized representative for purposes of making inspections and conducting investigations under this section who knowingly falsifies the results or findings of any inspection or investigation or who intentionally fails or refuses to make an inspection or conduct an investigation pursuant to this section shall be guilty of a [insert highest level] misdemeanor.

(H) No person shall act as the [insert reference to proper authority]'s authorized representative for the purposes of making inspections and conducting investigations under this section if such person has a beneficial interest in a person required to be licensed pursuant to this act and amendments thereto.

(I) Records of inspections pursuant to this section shall be maintained in the office of the [insert reference to proper authority].

Section 7. Release or disposition of animals from pound or shelter; use of proceeds from sale of animals.

The governing body of a political subdivision regulating the operation of a pound shall determine the method of disposition of any animal released from such pound. Any proceeds derived from such sale or disposition shall be paid
ANIMAL WELFARE

directly to the treasurer of the political subdivision, and no part of such pro-
ceeds shall accrue to any individual.

The board of directors of any incorporated humane society operating an
animal shelter as a pound, under contract with a municipality, shall determine
the method of disposition of any animal released from its animal shelter. Any
proceeds derived from such sale or disposition shall be paid directly to the
treasurer of the humane society and no part of such proceeds shall accrue to
any individual.

An animal shall not be disposed of by an operator of a pound or operator
of an animal shelter as a pound until after expiration of a minimum of six (6)
full days of custody during which the public has clear access to inspect and
recover the animal through time periods ordinarily accepted as usual busi-
ness hours. Such an animal may at any time be released to the legal owner,
moved to a veterinary hospital for treatment or observation, released in any
manner, if such animal was relinquished by its owner to an animal shelter, or
euthanized by an officer of a duly incorporated humane society or by a li-
censed veterinarian if it appears to such officer or to such veterinarian that the
animal is diseased or disabled beyond recovery. Any animal relinquished by
its owner to a pound or an animal shelter shall be held for a period of not less
than twenty-four (24) hours and written notice shall be provided to the owner
relinquishing the animal that euthanization may occur. Before an animal shel-
ter or pound may dispose of an animal, the animal shelter or pound must
make a reasonable, documented effort to notify the animals' owner if the
owner is known or may reasonably be ascertained through tags, tattoos, elec-
tronic identification or other means of identification.

Section 8. Animal control officer; licensee as or employment by ani-
mal breeder, distributor or pet shop operator prohibited; record of tak-
ing custody and disposition.

An animal control officer shall not be granted an animal breeder's or
distributor's or a pet shop operator's license. Each application for an animal
breeder's, distributor's or pet shop operator's license shall include a state-
ment that neither the applicant nor any of the applicants' employees are an
animal control officer. An animal control officer, upon taking custody of an
animal in the course of official duties, shall immediately make a record which
shall include the color, breed (or type), sex, approximate weight and other
description of the animal, the reason for seizure, the location of seizure, the
owner's name and address, if known, the animal license number and any
other identification number. Complete information relating to the disposition of
the animal shall be shown on the record; this shall be added to the record
immediately following the disposition of the animal.
REPORT OF THE COMMITTEE

Section 9. Regulations [rules].

(A) The [insert reference to proper authority] is hereby authorized to adopt regulations [rules] for all licensees. Such regulations [rules] shall include, but not be limited to, provisions relating to: (1) reasonable and humane treatment of animals in the possession, custody or care of a licensee or being transported to or from licensed premises; (2) a requirement that each licensee file with the [insert reference to proper authority] a certificate of veterinary inspection (health certificate) stating that animals entering or leaving the state are free from any visible symptoms of communicable disease; (3) identification of animals handled; (4) primary enclosures; (5) housing facilities; (6) sanitation; (7) euthanasia; (8) ambient temperatures; (9) feeding; (10) watering; (11) adequate veterinary medical care; (12) inspections of licensed premises, investigations of complaints and training of persons conducting such inspections and investigations; and (13) a requirement that each licensee keep and maintain, for inspection by the [insert reference to proper authority], such records as necessary to administer and enforce the provisions of this act.

(B) The [insert reference to proper authority] shall not adopt regulations that are below the minimum standards established under the federal Animal Welfare Act and any regulations [rules] promulgated by the secretary of the United States Department of Agriculture.

Section 10. Prohibiting sale or gift of certain animals; health certificate required.

The [insert reference to proper authority] may prohibit the sale or gift of animals which constitute a hazard to human health or safety or to animal health or safety.

Any animal sold by a pet shop operator licensed pursuant to the provisions of this act shall be accompanied by a written instrument issued by such pet shop operator on a form prescribed by the [insert reference to proper authority] certifying that such animal is in sound health.

Section 11. Violation of act or regulations [rules]; penalty; seizure and disposition of animals, when.

(A) Any violation of or failure to comply with any provision of this act or any regulation [rule] adopted hereunder, shall constitute a [insert highest level] misdemeanor. Continued operation, after a conviction, shall constitute a separate offense for each day of operation.

(B) Upon conviction of a person for any violation of this act, or any regulation [rule] promulgated hereunder, the court shall order the [insert reference to proper authority] to seize and impound any animals in the convicted person’s possession, custody or care if there are reasonable grounds to believe that the animals’ health, safety or welfare
ANIMAL WELFARE

is endangered. Such animals may be returned to the person owning them if there is satisfactory evidence that the animals will receive adequate care by that person or such animals may be sold, placed or euthanized, at the discretion of the [insert reference to proper authority]. Costs of care and services for such animals while seized and impounded shall be paid by the convicted person. Such funds shall be paid to the [insert reference to proper authority] for reimbursement of care and services provided during seizure and impoundment. If the person is not convicted, the [insert reference to proper authority] shall pay the costs of care and services provided during seizure and impoundment.

Section 12. Invalidity of part.

If any provision of this act, or the application of any such provision to any person or circumstance, shall be held invalid, the remainder of the act, and the application of any such provision to any person or circumstance other than those as to which it is held invalid, shall not be affected thereby.

Section 13. Unlawful to purchase from a person not licensed.

It shall be unlawful for any person to knowingly purchase a dog or cat for the purpose of resale to another from a person required to be licensed under public law 91-579, 7 U.S.C. 2131 et seq., or this act et seq., and amendments thereto, or both, if that person is not so licensed. Licensees shall not sell to animal distributors or pet shops operating within the state who are not licensed in accordance with this act.

Section 14. Dog and Cat Welfare Advisory Board.

(A) There is hereby created the Dog and Cat Welfare Advisory Board, consisting of [insert specific references to program administrator(s), representatives from each licensure group, industry representatives and persons representing community concerns for the welfare of the animals as appropriate for each state].

(B) Board members shall serve for a period of one (1), two (2), or three (3) years as appointed by the governor, so that appointments are staggered and alternating.

(C) A vacancy on the board of a member shall be filled for the unexpired term by appointment by the governor.

(D) The board shall meet in accordance with the provisions of [cite state open meeting law] at least once every calendar quarter regularly or at such other times as the chairperson or a majority of the board members determine. A majority of the members shall constitute a quorum for conducting board business.

(E) The members of the board shall annually elect a chairperson.
REPORT OF THE COMMITTEE

(F) The board shall have the following duties, authorities and powers:

1. To advise the [insert reference to proper authority] on hiring a director to implement this act;
2. to review the status of this act;
3. to make recommendations on changes to this act; and
4. to make recommendations concerning the regulations [rules] for this act.

Section 15. Injunctive relief to [insert reference to proper authority].

Notwithstanding the existence or pursuant of any other remedy, when it appears to the [insert reference to proper authority], as head of the licensing agency, that any person is violating any provision of this act, the [insert reference to proper authority], may in that capacity bring an action in a court of competent jurisdiction or other process against such person to enjoin, restrain or prevent such person from continuing operation in violation of this act without regard to whether administrative proceedings have been or may be instituted or whether criminal proceedings may be or have been instituted.

Section 16. Sterilization of all cats and dogs adopted or purchased from animal shelters or animal control agencies, procedure.

(A) Provisions shall be made for the sterilization of all dogs and cats sold or released for adoption or purchased from any public or private animal shelter or animal control agency operated by a humane society, or by a county or city, or other political subdivision. Such provisions may be made by:

1. Providing for sterilization by a licensed veterinarian before relinquishing custody of the animal; or
2. Entering into a written agreement with the adopter or purchaser of legal age guaranteeing that sterilization will be performed by a licensed veterinarian, in compliance with a sterilization agreement. In addition to signing a written agreement guaranteeing sterilization, the adopting party shall deposit with the pound or animal shelter funds sufficient to ensure that the dog or cat will be sterilized. Any funds deposited pursuant to such an agreement shall be refunded to the adopting party upon presentation of a written statement signed by a licensed veterinarian that the adopted dog or cat has been sterilized. All written agreements shall contain the following information:

  A. The date of the agreement;
  B. The name, address, and signature of the releasing agency and the adopter;
  C. A description of the animal to be adopted; and
  D. A sterilization completion date which shall be either:
      1. The thirtieth day after the date of adoption in the case of an adult animal; or
ANIMAL WELFARE

2. The thirtieth day after a specified date estimated to be the date an adopted infant female or male puppy or kitten becomes six (6) months of age; or

3. If the releasing agency has a written policy recommending sterilization of certain infant animals at an earlier date, the thirtieth day after the date contained in the written policy.

(B) An adopter that signs a sterilization agreement shall have the adopted animal sterilized on or before the sterilization date stated in the agreement. If the sterilization completion date stated in the agreement falls on a Saturday, Sunday or legal holiday, the deadline may be extended to the first day that is not a Saturday, Sunday or legal holiday. The releasing agency may extend the deadline for thirty (30) days upon presentation of a letter or telephone report from a licensed veterinarian stating that the life or health of the adopted animal may be jeopardized by sterilization. There shall be no limit to the number of extensions that may be granted for this reason.

(C) No person shall spay or neuter any dog or cat for or on behalf of a pound, animal shelter or humane society unless such person is a licensed veterinarian. No pound, animal shelter or humane society shall designate the veterinarian which a person must use, or a list from which a person must select a veterinarian, to spay or neuter a dog or cat adopted by such person from such pound, shelter or society, nor shall such pound, shelter or society in any way penalize a person for such person’s selection of a veterinarian to spay or neuter a dog or cat adopted from such pound, shelter or society.

Section 17. Animals considered sterilized when; exceptions to sterilization requirement; costs to be paid by adopter or purchaser.

(A) Each releasing agency shall agree to give title, possession, and control of the animal so long as the adopter complies with the terms and conditions of the adoption agreement.

(B) The releasing agency shall consider the animal sterilized upon receipt of written confirmation signed by the licensed veterinarian who performed the sterilization.

(C) Exceptions to the sterilization requirements of this act shall not apply to a dog or cat that is claimed from a releasing agency within the six (6) day holding period by a person who already owns the animal. The sterilization requirement may be waived after the six (6) day holding period at the discretion of the director of the releasing agency in cases where animals are returned to their previous owner, provided that any such waiver is documented and maintained as part of that animals’ permanent record. This section shall not apply to a releas-
REPORT OF THE COMMITTEE

ing agency located in a political subdivision that has in effect an ordinance providing standards for dog and cat sterilization that exceed the requirements of this act.

(D) All costs of sterilization pursuant to this act shall be paid by the prospective adopter or purchaser, unless otherwise provided.

Section 18. Euthanasia, approved methods.

No animal shall be euthanized by any animal control officer, officer of an animal shelter or officer of a pound by any means, method, agent or device, or in any way, except through a method currently approved by the American Veterinary Medical Association (AVMA) Panel on Euthanasia. [A copy of the most current version of the AVMA Panel on Euthanasia report shall be provided to each licensee.]

Section 19. Citation of Act.

[Insert reference to appropriate statutory citation] shall be known and may be cited as the Uniform Dog and Cat Welfare Act.

Revised - November 2, 1995

1 Copies of current AVMA Panel Report on Euthanasia may be obtained from AVMA, 1931 North Meacham Road, Suite 100, Schaumburg, Illinois, 60173-4360.
TAURA SYNDROME: 
AN ECONOMICALLY IMPORTANT VIRAL DISEASE 
IMPACTING THE SHRIMP FARMING INDUSTRIES 
OF THE AMERICAS 
INCLUDING THE UNITED STATES 

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KEYWORDS: Penaeid shrimp - aquaculture - Taura syndrome - Taura syndrome virus - TSV - Americas - United States 

Summary 
Taura Syndrome Virus (TSV) has had enormous negative impacts on the shrimp farming industries of the Americas. TSV has become widely distributed as a consequence of the movement of host stocks for aquaculture. TSV causes catastrophic losses in cultured P. vannamei. In less than three years after its discovery in Ecuador in 1992, TSV has spread rapidly and caused huge production losses in most of the shrimp growing countries in the Americas. In 1994 and 1995, TSV caused serious crop losses in the United States, affecting two farms on Oahu, Hawaii in mid 1994, and five of the six farms on the Texas coast in 1995. 

Introduction 
In less than 30 years, the penaeid shrimp culture industries of the world developed from their experimental beginnings into major industries providing millions of jobs and billions of U.S. dollars annually in export revenue (Weidner and Rosenberry 1992). Concomitant with the rapid growth of the shrimp culture industries has been the recognition of the ever increasing importance of pathogenic agents, among which the viruses that infect penaeid shrimp are especially well represented. 

More than twenty years have elapsed since John Couch described Baculovirus penaei (BP = PvSNPV), the first known shrimp virus, from wild penaeid shrimp collected from Florida's Gulf of Mexico coast (Couch 1974a, 1974b. By 1995, the list of penaeid shrimp viruses had grown to include nearly 20 viruses representing seven virus families (Table 1), with all but two or three of these 20 viruses having been described in penaeid shrimp from aquaculture settings. While some of the known penaeid shrimp viruses seem to be of little economic importance, others can cause serious disease in their penaeid shrimp hosts and significant economic losses to the industries which culture them. Devastating epizootics due to various virus pathogens of penaeid shrimp have caused significant, and sometimes catastrophic economic losses, in commercial penaeid shrimp culture (Boonyaratpalin et al. 1993; Brock 1992;
TAURA SYNDROME


Viral pathogens have been implicated in the collapse of important shrimp aquaculture industries in Asia. Taiwan’s production fell from 100,000 t in 1987 to 30,000 t in 1988 as the result of a country-wide epizootic in which environmental degradation and viral agents were implicated as causative factors (Chen 1995; Weidner and Rosenberry 1992). In 1992-1993 the Chinese shrimp aquaculture industry saw their production collapse from 220,000 t in 1991 to 30,000 t in 1993, a year in which their farms were stocked to produce 300,000 t (Chamberlain 1994; Rosenberry 1994; Wang 1995; Winarno 1995). Likewise, recent major epizootics in Thailand, Indonesia, Japan, Taiwan, and India have been accompanied by significant losses that, in some instances, reached 90% of expected production for the year (Chamberlain 1994; Chen 1995; Flegel et al. 1995; Takahashi et al. 1994; Winarno 1995).

The shrimp culture industries of the Americas have also been adversely affected by serious epizootics due to viral pathogens. Infectious hypodermal and hematopoietic necrosis virus, or IHHNV, (Brock and Lightner 1990; Lightner 1988, 1992, 1993) and Taura syndrome virus, or TSV, (Brock et al. 1995; Chamberlain 1994; Hasson et al. 1995; Lightner et al. 1995) have had enormous negative impacts on the continents’ developing aquaculture industries and, in one instance for IHHNV, on a commercial fishery as well (Moore 1991; Moore and Brand 1993). *P. vannamei* is perhaps the most favored species for culture in the Americas because it is relatively resistant to another virus disease caused by infectious hypodermal and hematopoietic necrosis virus (IHHNV). However, despite its resistance to IHHNV, chronic infection by IHHNV, nonetheless, results in poor culture performance in *P. vannamei*. TSV is the “mirror image” of IHHNV in its affect on *P. stylirostris* and *P. vannamei*. TSV causes catastrophic losses in *P. vannamei*, whereas *P. stylirostris* is highly resistant to TS disease (Lightner et al. 1995).

The present paper reviews the published literature and as yet unpublished, but available, recent information on TSV in penaeid shrimp aquaculture and fisheries in the Americas. The available information on the epizootic of Taura Syndrome at farms on Oahu, Hawaii in 1994 and in Texas in 1995 is also reviewed.

TAURA SYNDROME VIRUS AND DISEASE

Taura Syndrome Virus (TSV): Taura Syndrome virus (TSV) is perhaps the most recently characterized penaeid shrimp virus. TSV has been classified as a picornavirus based on its morphology (~30-32 nm icosahedron), cytoplasmic replication, linear ssRNA of approximately 9 kb, and its having three major (49, 36.8, and 23 kD) and two minor polypeptides (51.5 and 52.5 kD) in its capsid (Hasson et al. 1995; Lightner 1996; Bonami et al. manuscript in preparation).

Diagnosis of Taura Syndrome: The current diagnostic methods for TSV
include demonstration of diagnostic histopathology in acutely affected shrimp that show gross signs of the disease, and bioassay which demonstrates the presence of the virus in asymptomatic carrier shrimp (or other appropriate samples) using SPF (specific pathogen free) juvenile P. vannamei, which serve as the indicator for the presence of the virus. Shrimp with acute natural or induced TSV infections display a distinctive histopathology that consists of multifocal areas of necrosis of the cuticular epithelium and subcutis (of the general cuticle, gills, appendages, foregut and hindgut), which are characterized by the presence of several to extremely numerous, variably sized eosinophilic to basophilic cytoplasmic inclusion bodies that give TSV lesions a characteristic "peppered" or "buckshot" appearance, which is considered to be pathognomonic for the disease (Brock and Main 1994; Brock et al. 1995; Hasson et al. 1995; Lightner 1996; Lightner et al. 1995).

A cDNA probe has been recently developed for TSV. A non-radioactive digoxigenin (DIG) labeled probe has been used successfully as a diagnostic reagent in dot blot assays with partially purified TS virus and using in situ hybridization assays with fixed tissue. Both techniques have distinguished TSV infected samples from uninfected control samples. Pathognomonic TS lesions show a very strong reaction with cDNA probes by in situ hybridization assays (Lightner 1996; Mari, Bonami and Lightner, manuscript in preparation).

Taura Syndrome Disease: In the Americas, Taura Syndrome (TS) emerged in 1992-1993 as a major epizootic disease of P. vannamei that spread rapidly in the shrimp growing regions of Latin America, and it now threatens most of the shrimp farming industries of the Americas (Brock et al. 1995; Hasson et al. 1995; Jimenez 1992; Lightner et al. 1995; Wigglesworth 1994). P. vannamei accounted for more than 90% (about 132,000 t) of the farmed shrimp production in the Americas, or about 15 to 20% of the World’s production of farmed shrimp in 1993 and 1994 (Rosenberry 1993a, 1993b). Because P. vannamei is the principal penaeid shrimp species used in aquaculture in the Americas (Rosenberry 1994), TS may pose the most serious biological threat to date to the penaeid shrimp aquaculture industries of the Americas, and, perhaps, to its commercial shrimp fisheries as well.

Taura Syndrome was first recognized in commercial penaeid shrimp farms located near the mouth of the Taura River in the Gulf of Guayaquil, Ecuador, in mid-1992 (Jimenez 1992; Lightner et al. 1995; Wigglesworth 1994). Retrospective studies have shown that TS was present in at least one shrimp farm in the Taura region of Ecuador in September 1991 (Lightner unpublished data) and a TS-like condition has been reported to have occurred even earlier in cultured P. vannamei in Colombia (Laramore 1995). Shortly after the syndrome appeared in Ecuador, both toxic and infectious etiologies were proposed. However, the disease was eventually shown to be caused by a previously unrecognized infectious agent now called Taura Syndrome Virus or TSV (Brock et al. 1995; Hasson et al. 1995; Lightner 1996; Lightner et al. 1995).
these studies, TS was induced in healthy, juvenile *P. vannamei* by exposure to the virus via injection of cell-free homogenates prepared from the carcasses of TSV-infected *P. vannamei* (from Ecuador and Hawaii) or by directly feeding the same carcasses to the indicator shrimp. Identical results were obtained with TS-positive shrimp from both Hawaii and Ecuador (Brock et al. 1995; Hasson et al. 1995; Lightner 1996).

The syndrome is now known to have occurred in shrimp farms throughout much of Ecuador, as well as in single or multiple farm sites in Peru, both coasts of Colombia, western Honduras, El Salvador, Guatemala, Brazil, and the U.S. In less than two years after its initial discovery in Ecuador, TS had made its way into the U.S., occurring in the U.S. at isolated sites in Florida and Hawaii (Brock et al. 1995; Lightner 1996; Lightner et al. 1995).

In Hawaii, the outbreak of Taura Syndrome in mid-1994 at two adjacent farms on Oahu, resulted in a viral etiology being experimentally demonstrated for the disease (Brock et al. 1995, Hasson et al. 1995; Lightner 1996). The episode of Taura Syndrome at one of the two affected farms caused >95% cumulative losses in stocks of juvenile *P. vannamei* stocked at > 1,000 shrimp/m² in super-intensive raceway culture (Moore and Brand 1993) within 10-15 days of the onset of the first observed mortalities (Brock et al. 1995). The 1994 Oahu epizootic of Taura Syndrome resulted in the closure of one of the TSV affected facilities and in the second facility changing its operation to grow only TSV-resistant *P. stylirostris* (Brock et al. 1995).

In Florida, the disease was diagnosed in wild adult *P. vannamei* that had been imported from Central America after being collected from the Gulf of Fonseca off the Pacific coast of Honduras and El Salvador. The affected adult *P. vannamei* showed high mortalities and diagnostic lesions of the disease (Lightner 1995). Significantly, this occurrence of Taura Syndrome in wild broodstock from Honduras and El Salvador, when considered with the finding of the disease in wild postlarvae collected during mid-1993 off Puna Island near the mouth of the Gulf of Guayaquil in Ecuador, and in wild adults from Chiapas, Mexico, illustrate the potential for this disease to become established in wild stocks where its potential effect on commercial penaeid shrimp fisheries is unknown.

In May 1995, an epizootic of TS began at a shrimp farm near Brownsville, Texas (Rosenberry 1995c). By means of transfers of TSV infected postlarvae from the affected farms to other farms in south and central Texas, the disease was spread before its presence was recognized. Likewise, sea gulls and other shrimp eating sea birds were observed feeding on dead and dying shrimp that came to the pond surface and edges were found to very likely be involved in the epizootic. Feces collected from gulls that had rested on pond levees of TSV-positive ponds after feeding on shrimp with acute TS from the ponds, were found to be highly infectious. TSV content of the gull feces was demonstrated in laboratory bioassays in which TSV-free indicator shrimp (juvenile *P. vannamei*) were injected with cell-free extracts prepared from gull feces (Lightner,
unpublished data). Transmission of TSV from pond to pond within a single farm and between neighboring farms by sea birds and gulls may explain the very rapid spread of the disease in south Texas in May 1995. Only one in farm of six present on the central of south coasts of Texas escaped the TS epizootic in 1995.

TSV has also been documented in Mexico. In early 1995, TS was detected in wild adult P. vannamei collected from the offshore fishery of the southern Mexican state of Chiapas near its border with Guatemala and near where TS had first appeared in Guatemalan shrimp farms in 1994. Within weeks, TS had appeared in postlarve produced from the imported broodstock, or in the broodstock themselves, in at least two farms in northwestern Mexico. In addition to documenting the introduction of TSV into northwestern Mexico shrimp farms with wild broodstock, the findings also suggest that TSV may also be vertically transmitted in addition to its known methods of horizontal transmission (Lightner, unpublished data). By September 1995, the TS epizootic in Mexico had spread to impact farms raising P. vannamei in the states of Sonora, Sinaloa, and Guerrero (Lightner, unpublished).

**Effect of TSV on the Shrimp Aquaculture Industry:** The impact of Taura Syndrome on penaeid shrimp aquaculture in the Americas has been severe. In Ecuador, where Taura Syndrome first emerged in 1992 as a significant disease problem of cultured P. vannamei, the disease resulted in production losses that reached between 15 and 30% of the country's production in 1993 and 1994 (Rosenberry 1993a, 1993b, 1994a, 1994b, 1995b; Wigglesworth 1994). At 1994-1995 shrimp wholesale prices (~$13.00/kg for 31/35 count tails; (Rosenberry 1995a, 1995b), a 30% percent reduction in production relative to Ecuador's 1991 production of approximately 100,000 t translates to nearly a $400,000,000 loss in revenue per year Hence, in the four years since 1992, the estimated crop loss to Ecuador could be approaching $1 to 1.5 billion (Table 3).

Taura Syndrome has had a devastating impact on the shrimp farms of Honduras. The U.S. Embassy in Honduras reported that 1994 shrimp farm production was 2,300 t, down from 7,200 t in 1993 before TS had become well established in that country (Rosenberry 1995a). At ~$13.00 per kg, Honduras' 1994 estimated crop loss 4,900 t is $63.7 million. Reports from Honduras in 1995 indicated that the losses to TS remained very high, suggesting that for 1994 and 1995, shrimp growers in Honduras lost nearly $100 million to TS (Table 3).

While published reports are not yet available regarding the impact of TS on the aquaculture industries of other affected countries (eg. Colombia, Peru, Guatemala, Brazil, and Mexico), information that has accompanied diagnostic case submissions to our laboratory indicate that losses are occurring in a similar pattern to those experienced in Ecuador and Honduras (Lightner, unpublished data). Their collective losses for 1993-1995 to TS are estimated to
TAURA SYNDROME

be between $25 million and $75 million (Table 3).

Losses in the United States due to TS have also been severe. The outbreak of TS in 1994 at two farms on Oahu, HI resulted in closure of one farm and a total crop failure of cultured *P. vannamei* at the other. Crop losses (not investment) from these two farms is estimated at $1 million (Table 3). The 1995 TS epizootic in Texas is estimated to have resulted in crop losses of from $10 million to $25 million (Table 3).

**Possible Vectors of TSV:** Complicating the situation further is the very recent discovery that an aquatic insect (*Lightner 1996*) and sea birds may be involved in the epizootiology of TS. Increasing populations of the salinity-tolerant water boatman, *Trichocorixa reticulata* (*Corixidae*) (*Hungerford 1977*), were noted initially at a farm site in Ecuador which was in the midst of a severe epizootic of TS. TSV was demonstrated to be present in a sample of the insects by bioassay. Taura syndrome was induced in SPF juvenile *P. vannamei* by injection of cell-free crude homogenates of insects collected from TSV-positive shrimp ponds (Hasson and Lightner, unpublished data). In situ hybridization assays run with histological sections of water boatman collected from ponds in which a severe acute phase TS epizootic was ongoing, showed several individuals with TSV positive gut contents, but no indication that TSV was infecting or replicating in the insect. Hence, the available data suggest that the insect feeds on shrimp that have died from TS. Winged adults that have fed on TS positive shrimp presumably transmit the virus from pond to pond in affected farms or between farms by flying from an infected pond to others where they transmit the virus by defecating their gut contents or by being preyed upon by the shrimp in the pond.

*T. reticulata* is common in estuarine ecosystems in the coastal areas of the Americas. It is distributed from California and Hawaii southward to Peru on the Pacific side of the Americas and from Florida to Texas and southward to Brazil on the Atlantic coast of the Americas (*Hungerford 1977*). The insect has been reported as being abundant in Taura Syndrome affected ponds in Honduras (J. Brock, personal communication) and Colombia (R. Bador, personal communication). Perhaps this insect is a factor in the rapid spread of TS in the Americas.

Sea gulls (mostly laughing gulls, *Larus atricilla*) have been also shown to potentially serve as vectors of TSV. Gull feces collected from the levees of a TSV-infected pond during the 1995 epizootic, were found to be contain infectious TSV (*Lightner, unpublished*). Hence, gulls and other shrimp eating sea birds may transmit TSV within affected farms or to other farms within their flight range. What is not known is for how long TSV remains in the gut contents of gulls or other sea birds and, thus, how important these birds might be in spreading this disease beyond a given region.
Industry Dependence on Wild Stock: A factor which has played a significant role in the spread of IHHNV and TSV within the Americas, as well as in most of the devastating disease epizootics that have affected the shrimp culture industries of Asia, is the near total dependence of these industries on wild shrimp for "seed stock" (Pruder 1994; Pruder et al. 1995; Wyban 1992). Nearly all of the seed stock required to stock the world's 1.15 million hectares of shrimp farm ponds is derived either from postlarvae gathered directly from the wild or produced from wild-caught spawners (Pruder et al. 1995; Rosenberry 1994c). To provide for the needs of the rapidly growing shrimp farming industry, international commerce in wild penaeid shrimp seedstock (nauplii, postlarvae and broodstock) has become a characteristic of today's shrimp culture industry. This practice, however, has been implicated in the transfer and introduction of a number of important pathogens of penaeid shrimp viral pathogens from one geographic region to another (Lightner et al. 1983, 1992a, 1992b, 1992c). The international commerce in TSV-infected penaeid seedstock and broodstock is the most plausible explanation for the rapid dissemination of TS in the Americas.

Importation of Frozen Product: The importation of frozen shrimp from regions with epizootic disease in their aquaculture industries also poses a threat to the importing country's fishery and aquaculture industries. This is especially true for pathogens (like TSV and IHHNV) that remain infectious after one or more freeze-thaw cycles. Although less of a threat than introducing undetected pathogens with live virus-infected shrimp, there is a significant possibility that pathogens of concern to aquaculture (or human health) may also be imported with frozen shrimp and inadvertently released into a domestic fishery or aquaculture industry by waste streams from shrimp processing plants or retail outlets where imported shrimp are thawed and sold or reprocessed and re-packaged for subsequent marketing. Another route in pathogen introduction for pathogens like IHHNV and TSV could occur when fishermen use cheap imported frozen shrimp as bait near shrimp farm seawater intakes. Now that highly sensitive molecular probes are being developed for many of the penaeid viruses (Table 1; Lightner et al. 1994), this possibility has only recently begun to be addressed. Because many shrimp pathogens remain highly infectious in frozen shrimp tissue, and because emergency harvests are a common practice in the industry when serious disease epizootics strike shrimp farms, this mechanism may be a route by which some otherwise unexplainable shrimp pathogen introductions have occurred (Lightner 1995).
TAURA SYNDROME

SOLUTIONS TO THE DILEMMA
Domestication and Development of SPF/SPR Shrimp

The ICES Guidelines: Several sets of guidelines have been developed to aid governments and private interests in importing non-indigenous aquatic animal stocks for fishery or aquaculture uses in a responsible manner designed to reduce the risk of accidental introduction of pests and pathogens. The International Council for the Exploration of the Sea (ICES) adopted in 1979 a "Code of Practice to Reduce the Risks of Adverse Effects Arising from the Introduction of Non-indigenous Marine Species" (Sindermann 1990). Modifications of the ICES Guidelines have been used to develop specific pathogen free stocks of penaeid shrimp for the U.S. industry (Lotz et al. 1995; Pruder 1994; Pruder et al. 1995; Wyban et al. 1992). The ICES Guidelines provide a series of steps to be taken in evaluating the pathogen/disease status of the stock being imported. According to the Guidelines, evaluation of the stock begins at its source before importation. Disease status monitoring continues after importation through the stock's life-long quarantine, during broodstock development, and production of a $F_1$ generation. Only the $F_1$ stock is developed for fishery or aquaculture use, and its pathogen/disease status is also monitored.

These ICES Guidelines have been used as a model for importations of penaeid shrimp stocks, and, when combined with appropriate pathogen detection methods, some noteworthy successes have been achieved. After being plagued by IHHNV in its imported stocks at their research and development facility on Oahu, HI (Lightner et al. 1983a, 1983b; Moore and Brand 1993), Marine Culture Enterprises adopted the ICES guidelines in restocking their facility and developing the captive, domesticated, specific pathogen-free (SPF) breeding stocks of Mexican $P. stylirostris$ that they used for their commercial development in 1984. After four years of operating IHHNV-free, the facility was impacted in mid-1987 by a massive IHHNV epizootic which caused catastrophic losses in its stocks of highly IHHNV susceptible $P. stylirostris$. The source of the virus contamination could not be confirmed, but it was likely to have come from either neighboring facilities, or from other facilities located on Oahu, which were culturing IHHNV positive stocks that had been imported without going through ICES-type quarantine steps (Lightner et al. 1992a, 1992b; Moore and Brand 1993). The IHHNV episode at MCE in 1987 resulted in an ~$10 million loss and ultimately in sale of the facility and with its conversion to farm the more IHHNV-resistant $P. vannamei$ (Moore and Brand 1993).

Development of SPF Shrimp: The U.S. Marine Shrimp Farming Consortium (USMSFC, a group of non-profit research institutions that have been actively involved in shrimp culture technology since 1984), has made the development of breeding stocks of SPF shrimp its highest priority. Learning from the experiences of MCE, and recognizing that the threat of introducing unrecognized pathogens with imported live, wild seedstock can be reduced in time through the development of domesticated breeding lines of the commer-
cially important penaeid shrimp species, the USMSFC has adopted the ICES Guidelines in its efforts to develop fully domesticated, SPF stocks for the fledgling U.S. shrimp culture industry (Lotz 1992; Lotz et al. 1995; Pruder 1994; Pruder et al. 1995; Wyban 1992; Wyban et al. 1992). The list of specific, excludable pathogens has been published recently (Lotz et al. 1995), and the most recently revised list is given in Table 3.

Although many others have tried to domesticate wild shrimp stocks for aquaculture, virtually nowhere else in the world has the shrimp culture industry been successful in domesticating and maintaining breeding lines of shrimp. Nearly all attempts to domesticate wild penaeid shrimp have ended in failure and the only fully domesticated lines of penaeid shrimp currently in existence have been developed in the U.S. by members of the USMSFC (Wyban 1992) and in French Polynesia (Weppe et al. 1992). Experience has shown us that previously unrecognized pathogens are commonly present at low prevalence rates in wild populations, and that these pathogens emerge to cause serious disease or poor culture performance when the rearing and domestication of captive wild populations is attempted (Lightner 1993; Lotz et al. 1995; Wyban 1992). Predominant among such pathogens are certain viruses which were unrecognized in wild shrimp stocks, but which emerged as serious pathogens under aquaculture conditions and prevented the establishment of breeding populations in the U.S., as well as elsewhere in the world (Brock and Lightner 1990; Lightner 1993; Lightner et al. 1992d, 1994). Hence, while the industry learned to breed shrimp in captivity, it was unable to go to the next step of domesticating the stocks needed because of the adverse effects of pathogens (mostly viruses) present in most of the stocks of interest, which were not detectable with available diagnostic methods. The absence of reliable and sensitive methods for detection and exclusion of shrimp infected with these pathogens hampered the development of a sustainable domestic shrimp farming industry until such tools were developed early in this decade. The expansion of the U.S. shrimp culture industry since 1991 with the use of SPF shrimp stocks is an indication that this technology can be successfully applied.

**Development of SPR Shrimp:** The alternative approach to developing SPF domesticated shrimp stocks, is to select and breed survivors of "specific pathogen-infected" (by pathogens like IHHNV or TSV) stocks to develop "specific pathogen-resistant" or SPR stock. Following this scheme, French researchers successfully developed a stock of IHHNV resistant *P. stylirostris* in French Polynesia (Weppe et al. 1992). This stock has been used successfully to develop the shrimp culture industries of Tahiti and New Caledonia (Weppe 1992). Recently, the stock was introduced into an area of southwestern Mexico where IHHNV is enzootic in an effort to develop the stock as an alternative to the slower growing *P. vannamei* which currently makes up >90% of the shrimp farmed in Mexico (Rosenberry 1994c). In view of the recent accidental introduction and spread of TSV in Mexico, the potential
availability of this SPR stock, which is resistant to disease when infected by IHHNV and TSV, may provide a viable alternative to the culture of the highly TSV susceptible stocks of *P. vannamei* and the highly IHHNV susceptible stocks of *P. stylirostris*, which were previously the only viable options for shrimp farming development in Mexico.

Successful application of the ICES Guidelines and the SPF concept requires that specific pathogens are excludable. In situations where specific pathogens may not be excludable, the development and use of SPR stocks may be the only alternative. The fact that IHHNV and TSV have become widely distributed in the Americas, and that they have both made it into U.S. shrimp farms, indicates that either government or industry supported pathogen exclusion mechanisms and regulations must be implemented and enforced to achieve the goals of using SPF shrimp stocks, or, alternatively, that SPR stocks be developed and used to deal effectively with these pathogens.

**Acknowledgements**

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**References**


Lightner


TAURA SYNDROME

<table>
<thead>
<tr>
<th>DNA VIRUSES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paroviruses:</strong></td>
</tr>
<tr>
<td>IHHNV = infectious hypodermal &amp; hematopoietic necrosis virus</td>
</tr>
<tr>
<td>HPV = hepatopancreatic parovirus</td>
</tr>
<tr>
<td>LPV = lymphoidal paro-like virus</td>
</tr>
<tr>
<td><strong>Baculoviruses:</strong></td>
</tr>
<tr>
<td>BP-type = <em>Baculovirus penaei</em> type (PvSNPV type sp.):</td>
</tr>
<tr>
<td>BP from the Gulf of Mexico</td>
</tr>
<tr>
<td>BP from Hawaii</td>
</tr>
<tr>
<td>BP from the Eastern Pacific</td>
</tr>
<tr>
<td>MBV-type = <em>Penaeus monodon</em>-type (PmSNPV type sp.):</td>
</tr>
<tr>
<td>MBV from S.E. Asia</td>
</tr>
<tr>
<td>MBV from Italy</td>
</tr>
<tr>
<td>PBV = <em>Penaeus plebejus</em> baculovirus</td>
</tr>
<tr>
<td>BMN-type = baculoviral midgut gland necrosis types:</td>
</tr>
<tr>
<td>BMN from <em>P. japonicus</em> in Japan</td>
</tr>
<tr>
<td>TCBV = type C baculovirus of <em>P. monodon</em></td>
</tr>
<tr>
<td>WSBV-type = White Spot Syndrome baculoviruses:</td>
</tr>
<tr>
<td>SEMBV = systemic ectodermal &amp; mesodermal baculovirus</td>
</tr>
<tr>
<td>RV-PJ = rod shaped virus of <em>P. japonicus</em></td>
</tr>
<tr>
<td>HHNBV = hypodermal and hematopoietic necrosis baculovirus</td>
</tr>
<tr>
<td>Large Baculo-like virus:</td>
</tr>
<tr>
<td>PHRV = hemocyte-infecting nonoccluded baculovirus</td>
</tr>
<tr>
<td><strong>Iridovirus:</strong></td>
</tr>
<tr>
<td>IRDO = shrimp iridovirus</td>
</tr>
<tr>
<td>RNA VIRUSES</td>
</tr>
<tr>
<td><strong>Picomavirus:</strong></td>
</tr>
<tr>
<td>TSV = Taura syndrome virus</td>
</tr>
<tr>
<td><strong>Reoviruses:</strong></td>
</tr>
<tr>
<td>REO-III = type III reo-like virus</td>
</tr>
<tr>
<td>REO-IV = type IV reo-like virus</td>
</tr>
<tr>
<td><strong>Toga-like virus:</strong></td>
</tr>
<tr>
<td>LOVV = lymphoid organ vacuolization virus</td>
</tr>
<tr>
<td><strong>Rod shaped ssRNA viruses:</strong></td>
</tr>
<tr>
<td>YHV/YBV = yellowhead virus of <em>P. monodon</em></td>
</tr>
<tr>
<td>RPS = rhabdovirus of penaeid shrimp</td>
</tr>
</tbody>
</table>
## TAURA SYNDROME

### Table 2. A working list of excludable and certifiable pathogens of American and Asian penaeids¹.

<table>
<thead>
<tr>
<th>Pathogen Type</th>
<th>Specifically Listed Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viruses</strong></td>
<td>IHHNV - a systemic parovirus</td>
</tr>
<tr>
<td></td>
<td>HPV - enteric paroviruses of HP</td>
</tr>
<tr>
<td></td>
<td>LPV - a systemic IHHNV-like parovirus</td>
</tr>
<tr>
<td></td>
<td>BPV - an occluded enteric baculovirus</td>
</tr>
<tr>
<td></td>
<td>MBV - an occluded enteric baculovirus</td>
</tr>
<tr>
<td></td>
<td>BMN - a nonoccluded enteric baculovirus</td>
</tr>
<tr>
<td></td>
<td>YHV - a systemic nonoccluded cytoplasmic ssRNA rod shaped virus</td>
</tr>
<tr>
<td></td>
<td>WSBV - white spot syndrome viruses (nonoccluded systemic baculoviruses)</td>
</tr>
<tr>
<td></td>
<td>TSV - a picornavirus</td>
</tr>
<tr>
<td><strong>Protozoa</strong></td>
<td>Microsporidians</td>
</tr>
<tr>
<td></td>
<td>Haplosporidians</td>
</tr>
<tr>
<td></td>
<td>Gregarines</td>
</tr>
<tr>
<td><strong>Metazoan Parasites</strong></td>
<td>Larval nematodes</td>
</tr>
<tr>
<td></td>
<td>Larval trematodes</td>
</tr>
<tr>
<td></td>
<td>Larval cestodes</td>
</tr>
</tbody>
</table>

¹ For more information on these pathogens and the most appropriate diagnostic methods see references: Brock and Main 1994; Lotz et al. 1995; Lightner 1993; Lightner et al. 1994.
Table 3. Estimated economic losses due to Taura Syndrome in the Americas since 1992 (in millions of U.S. dollars).

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecuador</td>
<td>200</td>
<td>400</td>
<td>400</td>
<td>100</td>
<td>1,100</td>
</tr>
<tr>
<td>Honduras</td>
<td>0</td>
<td>0</td>
<td>64</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>Colombia, Peru, Brazil, Guatemala</td>
<td>0</td>
<td>10</td>
<td>30</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Mexico</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>United States</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>15</td>
<td>16</td>
</tr>
</tbody>
</table>

Cumulative losses: ~$1,000 to 1,300 million
AN INTRODUCTION TO THE SALMONID EGG INDUSTRY

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Troutlodge, Inc. PO Box, 1290, Sumner, WA 98390

Introduction
Commercial aquaculture is increasingly being considered as an agricul-
tural rather than a resource enhancement activity. As a result, regulational
authority is being transferred from natural resource agencies to agricultural
agencies in many states, as well as at the federal and international levels.
For this reason, we seek to educate the veterinary community about our in-
dustry, the global market and some characteristics of the product, and offer
some suggestions for codes of practice governing interstate and international
commerce.

The Salmonid Egg Industry
Although many species and genera of salmonids are cultured around the
world, the majority of fish raised are rainbow trout, *Oncorhynchus mykiss*,
15% of the world’s commercial salmonid seedstock is produced in the Pacific
Northwest and the fertilized eggs are sold in approximately 30 states and 30
countries (1).

Eggs are either manually stripped via the urogenital pore from anesthe-
tized females or eggs are removed via a ventral incision to scarified females.
Eggs are fertilized with sperm and water hardened. Water hardening is the
process in which water fills the perivitelline space, causing the egg to become
turgid. This step is often performed in the presence of disinfectants or antibi-
otics. The eggs are then incubated. As fish are poikilothermic, incubation is
not only species but temperature dependent. For the commercial salmonid
species, the incubations is roughly 400 degree days, i.e. 40 days at 10°C
or 80 days at 5°C, etc. Eggs are disinfected and shipped on ice a few days prior
to hatching. Fish are hatched in freshwater and are grown to market size in
either fresh or saltwater depending on the species (2).

Global Market:
Our estimates for global farmed salmonid production are shown in Table
1. Over half of the world’s harvestable product and eggs are produced in
Europe. It is estimated that purchasing eggs comprises about 5% of produc-
tion costs (1).

Although we expect global production to increase, we do not expect the
egg market to increase as rapidly. Fish are being harvested at a larger mar-
ket size and management practices have favored fish survival, necessitating
AN INTRODUCTION TO THE SALMONID EGG INDUSTRY

less eggs to produce a marketable product.

Table 1. Projected world farmed salmonid harvest and egg production

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>PRODUCTION (mt)</th>
<th># EGGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAINBOW TROUT</td>
<td>350,000</td>
<td>3.5 BILLION</td>
</tr>
<tr>
<td>ATLANTIC SALMON</td>
<td>360,000</td>
<td>210 MILLION</td>
</tr>
<tr>
<td>COHO SALMON</td>
<td>50,000</td>
<td>30 MILLION</td>
</tr>
</tbody>
</table>

Characteristics of the Product

In many ways salmonid eggs are similar to seedstock of other livestock industries. There are however some salient differences. Once processed for shipping, eggs have a shelf life of only a few days. Unlike poultry eggs, fish eggs must arrive in the same condition that they were packed. If they hatch en route, the product is no longer viable as it is shipped on ice and not in water.

From a commercial standpoint, the most salient feature of our industry is that most of our orders are confirmed at least one week prior to shipping. However, about 25% of orders are confirmed, placed, or delayed or order size is changed the evening before they are to be shipped. This uncertainty is a permanent feature of our business as the arrival of eggs is usually timed with some climatic occurrence such as the presence or absence of rainfall and/or change in temperature. Very often, a new order is filled with eggs from a delayed order. For this reason, it is a constraint on the egg producer and the receiving farmer to state the number of eggs on a health certificate or other document that must be pre-endorsed prior to the day of shipment. Small changes in the number of eggs that are actually shipped require that health certificate be re-endorsed when the actual health status of the product is, of course, unchanged. Shipment size is best stated in the bill of lading or some other separate document.

Codes of Practice

From a commercial standpoint, most regulations are aimed at facilitating egg commerce on a regional level, thereby reducing interstate and international commerce and distribution. This is unfortunate as it seems to show a lack of understanding as to why interstate and international trade does take place. Some reasons are listed below:
1. Lack of environmental conditions. Conditions that are ideal for grow-out do not necessarily favor cultivation of broodstock. Southern Europe, southern Idaho, and parts of Asia and South America are examples of major growing regions that are not suited for egg production. Therefore these countries rely on imported eggs. Many of these areas import heavily from the Pacific Northwest of North America.

2. Health considerations: Broodstock are cultivated under a variety of water sources which include sea water, surface water containing anadromous fish and ground water free of anadromous fish. Water source has obvious important health considerations. Many producers seek to obtain eggs from isolated and controlled water sources to decrease the possibility of disease transmission. One such source is the Pacific Northwest where the commercial hatcheries are supplied by first use spring or well water.

3. Availability: In nature, salmonids are seasonal spawners. Currently, industry is moving towards reducing the seasonality of eyed egg availability in order to produce a marketable fish throughout the year. Year round egg production has been achieved on only a few technologically advanced farms. Another source of eggs during the "off season" is to obtain them from the opposite hemisphere.

4. Increased farming productivity: This is probably the most important reason. As the salmonid industry becomes more competitive, the need to increase efficiency is paramount. Recently, some attention has been paid to disease resistant strains but basically most attention is paid towards performance criteria such as growth. The results of a selection program can be pronounced.

5. Increased production capacity: Broodstock are typically cultured at low densities and thereby reduce production capacity that could be used for rearing foodfish. Acquiring eggs from off farm sources allows more space and labor to be directed towards the production of harvestable product.

6. Product diversity: Producers want to grow all female, triploid, late maturing or fish selected for various phenotypes or disease resistance. Development of these product lines requires special selection and processing.

7. Uniformity: Many farms purchase one million eggs/month and the desire is that they are as uniform as possible so that they will grow and hatch at the same and predictable rates. Acquiring eggs from large farms is an easier way to achieve a homogenous egg supply than from brokers or co-ops. Eggs from the latter sources are more likely to be pooled from many sources and are more apt to be heterogeneous.

Well or spring water, technical expertise, special facilities such as photoperiod control houses, chillers, pressure vessels, and/or designated personnel are needed to meet these requirements. This is best carried out on a large number of farms, a situation that parallels that of other livestock industries. These types of farms are few in number and are scattered all over the world necessitating interstate and international commerce.
AN INTRODUCTION TO THE SALMONID EGG INDUSTRY

In order to promote the salmonid industry attention must be paid to minimizing the risk of disease transmission without cutting off access of eggs. One should be reminded that screening for pathogens is costly and adds substantially to the price of the produce. Most often the tests are lethal. To enhance trade and minimize the risk of disease transmission we make the following observations:

1. Farmed aquaculture products should be recognized as agricultural commodities and not as a natural resource.

2. Eggs should be governed by separate and distinct regulations than those of live fish. Attention should be focused on vertically transmitted diseases of economic importance, particularly those that cannot be treated.

3. Regulations should not include endemic diseases. Screening eggs for these diseases will not reduce incidence or prevalence. It will only increase the price of the eggs.

4. Regulations should not be a form of non-tariff trade barriers. Illustrations are situations where the health standards for imported product is more stringent that those for national product. Another example is when slight differences in laboratory methodology without any differences in sensitivity or specificity between the producing and receiving countries can bar product import.

5. Determining and monitoring the health history and specific pathogen free status of the farm and management practices is more practical and cost effective than monitoring the geographic zone in order to determine the risk of disease transmission.

Summary

In closing, it should be remembered that the genetic improvements have been the cornerstone of increasing commercial production and profitability of all agricultural commodities. Although fish health regulations have sometimes been put in place in an effort to protect the industry, more often they act to restrict the flow of genetic material and actually serve to reduce industry efficiency and profitability. Although clinical disease is one factor that can decrease industry profitability and productivity, it is not the only factor. Alternate forms of fish health management such as improved husbandry, vaccination and rearing of resistant strains of fish should also be used to prevent clinical disease.

References


The USAHA Aquaculture Committee met Tuesday, October 31, 1995, from 1:30 PM to 7:00 PM. Thirty people were in attendance.

Dr. Bob Goetz, Committee Chairman, gave an update on the National Aquaculture Association, whose executive director, Joe McCraren, recently died. A search is under way to fill the void left by Joe’s death. NAA recently participated in an Animal Health Association meeting held to gain support for 2 bills currently in Congress, HR2508 and S773, which increase the availability of therapeutants to the animal health industry and streamline the approval process.

Mr. Jim Curran, Chief, Fisheries Bureau, Division of Wildlife, Nevada, spoke on aquaculture and aquaculture regulation in Nevada. Nevada has little aquaculture because of the shortage of water and the high cost of pumping water. There are less than 20 aquaculture facilities in Nevada; several raising catfish, with assorted other species also raised, including bullfrogs, axolotl, and alligators.

Dr. Don Lightner described the shrimp industry of the world, including life cycle and stages, cultural practices, and economic values. He noted that 33% of the shrimp consumed in the US and 40% of the shrimp consumed in Europe and Japan are aquacultured. The Western Hemisphere produces 20% of the world’s supply, with the US producing less than 2%. Viral diseases have seriously impacted shrimp production in several major Asian and
Latin American shrimp-producing countries in the past 3 years.

Dr. Lightner gave a short presentation on the impact of Taura Syndrome virus on shrimp production in Latin America and Texas.

Dr. Tom Baldwin reported on activities of the aquatic animal section of the Washington Animal Disease Diagnostic Laboratory (WADDL), which has been in operation for a year and a half. This section provides services to the aquaculture industry in several states. Most of their work is in certification for movement, with some diagnostic work done for the Montana Wildlife Division. Twenty-two health inspections (60 fish per lot) were done in the first year of operation with a large increase this year; 5000 fish have been accessed by the lab since January of this year. Service to states other than Washington are on a fee-for-service basis.

Dr. Jerry Heidel, Chairman of the AAVLD Aquaculture Committee, discussed the activities of the committee and this year’s meeting, held Sunday morning, October 29, 1995. The committee produced and is updating a document, which is available from Dr. Heidel, listing facilities offering aquaculture diagnostic testing. A great deal of discussion took place about laboratory certification and qualification for export, leading to the forming of a subcommittee to address these topics.

Dr. Randy MacMillan, President of the U.S. Trout Farmers Association and the Idaho Aquaculture Association, and Director of Research and Development for Clear Springs Foods gave a presentation on the U.S. trout industry and Clear Springs. Clear Springs, a vertically integrated company, is the largest trout producer in the world, taking trout from bloodstock to market-ready fillets. It has its own feed mill and produces its own vaccines. Thirty to 35% of the trout grown in the US are produced by Clear Springs. Dr. MacMillan discussed disease prevention and the trout industry’s quality assurance program; 44% of US trout production is enrolled in the quality assurance program.

Dr. Maura Jansen representing the Washington Fish Growers Association presented a draft health and stock improvement program for salmonid bloodstock producers. The program would be industry-driven, and monitored by USDA.

Dr. Bev Schmitt of USDA, APHIS’ National Veterinary Services Laboratories discussed aquaculture activities at NVSL. The laboratory tests aquaculture vaccines, does bacteriologic diagnostic testing, and is preparing to become involved in aquaculture virology and possibly in production of standardized reagents.

Dr. Andrea Morgan, USDA, APHIS, Veterinary Services, gave an update on the status of the European Union’s requirements for aquaculture and seafood products. The US is on the provisional list of countries approved to export aquacultural animals and products to the EU. Due to budgetary constraints no visit from the EU is anticipated in the next year, and trade in aquacultural products will continue under present bilateral agreements with
individual countries. The US is continuing discussions with the EU on equivalency, and is moving forward with legislation to give USDA authority over aquatic animal health, which is necessary for implementation of a national aquatic animal health program and acceptance of equivalence by the EU.

Dr. Dan McChesney of the FDA’s Center for Veterinary Medicine discussed the role of the FDA with regard to fish and seafood, which lies in two centers, one regarding food safety, and the other animal feeds and drugs. He briefly discussed proposed HACCP regulations regarding processors, handling of investigational new drug applications for aquaculture, extra-label use of drugs in aquaculture, residue testing, and proposed legislation providing for veterinary feed orders.

Mr. Ray Brunson, Director of the US Fish and Wildlife Services’ Olympia Fish Health Center, gave a historical perspective of regulation of fish and other aquatic animals by the Department of the Interior. FWS has 72 national fish hatcheries, 9 fish health centers, and 5 technology centers, all involved in aquaculture. Some virology services are presently available to commercial aquaculturists from fish health centers on a case by case basis as time and funding permit, however the FWS is withdrawing from commercial aquaculture and concentrating on endangered species and impacts of environmental changes and disease on indigenous fish. Possibilities do exist however, for cooperative efforts with commercial aquaculturists and other agencies.

Dr. Joe Annelli, USDA, APHIS, Veterinary Services, National Animal Health Programs, discussed the progress of APHIS in addressing issues identified at the aquaculture round table held in Maryland earlier this year. He provided names and contact points for the APHIS aquaculture coordinator and APHIS’ multidisciplinary aquaculture team, and discussed APHIS’ involvement in aquaculture, including regulation and trade, assistance with bird depredation, licensing and regulation of veterinary biologics, testing and diagnostics, and provision of export health certification. Since May 1994, APHIS has endorsed 187 export health certificates for export of 42 million salmonid eggs (eyed embryos). Additionally many health certificates are endorsed for shipment of live fish, primarily tropicals and ornamentals.

Dr. Otis Miller, APHIS Aquaculture Coordinator, gave the status of legislation giving USDA authority over aquatic animal health, and the ability to prevent the introduction of aquatic diseases. APHIS heads an interagency working group which includes FDA, National Marine Fisheries Service, and the US FWS, and is working on European Union trade issues in aquaculture. Dr. Miller discussed progress toward development of a comprehensive national aquaculture program, and the legislation necessary in the farm bill is necessary for providing authority to implement this program.

Dr. Joe Gloyd of the American Veterinary Medical Association discussed the AVMA’s Aquaculture and Seafood Committee and AVMA support for legislation giving USDA authority in aquatic animal health. He discussed the need for extra-label use of hormones in aquaculture to parallel its use in other
food-producing animals, and pointed out that the proposed feed order legisla-
tion did not allow for extra-label prescription of drugs in aquaculture feeds, 
and thus did not serve the needs of the industry.

Dr. Randy MacMillan, past president of the American Fisheries Society’s 
Fish Health Section, spoke briefly on the role of non-veterinary American 
Fisheries Society certified fish pathologists and fish health inspectors in fish 
health.

The committee recommended that the USDA, APHIS support the con-
cept of high health and stock improvement plans for aquaculture.

The meeting was adjourned at 7:00 PM.
EVALUATION OF A POTENTIAL SWINE INFLUENZA VACCINE

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In 1798, an English doctor by the name of Edward Jenner published his observations on the immunity against smallpox provided by inoculation with cowpox virus. Prior practice had been to inoculate material from mild cases of smallpox, but the consequences of this procedure were not always protective. In too many instances this caused the disease one hoped to prevent. Others were aware that exposure to cowpox seemed to protect against smallpox, well before Jenner’s time. But, Jenner’s methodical approach and careful experimentation helped calm public fears and justify community vaccination programs, using a related but nonpathogenic virus to build immunity against a dreaded disease.

Since that time, there has been steady progress in finding and developing such vaccines. More recently, where they couldn’t be found, these vaccines have been made through the use of innovative biotechnology. At present, there are three killed and five modified live virus licensed veterinary vaccines that have had certain genes deleted, genes that through their absence serve as serologic markers to distinguish vaccinated from infected animals and to reduce virulence of the vaccine strain. Such vaccines have played a very important role in the national pseudorabies eradication effort.

As we approach the twenty-first century, biotechnology is changing the character of biologics even further. New procedures make it possible to isolate from the genome of a dangerous virus that portion which can provide antigenic immunity and clinical protection. Insertion of such genetic material into another ‘carrier’ virus then allows expression of specific protective genes safely in a vaccine. There are many such live vectored vaccines currently under development, and they require new standards and testing procedures for their regulation. At the National Veterinary Services Laboratories (NVSL), we have undertaken a project to evaluate a potential swine influenza vaccine that is vectored by a highly attenuated, host-restricted, and safety-tested strain of vaccinia virus known as modified vaccinia virus Ankara (MVA).

Swine influenza (SI) is a common worldwide disease of pigs caused by Type A influenza viruses, mostly of the H1N1 antigenic subtype. Affected animals display an abrupt onset of fever, anorexia, abnormal breathing, coughing, sneezing, depression, huddling and, in a low percentage of cases, severe pneumonia that may result in death. In acutely affected herds, there is 100%
POTENTIAL SWINE INFLUENZA VACCINE

morbidity, although mortality is low. Without depopulation, SI is likely to continue in the herd with episodic occurrences of respiratory disease and reproductive problems. Serologic surveillance at slaughter indicates that up to one-third of 6- to 7-month-old pigs and almost one-half of 2-year-old and older pigs in the United States have been exposed to the virus; hence, the economic impact of SI on the swine industry is high.²

Presently, there is one killed product but no live SI vaccines. No strain has yet been found to be both efficacious and sufficiently attenuated to safely serve as a live virus vaccine in pigs. In addition, there are ongoing public health concerns regarding the transmission of SI to humans, with the most recent fatality reported in 1994.⁷ A swine population that is vaccinated against SI would protect agricultural workers from exposure to zoonotic strains. Thus, for several reasons, evaluation of the safety and efficacy of a recombinant SI vaccine is desirable. As the antigenic characteristics of the dominant SI strains are very stable, without the marked drift observed in human strains, SI would seem an excellent candidate for control by vaccination.

The recombinant vaccinia-vectored influenza vaccine and the MVA strain from which it is derived have been well characterized.⁴⁶ MVA has been used without significant side effects in over 120,000 people for immunization against smallpox. It contains six major deletions that prevent virus assembly in mammalian cells but leaves gene expression unimpaired. Host restriction has been reported in four human, two monkey, one rabbit, one equine, one mouse, one canine, and two bovine cell lines.⁴ At the NVSL, we found this restriction to apply to porcine cell lines as well.

The recombinant MVA vector contains the hemagglutinin (HA) and nucleoprotein (NP) genes from the human influenza strain A/PR/8/34 under the control of two optimized synthetic promoters. Since antibodies to HA provide immunity to influenza viruses with a similar HA, the question was whether the MVA vector containing human genes would elicit protection against swine influenza challenge. Unlike human influenza strains, swine viruses have exhibited little antigenic variation over time. It has previously been shown that monoclonal antibodies generated against the human A/PR/8/34 strain are cross-reactive with antigenic sites on the A/Swine/Iowa/31 strain. This suggests that some degree of cross-neutralization will occur between the A/PR/8/34 and various swine influenza isolates of the dominant antigenic type, a type which has persisted among swine since the isolation of the A/Swine/Iowa/31 strain. Using a hemagglutination inhibition (HI) assay, we examined hyperimmune and conventional sera and found cross-reaction between the human and swine strains. However, gnotobiotic pigs that were twice inoculated intramuscularly with the recombinant strain were found to mount a good antibody response to A/PR/8/34, as measured by the HI assay, but not to A/Swine/IN/1726/88, a recent well-characterized isolate of the dominant antigenic type. This suggested that insertion of the HA and NP genes from A/Swine/IN/1726/88 into the MVA vector might provide a better SI vaccine. We
FOLEY, MOSS, LEVINGS, WYATT, SAARI, HANSON

are presently pursuing construction of such a recombinant.

To complete our evaluation of the MVA vector containing A/PR/8/34 genes, we conducted a vaccination-challenge study in pigs. The recombinant had previously been shown to successfully protect mice against lethal challenge with A/PR/8/34. If it also protected pigs against SI, it could be used to safely deliver influenza immunogens either intranasally, to maximize upper airway mucosal immunity (primarily IgA) against SI invasion, or intramuscularly, to optimize systemic response (primarily IgG). For our study, twenty pigs of mixed sex were sorted into five groups of four pigs each. Two groups were vaccinated with the MVA-HA-NP recombinant, one IM and the other IN, at $10^6$TCID$_{50}$/animal. Another two groups were vaccinated with the parent MVA strain, again one IM and the other IN, at the same dosage. The first dose of vaccine was given at 21 days of age and the second dose 2 weeks after the first. The animals were challenged by intranasal aerosol 14 days after the second vaccination, using $10^6$EID$_{50}$/nostril of A/Swine/IN/1726/88. One group of pigs served as nonvaccinated, challenged controls. These studies are currently ongoing, but preliminary evidence indicates the recombinant vaccine provides some protection against SI challenge.

It is likely that the HA and NP genes from swine influenza strains, especially those from pathogenic isolates, will provide as good or better immunity to this disease. In addition, the MVA vector may prove to be a valuable delivery system for other viral immunogens. Its extensive history of use, detailed characterization, and strong synthetic promoters make it a model candidate for expressing proteins of pathogenic agents. Our ability to test this system now against SI helps us to evaluate its potential to prevent other diseases and, at the very least, provides additional data useful in evaluation of the entire recombinant vector concept.

The NVSL has conducted other work to assist in regulation of genetically engineered veterinary biologics, including a study to determine duration of shedding of a recombinant vaccinia virus-vectored rabies vaccine following oral administration in raccoons; a study to evaluate in vivo responses in a model species (mice) and in a potential biologics target species (swine) to live Salmonella vectors used for delivery of heterologous protective antigens; and a project to develop a model swinepox virus vector system for evaluation of host-specific live pox virus-vectored vaccines. We hope, through these efforts, to prepare for vaccines of the new millenium and the regulatory challenges to come.

References

POTENTIAL SWINE INFLUENZA VACCINE


Mr. J. Bruce Addison, MO; Dr. Gary A. Anderson, KS; Dr. Connie L. Bacon, VA; Dr. Charles A. Baldwin, GA; Dr. Charles W. Beard, GA; Dr. Wes Bonner, TX; Dr. Gerald M. Buening, MO; Dr. Jerry J. Callis, NY; Dr. John A. Cobb, GA; Dr. William C. Davis, WA; Dr. James J. England, ID; Dr. William H. Fales, MO; Mr. John E. Finnell, IL; Dr. Richard H. Fulker, IA; Mr. Max E. Glass, KS; Dr. Joe S. Gloyd, DE; Dr. Belinda Goff, IA; Dr. Thomas D. Goodrich, WA; Dr. John R. Gorham, WA; Dr. Harvey S. Gosser, MO; Dr. James A. Gourlay, CA; Dr. Keith N. Haffer, SD; Mr. Majon Huff, CO; Dr. Richard D. Hull, IL; Dr. Wade L. Kadel, KY; Dr. Jonathan Katz, IA; Dr. John P. Kluge, IA; Ms. Kristi K. Krafka, IA; Dr. Jimmy Kwang, NE; Dr. Lloyd H. Lauerman, AL; Mr. Hank M. Lefler, NV; Dr. Randall L. Levings, IA; Dr. Raymond W. Loan, TX; Dr. Stewart McConnell, TX; Dr. Janis K. McMillen, KS; Dr. Robert W. Mead, WA; Dr. William L. Mengeling, IA; Dr. Rita D. Michaels, MO; Mr. Thomas R. Mickle, GA; Dr. Harley W. Moon, IA; Dr. Larry F. Moore, OK; Dr. Robert M. Nervig, CO; Dr. John B. Payne, TX; Dr. Nancy Pfeiffer, NE; Dr. Marshall Phillips, PA; Mr. Robert E. Pitts, GA; Dr. Donald Randall, Jr., IA; Dr. John A. Schmitz, NE; Dr. Roy A. Schultz, IA; Dr. George P. Shibley, KS; Dr. Randy R. Simonson, MN; Dr. Vaithianathan Sivanandan, MN; Dr. Clyde J. Stormont, CA; Dr. Al Strating, CO; Dr. R. Flint Taylor, NM; Mr. Olin H. Timm, CA; Dr. J. Donald Todd, KS; Dr. Deoki N. Tripathy, IL; Dr. Percy R. Turner, TX; Dr. George B. E. West, CA; Dr. Cecelia A. Whetstone, NY; Dr. Philip W. Widel, MO; Ms. Gwen Wilder, MO; Dr. Saul T. Wilson, Jr., AL; Dr. Richard L. Witter, MI; Dr. W. H. Wohler, TX; Dr. Mark D. Wood, VA; Dr. Erwin F. Workman, ME; Dr. Tilahun Yilma, CA.

The Biologics and Biotechnology Committee met Wednesday, November 1, 1995. Twenty-three members and seventeen guests were present.

An update on APHIS licensing activities and issues was presented by Dr. David A. Espeseth, Deputy Director, Veterinary Biologics. There were 184 product licenses issued in Fiscal Year 1995, 20 of which were for new products. Seventeen product licenses were terminated to give a total of 2,309 active product licenses; including 5 for diagnostic products, 40 for products for further manufacture and 1 for a category III biotechnology product. Approximately 68 billion doses of licensed products were produced in Fiscal Year 1995.
REPORT OF THE COMMITTEE

Five new establishment licenses were issued and one establishment license was terminated in Fiscal Year 1995, to give a total of 120 licensed establishments and permittees. Import permits were issued for 77 products for research and evaluation and 14 permits were issued for transit shipment only.

APHIS initiatives to implement quality improvement projects to improve its procedures, to ask industry to provide risk assessments and more complete biometric analysis, and to improve APHIS uniformity, consistency and response time by providing more guidelines for industry concerning preparation of data in support of licensure were reviewed.

The status of APHIS efforts to implement a master label concept to reduce the number of labels that need to be submitted and filed, user fees for the Veterinary Biologics Program, a revised definition of veterinary biological product, a new memorandum concerning minimum age recommendations on labeling the repackaging rule were discussed. APHIS policies permitting production of vaccines for highly pathogenic avian influenza, the testing of avian vaccine master seeds for reticulo-endotheliosis virus contamination, the production of chicken anemia virus vaccine, and the testing of bursal-origin bursal disease vaccines were also reviewed.

Dr. Don Randall presented updates from the Veterinary Biologics Field Operations, Ames, Iowa. In presenting the inspection system for U.S. Veterinary Biologics at international meetings this year, Dr. Randall has been stressing four levels of inspection including pre-licensing site inspections, laboratory check testing and review of firm testing for batch release, in-depth site inspections and post-release monitoring of products. For the year, inspections were down due to loss of inspectors, but other counts for the year were the same as previous years. Projects at Field Operations this year include:

- Gathering information on inadvertent human exposure to veterinary biologics;
- Reduce reporting requirements for first serial autogenous biologics;
- Reduce time to process serial releases;
- Develop a method for electronic submission of data between manufacturers and APHIS (joint project with A.H.I.).
- Speed up availability of outlines once approved (program wide project);
- Participate in program review.

Dr. David Siev, Biologics Epidemiologist, Veterinary Biologics Field Operations, gave an update on the post-release monitoring cooperative project with the licensed firms. The project objective is to establish general baseline reaction rates through use of the information received by the manufacturer.

An overview of Fiscal Year 1995 activities of the Veterinary Biologics Laboratory (VBL) of NVSL was presented by Dr. Randall L. Levings, Chief, VBL. Personnel and organization changes were reviewed. Summaries of testing were given. One hundred and eleven seeds and cells and 1822 serials of
11,714 eligible (15.55%) were tested, with 97.04% satisfactory. A total of 4,567 tests were run in the 10 categories of testing, with approximately one-half (2,270) in check testing. Percent unsatisfactory rates ranged from 0 to 14.7 depending on category. Developmental projects focusing on recombinant vaccines, in vitro potency assays, and safety issues such as strains, contamination, and endotoxin are ongoing. Procedures to assure consistent rigor and quality of recombinant DNA vaccine seed and serial testing were reviewed. The proposed Biologics Center to collocate the Veterinary Biologics Laboratory, Staff, and Field Operations in Ames, Iowa, adjacent to NVSL was described.

A report on the Institute for International Cooperation in Animal Biologics, a collaborative effort of the Iowa State University College of Veterinary Medicine, USDA, APHIS, and USDA, ARS, was given. The goal of the institute is to improve the availability, safety, efficacy, and use of veterinary biologics throughout the world. It seeks to do this through: (1) assembling impartial groups to serve on forums to build consensus on policy and standards; (2) serving as a resource for testing, reagents, and technology transfer; (3) implementing cooperative research programs between government, university, and industry scientists; (4) coordinating assistance for developing countries in receiving and/or manufacturing veterinary biologics.

Dr. Rick Hill, NVSL Quality Assurance (QA) Manager, presented an overview of the NVSL QA program. The program is based on existing QA programs worldwide. It is related to, but apart from, the total quality management initiatives at NVSL and in the Veterinary Biologics Program and international harmonization efforts. Protocols for NVSL-wide functions and high-output tests are being implemented. Support for the QA program has been received from management and bench scientists.

A presentation from the Animal Health Institute was read. This detailed the various activities of A.H.I. and summarized the nature of its members, the relatively small size of the veterinary biological industry, and the cost of licensing products. Important issues to A.H.I. are: (1) opposition to user fees for veterinary biological regulation, (2) continue to work on an equitable solution to reference requalification proposals (3) supporting efforts to help APHIS operate more efficiently and (4) to promote international harmonization through mutual acceptance of technical standards and the need for risk assessment.

A new trade organization of vaccine manufacturers was announced by Mr. Ron Plylar. The Association of Veterinary Biologics Companies has just been formed with approximately 12 members. The group’s primary focus is to promote the current APHIS regulatory scheme as delineated in 9 CFR 101-124. The group opposes the acceptance of a common European-type GMP system.

A paper by Dr. Patricia Foley entitled “Evaluation of a Potential Swine Influenza Vaccine” was presented concerning a candidate gene-inserted vaccinia-vectored product developed by the Veterinary Biologics Laboratory of
REPORT OF THE COMMITTEE

NVSL. This paper was presented to the general session and is published in these proceedings.

The committee discussed several issues and adopted the following:

Recommendation:

That APHIS make no labeling requirements at this time regarding the endotoxin content on veterinary vaccines until more data is accumulated and the problem more fully understood.

Resolution:

USAHA resolves to support the current Veterinary Biologics Regulatory System governed by Title 9 of the Code of Federal Regulations (9CFR) and to urge APHIS to take immediate action to secure a Mutual Recognition Agreement (MRA) based on equivalence, appropriate risk assessment and final product testing for purity, potency, and safety and efficacy.
BOVINE LENTIVIRUS (BIV) IN PERIPHERAL BLOOD, MILK, AND SEMINAL LEUKOCYTES OF CATTLE: IMPLICATIONS FOR TRANSMISSION

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Introduction

Bovine immunodeficiency virus (BIV), a unique lentivirus of cattle, is an infectious agent detected serologically in cattle in many regions of the world (8,9,13,14,23,24,34,36,50,52,55). BIV was first isolated from a Holstein cow (R29) with lymphoproliferation, neuropathy, and wasting (55), and the virus has since been detected in cattle showing signs of chronic disease in the United States and abroad (8,29,49). Lentiviruses of other species are frequently associated with chronic, progressive, and often lethal diseases in their respective host species. Thus, it is logical to assume that BIV may be a bovine pathogen. Yet, the paucity of infectious field isolates of BIV, the chronic nature of infection, and the typical coinfection of BIV-infected animals with other leukocyte-tropic viruses has resulted in difficulty in adequately fulfilling Koch’s postulates for this virus. Consequently, the role of BIV in bovine disease remains unclear.

BIV is the most genetically complex non-primate lentivirus. The proviral genome, approximately 9 kbp in length, encodes three genes, gag, pol, and env, which are characteristic of all retroviruses, and at least six accessory genes (16-18). Like human immunodeficiency virus (HIV) the BIV genome encodes vif (viral infectivity factor), tat (trans-activator of transcription), and rev (regulator of virus expression) genes, as well as three additional genes, designated vpw, vpy, and tmx. The functions of the BIV accessory gene products are thought to be analogous to those of the primate lentiviruses. The BIV long terminal repeat (LTR) region is similar to that of the primate lentiviruses and equine infectious anemia virus (EIAV). The U3 region of the BIV LTR encodes binding sights for the cellular transcriptional factors NFkB, SP-1, AP-1, and AP-4, and a core enhancer region which is required for transcription to occur. A TAR (trans-acting region) is encoded in the R region of the LTR. TAR is located at the 5' end of all viral transcripts and presumably enhances viral gene expression by binding the Tat protein (5).

Like other lentiviruses, hypervariability in the env gene of BIV results in amino acid sequence diversity in its envelope glycoproteins (16,53). The importance of these sequence changes to the pathogenicity of BIV are currently unknown. The antigenic relatedness of BIV to HIV-1, simian immuno-
BIV IN BLOOD, MILK AND SEMINAL LEUKOCYTES

deficiency virus (SIV), and EIAV was demonstrated by serologic cross-reactivity between the capsid proteins of these viruses (19). This antigenic relatedness indicates the conservation of epitopes in the capsid proteins.

Pathogenesis and Cell tropism

BIV infection has been associated on occasion with bovine disease of unknown etiology. Bovine R29, the source of the original BIV isolate (55), was very ill with a persistent lymphocytosis, lymphadenopathy, central nervous system lesions, and a progressive wasting syndrome. Following the delivery of her calf in 1969, the health of R29 continued to decline. She was euthanized, and histological examination of tissues revealed a generalized hyperplasia of lymph nodes and mild lymphocytic perivascular cuffing in the brain. Inoculation of bovine embryonic spleen cells with leukocytes and tissues from R29 allowed the isolation and later characterization of BIV (355). Inoculation of colostrum-deprived calves with the isolate produced mild lymphocytosis and moderate lymphoproliferation in subcutaneous lymphatic nodules (55).

Last year a news report in Nature (8) revealed that animals in a dairy herd in Cheshire, Great Britain were ill with a syndrome which included nerve degeneration, weight loss, mouth ulcers, and respiratory infections. Several of the ill animals had serological evidence of BIV infection. This incident prompted Britain’s Ministry of Agriculture to invest in a major research effort to diagnose BIV infection in that nation.

Snider et al (49) reported a very high incidence of death in a Louisiana State University dairy herd in 1990-91. The animals exhibited a variety of clinical signs of disease, including a high rate of opportunistic infections, neurological abnormalities, lymphoproliferative disorders, and other symptoms. The seroprevalence of BIV was very high among these animals, but many were coinfected with BLV. Therefore, the cause of illness in these animals was unresolved.

Jembrana disease virus (JDV), a bovine lentivirus, causes an acute, lymphoproliferative disorder in Bali cattle (29). Consistent signs of disease include fever, lethargy, anorexia, and enlargement of the superficial lymph nodes. The acute nature of JDV differs remarkably from most other lentivirus-induced diseases, but pathologic signs of this disease parallel those of SIV, which causes a similar disorder in infected pig-tailed macaques (15). Using Western blotting, antigenic cross-reactivity between the 26 kd core proteins of JDV and BIV was revealed. Morphologically, JDV and BIV differ. JDV has the appearance of a C-type retrovirus, while BIV has a bar-shaped nucleoid (29). Nucleotide sequence analysis of JDV revealed 74% sequence identity with BIV (6,7).

Experimental infections of calves with BIV R29 have produced only mild clinical consequences including early seroconversion, transient leukocytosis, and lymphoid follicular hyperplasia (4,12,52,55). Flaming et al (12) evaluated
the effect of BIV on immune function and reported an increased lymphocyte blastogenic response to phytohemagglutinin in BIV-infected calves. In addition, neutrophil antibody dependent cell mediated cytotoxicity and neutrophil iodination were decreased in BIV-infected cattle. Jacobs et al (26) reported that in BIV-infected sheep neutrophils were increased at 3 months postinoculation, and eosinophils were increased between 6 to 8 months postinoculation. By two months postinoculation B, CD2+, and CD4+ cells, and CD4+/CD8+ ratios were increased in BIV-infected sheep. Two calves experimentally infected with BIV FL112, a wild-type BIV isolate from Florida cattle, developed an elevated mononuclear cell count which paralleled the results of experimental inoculation of calves with BIV R29 in the original calf inoculations (52).

The monocyte tropism of BIV was determined by the isolation of BIV from the monocytes of infected animals and the ability to infect primary monocytes in culture (39,46). Monocytes from BIV-infected cattle were subjected to functional analyses. Superoxide anion release, phagocytic activity, and chemotactic responsiveness were depressed in BIV-infected cattle within one year of infection (39). Rovid et al (46) reported depressed monocyte phagocytosis within 4-8 months after infection of cattle, but phagocytosis did not differ from uninfected control animals after 8 months. No other abnormalities were detected between infected and control groups. When primary normal bovine monocytes were infected in vitro with cell-free virus, significant functional differences were detected between infected and uninfected cells. Random and chemotactic migration were increased, phagocytosis was increased, and antibody-dependent cell-mediated cytotoxicity (ADCC) was decreased.

Using PCR or virus isolation, BIV can be detected in tissues of infected animals. The virus has been identified in peripheral blood mononuclear cells, spleen, and lymph nodes of cattle (4,51,52,55). BIV was detected in the lymph nodes, spleen, peripheral blood leukocytes, peritoneal wash, bone marrow, intestine, thymus, omentum, brain, lung, and liver of rabbits persistently infected with the virus (44).

BIV can be propagated in culture in a variety of cells (Reviewed in 17). Bovine embryonic spleen (BESP) and fetal bovine lung (FBL) cells at low passage level support the replication of the virus and produce high yields of virus. BIV will also replicate in a variety of established cell lines including several bovine cell lines, canine thymus (CF2Th) and canine osteosarcoma (D-17), and embryonic rabbit epithelium (EREp). BoMac cells, a transformed bovine macrophage cell line, support the replication of BIV (56).

Seroprevalence

Although epidemiologic data addressing the distribution of BIV-infected cattle is limited, the serologic detection of BIV-infected cattle in diverse geographic locations suggests a global distribution of the virus. BIV-infected cattle in the United States are well-documented. BIV was present in 56% of
cattle in the Louisiana State University (LSU) dairy. Two LSU beef herds were tested serologically for BIV infection, and seroprevalences of 27% and 21% were determined (R. Snider, personal communication; M.A. Gonda, et al, manuscript in preparation) In a recent study of the seroprevalence of BIV in two Mississippi State University dairy herds, seroprevalences of 38% and 58% were detected (50). BIV-infected cattle were detected in a Colorado dairy herd where 21% of the cows tested were seropositive (9). A serologic survey of BIV in Ontario cattle revealed a seroprevalence of infection of 5.5%, and 18.1% of herds tested had at least one seropositive animal (34). BIV-infected cattle were identified in countries in western Europe, including The Netherlands, Germany, and Great Britain (8,24,36). The virus was detected in cattle in New Zealand and Australia (14,23), and recently the virus was detected in Costa Rica (13). JDV is endemic in cattle in Bali, Indonesia (6,7,29).

Transmission of Lentiviruses

Collectively, lentiviruses may be transmitted by both horizontal and vertical modes. Perinatal transmission is well-documented for EIAV, SIV, and HIV (27,32,33,40). Approximately 25% of pregnancies involving HIV-infected women result in an infected infant (40). Lentiviruses also may be transmitted by the lactogenic route. Visna, caprine arthritis-encephalitis virus (CAEV), feline immunodeficiency virus (FIV), SIV, and HIV can be recovered from the milk and/or colostrum from their respective host species, and transmission to nursing offspring was documented (1,22,28,31,41,48,54).

Lentiviruses are frequently blood-borne pathogens. Leukocytes harboring proviral DNA can be detected in the peripheral circulation of humans infected with HIV, as well as animals infected with their respective lentiviruses. The transmission of HIV through blood transfusion was documented in a case study of blood transfusion recipients who later developed AIDS (10).

EIAV is mechanically transmitted among horses by horse flies, particularly Hybomitra spp. and Tabanus spp. (21,25). Transmission occurs when a horse fly feeds on an infected horse, is disturbed when the horse trembles or swishes its tail in response to the bite, then flies to a nearby uninfected horse and continues feeding. The role of insect vectors in transmission of lentiviral infections of other species is unknown. There has been some speculation that insects may be involved in the transmission of BIV in cattle. The seroprevalence of BIV infection is higher in the southeastern United States than in regions of North America where the climate is cooler and fewer biting insects thrive. However, there is no data concerning insect transmission of BIV to support this theory.

The predominant means of transmission of HIV is sexual intercourse. The virus was detected in the seminal leukocytes of infected males (20,35,58), and evidence suggests that seminal fluids may enhance virus transmis-
sion by facilitating contact between infected leukocytes and epithelial cells of mucosal surfaces (43). Although transmission of SIV through scratching or biting is possible, sexual transmission appears to be the most likely mode of SIV transmission (30). The importance of sexual transmission of lentiviruses of domestic animals is unknown.

Other means of direct contact may also promote lentiviral transmission. Visna virus induces pulmonary adenomatosis in Icelandic sheep. This syndrome results in the production of excessive amounts of pulmonary exudate, facilitating the spread of this disease by nose-to-nose contact between sheep (11,42). FIV is present in the saliva of infected cats, yet saliva did not appear to pose a great threat to confined, specific pathogen free kittens under experimental conditions (57). Territorial aggression probably contributes to the transmission of FIV. Bite abscesses occur at a high rate in free roaming cats and at a low rate in confined cats. FIV is prevalent at a higher rate in free-roaming tom cats than free-roaming female cats.

Horizontal transmission of CAEV was investigated in an experiment in which five uninfected wethers were placed in a pasture with seropositive goats for 7-12 months (1). The goats were tested for serum antibody against CAEV at monthly intervals. Two of the five wethers seroconverted within 9 months, indicating that CAEV is transmitted by a horizontal route.

Although BIV is prevalent in large numbers of cattle in portions of the United States and abroad, the mode(s) of transmission of this virus are completely undefined. Considering the relatedness of BIV to HIV, we presume that mechanisms of transmission are similar. Thus, blood, milk, and semen are likely to play a role in transmission of BIV. Since lentivirus-infected cells are thought to be the most efficient vehicles for virus transmission (47), our goal was to probe leukocytes from these fluids for the presence of BIV proviral sequences. Therefore, we developed a polymerase chain reaction (PCR) protocol which specifically amplifies a BIV proviral sequence in the DNA of infected leukocytes (37,38). The target sequence is 235 bp in length and is located within the reverse transcriptase domain of the pol gene. To determine whether BIV seropositive animals harbored infected cells in the peripheral circulation, blood samples were collected from three BIV-seropositive cows; leukocytes were purified from these blood samples; and crude DNA samples were obtained from the cells by boiling the cells in distilled water to lyse the cells. Likewise, DNA was prepared from pooled blood leukocytes from randomly selected, BIV seropositive cattle. The DNA was used as template in the PCR technique, and the PCR products were visualized on ethidium-bromide stained gels. A band of 235 bp was amplified from the leukocyte DNA of the three BIV seropositive cows, as well as the pooled DNA sample. A PCR product was not detected when DNA from uninfected animals or uninfected cultured cells was used as template in the reaction. Milk samples were obtained from these three cows at a single time point, and a milk sample was collected from the farm bulk milk holding tank following the morning milking.
The bulk milk was a pool of milk from all lactating animals on the farm. Leukocytes were purified from all milk samples, DNA was prepared as described above, and the DNA was used in the PCR procedure. The BIV-specific band was amplified from the milk-derived leukocytes of all three infected animals and the bulk milk sample.

The BIV specificity of the amplified product was confirmed by use of nucleotide sequencing. The fragments selected for sequencing were those amplified from the pooled blood leukocytes and the bulk milk-derived leukocytes. The nucleotide sequences of the DNA fragments were compared with the sequence of BIV 127, a molecular clone of BIV R29 (16). The sequences of the amplified products from blood and milk-derived leukocytes had 98.5 and 96.9% homology with BIV 127, respectively (38).

To begin evaluating the importance of sexual transmission of BIV in dairy cattle, we obtained 11 frozen semen samples from a stud semen repository, including samples from 4 Holstein, 5 Jersey, and 2 Guernsey bulls. The semen was thawed, and the seminal leukocytes were purified from seminal plasma. A crude DNA preparation was prepared by boiling the cells to lyse them. The seminal leukocyte DNA was tested in the PCR technique discussed above. The target sequence was amplified from 9 of the 11 DNA samples (82%). The seminal leukocytes from 5 Jersey, 2 Holstein, and 2 Guernsey bulls were positive for the virus. One semen sample was selected for reevaluation to rule out the possibility of laboratory contamination of DNA samples. A second semen sample was procured from this animal, and the DNA was prepared and tested as described above. Again, this semen sample was positive for the BIV proviral sequence, negating the possibility that the amplified product was a laboratory artifact. This amplified product was nucleotide sequenced, and the sequence was compared to the same region of BIV 127. The BIV sequence amplified from semen leukocyte DNA shared 98.1% identity with BIV 127 (37).

Implications for the Dairy Industry

The detection of BIV-infected cells in the peripheral circulation, milk, and semen of infected cattle suggests the possibility that these fluids may be important in the transmission of the virus. If the virus can be transmitted by milk or colostrum, then traditional dairy husbandry may contribute largely to the spread of the virus through herds. Calves in production dairy herds are hand-fed pooled colostrum and milk before weaning. Therefore, it is possible that a single infected dam, contributing colostrum or milk to the pool, could infect many young calves being fed from the contaminated colostrum and milk supply. This husbandry practice is known to play an important role in the transmission of CAEV in goat farming. Natural rearing of kids is typically performed in South America and Africa, where the rate of CAEV seropositive kids is 10% or less. Hand rearing of kids with pooled milk is a standard practice in the United States and western Europe, and the seroprevalence of

74
CAEV in these animals is approximately 80% (2).

The detection of BIV-infected cells in the semen of stud bulls demonstrates a potentially important reservoir of infection. Semen provides an efficient vehicle for transmission of HIV. Compounding the importance of this putative source of infection is the fact that dairy cattle are typically impregnated by artificial insemination. Thus, a single BIV-infected stud animal may infect literally thousands of receptive females through cryopreserved semen. If semen is indeed infective, then artificial insemination may provide the most effective mechanism for widespread dissemination of BIV in dairy cattle.

BIV-infected cells are routinely detected in the peripheral circulation of BIV seropositive cows by PCR (38,51,52), and the virus can be transiently isolated from the peripheral blood leukocytes (39,46,52,55). The presence of the virus in blood cells indicates the potential for blood-borne transmission of this virus. Iatrogenic transmission of BIV as a result of veterinary care is a possibility. It is typical for a common needle to be used to vaccinate multiple animals. Blood carry-over from infected animal to uninfected animal could serve as a source of inoculum if the virus or virus-infected cells are present in sufficient numbers. Improperly sterilized instruments for dehorning or castration may also provide a source of virus inoculum.

Another putative means of iatrogenic transmission is rectal palpation. Veterinarians rarely change the palpation glove between animals, and fresh feces are often used to lubricate the glove before insertion into the rectum. The importance of this source of infection is completely unstudied.

It is not known which, if any, of these potential sources of BIV infection are important to the transmission of this virus. Clearly, experimentation is necessary to determine the most efficient means of transmission of BIV. While BIV has not been definitively associated with bovine disease, it is possible that early stages of an "immunodeficiency-like" syndrome may contribute to poor productivity and recurrent infections in bovids. Animals are culled from dairy herds at a high rate, due to such problems as reproductive inefficiency, low milk production, foot and leg problems, disease, or injury. BIV-infection was linked to decreased milk production in Canadian dairy animals (34), and opportunistic infections are hallmark features of lentiviral infection of other species. Therefore, it is plausible that BIV infection may result in animals being culled from the herds before BIV-induced disease is manifested. If so, then BIV is of significant economic importance to the dairy industry. We believe that BIV has sufficient pathogenic potential to warrant its further study and to attempt to minimize its spread. Knowledge of the mode(s) of transmission of this virus may indicate areas of dairy husbandry which contribute to dissemination of the virus. In many cases very simple changes in dairy management might severely limit the transmission of this bovine lentivirus.
BIV IN BLOOD, MILK AND SEMINAL LEUKOCYTES

References


39. Onuma, M., Koomoto, E., Furuyama, H., Yasutomi, Y., Taniyama,


THE IMPLICATIONS OF GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE VIRUS INFECTION

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Summary
Bluetongue viruses are genetically heterogeneous. The complex natural cycle of BTV involves two hosts (the ruminant and the insect vector) and provides opportunity for genetic polymorphism. Mutation, deletions, and reassortment are the three mechanisms which produce the genetic changes necessary for successful adaptation by bluetongue viruses to modifications in the environment resulting in considerable genetic diversity. This genetic diversity is reflected in phenotypic changes in bluetongue virus characteristics such as virulence, antigenicity, and tropism. The understanding of BTV genetic variation in nature provides a valuable tool for increasing our knowledge of the interactions between the virus and its vector and hosts. This will make it possible to follow the response by BTV to changes in its environment and to better monitor the distribution of BTV throughout the U.S. and neighboring countries. This knowledge is essential for the design of more effective and rational control measures and trade regulations.

Bluetongue is a noninfectious arthropod-borne viral disease of ruminants. The viruses causing the disease belong to the Genus Orbivirus. Four different serotypes of the virus (BTV 10, 11, 13 and 17) have been observed in western United States (1). The presence of the viruses is limited by the distribution and habitat of the vector, Culicoides variipennis var. sonorensis (2). As a result, infection is seasonal with infections in ruminants being most common in late summer and fall. Sheep, pronghorned antelope, Desert Bighorn Sheep and white-tailed deer are most susceptible to clinical disease (3). Cattle are commonly infected but rarely show evidence of clinical signs (4). Clinical expression of disease in sheep, antelope and deer is associated with viral-based vascular lesions that lead to local thromboses and infarcts of tissues in sheep and disseminated intravascular coagulopathy in the free ranging ruminants. Clinical expression of disease in cattle is associated with an IgE mediated hypersensitivity (4). Congenital BTV infection in sheep and cattle may result in hydranencephaly or porencephaly in sheep and cattle and retinal dysplasia in lambs (5, 6).

Evidence of strain differences in virulence and pathogenic characteristics of viruses of BTV serotypes became apparent during surveillance surveys for prevalence of infection in ruminants. BTV was isolated from sheep flocks that had no evidence of clinical disease (7). Electropherotyping of BTV isolates
indicated that there was considerable variation in genome migration patterns within and between serotypes (8). Further, studies with plaque picked BTV 11 isolates with different electrophoretic patterns, designated UC2 and UC8, indicated a difference in virulence and pathogenic properties of these viruses in newborn Balb/c mice and fetal calves (9, 10). The potential for genetic polymorphism in the BTV serogroups seemed apparent.

Genetic polymorphism is reflected in differences in antigenic properties, vector susceptibility, tissue tropism and virulence exhibited by individual members of the same virus group or serotype. Even viruses isolated at the same time and from a common geographical region may be genetically heterogeneous, as may RNA viruses isolated from a single outbreak of disease or even from a single infected host (11). It has been demonstrated that the viral population of some RNA viruses, such as foot and mouth virus, influenza virus and vesicular stomatitis virus, consists of multiple related, but nonidentical, genomes known as quasispecies (12). The natural replication cycle of bluetongue viruses, which includes an insect vector, various ruminant and carnivore hosts (13), offers significant opportunity for the generation or selection of genetically novel viruses (8, 14-18). In this manuscript, we present evidence and examples of genetic polymorphisms and discuss the implications of these changes.

Examples of Genetic Polymorphism

The three principle mechanisms by which genetic polymorphisms occur with BTV include: (1) mutations, (2) nucleotide deletions and (3) gene reassortment. Figures 1, 2 and 3 represent examples of the mechanism of genetic alterations that occur with BTV.

Genetic analyses for this study were done on the variable gene segment 2 and the conserved gene segment 9 of prototype viruses 2, 10, 11, 13 and 17, BT Vaccine Virus 10 (VAC 10) and field isolates of BTV from the western U.S.A.

Examples of mutations observed in the variable gene segment 2 of BTV 10 and 17 are shown in Figure 4 where nucleotide substitutions occurred. Examination of 12 different viruses indicated that they could be grouped so that the 1953 prototype, VAC 10 and the 1980 field isolates were similar, differing by only 0.1-0.5%. In contrast, the group of 1990 field isolates had similarities between 98.2%-99.7%, but showed 102 nucleotide changes (4.8% divergence) from the prototype, VAC 10, 1980 group. The vaccine strain, a chick embryo derived modified live virus, had nine mutations when compared to the prototype virus. Five of the mutations were unique to VAC 10, whereas four of them were shared with all the BTV 10 field isolates. These results indicate the presence in California of two distinct prototype consensus sequences in gene segment 2 of BTV 10 viruses over the last 37 years (Figure 5).

The nucleotide sequence homology of BTV 17 prototype and field isolates obtained in 1980 and 1991 ranged from 93.8 to 95.1%. The 1981 virus
isolates differed from one another in 25-71 nucleotides and, as a group, differed from the 1962 prototype by 140-164 nucleotides. The 1990 isolates had 26-34 nucleotide differences between them and had 178-181 nucleotide differences from the prototype virus. In contrast, the 1980 and 1991 field isolates differed from one another by 74-91 nucleotides. These results suggest the presence of two different prototype consensus sequences of segment 2 of BTV 17 circulating in two different regions of the western U.S., one in California and the other in Wyoming.

The analyses of the alignment of the nucleotide sequence of genome segment 2 from U.S. bluetongue viruses showed the occurrence of deletions in the gene during its evolution. Six common deletions clearly supported the grouping of BTV 10, 11 and 17 into one monophyletic group and BTV 2 and BTV 13 into a second group. Prototype and field isolates of BTV 17 share a common deletion between positions 1827-1828 which is not present in other U.S. BTV serotypes (Figure 4). Additional deletions are present between prototype strains of BTV 10 and 11 and in positions 1916-1917 of prototype and field isolates of BTV 17. The common deletions of nucleotides from gene segment 2 of BTV 10, 11 and 17 suggest that the deletions occurred in a common ancestor prior to the divergence of each serotype.

Genetic reassortment appears to be common with bluetongue viruses. Evidence of reassortment was suspected with electropherotyping (8), oligonucleotide fingerprint analyses (16), nucleic acid hybridization (19, 20) and, now, nucleotide sequence analysis (21). Nucleic acid hybridization and nucleotide sequence analyses have further refined and confirmed the significance of gene reassortment for the conserved and variable genes of the bluetongue viruses. Hybridization analyses of gene segment 5 have clearly demonstrated reassortment between serotypes BTV 10 and 11 (21) as schematically shown in Figure 3. This has also been associated with phenotypic changes reflected in the biological characteristics of the virus, such as virulence (22).

Sequence analysis of gene segment 9 of BTV 10 field isolates and prototype viruses showed that they segregate into two different lineages. One lineage consists of BTV 13, VAC10, BTV 10 prototype and the 1980 field isolates. The other lineage consists of 1990 BTV 10 field isolates and BTV 11 and 17 prototype viruses. This indicates that gene segment 9 from the viruses in this study could not be clearly separated into the classical serotype groups.

Discussion

Bluetongue viruses have three primary mechanisms for obtaining genetic variability. The mechanisms include deletions, mutations and reassortment of the segmented genome. The implications of these three means of genetic alteration are considerable and include important phenotypic expressions such as serotype classification, viral host and vector interactions, cellular tropism, virulence and regulation of viral replication. Bluetongue viruses are excellent examples of viral genetic variability due to the characteristics of their double
stranded RNA segmented genome and the possibility of simultaneous infection of the host and the vector with more than one serotype. Also, evidence suggests that bluetongue viruses behave as quasi-species (18).

Nucleotide deletions have been observed in bluetongue viruses of the U.S. These deletions have contributed, along with mutations, to divide U.S. BTV serotypes into two monophyletic groups when genome segment 2 is considered. The groups are BTV 2 and 13 and BTV 10, 11 and 17 (17). Depending on where deletions occur, the consequences can vary from altered subunit proteins to altered antigenic characteristics.

Mutations may occur in any of the gene segments. However, they are most common in the variable genes, such as gene segment 2 of BTV 10 and 17. Mutations can be detected with oligonucleotide fingerprints (16), monoclonal antibodies (23) or by sequence analysis (17, 18). Mutations occurring on gene segment 2 of bluetongue viruses may be associated with antigenic changes. These changes are best detected with monoclonal antibodies. There are reports which demonstrate that the addition of monoclonal antibodies to virus infected cell cultures leads to escape mutant viruses which are no longer neutralized by those monoclonal antibodies (24). Mutations occurring in the more conserved genes may be associated with other phenotypic characteristics, such as virulence or vector competence/selectivity.

Bluetongue viruses readily reassort because of their segmented genome. Reassortment occurs when two parent viruses infect a single cell simultaneously and as the progeny viruses assemble for packaging into infective viruses. Gene segments from either of the parental viruses may be encapsulated together forming a new variant. The chance for this to occur in field situations is significant. In epidemiological studies in California, it was found that two or three different bluetongue virus serotypes were circulating simultaneously in approximately 30% of the herds sampled (7). In an experiment, simultaneous inoculation of calves or sheep with two different plaque-picked viruses resulted in as many as 89% of the progeny viruses being of the nonparental type (25). Reassortment indices of 78% have been reported in the culicoides vectors (26).

Reassortment of genes has been reported previously with oligonucleotide fingerprints (16), nucleic acid hybridization studies (27) and sequence analysis (21) of viruses, such as the one of gene segment 9 reported herein. Previous studies on the genetic characteristics of two strains of BTV 11 (UC2 and UC8) with different neurovirulence revealed that the neurovirulent strain, UC8, was a reassortant with gene segment 2 from BTV 11 and gene segment 5 from BTV 10 (21, 22). Gene segment 5, coding for an outer coat protein, may influence both the structural conformation and antigenicity of the variable gene segment 2. It is possible that reassortment of core protein genes may generate a novel viral variant with a new core protein constellation which may be important for viral adaptation to a competent vector.

Genetic studies, as are reported here, indicated that conserved genes
such as gene segment 9 have had sufficient mutations to form at least two monophyletic groups in California. These two groups do not correlate with the segregation found with gene segment 2. A surprising finding was that gene segment 9 from VAC 10 derived from the original BT8 (now BTV serotype 10) in 1953 was highly homologous to that of BTV 13 isolated from Idaho in 1965. Blucine, a precursor of VAC 10 was a chick embryo-adapted vaccine virus introduced in 1954-55. It was demonstrated that this vaccine could be transmitted from vaccinated sheep to unvaccinated sheep by the insect vector, culicooides (28). Blucine was widely used in the western U.S. The high degree of homology of genome segment 9 between VAC 10 and the prototype BTV 13 strongly suggests that BTV 13 prototype virus has a reassorted gene segment 9 from the vaccine virus VAC 10. It is likely that either a culicooides vector or animal had a dual infection consisting of BTV 13 and VAC 10, and the packaged BTV 13 progeny virus contained gene segment 9 from VAC 10.

In summary, the data reported in this paper demonstrate the genetic heterogeneity of bluetongue viruses. The three principle means of genetic alternations include nucleotide deletion, mutation and gene reassortment. The finding of extensive genetic heterogeneity further supports the concept of quasi-species of viruses with multiple strains in nature.

References

GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE


Legends

Figure 1. Illustration showing the occurrence of a mutation in the nucleotide sequence and the resulting change in the amino acid composition.

Figure 2. Illustration showing the occurrence of a nucleotide deletion from the DNA sequence and the resulting change in the amino acid composition of the protein.

Figure 3. Schematic representation of simultaneous infection of a cell with two different viruses and the production of novel viruses in the progeny by reassortment.
GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE

Figure 4. Alignment of a portion of the nucleotide sequences of gene segment 2 of BTV 17 prototype and field isolates showing unique and shared mutations.

Figure 5. Phylogenetic tree of the L2 genes of the six BTV 10 isolates, the modified live vaccine VAC 10 and the five U.S. BTV prototype strains. EHDV 1 was used as an outgroup.

Figure 6. Alignment of a portion of the nucleotide sequence of gene segment 2 of the U.S. BTV prototypes (BTV 2, BTV 10, BTV 11, BTV 13 and BTV 17) and BTV 17 field isolates obtained from different species in California in 1981 and 1990: (a) Example of a deletion specific for BTV 17 and the field isolates from the same serotype and (b) Example of a deletion shared by BTV 10, BTV 11, BTV 17 and the BTV 17 field isolates.
GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE

- Leu Gly Asp
  - TTA GGT GAT G
  - Deletion
  - TTA GGT ATG

- Leu Gly Met
Reassortment

Progeny - Reassortants
1141
17bts2
17b81s2
17c81s2
17o81s2
17b90zs2
17o90xs2
17o90ys2
AGGTGATGTT TACAGTACAC TCCGACGTGT GTATAATGG AGTCTAAGGC CAGAATATGG
C........G...C.G.........G.G....
C........G...C.G.........G.G....
C........G...C.G.........G.G....
C........G...C.G.........G.G....
C........G...C.A....G...T....G.G....
C........G...C.G.........G.G....

GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE
GENETIC VARIABILITY OF VIRUSES IN BLUETONGUE

(a)

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The Bluetongue and Bovine Retrovirus Committee met in the Bonanza A room from 1:30 to 5:40 p.m. on Tuesday, October 31, 1995. There were 34 persons in attendance. Dr. Lyle Miller, Committee Chair, commented on a questionnaire received from the USAHA Committee on Animal Disease Surveillance and Animal Health Information regarding disease definition and methods of reporting. Responses were prepared for bluetongue, enzootic bovine leukosis, and bovine lentivirus infection. Also a request for review of three items in the protocol entitled “Standards for Certification of Cattle Herds as Bovine Leukosis Virus Free” was forwarded from the USAHA office in Richmond, Virginia. The issues were discussed later in the meeting. Dr. James Mecham, Committee Vice-Chair, conducted the portion of the meeting relating to bluetongue.

Summary of 1995 International Orbivirus Workshops

Summaries of three International Orbivirus Workshops were presented. Dr. Walter Tabachnick, USDA, ARS, Arthropod-borne Animal Diseases Research Laboratory (ABADRL), presented information on the “Joint South Africa-U.S. Orbivirus Workshop,” hosted by the Onderstepoort Veterinary Institute, Pretoria, South Africa, and held in Pretoria, South Africa, July 1995. Dr. James Maclachlin, University of California at Davis, presented information on the “Southeast Asia/Pacific Regional Bluetongue Symposium,” co-hosted by the Yunnan Tropical and Subtropical Animal Diseases Laboratory, Kunming, People’s Republic of China, and the Australian Centre for International Agri-
cultural Research, Canberra, Australia, and held in Kunming, People’s Republic of China, August 1995. Dr. Bennie Osburn, University of California at Davis, presented information on the "African Horsesickness and Related Orbivirus Workshop," hosted by the Japan National Institute of Animal Health and held in Tokyo, Japan, February 1995. These workshops attempted to facilitate communications between scientists, assess the current status of information, evaluate research and management needs, and identify areas of potential cooperation and collaboration pertaining to bluetongue and related orbiviruses.

Development of an Enzyme-linked Immunosorbent Assay (ELISA) for Detection of Antibodies to Epizootic Hemorrhagic Disease (EHD) Viruses

Dr. James Mecham, USDA, ARS, ABADRL, presented information on the development of ELISA testing for EHD. Monoclonal antibodies were produced to EHD serotype 2 virus and characterized for reactivity and specificity by immune precipitation and Western blotting. The monoclonal antibodies reacted with VP7 in either a serotype-specific or a group-specific manner. The monoclonal antibodies were evaluated in an antigen-capture ELISA and a competitive ELISA (C-ELISA) for detection of virus and antibody to virus. The monoclonal antibodies were serotype-reactive in the antigen-capture ELISA and detected only EHD serotype 2 virus. In the C-ELISA, the monoclonal antibodies were group-reactive and detected antibodies in the serum of animals infected with either EHD serotype 1 or serotype 2 virus. The gene coding for VP7 has been cloned into both a procaryotic and an encaryotic vector. Expression of this gene will provide a standardized source of antigen for use in the competitive ELISA.

Pathogenicity Evaluations and Insect Studies with Caribbean Basin Bluetongue (BT) Virus Isolates

Mr. Lee Thompson, USDA, ARS, ABADRL, reported on pathogenicity evaluations and insect studies with Caribbean Basin BT virus isolates. A prospective epidemiological study of bluetongue activity in 11 countries of the Caribbean Basin was conducted from 1987 to 1992. During this time, 300 BT virus isolates, representing serotypes 1, 3, 4, 6, 8, 12, and 17, were obtained from sheep and cattle sentinel herds. Bluetongue infection was endemic in the absence of confirmed clinical cases. Host and vector species in the Caribbean Basin differ from those in North America; therefore, a study was undertaken to determine if these exotic serotypes of BT virus are capable of causing disease in North American host species and whether the North American vector, Culicoides variipennis sonorensis, is capable of host-to-host transmission of disease. All seven serotypes produced moderate to severe disease when inoculated into bluetongue-free, White-Face sheep. Preliminary
studies of sheep-to-sheep transmission by C. v. sonorensis were unsuccessful. This species of vector did not become infected with these viruses under the test conditions. Further studies will be conducted to assess the pathogenicity of these exotic viruses in North American hosts and the ability of C. v. sonorensis to transmit them.

Molecular Epidemiology of Bluetongue Viruses

Dr. Bennie Osburn, University of California, Davis, discussed the implications of genetic variability of viruses in bluetongue infection. The complex natural cycle of bluetongue viruses, involving both a ruminant host and an insect vector, provides opportunities for genetic variation. Genetic heterogeneity supports the concept of quasi-species of viruses with multiple strains in nature. Genetic variation leads to changes in phenotypic characteristics such as antigenicity, tropism, and virulence that affect how virus strains interact with the vertebrate host and insect vector. Understanding the basis of such interactions will help us develop more rational and effective control measures and trade regulations. The paper is printed in the proceedings of the meeting.

Hemorrhagic Disease in White-tail Deer

Dr. David Stallknecht, Southeastern Cooperative Wildlife Disease Study, University of Georgia at Athens, presented a model for hemorrhagic disease in white-tail deer based on herd immunity to epizootic hemorrhagic disease (EHD) and bluetongue (BT) viruses. Hemorrhagic disease, which is caused by viruses in the EHD and BT virus serogroups, is the most important viral disease affecting white-tail deer in the United States. Although these viruses are widely distributed over much of this species range, much regional variation exists in the extent of exposure and in the severity of disease. A simple 3-step model was developed and tested to represent the relationship between herd immunity and reported disease. In the southeastern United States, reports of deer deaths attributable to hemorrhagic disease occurred most frequently from areas of limited exposure to either the EHD or BT virus serotypes. In areas of increased exposure to multiple serotypes, most reports of hemorrhagic disease involved the "chronic form" of the disease as detected by hoof and rumen lesions. In areas of extremely high exposure to multiple EHD and BT virus serotypes, hemorrhagic disease seldom has been reported. Results indicate that exposure does not equate with disease and that herd immunity patterns can be used as a predictor of disease risk.

Update on Bluetongue (BT), Epizootic Hemorrhagic Disease (EHD), and Testing for Bovine Leukosis Virus (BLV) in the U.S.

Dr. James Pearson, USDA, APHIS, National Veterinary Services Laboratories, gave an update on BT, EHD, and testing for BLV in the United States.
BLUETONGUE AND EPIZOOTIC HEMORRHAGIC DISEASE VIRUS ISOLATIONS

In calendar year 1994, the National Veterinary Services Laboratories (NVSL) made BT virus isolations from California, Florida, Georgia, Oklahoma, and Washington and an EHD virus isolation from North Dakota (Table 1). Deer were the source of an EHD type 2 virus isolate and one BT type 17 virus isolate. All other isolates were from domestic animals.

Dr. Pearson also reported that the Southeastern Cooperative Wildlife Disease Study at the University of Georgia, Athens, made 17 isolates of EHD type 2 virus and 1 isolate of BT type 10 virus from deer in 1994. The EHD type 2 virus isolates were made in Delaware, North Carolina, South Carolina, Georgia, Mississippi, Tennessee, and Kansas, and the BT type 10 virus isolate was made in Georgia.

In fiscal year (FY) 1995, there were 135 BT/EHD virus isolation submissions (including 38 import/export submissions), and there were 115 submissions of imported fetal bovine serum for BT safety testing requiring 231 sheep. So far this year, there have been no BT or EHD virus isolates.

It was reported that two isolates of EHD type 2 virus have been made at the ABADRL from samples obtained from the current hemorrhagic disease outbreak among white-tail deer in northeast Wyoming and South Dakota.

Bluetongue Survey

The 1994/95 BT survey of 18 northeastern and north central states plus Alaska and Hawaii was conducted from October 10 through December 16, 1994 (Table 2). It utilized the competitive enzyme-linked immunosorbent assay (C-ELISA) test. A total of 8,004 slaughter samples were tested, of which 31 (0.4 percent) were C-ELISA positive. None of the 13 geographic areas sampled had 2.0 percent or greater C-ELISA-positive samples. Twelve C-ELISA-positive samples were negative for neutralizing antibody against BT and EHD viruses. The other samples had neutralizing antibody against types BT virus types 10, 11, 13, and 17 (5 samples), BT and EHD virus (6 samples), and EHD type 2 virus only (8 samples).

BT Proficiency Test

The 1995 BT proficiency test was divided into C-ELISA and agar gel immunodiffusion (AGID) with 29 laboratories doing the C-ELISA test and 36 the AGID for a total of 65 USDA approved BT laboratories. The average number of BT C-ELISA samples missed was 0.52, and the results of 21 laboratories agreed with the NVSL on all 30 samples. The average number of BT AGID samples missed was 2.9, and 1 laboratory agreed with the NVSL on all 30 samples.
BLUETONGUE AND BOVINE RETROVIRUS

Bovine Leukosis Proficiency Test
A total of 77 laboratories took this proficiency test. The average number of samples missed was 0.5. Results of 60 laboratories agreed with NVSL on all 30 samples.

Bovine leukemia diagnostic test results from 29 laboratories are reported in the DxMONITOR Animal Health Report which is published by the Centers for Epidemiology and Animal Health, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture. The July 1994-June 1995 serology results are summarized on Table 3.

Table 1. Bluetongue (BT) and epizootic hemorrhagic disease (EHD) virus isolates for calendar year 1994.

<table>
<thead>
<tr>
<th>Isolate</th>
<th>Location</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT 17</td>
<td>California</td>
<td>Sheep</td>
</tr>
<tr>
<td>BT 17</td>
<td>Florida</td>
<td>Deer</td>
</tr>
<tr>
<td>BT 10</td>
<td>Georgia</td>
<td>Cattle</td>
</tr>
<tr>
<td>EHD-2</td>
<td>North Dakota</td>
<td>Deer</td>
</tr>
<tr>
<td>BT-13</td>
<td>Oklahoma</td>
<td>Cattle</td>
</tr>
<tr>
<td>BT-11(2)</td>
<td>Washington</td>
<td>Cattle</td>
</tr>
</tbody>
</table>

Table 2. 1994/95 BT Survey C-ELISA test results for the 13 geographic areas from slaughtered animals.

<table>
<thead>
<tr>
<th>State</th>
<th>Samples</th>
<th>Positive</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>553</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Hawaii</td>
<td>603</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Indiana</td>
<td>604</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>Maryland-Delaware</td>
<td>608</td>
<td>8</td>
<td>1.3</td>
</tr>
<tr>
<td>Michigan</td>
<td>606</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Minnesota</td>
<td>610</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>New England</td>
<td>745</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td>New York</td>
<td>605</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>North Dakota</td>
<td>608</td>
<td>7</td>
<td>1.2</td>
</tr>
<tr>
<td>Ohio</td>
<td>606</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>Pennsylvania-New Jersey</td>
<td>610</td>
<td>0</td>
<td>0.8</td>
</tr>
<tr>
<td>West Virginia</td>
<td>635</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>611</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>8,004</td>
<td>31</td>
<td>0.4</td>
</tr>
</tbody>
</table>
Table 3. Bovine leukosis immunodiffusion test results as reported by diagnostic laboratories.

<table>
<thead>
<tr>
<th>Dates</th>
<th>Positive</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>July-September 1994</td>
<td>2,575</td>
<td>11,896</td>
<td>21.6%</td>
</tr>
<tr>
<td>October-December 1994</td>
<td>1,923</td>
<td>10,414</td>
<td>18.5%</td>
</tr>
<tr>
<td>January-March 1995</td>
<td>2,271</td>
<td>9,538</td>
<td>23.8%</td>
</tr>
<tr>
<td>April-June 1995</td>
<td>1,776</td>
<td>9,894</td>
<td>18.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>8,545</strong></td>
<td><strong>41,742</strong></td>
<td><strong>20.5%</strong></td>
</tr>
</tbody>
</table>

Bovine Lentivirus (BIV) in Peripheral Blood, Milk, and Seminal Leukocytes: Implications for Transmission

Dr. Karen St. Cyr Coats, Mississippi State University, Mississippi State, Mississippi, presented a paper on the presence of lentivirus in leukocytes and the implications for transmission. The paper is printed in the proceedings of the meeting.

Observations on Cattle Experimentally Infected With Bovine Lentivirus (BIV)

Dr. Lyle Miller, Iowa State University, Ames, Iowa, reported on a collaborative study between scientists at Iowa State University and the USDA, National Animal Disease Center, that has been ongoing for about 4 years. Several virologic, immunologic, and pathologic methodologies have been used. Virus persists in infected animals and can be isolated from peripheral bloodmononuclear cells from most animals for long periods of time. Sites of viral persistence are variable from animal to animal and at necropsy, examination of multiple tissues and organs is needed to recover virus or provirus. Alterations in some immune parameters such as neutrophil iodination, antibody dependent cell-mediated cytotoxicity, monocyte chemotaxis, and monocyte random migration are seen. Overt clinical disease has not been seen in the infected cattle, except for the development of thymic lymphosarcoma in one animal. The role of BIV in this event is unclear.

Discussion of the leukosis certification protocol resulted in one resolution to amend paragraph II B regarding animal identification. The resolution was passed by unanimous vote. The amended protocol follows:

Standards for Certification of Cattle Herds as Bovine Leukosis Virus Free

I. Introduction

Owners of cattle participating in the voluntary certification program are required to obtain the services of accredited veterinarians and to submit samples
BLUETONGUE AND BOVINE RETROVIRUS

to the National Veterinary Services Laboratories or other laboratories approved by the National Veterinary Services Laboratories to conduct tests for bovine leukosis. The serologic test(s) to be used must be approved by USDA, APHIS.

II. Definitions

A. Herd:
   1. All cattle under common ownership or supervision that are grouped on one or more parts of a single premises (lot, farm, or ranch). More than one herd may be maintained on a single premises if they are separated to preclude any physical contact between herds and have separate feed, water and drainage systems. or
   2. All cattle under common ownership or supervision on two or more premises that are geographically separated, but on which cattle have been interchanged or where there has been contact among cattle on different premises. Contact between cattle on the different premises will be assumed unless the owner establishes otherwise. or
   3. All cattle on common premises, such as community pastures or grazing association units, but owned by different persons. Other groups of cattle owned by the persons involved that are located on other premises are considered to be part of a herd unless the epidemiologic investigation establishes that cattle from an affected herd have not had the opportunity for direct or indirect contacts with cattle from that specific premises.

B. Identification: All cattle in BLV certified free herds will be identified with a mark which identifies the animal to the herd and identifies the individual animal in the herd. Official identification as described in Title 9, Code of Federal Regulations, is permissible. This mark may be permanent or semipermanent. Permanent indelible marks may include tattoos, brands, electronic non-removable implants or registration certificates issued by a recognized breed registry organization that uniquely identifies each animal. Additionally, animals should have a semipermanent visible identification device. Alternatively, two semipermanent visible devices can be used. Semipermanent visible devices may include eartags or other tags which are surgically attached to the animal. Neck chains or other externally attached numbers are not considered semipermanent devices.

C. Representatives of the State Department of Agriculture shall approve applications for BLV herd certification and recertification.

III. Initial Certification

A. To qualify a herd for certification, all cattle must have two negative tests not less than 6 months nor more than 12 months apart.

B. Send application for Bovine Leukosis Free Herd Certification to the
REPORT OF THE COMMITTEE

State Animal Health Official along with copies of the last two negative herd test reports. Application must be signed by the herd owner and the accredited veterinarian who did the herd testing.

C. On acceptance by the State Animal Health Official, certification will be approved for one year from the date of the second negative herd test. The Month and Day of the second negative herd test will become the anniversary date for subsequent recertification.

D. Herds certified by State Animal Health Officials will be recognized by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), as free of BLV. Accordingly, APHIS will certify the BLV-free status of such herds for purposes of export to countries requiring that cattle and bovine germplasm originate in herds that are free of BLV.

IV. Recertification

A. A complete test of all cattle in the herd must be completed within 60 days prior to the anniversary date to maintain certification of the herd. Certification terminates on the anniversary date if the herd test is not completed prior to the anniversary date. Certification may be reinstated with one complete negative test of all cattle in the herd conducted within 60 days after the anniversary date.

B. Application of recertification must be submitted to the State Animal Health Official along with a copy of their herd recertification test. Test results of all herd additions during the previous certification period must be included. A complete accounting for all cattle in the herd including all herd additions or deletions is required.

V. Herd Additions

A. Cattle originating from a Certified BLV-free herd. Cattle from another certified herd must have one negative test 30 days prior to or 30 days after entry into the certified herd. Included are cattle returning to the herd from shows or sales or in transit situations where contact with cattle of unknown status could have occurred. Additions should be segregated from the herd until they have a negative test.

B. Cattle originating from a BLV negative herd. Cattle originating from a herd with a complete negative herd test within 1 year prior to addition may enter the herd with a negative test 30 to 60 days prior to addition to the herd and a second test 30 to 60 days after entry onto the premises of the certified herd. Additions must be segregated from the certified herd until after the second negative test.

C. Cattle originating from infected herds or herds of unknown status. Cattle from such herds must have 3 negative tests conducted at not less than 60 day nor more than 120 day intervals. During that time they must be segregated from untested and BLV seropositive cattle.
BLUETONGUE AND BOVINE RETROVIRUS

and not commingled with cattle in the certified herd. If cattle can be segregated at the place of origin, the first or first and second qualifying tests may be completed there; however, the third qualifying test must be conducted after entry onto the premises of the certified herd. If any cattle in the group are found to be positive, none of the group may be added to the certified herd until the positive cattle are removed and the testing process started again from the beginning.
PLACENTITIS INDUCED BY *BRUCELLA ABORTUS* STRAIN RB51 IN PREGNANT CATTLE

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Norman F. Cheville D.V.M., Ph.D.,²

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Ames, IA, 50010.¹

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The eradication of bovine brucellosis has centered on the use of *Brucella abortus* strain 19 (S19), an attenuated, live vaccine introduced into the federal brucellosis program in 1940. Recently, another strain of *B. abortus*, strain RB51 (SRB51), has emerged as a potential vaccine candidate.³⁴ SRB51 is a stable rough mutant of *B. abortus* strain 2308 (S2308) which lacks much of the LPS O-side chain.¹⁴ Although protective in cattle,³ the rough nature of SRB51 does not result in the production of antibodies detected by standard serologic tests in use today to determine *B. abortus* exposure.¹⁵ This provides animal health officials with a means of differentiating vaccinated from naturally infected animals. Although S19 has been effective in controlling bovine brucellosis for over 50 years it has significant limitations. These include the ability to induce production of antibodies indistinguishable from those resulting from natural infections and the ability to induce abortions in pregnant cattle.²⁵⁸⁹ As early as 1937 it was noted that experimental subcutaneous injection of pregnant cattle with a dose of 2 x 10¹¹ S19 organisms may produce typical clinical signs and lesions of brucellosis with the discharge of large numbers of organisms in uterine material at the time of parturition.⁵ Cattle in which S19 vaccination induced weak or dead calves were in late gestation when vaccinated. However, one cow vaccinated at 4 months of gestation and challenged with a virulent strain 32 days later gave birth to a weak calf with S19 isolated from placental and fetal tissues.⁶

Experimental intravenous inoculation of pregnant cattle with S19 typically leads to placentitis and abortion. Studies in the United States⁷ and Great Britain¹⁶ utilized intravenous inoculation of pregnant cattle with S19 in larger than recommended doses.⁷¹⁶ In both studies, 100% of the cattle aborted at 16 to 42 days following inoculation with S19.

Abortions occur less frequently in pregnant cattle following subcutaneous inoculation with S19. In a Canadian study, 16 (14.29%) of 112 cattle aborted when vaccinated subcutaneously with S19 at one to nine months of gestation.⁸ However, it was noted that of 30 cows between six and nine months of gestation, four (13.33%) aborted and S19 could not be recovered from colostrum or uterine exudate in any of the four.⁹
Abortions induced by S19 vaccination depend on both route of vaccination and vaccine dose. In cattle vaccinated during pregnancy with 1/20th the recommended dose of $1.12 \times 10^{11}$ and challenged with a virulent strain 10 weeks later, strain 19 was recovered in 4/9 (44%) following parturition with one abortion and one premature birth.\(^1\) Vaccination with a lower dose (1/400th the recommended dose) caused no abortions and low recovery of S19 from thecolostrum.\(^1\)

S19 vaccination of pregnant cattle can safely be achieved with minimal concern for large numbers of vaccine-induced abortions. A large field trial in Florida determined that less than 1% of more than 10,000 head of cattle aborted following vaccination in late gestation with S19 at a dose of $1 \times 10^{11}$ organisms per animal.\(^6\)

A small percentage of calves vaccinated with S19 may retain S19 infection into adulthood and in some instances this persistent infection may cause abortion.\(^17\) A study in the United Kingdom showed that of 34 isolates of bovine origin determined to be S19, 11 were from abortion material.\(^17\) Calfohood vaccination was the only known exposure to S19 in all cases.

Interruption of placental transfer of nutrients and oxygen has been proposed as a possible cause of brucellosis abortion.\(^11\) Although this mechanism of abortion has not been fully elucidated, placentitis, necrosis, and release of inflammatory mediators are likely integral parts of the pathway to abortion. Therefore, a major concern with any potential vaccine is the possibility of vaccine tropism for the bovine placenta that may result in placentitis and abortion.

Research with SRB51 in pregnant animals suggests that SRB51 has less tropism for the placenta than S19. In mice, SRB51 produces a mild to minimal placentitis but no fetal death.\(^18\) In addition, SRB51 does not induce abortion in pregnant goats when fetuses are surgically exposed and inoculated intramuscularly with SRB51.\(^12\) In bovine chorioallantoic explants, SRB51 colonizes the chorioallantois in a manner similar to S19 and S2308. However, the degree of cytotoxicity associated with SRB51 infection is much less than that for S2308 infection and is not significantly different from that seen with S19.\(^13\) Although these results suggest SRB51 may be less virulent than S19, the tropism of SRB51 for the bovine placenta in vivo and its abortifacient potential have not been fully elucidated.

Preliminary results of SRB51 vaccination in pregnant cattle suggest that vaccine-induced abortion does not occur. Over 350 adult pregnant cattle have been vaccinated subcutaneously with $1 \times 10^{9}$CFU SRB51 with no abortions (S.C Olsen, personal communication). Furthermore, in field conditions no clinical signs of disease have been noted in pregnant dams. Of 11 pregnant, cross-bred cows, inoculated subcutaneously in various stages of pregnancy, with $1 \times 10^{9}$ CFU SRB51, one had SRB51 in vaginal secretions at parturition and 2 had SRB51 in colostrum. One cow was 2 months pregnant at vaccination (SRB51 positive colostrum) and one cow was 5 months pregnant at vac-
Experimental intravenous inoculation of pregnant cattle during the sixth month of gestation with $1 \times 10^{10}$ SRBSI results in placentitis and the presence of SRBSI in placentomes and uterus in 80% of the cattle. Infection of the placenta and placentitis is present at 8-weeks post-inoculation as well as in full term pregnancies. The morphology of the placentitis is similar to placentitis induced by virulent *B. abortus* strains. Placentitis is most prominent in the placentomal arcade zone. Trophoblast epithelial cells in this region contain abundant intracellular SRBSI. No abortions occurred following inoculation of pregnant cattle with SRBSI even though placentitis occurred in 80% of the cattle. However, one calf was born weak, one month premature, and contained SRBSI in all tissues and fluids sampled. The only fetal lesion noted was a minimal interstitial pneumonia with minimal expansion of alveolar septae by macrophages, some of which contained intracellular SRBSI.

In intravenously inoculated pregnant cattle, mammary glands are less commonly infected than placenta. Twenty percent of pregnant cattle have SRBSI in mammary tissue at necropsy and only 10% have SRBSI in colostrum. Infected mammary glands have a lymphoplasmacytic mastitis with numerous neutrophils within alveolar and ductular lumina.

Persistence of RB51 infection into adulthood following calfhood vaccination is not likely. Calves inoculated subcutaneously with SRBSI at a dose of 5 to $7 \times 10^8$ CFU clear the infection from the draining lymph node by 6 weeks post-inoculation. This clearance is more rapid than that observed for S19.

Our studies show that *B. abortus* SRBSI has a tropism for the bovine placental trophoblast which results in placental infection and placentitis. Furthermore, these studies show that SRBSI-induced placentitis can occasionally lead to premature delivery. However, they also establish that SRBSI is less virulent than S19 in pregnant cattle when both strains are injected intravenously. The results of studies using SRBSI are promising and show that further research on SRBSI vaccination in pregnant cattle is warranted.

References

4. Cheville, N.F., Stevens, M.G., Jensen, A.E., Tatum, F.M., Halling,
PLACENTITIS INDUCED BY BRUCELLA ABORTUS RB51


EFFICACY OF \textit{BRUCELLA ABORTUS} STRAIN RB51 TO PROTECT CATTLE AGAINST BRUCELLOSIS

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The \textit{Brucella abortus} strain 19 (S19) vaccine has been used in cattle for over 50 years to prevent abortion and infertility caused by natural infection with virulent \textit{B. abortus} strains. The combination of S19 vaccination with serological surveillance tests has been instrumental in the success of the Brucellosis Eradication Program. However, disadvantages of S19 include: ability to infect humans; chronic infections in cattle; abortion in pregnant cattle; and, antibody titers which cannot be differentiated from field infections. As the numbers of \textit{Brucella}-infected herds are reduced, the problem of retained antibody titers following S19-vaccination becomes more significant and may impair the progression of the eradication program.

Recently a rough mutant of the virulent 2308 strain of \textit{B. abortus}, strain RB51 (SRBSI), has been proposed for use as a vaccine for cattle of all ages.\textsuperscript{1} SRBSI is genetically stable \textit{in vivo} and does not revert to smooth forms after 15 serial passages in mice.\textsuperscript{2} This strain has also been shown to be stable \textit{in vitro} after 93 passages in cell culture.\textsuperscript{2} Although SRBSI expresses low levels of the O-side chain,\textsuperscript{2} naïve animals remain seronegative on surveillance tests following vaccination.\textsuperscript{3} Potential use of SRB51 could include use as a calfhood vaccine, or vaccination of adult cattle in infected or exposed herds. We have used a 3 phase program to evaluate SRB51 for use as a vaccine: biosafety, vaccine efficacy, and field tests.

As reported in mice, SRB51 is genetically stable in cattle as it does not revert to virulent or smooth forms after growth in cattle for up to 10 weeks. We have failed to document shedding of SRB51 from calves after vaccination. Uninoculated control animals housed with SRB51-vaccinates did not develop serological or cultural evidence of infection by SRB51. Pharmacological immune suppression with dexamethasone at 12 weeks after vaccination failed to document serological, cultural, or clinical evidence of recrudescence by SRB51.

We evaluated the clearance, serology, and protection against challenge of 3 to 10 month old calves after calfhood vaccination with SRB51 (1 x 10\textsuperscript{10} to
Efficacy of Brucella abortus Strain RB51

3 x 10^{10} CFU. The SRB51 vaccine could not be recovered from prescapular lymph nodes of 6 calves when examined at 12 weeks after vaccination with 1 x 10^{10} CFU (Table 1). Although a titer against SRB51 can be detected on a dot-blot assay, calves remain seronegative on the standard tube agglutination test. Calves vaccinated with 3 x 10^{10} CFU SRB51 had dot-blot antibody responses which were greater than those of animals receiving 1.5 x 10^{10} CFU. When challenged with virulent *B. abortus* strain 2308, SRB51-vaccinates demonstrate protection against infection and abortion that is greater than non-vaccinates and similar to S19-vaccinates (Table 2). Following challenge, SRB51-vaccinates develop antibody titers which can be detected on the standard tube agglutination assay with the magnitude inversely related to age of SRB51 vaccination.

Field studies have been conducted in which more than 350 adult pregnant cattle have been vaccinated with SRB51. Adult vaccination with SRB51 (1 x 10^9 CFU) induces antibody responses which can be detected on a dot-blot assay but does not cause seroconversion on brucellosis surveillance tests even in animals which received S19 as a calfhood vaccination. Adverse clinical signs (abortion, arthritis, etc) have not been seen in calves or pregnant adult cattle after vaccination with SRB51.

A commercially prepared SRB51 vaccine has also been evaluated in 3 month old calves. Serology, clearance, and clinical effects of this vaccine are consistent with previous studies using SRB51 in our laboratory. Studies are continuing with this commercial product to assess protection against intraconjunctival challenge with *B. abortus* strain 2308.

Table 1. Mean colony forming units of live *B. abortus* in prescapular lymph nodes draining sites of vaccination (n=6).

<table>
<thead>
<tr>
<th>Weeks PI</th>
<th>1</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>10</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>RB51</td>
<td>4,355</td>
<td>1,185</td>
<td>82</td>
<td>29</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Strain 19</td>
<td>3,748</td>
<td>21,896</td>
<td>1,205</td>
<td>43</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2. Mean antibody titers (dot-blot) after vaccination with 2 different concentrations of *B. abortus* of SRB51 (3 x 10^{10} or 1.5 x 10^{10} CFU).

<table>
<thead>
<tr>
<th>Weeks PI</th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>10</th>
<th>103</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 x 10^{10} CFU</td>
<td>17</td>
<td>60</td>
<td>107</td>
<td>113</td>
<td>103</td>
<td></td>
</tr>
<tr>
<td>1.5 x 10^{10} CFU</td>
<td>13</td>
<td>47</td>
<td>93</td>
<td>55</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>19</td>
<td>13</td>
<td>4</td>
<td>6</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
References


IDENTIFYING CANDIDATE GENES FOR NATURAL RESISTANCE TO BRUCELLOSIS

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Summary
We have shown that natural resistance to a standardized challenge of *B. abortus* in nonvaccinated cattle is heritable and associated with a polymorphism in the 3' untranslated region of the bovine *Nramp1* gene. Immune parameters that correlate with the natural resistance (R) and susceptible (S) phenotypes are: (a). macrophage (Mφ) control or failure to control *B. abortus* replication *in vitro*; (b). response of oligoclonal T lymphocyte cell lines to various species of Brucellae; and (c) the IgG2a-A1 & A2 allotypic postchallenge antibody response to *B. abortus* LPS.

Introduction
Studies of genetic control of resistance to *Brucellae* infections have been done in mice, rabbits and swine. Ho and Cheers (1982) reported that resistance to *B. abortus* S19 infection is under polygenic control in BALB/c mice. Manresa and Laguna (1932) reported that resistance to brucellosis is controlled by a single dominant allele in rabbits.

In swine, a series of studies of genetic control of resistance to *B. suis* were conducted by Cameron and colleagues (Cameron et al., 1942, 1943). In the first experiments, two sows and a boar, which did not develop antibody when exposed to *B. suis*, were saved for breeding. The progeny of these three apparent resistant (R) swine were challenge infected and their antibody titers to *B. suis* were compared to control groups of unselected pigs that were challenge infected. Seventy three percent (24 of 33) of the progeny from the R swine parents were R to the challenge infection as compared to only nine percent R (3 of 24) progeny in the controls. In subsequent breeding - challenge infection studies R X R matings produced 128 progeny - 76.6% were R, 22.6% were of uncertain status and 0.8% were susceptible (S). It is remarkable that in one generation of mass selection, resistance to *B. suis* could be increased by approximately 65% over unselected controls. Obviously very few genes are involved in controlling resistance to *B. suis* in these swine.

In cattle, resistant and susceptible animals produce antibodies to *B. abortus* and have a cellular immune response (Baldwin et al., 1985; Klesius et al., 1975; Harmon et al., 1985; Splitter & Everlith, 1986; Smith III, et al., 1990). The relative importance of these two immune responses is not known.
IDENTIFYING CANDIDATE GENES
FOR NATURAL RESISTANCE TO BRUCELLOSIS

Materials and Methods

A group of 21 cross-bred (Bos taurus X Bos indicus) cows were assembled. The cattle were non-vaccinated and immunologically naive to B. abortus strain 2308 (S2308). Non-exposure to B. abortus was confirmed on at least 3 separate occasions in an 8 month period prior to challenge by card, rivanol, complement fixation, enzyme-linked immunosorbant assay (ELISA), and hemolysis-in-gel test (Harmon et al, 1985). The cattle were challenged by conjunctival administration of 1 X 10^7 colony forming units (CFU) of live B. abortus S2308 during mid gestation of their first pregnancy. The resistant cattle (n=11), retrospectively classified, developed low transient serologic titers, did not abort and cultures of the post partum uterus, lacteal secretions and calf meconium were negative for Brucella. Susceptible infected cows (n=10) developed high titers, aborted and Brucella was isolated from lacteal secretions, uterus, placenta or fetuses (Harmon et al, 1985). A group of bulls were challenged in the same manner as mentioned above and one bull was selected for breeding studies. We classified this bull as R based on negative culture of his semen for B. abortus and his anti-Brucella serologic profile postchallenge was similar to the resistant cows.

The progeny resulting from mating of this bull and the R and S founder cows were challenged with B. abortus for phenotyping as R or S. The heifers were challenged at midgestation of their first pregnancy and ranged in age from 16 to 24 months. The bulls were from 12 to 16 months of age at challenge. Following challenge the heifers were retrospectively classified as resistant or susceptible heifers based on their serologic titers, abortion, and culture results of the postpartum uterus, lacteal secretions and calf meconium. The bulls were retrospectively classified as resistant or susceptible based on their serologic titers postchallenge and whether or not B. abortus was cultured from 50 different tissues when slaughtered ninety days postchallenge (Adams et al 1983).

An in vitro test to measure the ability of mammary Mø or peripheral blood monocyte derived Mø to control intracellular replication of B. abortus was developed (Harmon et al, 1989; Price et al, 1990). Murine monoclonal antibodies were produced that recognize bovine IgG2a allotypes- A1 and A2. The IgG2a allotype response of the cattle to B. abortus lipopolysaccharide (LPS) and outer membrane proteins were measured postchallenge by the ELISA (Estes et al, 1990a; Estes et al, 1990b). Oligoclonal T lymphocyte cell lines were established from R and S cattle using whole cell B. abortus Strain 2308 as the primary stimulating antigen. The oligoclonal T lymphocyte cell lines were restimulated by killed whole cells of B. abortus, B. canis, B. melitensis, and B. suis and the proliferative responses were measured by ^3H thymidine incorporation (Smith et al, 1990).
ADAMS, TEMPLETON

Results

The frequency of natural resistance to brucellosis in B. abortus challenged nonvaccinated cattle was 20% (30/150). Breeding a naturally resistant bull to naturally resistant cows increased the frequency of natural resistance in their progeny to 53.6% (15/28). The ability of Mø's from the R cattle to control the intracellular replication of B. abortus in vitro is significantly (p<0.05) better than for S cattle both pre- and post-exposure to B. abortus (Price et al., 1990). Susceptible cattle heterozygous for IgG2a allotypes A1/A2 respond to B. abortus LPS postchallenge significantly (p<0.05) more often with IgG2a allotype A1 than do R cattle eight weeks postchallenge (Estes et al., 1990b). The oligoclonal T lymphocyte cell lines from S cows established using B. abortus S2308 as a mitogen are significantly more cross-reacting than the oligoclonal T lymphocyte cell lines from R cows. The S cows oligoclonal T lymphocyte B. abortus cell lines are stimulated by B. abortus, B. canis, B. melitensis, and B. suis, whereas the oligoclonal T lymphocyte B. abortus cell lines from R cows are stimulated by B. abortus and B. canis and not by B. melitensis, and B. suis (Smith et al., 1990).

Cattle naturally resistant to Brucella abortus were bred and progeny from five generations of families were used to study the heritability of genes controlling this trait. Back-crossed calves were phenotyped by challenge with B. abortus and the results from genetic analyses indicated that at least two genes control this trait. Macrophages (Mø) from resistant cattle significantly restricted the in vitro growth rate of Mycobacterium bovis, B. abortus and Salmonella dublin which was correlated 83% with in vivo resistance. Application of differential display reverse transcriptase PCR (DD RT-PCR) to Mø from resistant or susceptible cattle infected or un-infected with M. bovis or B. abortus identified several differentially expressed mRNAs two of which were characterized for their potential role in controlling the intracellular growth rate. From infected resistant macrophages, a quantitatively expressed gene with homology to the human calcium dependent potassium channel gene was identified, and a new gene qualitatively expressed was sequenced. Quantitative mRNA expression of MCP-1, TNFa, TNFaR, GM-CSF, TGFr3, IFNg, IL-1, IL-2, IL-2r, IL-3, IL-4, IL-6, IL-8, L-8r, IL-10, IL-12, Nram, iNOS and the two newly identified genes as compared to GAPD and histone profiled by reverse transcription-T7 RNA dependent amplification (RT-TRDA) from resistant or susceptible challenged and un-challenged Mø revealed unique patterns.

Discussion

During the past 15 years, we have been studying the inheritance of natural resistance to a standardized challenge of Brucella abortus in a herd of naturally resistant and susceptible cattle. To date, we have shown that natural resistance to brucellosis can be dramatically increased by simple mass selection in one generation of selective breeding. We have been characterizing the immune response of the founding breeders to B. abortus for the follow-
IDENTIFYING CANDIDATE GENES FOR NATURAL RESISTANCE TO BRUCELLOSIS

ing: (a) the profile of the antibody response to *B. abortus* challenge infection (Estes, 1990b); (b) ability of the macrophages/monocytes (Mφ) to control replication of *B. abortus* in vitro (Harmon et al, 1989; Price et al, 1990); (c) patterns of response of oligoclonal T lymphocytes to different strains of *B. abortus* and species of *Brucellae* (Smith et al, 1990); and (d) determining the BoLA types of parents and offspring (Harmon et al, 1985). We have observed that the IgG2a-A1 & A2 allotype response to *B. abortus* LPS postchallenge with *B. abortus* is significantly different between R and S cattle (Estes et al, 1990b). The ability of the Mφ’s to control replication of *B. abortus* in vitro is significantly correlated before and after challenge (Harmon et al, 1988; Price et al, 1990) between the R and S phenotypes of the *B. abortus* challenged cattle. We did not observe any direct correlation between BoLA locus A specificities and resistance or susceptibility in these cattle. We interpret these data as meaning that the natural resistance to *B. abortus* is an innate resistance that is at least operational at the level of Mφ’s.

The ability of Mφ’s from these R and S cows to control replication of *Salmonella dublin* and *S. typhimurium* in vitro correlates with resistance to *B. abortus* in vivo and in vitro. Currently we are attempting to determine if this model of natural resistance to *B. abortus* might be the bovine equivalent of the murine genetically controlled R and/or S to infectious disease involving macrophages. The role of macrophages in resisting infectious diseases has been shown to be controlled by a single gene or gene complex for four infectious organisms: *Bcg* gene - *Mycobacterium lepraemurium* (Brown et al, 1982), *Itv* gene - *Salmonella typhimurium* (Plant and Glynn, 1981), *Lsh* gene - *Leishmania donovani* (Bradley et al, 1979), and *Bcg* gene - *Mycobacterium bovis* (Gros et al, 1981). The gene(s) controlling resistance to all four of these infectious organisms have been mapped to chromosome 1 and could possibly be the same gene (Brown et al, 1982). It has been shown in mice that the gene(s) controlling the macrophage function in these four diseases is linked to *ldh-1*, *g Cry*, *Fn-1*, *Bcg/Lsh/Itv*, and *Vil*, in the order given with the *ldh-1* gene being closest to the centromere (Schurr et al, 1989). Obviously, this gene or cluster of closely linked genes on chromosome 1 is very important in infectious disease resistance to these four organisms but interaction with genes on other chromosomes have also been shown to be important for two of the diseases. Susceptibility to *Salmonella typhimurium* has been shown to be regulated by two genes - the *Itv* on chromosome 1 and the *Lps* on chromosome 4 (Blackwell et al, 1980). Susceptibility to *Leishmania donovani* is regulated by two genes - *Lsh* on chromosome 1 and *H-2* on chromosome 17. Apparently, the *Lsh* gene provides immediate resistance for the first 15 days of infection but *H-2* interacting genes are crucial for long term resistance (O’Brien et al, 1980).

The linkage of the genes *gCry*, *Fn-1*, and *Vil* has been conserved in cattle, mice, and men (Adkison et al, 1988, Schurr et al, 1989, L. Skow, Texas A&M University, personal communication) and this linkage group has been placed
ADAMS, TEMPLETON

on bovine chromosome 2 by in situ hybridization (J. E. Womack, Texas A&M University, personal communication). Dr. Jainwei Feng in our laboratory recently identified and sequenced the bovine homolog (BovNrampl) of the murine natural disease resistance macrophage protein (Nrampl) (Vidal et al., 1994) encoding resistance to Mycobacterium bovis BCG, and located a polymorphism associated with natural resistance to bovine brucellosis. Results suggest that genetic control of macrophage bactericidal mechanisms play a major role in the control of these zoonotic pathogens and may offer an additional approach to pre-harvest pathogen reduction.

References
IDENTIFYING CANDIDATE GENES
FOR NATURAL RESISTANCE TO BRUCELLOSIS

REPORT OF THE COMMITTEE ON BRUCELLOSIS

Chairman: Dr. J. Lee Alley, Montgomery AL
Vice Chairman: Dr. Claude E. Barton, Nashville, TN

Mr. John Adams, VA; Dr. L. Garry Adams, TX; Mr. John B. Armstrong, TX; Dr. Terry L. Beals, TX; Dr. Paul Becton, FL; Dr. Valerie E. Benson, TN; Mr. Neal Black, MN; Dr. Lee M. Brooks, GA; Mr. John S. Cargile, TX; Dr. Norman F. Cheville, IA; Dr. Max E. Coats, Jr., TX; Dr. Thomas Dees, GA; Dr. B. L. Deyoe, IA; Dr. John C. Doyle, OK; Dr. Fred M. Enright, LA; Dr. Brian H. Espe, OK; Dr. Granville H. Frye, MD; Dr. Michael J. Gilsdorf, MD; Mr. Don D. Gingerich, IA; Mr. Francis D. Gregerson, CO; Mr. Ted A. Hickerson, TX; Dr. Bob R. Hillman, ID; Dr. Sam D. Holland, SD; Mr. Majon Huff, CO; Mr. Jon G. Johnson, TX; Mr. Denis Joyce, ND; Dr. John D. Kopec, MD; Dr. Maxwell A. Lea, Jr., LA; Dr. Delorias M. Lenard, SC; Mr. Larry D. Mark, VA; Dr. Bret D. Marsh, IN; Dr. Charles E. Massengill, MO; Dr. Harry F. Moberly, Jr., IL; Mr. Richard E. Nelson, VT; Dr. Tomas A. Neuzil, IA; Dr. Donald L. Notter, KY; Dr. Roger J. Odenweller, KY; Mr. J. O. Pearce, Jr., FL; Dr. Frank Y. Rogers, MS; Dr. William A. Rotenberger, ND; Dr. Robert B. Sanders, AR; Dr. John J. Schiltz, IA; Dr. Roy A. Schultz, IA; Dr. Gerhardt Schurig, VA; Mrs. Sherry Seubert, WI; Mr. Gary Simpson, CO; Dr. Clarence J. Siroky, MT; Mr. Glenn N. Slack, KY; Dr. Barrett D. Slenning, NC; Dr. Arnold C. Taft, MD; Mr. George Teagarden, KS; Dr. Lewis P. Thomas, WV; Dr. E. Tom Thorne, WY; Dr. Daryl K. Thorpe, SD; Dr. Kenneth J. Throlson, ND; Dr. Gary M. Weber, DC; Mr. Raleigh Wilkerson, AL; Dr. Richard D. Willer, AZ; Dr. Larry L. Williams, NE; Dr. Ernest W. Zirkle, NJ.

The Brucellosis Committee met on October 30, and October 31, 1995, at the John Ascuaga's Nugget Hotel, Reno, Nevada. Listed below are the presentations given and actions taken by the committee.

Dr. Granville Frye, APHIS, VS, presented the current status report of the National Brucellosis Eradication Program. He reported that there were only 68 brucellosis infected herds at the end of September 1995. The full text of this report is included in these proceedings.

Dr. Claude Barton, APHIS, VS, National Brucellosis Program Director, gave a presentation on progress in the brucellosis program during the past year. Apparent prevalence and incidence trends during the year were reviewed. Surveillance, utilizing all case finding methods, was reemphasized as being the element of highest priority and importance in the current brucellosis program. Depopulation, vaccination, program reviews, the brucellosis budget, and training were also reviewed in the context of their impact on the accelerated effort to reach zero brucellosis infection by December 31, 1998.

Dr. Bob Hillman, Idaho State Veterinarian, presented an update on the activities of the Greater Yellowstone Interagency Brucellosis Committee (GYIBC). The entire report is included as a formal presentation in these proceedings.
Rick Moler, Administrative Assistant to Senator Conrad Burns, briefed the committee on the Senator's position concerning the bison brucellosis problem in the Greater Yellowstone Area (G.A.). He reviewed the status of Senator Burn's senate bill relative to the Yellowstone brucellosis problem. Public hearings are in progress. He urged committee members to contact their congressional delegations to support the bill.

Dr. Clarence Siroky, Montana State Veterinarian reported on the settlement of the Montana law suit against the National Park Service and APHIS. Within this settlement an Interim Agreement was reached that allowed for capture of bison within Yellowstone National Park and on adjacent land outside the park. It further allows for the destruction of bison that stray out of the park and are not captured. Captive bulls and non-pregnant cows, negative for brucellosis may be released to occupy public lands only during the winter months.

Dr. M. V. Palmer, ARS, NADP, brucellosis researcher, presented a paper on the pathology of placentitis induced in pregnant cattle by Brucella abortus RB51. This paper is included in these proceedings.

Dr. Norman Cheville, ARS, NADP, brucellosis researcher, reported on research done at NADP with Brucella abortus RB51 in cattle. This presentation included the biological characteristics of RB51, its efficacy as a vaccine, vaccination procedures, and test procedures to detect antibodies generated by the organism. This paper is included in these proceedings.

Dr. Gary Adams, Texas A&M University, brucellosis researcher, gave a presentation on the identification of candidate genes that control natural resistance to bovine brucellosis. This presentation included examples of situations whereby the resistance to disease might be enhanced through genetic selection or manipulation. This paper is included in these proceedings.

Dr. Donald Bridgewater, APHIS, VS, presented a draft protocol for the quarantining and handling of bison in the Greater Yellowstone Area (G.A.) to assure their freedom from brucellosis. This protocol originated in the technical subcommittee of the GYIBC. It was referred to the Scientific Advisory Subcommittee for evaluation. Action taken is in the report of the Scientific Advisory Subcommittee below.

Dr. Sam Holland, South Dakota State Veterinarian, presented a resolution requesting that South Dakota be recommended for brucellosis Class Free status although there is an affected domestic bison herd within the state. This resolution was referred to the Scientific Advisory Subcommittee for review. Action taken is in the report of the Scientific Advisory Committee below.

Dr. Armando Mateos, Director of the Brucellosis and Tuberculosis Programs in Mexico, reported on the progress of Mexico's Brucellosis program. Included was an outline of the brucellosis campaign including the organization and personnel involved.

Dr. Gustavo Martinez, Director of the Brucellosis and Tuberculosis Programs for the State of Sonora, Mexico, gave a report on the progress of the
BRUCELLOSIS

brucellosis program in Sonora. He reported that 99% of the cattle herds in Sonora have been tested for brucellosis. Currently there are 55 brucellosis affected herds in the state. It was encouraging to hear of this significant progress in eradicating brucellosis from the state of Sonora.

Dr. Claude Barton, APHIS, VS, Brucellosis Program Director, gave a preliminary report on the development of the Rapid Automated Presumptive (RAP) Test for brucellosis. This report included a description of the equipment and technology involved in the test as well as the results of approximately 17,500 tests. It is anticipated that developmental work will be completed within a few months.

Dr. Clarence Siroky, Montana State Veterinarian, discussed efforts by the Montana Stockgrowers Association, the North Dakota Stockmen's Association, the National Cattlemen's Association, and the Canadian Cattlemen's Association to simplify requirements for movement of cattle between these two states and Canada. Two resolutions concerning this activity were approved by the committee and are forwarded to the Committee on Resolutions.

Dr. Mike Gilsdorf, APHIS, VS, National Brucellosis Epidemiologist, discussed proposed changes to the Brucellosis UM&R. Because of the lawsuit settlement with Montana, the cattle and bison brucellosis UM&R must be changed to include creating bison management areas within Class Free States.

Dr. Gilsdorf discussed the problem of limits not being set on the IDEXX Herd Check ELISA test. The need for herd test limits were referred to Scientific Advisory Subcommittee. The action taken is included in the subcommittee report below.

Larry Davis and Dr. Julia Bevins, Reindeer Herders Association, gave a brief report on reindeer husbandry in Alaska and two offshore islands. They discussed the problems involved in establishing brucellosis free status in reindeer herds. They requested consideration for establishing brucellosis free herds based on statistical sampling techniques. The committee recommended that APHIS, VS, CDSS, explore the possibility of developing statistically valid sampling procedures for establishing and maintaining brucellosis free reindeer herds on the islands of St. Lawrence and Nunivak.

Dr. Mike Gilsdorf, APHIS, VS, National Brucellosis Epidemiologist, reported on the revisions to the 1994 UM&R for Cervidae. There were a number of proposed revisions some of which were controversial. An ad hoc committee representing both industry and government was appointed to develop a consensus on the proposed revisions. After reaching accord, the committee concluded that the UM&R for Cervidae could not be implemented until the tests utilized for the serologic diagnosis of brucellosis have been validated for the various species involved. This was referred to the Scientific Advisory Subcommittee to develop criteria for the validation of brucellosis serologic tests in cervids.

Dr. Thomas Howard, Wisconsin State Veterinarian, discussed the possibility of private laboratories being utilized to conduct the Brucellosis Ring
REPORT OF THE COMMITTEE

Tests (BRT). The committee recommended that APHIS, VS, CDSS, study the possibility of utilizing private laboratories in this capacity.

Dr. John Doyle, Oklahoma Brucellosis Epidemiologist, discussed the benefits of the PCFIA test in the brucellosis program. The committee recommended that APHIS, VS, continue to fund PCFIA in Class A states for both on-farm and market testing.

Dr. Doyle also discussed the need for early approval and availability of Brucella abortus RB51 vaccine for field use. The committee recommended that APHIS, VS, expedite and hasten the regulatory process to make RB51 vaccine available at the earliest possible date.

There were three resolutions referred to the Committee on Brucellosis from the Western States Animal Health Association and the Southern Animal Health Association relating to brucellosis in the Greater Yellowstone Area (GA.). These three resolutions were referred to an ad hoc subcommittee for review and recommendation and for committee action. The ad hoc committee proposed three resolutions that were approved and forwarded to the committee on resolutions.

Bob Hillman, Idaho State Veterinarian, presented a resolution requesting support for research on the use of Brucella neotamia as a potential vaccine against brucellosis in the wild bison and elk in the Greater Yellowstone Area (GA). The committee approved the resolution and forwarded it to the committee on resolutions.

Clarence Siroky, Montana State Veterinarian, recommended that the USAHA endorse legislation presented to the 104th Congress by Senator Conrad Burns of Montana mandating brucellosis eradication among bison and elk in the Greater Yellowstone Area (GA) and that USAHA urge state animal health officials to seek support of their congressional delegations for this legislation. This recommendation was approved by the committee.

Dr. Terry Beals, Texas State Veterinarian, a member of the Mexico Binational Tuberculosis Committee, requested that the Brucellosis Committee ask USAHA to recommend to USDA, APHIS, VS, to expand the US/Mexican Binational Tuberculosis Committee to include the disease Brucellosis and that the binational committee be known as the US/Mexican Binational Tuberculosis and Brucellosis Committee. Also, that the chairperson of the USAHA Brucellosis Committee be a member of the binational committee.

Dr. John Kopec, APHIS, VS, Staff Veterinarian, recommended that the Committee on Brucellosis support research efforts to develop a vaccine which will allow discrimination of vaccinated and infected deer and to develop other control systems based on selection of reindeer for natural disease resistance.

Brucellosis Scientific Advisory Subcommittee

The subcommittee met: Sunday evening, 6:00pm, October 29, 1995. Members contributing: Cheville, Adams, Enright, Barton, Slenning

The subcommittee agenda included the following five items and the
BRUCELLOSIS

decisions on all five were unanimous:

1. **Greater Yellowstone Interagency Brucellosis Committee Quarantine Protocol**
   
   There is no serious concern regarding the substance of the protocol. The subcommittee suggests that the protocol be accepted as a preliminary statement of intent, but not as an operational document. The subcommittee recommends that the document be referred to the Cattle Diseases Staff, APHIS, USDA, for reconstruction in UM&R format. The reconstructed document should be returned to the GYIBC for review.

2. **Maximum Herd Size for Idexx Herdcheck® Milk Antibody Test**
   
   Noting that the Idexx Herdcheck Test® results suggest that the test is more sensitive but less specific than the current test, the subcommittee suggests that the limit on the bulk test be 500 animals.

3. **Resolution that South Dakota be Classified as Class Free in the Brucellosis Control Program (Exception from Uniform Methods and Rules)**
   
   Subcommittee recommended unanimously that this resolution not be accepted. It is not appropriate to make an exception on this bison herd because of its negative impact on the cattle program and on the developing program for Greater Yellowstone Area bison.

4. **Recommendations to USAHA Brucellosis Committee on Uniform Methods and Rules by Kawerak, Inc., Reindeer Herders Association**
   
   The subcommittee advises that this proposal is a good first attempt at dealing with practical aspects of the reindeer problem but the protocol should be redesigned to provide a more valid statistical basis for sampling reindeer populations; i.e., to develop a more defined base line. These procedures must be epidemiologically sound to control eradication of brucellosis.

   Subcommittee suggest that this matter is not an appropriate item for the committee. The recommendations deal with exceptions to official UM&R’s and are a matter for program standards and compliance.

5. **Resolution for Reclassifying Cattle That Are Positive to the Card Test**
   
   The subcommittee is unable to approve this resolution based on the following reasons: (1) Does not account for the differential risks based on animal origin, vaccination status, or exposure history. (2) Impact on the marketing system and credibility for the new buyer. (3) Credibility of the bill of sale and testing program integrity.

   The Subcommittee report was accepted.
Brucellosis Subcommittee on Education

The Brucellosis Subcommittee on Education met on October 30, 1995. There were 11 persons in attendance.

Reports were given by the various States represented on what educational efforts and materials were being utilized in continuing to stress the importance of reaching the final goal of total bovinebrucellosis eradication.

Glen Slack of LCI presented a draft copy of a special edition of "The Final Countdown" which will highlight the progress being made by the A States in reducing the number of affected herds.

It was the consensus of those present that the reporting of quarantined herds may give a false impression of the actual status of the program, for as long as depopulation funding is adequate this number will remain low. We felt that the best indicator of progress should be the newly affected herds detected and this should be the information which is widely distributed in official reports.

The need for factual, easily understood material for the swine producers was also noted. Again some states are doing this, but there needs to be a central source of this material for those states who do not have the resources to develop their own material.

A lengthy discussion was held on the educational needs which will accompany the potential introduction of RB51 in the near future. It was felt that the education of both regulators and accredited veterinarians should begin now, and work should begin on development of producer information to be available when the vaccine becomes available. A resolution to this effect has been developed.

The subcommittee recommends that:

1. Texas be commended for their ongoing educational efforts in both bovine and swine brucellosis.
2. LCI's role in providing timely and accurate material to a large portion of the industry is recognized and appreciated. This becomes more and more important as funding for brucellosis declines.
3. APHIS utilize the statistics on cumulative newly affected herds as the primary measure of program progress, rather than herds under quarantine.
4. APHIS develop and distribute educational materials on RB51 vaccine.
   a. To distribute to regulatory officials the technical information on RB51 in a summary form.
   b. In conjunction with certain other persons or groups, educational material that fully explains RB51 for distribution to both accredited veterinarians and policy makers in the various States.
   C. For both the livestock industry and individual livestock producers so they may make an informed decision on how and where this vaccine will be used.

The Subcommittee report was accepted.
BRUCELLOSIS

Report of the Swine Brucellosis Subcommittee

Chairman Terry Beals called the subcommittee meeting to order at 8:00 p.m., October 29, 1995, with 11 members and about 20 guests present.

Dr. Arnold Taft of APHIS, VS, reported that as of June 30, 1995, there were 16 infected herds in the country, about the same as the year before. During the 12-month period 50 new infected herds were found, 16 in Florida, 19 in Texas, 5 in Arkansas, 4 in Alabama, 2 in Georgia and single cases in other states. Currently, he said, there are 17 infected herds, 16 in Florida, 19 in Texas, 5 in Arkansas, 4 in Alabama, 2 in Georgia and single cases in other states. Currently, he said, there are 17 infected herds, 16 in Florida.

Sources of this new infection were purchased swine, mostly with no change of ownership testing requirement, 19; community spread, 16 and feral swine 4, with the rest unknown. He said the Florida herds await depopulation, which was delayed when funds were exhausted. They will be depopulated when funds become available in the current fiscal year.

Taft suggested that the expectations at last year’s meeting may have been overly optimistic. The subcommittee had thought that there were only a few infected swine herds remaining that would be quickly identified and depopulated with market value appraisals. This may not have been a realistic assessment of the situation.

Dr. Ernest Zirkle of New Jersey reviewed a case in that state in a large herd feeding garbage from Atlantic City hotels. The average weight of the hogs when the herd was depopulated was 440 pounds. The hogs were a disposal system for the food waste and were routinely marketed at about 900 pounds. About $200,000 indemnity is being paid for the herd, which was a factor in exhausting indemnity funds during the past year.

Dr. Bill Pace of Florida reported that first-point testing was begun in the state July 1. There are about 200 small garbage feeders in the state, he said. Plans are to amend state law to place all garbage feeding herds under permanent quarantine unless tested free of brucellosis.

But less than half of the newly infected herds discovered in Florida are garbage feeders and community spread, by such means as borrowed boars, is a factor in the spread. Of the 22 herds under quarantine, three have already been depopulated, 2 have been approved for depopulations and three others are voluntarily depopulating. Of the rest, six are in the Panhandle, nine in the central area from Ocala to Tampa, three in Dade County around Miami, and the rest are scattered.

Pace said only one slaughter plant in the state will accept hogs from known brucellosis-infected herds.

Dr. Max Coats of Texas said plans to begin first-point testing in that state were suspended when industry support was lost, so attempts are being made to improve slaughter surveillance through use of a swine back tag encased in fiberglass mesh to improve its retention. Also, mature breeding swine sold through markets other than directly to slaughter, will be permitted out of the market and a test required.
The state has also instituted area testing of all herds in the Dallas-Fort Worth hog complex, the location of many recent cases. Coats said a weekly status report on swine brucellosis activities has been effective in maintaining emphasis on the program.

Dr. Charles Starkey said the one infected herd in Arkansas is being depopulated and the state will be back to no infected herds next week. He said a series of abortion problems in the 300-sow herd was misdiagnosed for several months. Samples sent to laboratories out of state were tested for many months. Samples sent to laboratories out of state were tested for many diseases, but not brucellosis, before samples sent to the Arkansas lab revealed the infection. Four human cases, three farm workers and one slaughterhouse worker, resulted from that case.

Dr. Joe Annelli of APHIS, VS, suggested that area testing in areas where infected herds have been concentrated may be the best surveillance system, rather than slaughter testing.

Dr. Lee Alley of Alabama suggested retest of all herds every 6 months in problem areas of previous infection.

Dr. Tommy Dees presented a summary analysis of 21 cases of swine brucellosis and 26 cases of PRV in domestic swine in which feral/wild swine were reported as the most probable source of the infection. These cases involved reports from 11 different states. A detailed description and discussion of the epidemiology of these cases was provided. Three pages extracted from his report that list potential preventive measures and actions subsequent to confirmed transmission of disease from feral/wild swine to domestics are attached to this report.

Dr. Fred Enright reported that with the support of USDA and the assistance of Virginia Tech and Texas A&M, we are investigating the efficacy of \textit{brucella abortus} strain RB51 as an oral vaccine to control brucellosis in feral swine. We have established that oral exposure of RB51 in the appropriate vehicle (pecans) colonizes regional lymph nodes in gilts, and is quickly eliminated within a month. RB51 is non-abortogenic in late gestational sows. Partial protection against virulent B. suis challenge has been demonstrated in both subcutaneous and oral vaccinates. This protection is exhibited through increased litter size, increased live-dead ratios, and decreased colonization of the virulent strain among vaccinates, when compared to infected control sows. We are currently studying the colonization of boars by B suis, as we feel the boar is the most likely carrier in the feral swine population. We would like to study other possible routes of challenge after oral vaccination.

Dr. Enright said that 50\% of feral swine are naturally resistant. Their data indicates that RB51 will protect 25\% of the susceptibles, resulting in a 70-75\% protected population.

Dr. Tom McGinn of North Carolina reported on a survey of 22 states which earlier had indicated they would not accept state validated free status as sufficient of interstate movements. He said four states—Connecticut, Ken-
tucky, Maryland, and Puerto Rico--indicated they would continue that policy and he hasn’t herd from seven other states.

Two resolutions were approved for forwarding to the Brucellosis Committee. The meeting adjourned at 11:10 p.m. A slide presentation followed on swine carcass disposal alternatives. Air curtain incinerator (burning) is rendering. Texas has two detailed narrated videos available for information on these alternatives.

The subcommittee report was accepted and two resolutions were forwarded to the committee.

**Preventing Disease Transmission From F/W to Domestic Swine**

A. **PREVENT F/W SWINE FROM ENTERING DOM SWINE TRADE CHANNELS**
   1. Herd was Feral/Wild (F/W) Swine not Domestic (DOM).

B. **REQUIRE F/W SWINE RESISTANT FENCING**
   2. F/W seen w/DOM & F/W disease status unknown (DSU).
   3. F/W seen w/DOM & F/W w/l 50 miles are infected.
   4. F/W seen w/DOM & F/W w/l 5 miles are infected.

C. **INSTITUTE BETTER EPIDEMIOLOGY AND/OR HUNTER-KILL OR TRAPPER SURVEY OF F/W SWINE TO ASCERTAIN EXTENT OF PROBLEM**
   2. F/W seen w/DOM & F/W DSU
   3. F/W seen w/DOM & F/W w/l 50 miles are infected.
   7. F/W not seen w/DOM & F/W w/l 50 miles are infected.
   10. Unknown

D. **EDUCATION, REGULATION AND PROBABLY LITIGATION ARE NEEDED**
   5. F/W from infected population added DOM.
   6. DOM are part-time free-roamers & F/W are infected.
   8. F/W added to DOM & F/W w/DSU.
   9. DOM are trader/trash (TNT) hogs w/DSU F/W added.

E. **FUTURE POSSIBILITIES—VACCINE AND GENETIC RESISTANT BOARS (SB)**
   4. F/W seen w/DOM & F/W w/l 5 miles are infected.
   6. DOM are part-time free-roamers & F/W are infected.

**Future Actions When Domestic Swine Get Disease From F/W Swine in Free States?**

1. Determine that F/W swine were not deliberately introduced into the domestic herd or used to breed domestic stock. (Eurasian boar or Eurasian X boar bred to domestic sows)
2. Determine that F/W swine are in the immediate vicinity.
3. Determine that F/W swine are infected with the disease by way of hunter-kill or trapper obtained blood serum samples and specimens.
4. Reduce future threat of disease transmission from the F/W to domestic swine by the following:
REPORT OF THE COMMITTEE

a. Reduction of F/W population by hunting and/or trapping and/or habitat management.
b. Future use of oral vaccines in the F/W swine.
c. Future use of genetic disease resistant boars in combination with population reduction, i.e., save and release the genetically resistant boars back into the wild when population reduction by trapping is used.*
d. Construction of man-made barriers (Expensive and not always effective or easy to maintain).
e. Continue monitoring disease prevalence in the F/W popn.

5. Eradicate the disease in the domestic herd ASAP and prevent spread to additional domestic herds by the following:
a. Construction of F/W swine resistant barriers such as multiple row—multiple strand high-intensity electric fencing.
b. Stop the spread of the disease and eradicate it within the herd ASAP through intense management that may include depopulation, vaccination, segregation, frequent test and removal of reactors and the future use of genetic resistant stock.
c. Establish methods of repetitive active monitoring of neighborhood domestic herds.
d. In the future it should be possible to maintain a high level of resistance within the domestic herd by using vaccine and/or genetic resistant boars.**

* One theoretical study in the Southeastern Region suggested that for each 1000 head of F/W swine, approximately 25 homozygous genetically SB resistant boars could be found at a total cost of approximately $7,000.00 or $280.0 per boar salvaged during population reduction of an overstocked area. This assumed a 50% seroprevalence and cull rate because of PRV before the DNA probe for SB resistance could be attempted. It also included the use of regulatory personnel already on duty and already salaried.

** Theoretical disease models developed in the Southeastern Region, independently and in conjunction with CEAH, Fort Collins, Colorado, has shown rapid and highly effective herd protection through the use of boars that are genetically homozygous resistant for SB, especially when used in conjunction with RB51 vaccine. Data on the vaccine was extrapolated from foreign trials with RB51.
STATUS REPORT - FISCAL YEAR 1995
COOPERATIVE STATE-FEDERAL BRUCELLOSIS
ERADICATION PROGRAM

G. H. Frye, DVM
Michael J. Gilford, DVM, MS

Fiscal year (FY) 1995 was a very significant year in the National Brucellosis Eradication Program. In June a major milestone was reached when the number of herds under quarantine for brucellosis in the United States dropped below 100 for the first time. This number continued to decline and only 68 herds were quarantined at the end of the fiscal year compared to 152 on the same date a year earlier. Of equal, or even greater, importance, was the reduction in the number of newly infected herds found from 279 in FY 1994 to 202 this year, a decline of 28 percent. During the year the salient recommendations of the White Paper, which was discussed in last year’s report, were adopted and put into effect.

In keeping with those recommendations, the indemnity rate for depopulation was increased to encourage depopulation, program and technical reviews were increased (and will be further increased this year), a Federal policy on calfhood vaccination was developed, and herd depopulation was successfully accelerated. The creation of the position of Brucellosis Program Director and the appointment of Dr. Claude Barton to that leadership position fulfilled an important recommendation of the White Paper. The respect, trust, and experience Dr. Barton has gained as a successful brucellosis epidemiologist in Tennessee and in the Southeastern Region of Veterinary Services will be important factors in maintaining the National program emphasis required to achieve eradication in 1998.

Brucellosis continued to be a problem in Yellowstone National Park (YNP) and in the greater Yellowstone area during FY 1995. The presence of infected and exposed YNP bison in Montana caused several States to impose or threaten to impose additional testing requirements on the Montana cattle they import. Montana, in an effort to stop the incursion of Park bison and to protect its Class Free status, brought legal action to cause the National Park Service and APHIS to address this longstanding issue. It was joined in its law suit by the Royal Teton Ranch whose proximity to the Park made its cattle particularly vulnerable to infection. Negotiations are underway to resolve the suit by permitting certain Yellowstone bison to remain in Montana in a wilderness area and in a specified management area in West Yellowstone during the winter months. This agreement would relieve Montana of the need to destroy all bison found in those areas in order to maintain its Class Free status.

The Environmental Impact Statement (EIS) on brucellosis in YNP is still
in preparation by representatives of the Interior Department, the Forest Service, the State of Montana, and APHIS. The final version of the EIS should be completed by May 1, 1997. A hopeful sign for the future occurred recently when representative of 8 State and Federal Agencies (National Park Service, National Biological Survey, Agricultural Research Service, Forest Service, Montana Fish, Wildlife and Parks, Idaho Department of Livestock, Montana Department of Livestock, and APHIS) cooperated in initiating a project to study the transmission of brucellosis between bison in YNP. This effort involved capturing, testing, and identifying a number of bison inside the Park. All of the animals were released after being fitted with radio collars that permit them to be tracked and located from the air.

The progress made during FY 1995 adds credibility to the goal of eradicating brucellosis from the United States in 1998. During FY 1995, the number of reactors, and as mentioned earlier, the number of quarantined and newly infected herds were all less than the previous year. Two States, Colorado and Nebraska, attained Class Free status during the year and two States are currently in the qualifying period for Class Free and are expected to reach that status in FY 96. Eight additional States, each with only one known affected herd, should enter the qualifying period for Class Free during the coming year.

The draft Cervid Brucellosis Uniform Methods and Rules discussed by the Committee last year were amended and circulated for comment during FY 1995. The amended rules will be reconsidered during this years USAHA meeting.

During the year, 421 bison were intercepted as they left YNP. The 270 tested for brucellosis disclosed 132 reactors, 31 suspects, and 107 negative. In a related issue, 2,190 elk calves and 1,133 adult females were vaccinated on 12 Wyoming feed grounds by the Wyoming Game and Fish Department using bio bullets containing Strain 19. This project, and efforts to improve the elk’s habitat to reduce their dependency on feed grounds, are partially funded by APHIS.

The Greater Yellowstone Interagency Brucellosis Committee (GYIBC), formed by the governors of Idaho, Montana, and Wyoming, is developing a brucellosis eradication plan whose goal is the elimination of brucellosis from the Greater Yellowstone Area by the year 2010.

Due to normal reporting delays from the field stations, certain of the following graphics contain estimated data for the last month of the FY.

On September 30, 1995, 34 States, Puerto Rico, and the Virgin Islands held Class Free status and 16 States were Class A. (Figure 1). Thirty-seven percent of the Nation’s 36 million beef cows that have calved are located in Class Free States and 63 percent in Class A States (Figure 2). Of 9.6 million dairy cows, 68 percent are in Class Free States and 32 percent are in Class A States (Figure 3). The 4 dairy herds under quarantine for brucellosis on September 30, 1995, were located in 2 States: 1 in New Mexico, and 3 in California (Figure 4).
FRYE

Of all beef and dairy cattle, 48 percent are in Class Free States and 52 percent are in Class A States (Figure 5).

A total of 309 brucellosis affected herds were found in FY 1995. This was a decrease of 41 percent from the 442 affected herds found in FY 1994 (Figure 6). These 309 herds were in 16 States, with 89 percent located in 8 States and 11 percent in the remaining States. There were no affected herds in 34 States. Texas, with 152 brucellosis affected herds, represented 49 percent of the national total. The States of Arkansas with 10 reactor herds, Florida with 24, Georgia with 36, Louisiana with 18, Mississippi with 12, Tennessee with 2, Missouri with 16, Oklahoma 11, Alabama with 9, Kentucky 5, and California 5 together represented 50 percent of the total for the year. Iowa, South Dakota, and New Mexico, had the remaining 4 herds (Figure 7).

We will again explain the preceding figure to clarify this traditional method of presenting annual reactor herd data. As shown, the data implies that all of the herds were found during the FY covered by the report. However the reactor totals in these figures includes not only those herds found infected this year but also those found last year in which reactors were found during FY 1995. If the herds carried over from FY 1994 are subtracted, the number of infected herds actually found in FY 1995 was 202 in 16 States (Figure 8). Eight of the fifteen States were successful in reducing their newly infected herds in FY 1995 from the number they had the previous year.

The number of herds under quarantine for brucellosis dropped dramatically during the year from 152 on September 1994, to 68 on September 30, 1995; a reduction of 59 percent (Figure 9).

Brucellosis Ring Test (BRT) surveillance detected two brucellosis affected dairy herds in FY 1995 with a third affected herd found by MCI testing. A total of 732 suspicious BRT laboratory reports resulted in 235 herds being blood tested for a herd test rate (HTR) of 32 percent. The HTR in FY 1994 was 72 percent (Figure 10).

There were 9.9 million Market Cattle Identification tests conducted in FY 1995, 2.4 million less than the number collected the previous FY. Of these, 5.6 million samples (57 percent) were collected at slaughter plants and 4.3 million (43 percent) were collected at stockyards.

The total number of cattle tested for brucellosis in FY 1995 was 12.5 million, a decrease of 3.2 million over FY 1994. Of these, 2.6 million (20 percent) were sampled on farms or ranches and 9.9 million (80 percent) were tested under the MCI program (Figure 11). Although the total number of tests decreased by 20 percent, there was a 55 percent decrease in reactors from 13,000 in FY 1994 to 5,900 in 1995, 1,464 of which were found on farms (Figure 12).

The 6.7 million calves vaccinated for brucellosis in FY 1995 was the same as the number vaccinated during the previous FY (Figure 13).

One-hundred-seventy brucellosis affected herds were depopulated in the U.S. in FY 1995, at a cost of over $3.5 million in indemnity. Depopulation
1995 STATES-FEDERAL BRUCELLOSIS ERADICATION PROGRAM

continues to be the preferred method of handling infected herds under the Rapid Completion Plan.

The remarkable progress of the brucellosis program last year and in recent years is clear evidence that brucellosis can be eradicated from the United States by the goal of December 30, 1998. Many of the remaining Class A States are already poised on the verge of Class Free Status. But many States similarly poised in the past have been set back by finding infected herds that should have been, and could have been, found earlier through more rigid enforcement of program procedures and principles. Every incomplete investigation, every shortcut, and every affected herd not correctly managed provides an opportunity to leave infection behind and to delay at least a year a States attainment of Class Free Status. With only three years remaining, we can neither permit nor condone such program laxity if the National goal of eradication is to be achieved by the date that has been established.
BRUCELLOSIS ERADICATION PROGRAM
OCTOBER 1995

Figure 1

Class Free   Class A
Brucellosis Eradication
Distribution of Beef Cattle by Brucellosis Status

CLASS A
63%

CLASS FREE
37%

October 1995

Figure 2
Distribution of Dairy Cattle by Brucellosis Status

Class Free: 68%
Class A: 32%

October 1995

Figure 3
DAIRY HERDS UNDER QUARANTINE
OCTOBER 1995

Figure 4
Brucellosis Eradication
Distribution of All Cattle by Brucellosis Status

CLASS FREE
48%

CLASS A
52%

October 1995

Figure 6
Brucellosis Eradication

Number of Reactor Herds Found (According to State Classification)

Figure 6

34 Class Free States & 16 Class A States (October 1995)
Brucellosis Eradication

Percent of Total Reactor Herds Found

Fiscal Year 1995
Total herds: 309

49%
States: 1
Herds: >100
Total reactor herds = 152

11%
States: 1
Herds: 25 - 100
Total reactor herds = 31

29%
States: 6
Herds: 10 - 26
Total reactor herds = 91

* Estimated

Figure 7
Brucellosis Eradication
New Reactor Herds
October 1994 through September 1995 - 202
October 1993 through September 1994 - 279

Figure 8
BRUCELLOSIS AFFECTED HERDS
AS OF SEPTEMBER 30, 1996 - 68
AS OF SEPTEMBER 30, 1994 - 152

Figure 9
Milk Ring Test Results (BRT)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Suspicious BRT Tests</th>
<th>Follow-up Herd Blood Tests</th>
<th>Infected Herds Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>1,200</td>
<td>1,400</td>
<td>1,600</td>
</tr>
<tr>
<td>1989</td>
<td>1,400</td>
<td>1,500</td>
<td>1,700</td>
</tr>
<tr>
<td>1990</td>
<td>1,200</td>
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<tr>
<td>1995</td>
<td>1,200</td>
<td>1,400</td>
<td>1,600</td>
</tr>
</tbody>
</table>
Brucellosis Eradication

Blood Testing: Cattle

Figure 11
REACTORS FOUND (thousands)

- Farm or Ranch
- MCI

Figure 12
Brucellosis Eradication
Calves Vaccinated

Figure 13
CURRENT BRUCELLOSIS SITUATION
IN THE
GREATER YELLOWSTONE AREA

Bob Hillman, DVM

There have been a number of events and activities relative to brucellosis in the Greater Yellowstone Area (GYA) since the last USAHA meeting. Several of these are significant. Two will be covered by other presenters at this meeting so I will only mention them, then focus on the other items.

The state of Montana has initiated a legal suit against the Department of Interior, National Park Service and USDA, APHIS/VS. Dr. Clarence Siroky will address this issue.

Senator Conrad Burns, Montana, has introduced legislation in the U.S. Congress that addresses Brucellosis in bison in Yellowstone National Park. Senator Burns will address this legislation.

The Memorandum of Understanding (MOU) creating the GYIBC was signed by the Governors of Idaho, Montana and Wyoming and the Secretaries of Agriculture and Interior in June/July, 1995. The execution of the MOU formalizes the GYIBC and gives it official recognition. We believe this is a milestone in the process of finding and implementing equitable solutions to brucellosis in the GYA.

The GYIBC is meeting four times each year in order to keep focused on our mission, goal and objectives. The GYIBC met in February, May and August and has scheduled the next meeting for November. The committee has dealt with a number of significant issues:

1. Federal Advisory Committee Act (FACA) - The federal agencies had insisted that the GYIBC would have to operate under the FACA. Operation under the FACA would probably have destroyed the ability of the GYIBC to achieve its purpose. Fortunately the passage of the Unfunded Mandates Act removed the requirement for FACA compliance.

2. National Environmental Policy Act (NEPA) - This act requires that prior to any federal action there be an Environmental Assessment to determine if the proposed action is likely to cause an impact on the environment. If there will be a significant impact to the environment, an Environmental Impact Statement is required.

Currently in the GYA there is an EIS process ongoing between National Park Service and the state of Montana for the management of YNP bison that migrate into Montana. This process has been going on for over six years and is expected to take at least another year.

There is an Environmental Assessment being conducted in Grand Teton National Park for the management of GTNP bison. This pro-
BRUCELLOSIS SITUATION IN YELLOWSTONE AREA

cess has been going on for over four years and is not expected to be completed for another year.

Federal members of the GYIBC have informed the committee that an EIS For the Elimination of Brucellosis from the GYA will have to be developed for the entire GYA. This was discussed extensively at the last meeting. The Technical Subcommittee was assigned the job of developing a Task Directive for the EIS. Some members have estimated that the EIS process could take five or more years and cost between $750,000 and $1,000,000 per year. The committee suggested that USDA/APHIS be the lead agency in the development of this EIS and that other member agencies be "cooperating agencies." Since the last meeting APHIS has indicated a willingness to take this role and has estimated that a Programmatic Brucellosis EIS could be developed within one year utilizing available funds. Under this approach, it would be necessary to develop site specific EA's for the various wildlife herd units within the GYA. This topic will be discussed in detail again at the next meeting of the committee.

It is my strong belief that the NEPA process is the greatest impediment we face to continued progress in our efforts to address brucellosis in the GYA. We need to find ways to eliminate the NEPA requirements for disease control issues or to shorten the time requirement and reduce the cost of the NEPA process. In this time of tight budgets, I do not believe the expenditure of $3,000,000 - 5,000,000 for a NEPA document is the best use of scarce resources. I also believe that some people are using the NEPA process to prevent or delay meaningful action in the GYA. It will be extremely difficult for the committee to maintain its focus on the problem and make progress in disease control if we have to wait five years, for the completion of a NEPA document, before we can do anything on the ground.

3. Risk of Transmission of Brucellosis from Infected Bull Bison to Cattle - Significant numbers of bull bison migrate from the national parks each year. Most of these animals are serologically positive to the brucellosis tests. The three states have been destroying these animals to protect state cattle herds from exposure and to maintain state status. Some committee members have contended that bull bison do not pose a threat to cattle because bulls allegedly cannot spread brucellosis. In order to address this issue the Technical Subcommittee conducted a literature review. Most of the available information was accumulated in cattle. Only one research project has been conducted on bison. The subcommittee report concluded that "...the risk of transmission, though logically small, cannot be entirely eliminated based on existing information."

4. Sampling Protocol - A number of bison, that migrate into the states from the national parks, are destroyed each year. Attempts have
been made to collect laboratory samples from all bison destroyed so that brucellosis data can be accumulated on these animals and the herds they represent. Even though some samples have been collected from almost all bison that have been destroyed, there has not been consistent collection of appropriate samples. This has resulted in a poor correlation between serological and culture results, which has been misinterpreted, by some people, to imply that very few bison pose a threat for spread of brucellosis. The GYIBC has developed a protocol that is to be used for all sampling of bison that are harvested in the GYA. The use of this sampling protocol should result in the accumulation of reliable data on brucellosis in national park bison.

5. Brucellosis White Paper - Much information and mis-information has been distributed about brucellosis in wildlife in the GYA. Mis-information is causing most of the adverse public outcry about our efforts to address the disease issue. The GYIBC is developing a "White Paper" which will contain the available facts about the disease in the GYA. We believe this will help dispel some of the adverse reaction from the public. It will certainly help for all the GYIBC members to be in agreement on the facts. This paper is nearing completion.

6. Identification and Mapping of Wildlife Herd Units - The GYIBC has recognized the need to identify the various wildlife herd units within the GYA. The Technical Subcommittee has almost completed the task of identifying the various herd units and mapping their ranges. Twenty-two elk herd units with approximately 100,000 head of elk and 4 bison herd units with approximately 4,250 bison have been identified.

7. Site Specific Management Plans - Eradication efforts will have to be tailored to the characteristics of each herd unit. The Technical Subcommittee has been assigned the task of developing a management guideline that will serve as a blueprint for site specific disease management plans.

8. Absarokee Bison Herd Management Unit - The Wyoming Department of Game and Fish has proposed the establishment of a bison management unit east of Yellowstone National Park, on National Forest lands, to satisfy the public's desire to observe bison. The unit would be established for bulls only. No female bison would be allowed. Contact with cattle would be possible, but unlikely to occur if adequate controls are maintained. This proposed unit has been approved by the Game and Fish Commission, but is opposed by the Wyoming Livestock Board. Final disposition has not been determined. Several members of the GYIBC believe the establishment of free-roaming, brucellosis infected bison herd units outside the national parks would be a very bad precedent and would threaten the
brucellosis status of the state of Wyoming.

9. Bison Quarantine Protocol - One of the problems facing the GYIBC is the disposal of migratory bison and the removal of excess bison from the GYA. There are too many bison for the available ranges. The bison are exposed to brucellosis, so they cannot be sold or released. The destruction of large numbers of bison each year is becoming more and more difficult.

One alternative, which was presented to the Committee on Brucellosis last year, is the capture of bison and removal of the animals to a quarantine facility for testing and eventual release of those bison that are unequivocally brucellosis free. In order to bring this procedure to fruition, the GYIBC has developed a draft Bison Quarantine Protocol for consideration by the Committee on Brucellosis. Once approved this protocol would be employed in all bison quarantine facilities. Dr. Don Bridgewater, who is on the Technical Subcommittee and helped draft the protocol, will present it to this committee. If the protocol is approved the UM&R and the CFR will have to be amended.

10. Brucellosis Feedground Habitat Project - Wyoming Game and Fish Department began this project several years ago to conduct a vegetation inventory, conduct brucellosis surveillance, determine elk distribution, provide stackyard fencing to ranchers, and enhance natural elk habitat. Last year they developed feedground specific feeding plans for the 22 Wyoming feedgrounds in order to reduce time on feedgrounds. They have been vaccinating elk on the feedgrounds since 1985 and vaccinated elk on 15 feedgrounds last winter. Serological surveys, conducted on some feedgrounds last winter, using the C-ELISA test indicate that the vaccination project has significantly reduced the prevalence of brucellosis in elk on some of the feedgrounds.

Those of us who are a part of the GYIBC, and particularly those of us who have been involved in this issue for many years, believe that a great amount of progress has been made. We are still a long way from final resolution of the brucellosis problem in the GYA and it is difficult to see the progress unless you have been involved in the process. We believe the GYIBC is the best avenue to solve the problem and ask for the continued support of the Committee on Brucellosis and the USAHA.
REPORT OF THE COMMITTEE ON
CAPTIVE WILDLIFE AND ALTERNATIVE LIVESTOCK

Chairman: Dr. Calvin W.S. Lum, Honolulu, HI
Vice Chairman: Dr. Robert Temple, Bristolville, OH

Dr. Wilbur B. Amand, PA; Dr. Jack N. Armstrong, NV; Dr. Don Bosman, WY; Dr. Robert A. Cook, NY; Dr. Richard L. Crawford, MD; Ms. Barbara R. Fox, MD; Dr. Werner P. Heuschele, CA; Mr. Harvey Hilderbran, TX; Dr. Patrick D. Hoctor, IN; Dr. Sam D. Holland, SD; Dr. David L. Hunter, ID; Dr. David A. Jessup, CA; Dr. David J. Ligda, IN; Dr. Chester J. Mikel, OK; Dr. R. Eric Miller, MO; Dr. John H. Olson, FL; Dr. Lisa H. Rothe, CO; Dr. Dale F. Schwindaman, MD; Dr. Morton S. Silberman, GA; Dr. Charles O. Thoen, IA; Dr. E. Tom Thorne, WY; Mr. Dave Whittlesey, CO; Dr. Richard W. Winters, TX; Dr. Peregrine Wolff, MN.

The meeting of the Committee on Captive Wildlife and Alternative Livestock was called to order by Chairman Calvin Lum at 1:30 PM. There were 38 attendees, of whom 19 were committee members.

The first speaker was Dr. David Hunter from the Idaho Department of Agriculture. Dr. Hunter spoke about the problems that can arise during the translocation of wildlife. He gave examples of cases of wildlife where no consideration was given to diseases that the translocated animals were harboring. Some of these early translocations had disastrous effects on the local wildlife. He emphasized the necessity for State Agriculture Departments, Fish and Game Departments, and private producers to work together for the common goal of disease prevention. Agencies and producers must work together first and foremost to prevent the introduction and spread of disease among the animals under their jurisdictions. Dr. Hunter outlined how the Western States Wildlife Health Co-operative was formed to accomplish this end. Through this organization the various agencies in different states have worked together to keep each other informed as to the impending movement of animals and the disease problems that may be involved. He indicated that this Co-operative has made it much easier for the different states' agencies to be informed on a timely basis.

The second speaker was Dr. Dale Schwindaman, Deputy Administrator for USDA, APHIS, REAC, who gave an update on the agencies activities. Dr. Schwindaman indicated that the proposed rules for farmed animals would probably be ready for comment within eight months. The agency is currently working on the definitions of farm animals versus exotic animals. He encouraged industry representatives to submit comments when the proposed rules are published regarding these definitions and other subject matter in the proposed rules. Certain exotic cattle will now be reclassified as farm animals. Bison and reindeer will be classified as farm animals. He indicated that con-
cerns for animal health issues were being voiced by numerous members of Congress and indicated that the Secretary of Agriculture has made animal health issues a priority matter within the agency. Exotic animal auctions will come under the agency’s jurisdiction, as will the “Swim with Dolphins” programs. Exotic animal licensees will be required to employ only animal care personnel who are trained and experienced. There will also be a minimum age requirement for transportation of canids and felids. The agency is also seeking to expand their injunctive authorities. The formal negotiated rule making process for amendments to the marine mammal regulations which has been delayed because of budget problems was recently resumed with a meeting held in September. Dr. Schwindaman concluded by citing four suits which have been filed against USDA regarding the handling of elephants in circuses where incidents resulted in injury or deaths of both elephants and humans.

The next speaker was Dr. Robert Cook, Chief Veterinarian and Director of Wildlife Health Science of the Wildlife Conservation Society. He explained the self regulation system that is in place for all member institutions of the Association of Zoos and Aquariums (AZA). They have stringent requirements for medical care, quarantine, and the necropsy of all animals which die in these institutions. They have an inspection process and a periodic re-inspection where all aspects of the institution are reviewed. He explained that other organizations work closely with the AZA, and an example cited was the infectious diseases manual of the American Association of Zoo Veterinarians which was circulated by this committee and the AAZV to the fifty state veterinarians this year. Updates to this manual occur every three years. Record keeping which include individual animal identification, medical history, and husbandry is contained in a central data base which can be accessed by all member institutions. Dr. Cook indicated upon inquiry that the AZA would be willing to share information on the systems with those industries which would care to develop their own self regulating programs. The AZA is also involved in worldwide field projects to gather disease data for baseline references on various wildlife species. Dr. Cook discussed the long held misconception that zoos were reservoirs of various diseases. He indicated that this misconception was probably due to the fact that zoos have meticulously searched for diseases within their institutions and have been faithful in reporting their findings to the regulatory agencies.

Dr. Robert Nervig, Director of the Western Region, USDA/APHIS/VS was the next speaker. He discussed an application for the importation of New Zealand red deer by a rancher in Hawaii. It is the intention of the rancher to raise this species for meat and velvet production solely for local consumption. There is no intention to export live red deer out of Hawaii. This project is supported by the Department of Agriculture of the State of Hawaii as an effort to promote diversified animal agriculture in the State. Veterinary Services has conducted a risk assessment regarding TB and *Elaphostrongylus cervi*
and is currently consulting with wildlife disease experts, members of the cattle industry, deer farming associations, and New Zealand and Canadian regulatory officials. During this meeting, it was agreed that other interested industry representatives will also have an opportunity to review and comment on the proposed protocol. A recommended protocol will be evaluated and a decision on this request will be forthcoming after all parties have been consulted. Dr. Nervig discussed the potential closure of the Hawaii import center and the budgetary problems of the other two import centers in Key West and Newburgh. He discussed the under-utilization of these facilities, the need for capital improvements and lack of agency funding. There was information from an agency task force investigation that the closure of the Hawaii facility would not adversely impact current importers.

Mr. Phil Bradshaw, Chairman of the Emergency Diseases Committee of LCI was the final presenter. He discussed the formation of a LCI task force to address issues dealing with the intra and inter-state movement of captive wildlife and alternative livestock. As its first project, the task force will be developing a brochure explaining the need for shippers to comply with all state and multi-jurisdictional regulations. Members of this committee and the wildlife diseases committee will be drafting this brochure. It was indicated that the draft brochure will be shared with members of both committees for review and comments. Included in this brochure will be a list of various regulatory agencies and contact telephone numbers. LCI will be underwriting the publication of this brochure and will help in its circulation.

Discussion was held regarding the purpose statement of the committee which needs to be amended to conform with the new name of the committee. A draft was circulated and committee members were asked to submit their comments and suggestions during the next few months. A final purpose statement will be forwarded to the President of USAHA.

A resolution dealing with the USDA Import Quarantine Centers requesting that all present import centers be maintained and that they be brought to standards that would meet USDA's commitment to the humane care of animals in their charge. The resolution was adopted by the committee.

The meeting was adjourned at 5:00 PM.
REPORT OF THE COMMITTEE ON ENVIRONMENTAL RESIDUES

Chairman: Dr. Henry M. Stahr, Ames, IA
Vice Chairman: Dr. John C. Reagor, College Station, TX

Mr. John Adams, VA; Mr. Don Benson, SD; Dr. Delmar R. Cassidy, IA; Mr. L. Wayne Godwin, FL; Dr. Carl H. Graham, MO; Dr. John P. Honstead, MD; Dr. William E. Ketter, MD; Dr. Tari P. Kindred, MD; Dr. Gavin Meerdink, IL; Dr. Gary D. Osweiler, IA; Dr. Jane F. Robens, MD; Mr. Frank Ross, IA; Dr. Larry G. Sullivan, MI; Dr. Manuel A. Thomas, Jr., TX; Dr. Janice Webb, FL.

The first topic considered was residue problems in 4-H animals. The problem is twofold. The first consideration is the ethical problem exhibited by Advisor (mentor) student (advisee) relationship which is willing to do anything to win. This is to be addressed by a National Conference December 2 & 3, 1995, which is to be held at Bally’s in Las Vegas. People who advise 4-H members are being solicited to attend. The second problem is the residue itself, if it is clenbuterol it is a legal, as well as, a toxicological problem in Food Safety. The customers for project animals are either buging them subject to reside testing or asking a written affidavit that the animals are residue free.

The committee recommended action is to educate the advisors, parents and 4-Her’s that testing will be done. When the education and threat issued, residues detected fall 80% to <1%. Residues can be detected in eyes from animals exposed to drugs, months after exposure.

TCDD's (chlorodioxins) were addressed next. Ken Davidson, USDA/ARS presented their project findings. Two States' residues in their survey had very much higher levels of chlorodioxin (10X), than other sites. The studies are being continued. The specific cause of these high levels will be sought. Generally non lactating bulls are higher than cows and older animals are higher than young animals. Preliminary results show most of the dioxin is excreted by the animals, a similar pattern is observed from beef and rats.

The committee recommends a close communication between EPA and the USDA/ARS metabolism lab be maintained to assure the EPA proceeds with their enforcement of initiatives with the best possible information. It is particularly important to ascertain the source of the chlorodioxin before initiatives are undertaken. Especially since the best estimate is that human residues are falling under existing programs to contain them. The committee may take more definitive action when the studies are complete.

The mycotoxin subcommittee AAVLD reports high levels of Fumonisins and Aflatoxin in Texas 1995 Crop Commodities with disease conditions being observed from their effects on livestock. High incidence of vomitoxin was observed in small grain in the Midwest. North Central areas of the country.
REPORT OF THE COMMITTEE

Relatively low levels of mycotoxin were observed in Pennsylvania, Kentucky, California. Isolated incidents of leucoencephelomalica in horses in Kentucky and Virginia were reported. Indiana and Iowa 1995 crop surveys indicated a low incidence of aflatoxin, low levels of vomitoxin and fumonisin in this year's corn crop.

Evidence of misrepresentation of results for mycotoxin in animal feed, misuse of test kits, and results have been observed. The advice to be diligent on sampling and use screening methods with appropriate matrices and use confirmation is to be emphasized in reissuing a memorandum. The advice was first issued a few years ago. The memo will be reissued with advice to heed it and make the information generally available to the animal industry.

There are concerns about potentially toxic residues from the use of zincoxide and copper sulfate in animal feed and accumulation of these metals in the environment due to the use of manures as fertilizers.

A concern over new laws which impact animal agriculture with restrictive measures and still do not address potential residues from production practice was discussed. These laws will be followed closely and progress with their revision and interpretation will be the subject of future resolutions as further experience helps to suggest concerns and needs.

The need for flexible limits for elemental levels (e.g., Selenium) in feeds to reflect local deficiencies was discussed. While the committee welcomes the reestablished feed levels of 0.3 ppm selenium having been approved. Higher levels are necessary for deficient areas (e.g., areas in Kentucky). Flexibility in levels based on local and state needs are recommended for consideration.

The committee feels this committee would profit from an earlier meeting time, where input from AAVLD toxicologists can be used, to assist in reviewing and recommending action, for USAHA on Environmental Residue Concerns.

Respectfully submitted,

Henry M. Stahr
Diagnostic testing to support international trade has, in the past, been primarily limited to the testing of the animals prior to movement. The new trade agreements will expand and change the role that diagnostic laboratories will play in trade.

Background

The Uruguay Round of the General Agreement for Tariffs and Trade (GATT) was completed in December 1993, signed by the member countries in April 1994, and went into effect on January 1, 1995. GATT is aimed at reducing and eliminating barriers to trade, investment, and services between the 120 signatory countries. Besides eliminating traditional trade barriers, such as quotas and tariffs, GATT attempts to control the use of nontariff barriers, such as unjustified technical health standards. The GATT Uruguay Round Agreement also resulted in the formation of the World Trade Organization (WTO). This multilateral organization was created to oversee implementation of the various agreements, facilitate further trade-liberalizing discussions among member countries, and administer the dispute settlement system. Overall, the GATT Uruguay Round negotiations resulted in a set of trade agreements covering a number of different sectors, one of which is the “Agreement on the Application of Sanitary and Phytosanitary Measures,” commonly referred to as the SPS Agreement. The establishment of the WTO and the SPS Agreement have major implications for how countries regulate imports as well as the testing necessary for developing and supporting these restrictions.

The SPS agreement maintains every country’s right to establish measures to safeguard human and animal health. However, these measures must be based on scientific evidence, transparent in the way they are developed and implemented, and not discriminate arbitrarily or unjustifiably. Furthermore, sanitary measures, including diagnostic testing, should be based on relevant international standards or guidelines (i.e., Office of International Epizootics (OIE) standards). The SPS agreement specifies that import regulations be based on a risk assessment which is generally described as the process of evaluating the likelihood of the entry, establishment, or spread of a disease within a country and the potential consequences of such spread. The risk assessment must be based on scientifically collected data and must be transparent. Setting the acceptable level of risk, or the level of protection
deemed appropriate to protect human or animal life and health, is a sovereign right of countries. However, the level of protection which is ultimately chosen should be supported by the risk assessment and the relevant biological and scientific evidence. The SPS agreement also commits signatory countries to implementing the concept of regionalization. As specified in the SPS agreement, a disease-free area can be one country, several countries, part of a country, or parts of several countries. A disease-free area may be surrounded by an area in which the disease is present if the appropriate protection, surveillance, and other necessary quarantine measures exist to confine the disease in question. The exporting country has the burden of demonstrating that its internal measures provide the level of protection demanded by the importing country.

The North American Free Trade Agreement (NAFTA) between Mexico, Canada, and the United States went into effect in January 1994. NAFTA contains an SPS Agreement with principles and rules which are identical to those established under the GATT Agreement. Generally, disputes that may arise between the United States, Canada, or Mexico will be managed under the NAFTA dispute settlement rules, unless the complaining country requests that the dispute be addressed in the GATT/WTO dispute settlement system.

The SPS agreements encourage countries to base standards as much as possible on international standards. It specifies that the animal health measures should be based on OIE standards. The OIE has a long history of playing a significant role in global animal health affairs, including the trade of live animals and animal products. The basic OIE goal is to prevent the spread of animal disease in international commerce. The OIE Code provides sanitary standards that countries should use to develop their own sanitary measures. The OIE is also responsible for developing standard diagnostic techniques.

The Future Role of Diagnostic Laboratories in International Trade

Diagnostic laboratories will continue to play the traditional role of doing import and export testing. However, there will be changes in how this and other diagnostic testing is done and reported.

Harmonization

As mentioned previously, the SPS agreements specify that if OIE standards have been developed and accepted by OIE member countries, they will be followed. The OIE has developed standard testing techniques that are published in the Manual of Standards for Diagnostic Tests and Vaccines. This manual was published in 1992 and is currently being revised. The new edition will be published in 1996. If the OIE Code specifies that a test is required to qualify an animal for export, the Manual will describe one or more prescribed tests. This description will include an outline of how to prepare the reagents, perform the test, and interpret the results. The diagnostic laboratory performing an export test is obligated to follow the procedures outlined.
Harmonization of tests in a country like the United States with a large number of state diagnostic laboratories can be difficult. However, standard protocols and the availability of reagents from the National Veterinary Services Laboratories help to harmonize test procedures.

To assist in the harmonization of test procedures, the OIE has designated reference laboratories for 37 diseases. These laboratories will provide reagents, reference standards, training, and testing. They also provide scientific guidance on the development and validation of new test procedures.

**Equivalence**

The SPS Agreement encourages countries to recognize that different procedures can be used to achieve the level of protection demanded by the importing country. This gives the testing laboratory the freedom to develop detailed protocols based on the OIE standard. If a test is required and there is no OIE standard prescribed, the laboratory can perform a described procedure; but the laboratory must be able to demonstrate that the sensitivity and specificity of the test method has been validated. The 1996 revision of the OIE Manual will have a chapter on test validation. In addition, the OIE has designated experts for a number of diseases and will nominate experts who can advise a country on the equivalence of certain test procedures.

**Transparency**

The NAFTA and GATT includes various provisions that encourage greater transparency of all policies, practices, and regulations which affect trade. From a laboratory standpoint, an importing country can request access to information and documents regarding laboratory procedures and test results. Making such information available and fulfilling the intent of the transparency provisions in the SPS Agreement may mean providing access to representatives from the importing country to visit and evaluate the laboratory capabilities, including its infrastructure and testing methods.

**Veterinary Infrastructure**

The trading countries must have a veterinary infrastructure adequate to support the sanitary measures that are specified. One part of that infrastructure is a diagnostic laboratory that has the appropriate facilities, equipment, reagents, and staff.

**Risk Assessment**

The requirement to use risk assessment as a basis for animal health measures will affect diagnostic laboratories. One of the criteria is disease prevalence. This can be established by serologic surveys. The laboratory technique used must meet the criteria outlined previously. In addition to surveys, the results from testing done for diagnostic and import/export may also
be used to establish disease prevalence. This broadens the obligations of diagnostic laboratories, as any disease prevalence data used for risk assessment should be based on diagnostic tests using standard or OIE recognized techniques.

Regionalization

The commitment to recognize disease-free areas and areas of low disease prevalence will have a tremendous impact on trade. To establish that an area is disease-free, or has a low disease prevalence, requires reliable disease information. This requires a laboratory that has an adequate infrastructure and that uses standard or internationally accepted techniques. As a part of establishing an area as disease-free or maintaining a disease-free area, the country must be able to detect and report the disease if it is introduced. In high risk areas, there may be an obligation to increase diagnostic testing as is now being done for avian influenza along the Mexican border. This not only requires that standard techniques are used but also that diagnostic laboratories must report to regulatory officials any evidence of introduction of a disease into a free area. The reliability of the reporting of diagnostic laboratory results has been a concern to some of our trading partners. This credibility must be maintained, or all trade may be jeopardized. The OIE requires that member countries must report any introduction of any of the 16 list A diseases within 24 hours.

Dispute Settlement Process

Both the NAFTA and GATT Agreements include procedures for resolving disputes. The first step in the dispute settlement system begins by addressing complaints at the technical bilateral level. In a formal challenge, one which was not resolved bilaterally, expert panels may be formed to review and give recommendations for resolving a technical dispute, including dispute over a sanitary measure. Laboratory data can play a vital role in preventing and resolving such disputes by being in a position to provide, explain, and/or justify the results that they obtain.

Quality Assurance

The SPS agreement does not require that a laboratory have a quality assurance program, but the transparency, harmonization, and dispute resolution principles of the NAFTA and GATT SPS Agreements make it advisable to have such a program. The programs are usually based on the ISO 9000 series of standards and on the ISO/IEC Guide 25. OIE guidelines also exist for conducting laboratory quality evaluations. The ISO and OIE guidelines are similar; the key components of the OIE program are as follows: 1) Laboratory organization and management—the laboratory has appropriate supervisory and administrative support staff and a quality manager, 2) Environment—adequate physical facility, 3) Human resources—trained qualified technical staff, 4) Equip-
ment—adequately and properly maintained and calibrated equipment, 5) Sample handling—a method to insure that samples are handled and stored properly, 6) Test methods and procedures—reagents and chemicals have proper documentation and each assay has a protocol, work sheets, and record of controls used, 7) Record keeping and reporting—there is a record keeping system for all laboratory procedures, and test results are recorded accurately, clearly, objectively, and with the appropriate interpretation of the results, and 8) Internal and external check sample program—the laboratory should establish its own internal check sample program and whenever possible it should participate in a national or international check sample program.

New Technology

A number of new techniques have recently been described for diagnosis of animal diseases and are currently being evaluated. However, as discussed previously, diagnostic techniques used to qualify animals for export must be based on established international standards. Because of the SPS requirement to harmonize test procedures between countries, through the OIE standard setting activities, changes in technology are adapted slowly and only after validation. In addition, procedures should be ones that can be performed in most laboratories. In the 1992 OIE Manual, the prescribed tests for many of the diseases are the traditional methods, such as hemagglutination-inhibition, immunodiffusion, and complement-fixation. The 1996 OIE Manual will include a section on biotechnology. In addition, there is an increase in the number of ELISA tests included as prescribed tests. Usually before a test is OIE recognized, the procedure has been validated in several laboratories, preferably in different countries, and the results published. In the case of the bluetongue competitive-ELISA (C-ELISA), there was an international meeting of the people who did the validation. An OIE representative attended the meeting. This group recommended that the C-ELISA be a prescribed test; it will be added in the 1996 Manual. The immunodiffusion test will remain a prescribed test too. Several molecular tests, including the polymerase chain reaction, will be described in the 1996 Manual as alternative procedures for the diagnosis of diseases but not for use in trade. As the OIE Manual is only revised every 5 years, it will be after the year 2000 before additional new prescribed tests are included.

Conclusion

The GATT and NAFTA SPS Agreements will change the laboratory support needed for world trade. This support can include diagnostic and disease surveillance testing, as well as import/export testing. The Agreements require the use of standard internationally accepted procedures and that all supporting information and results be available for review to insure that decisions are science-based.
REPORT OF THE COMMITTEE ON EPIZOOTIC ATTACK

Chairman: Dr. John P. Huntley, Albany, NY
Vice Chairman: Dr. Saul T. Wilson, Jr., Tuskegee, AL

Dr. J. B. Anderson, TN; Dr. Richard E. Breitmeyer, CA; Dr. Bill Brown, KS; Dr. William W. Buisch, NY; Dr. Jerry J. Callis, NY; Dr. H Michael Chaddock, MI; Dr. Dorothy Davis-York, Creston, CA; Mr. Eric Dee, IA; Dr. George C. Edwards, NC; Dr. A. K. Eugster, TX; Dr. Walter D. Felker, IA; Mr. Joe B. Finley, TX; Dr. Don A. Franco, VA; Mr. Don D. Gingerich, IA; Dr. Adam G. Grow, MD; Dr. Farouk Hamdy, FL; Dr. P. R. Henry, CO; Dr. Billy R. Heron, CA; Dr. Owen W. Hester, AL; Dr. John L. Hyde, NY; Dr. Brian R. Jamieson, CAN; Dr. Ulysses J. Lane, FL; Mr. John H. Lang, WI; Dr. Donald W. Luchsinger, DC; Dr. Edward T. Mallinson, MD; Dr. Bret D. Marsh, IN; Dr. Armando Mateos, Mex; Dr. Peter D. Mc Ardle, MA; Dr. Richard H. McCapes, CA; Dr. H. A. McDaniel, MD; Dr. Norvan Meyer, VA; Dr. M. A. Mixson, NC; Dr. J. E. Novy, APO, AA; Dr. Richard E. Omohundro, AZ; Dr. John S. Orsborn, Jr., CA; Dr. Bennie I. Osburn, CA; Dr. E. C. Sharman, GA; Dr. William G. Sterrett, CAN; Dr. Kenneth L. Thomazin, CA; Dr. Dennis L. Thompson, CA; Mr. Olin H. Timm, CA; Mrs. Michele C. Turner, TX; Dr. Max A. Van Buskirk, PA; Dr. Stanley A. Vezey, GA; Dr. Gary M. Weber, DC; Dr. John L. Williams, MD; Dr. John H. Wyss, TX.

The committee met jointly with the committee on Foreign Animal Diseases at 1:30 p.m. through 4:00 p.m. on Wednesday, November 1, 1995, in the Southern Pacific CD room of John Ascaga's Nugget Hotel, Sparks, Nevada. Please refer to that committee's minutes in this proceedings. The committee met again at 1:30 p.m. on Thursday, November 2, 1995, in the Ponderosa A room of John Ascaga's Nugget Hotel, Sparks, Nevada. In attendance were 20 committee members and 30 guests. Dr. S. T. Wilson presided.

Rabies Epizootic in Texas

Dr. Keith Clark, director of the Zoonoses Control Center of the Texas Department of health gave a report on canine and gray fox rabies epizootics in Texas. In 1994, two ongoing rabies epizootics were declared a state health emergency: canine rabies in South Texas and gray fox rabies in West Central Texas. Subsequently, in 1995, a statewide rabies quarantine was enacted. Prior to 1988, rabid coyotes were infrequently reported in Texas. In 1988, Starr and Hidalgo Counties, located in extreme South Texas, experienced an epizootic of canine rabies resulting in eleven laboratory-confirmed cases of canine rabies in domestic dogs and six cases in coyotes. By 1991, the epizootic had expanded approximately 160 km north of the US-Mexico border and included ten counties. During the next three and a half years, ten additional counties became involved in the epizootic as it continued to move
REPORT OF THE COMMITTEE

northward. During the seven and a half year period, there were 644 cases of canine rabies in a twenty county area. Gray fox rabies, which was endemic in West-Central Texas, also by the end of the year with twenty-three laboratory confirmed cases of gray fox rabies. The epizootic continued through 1993, with 260 gray fox rabies cases in twenty-two counties during a six year period. In 1994, there was an upsurge in the epizootic as it expanded in a northeasterly direction; thirteen additional counties became involved and there were 264 recorded cases of gray fox rabies. The expansion of the epizootic continued in 1995 with the inclusion of 200 cases and ten new counties during the first six months. From 1988 through June 1995, the epizootic included 724 cases of gray fox rabies in a forty-five county area. Antigenic and genetic analysis revealed the ecotype primarily affecting domestic dogs and coyotes in South Texas to be urban Mexican dog and the rabies ecotype primarily affecting gray foxes in West-Central Texas to be Texas fox. The epizootics are approaching large metropolitan areas; an increase in vaccination levels of domestic animals would help provide a barrier between rabid wild animals and humans.

A pilot Oral Rabies Vaccine Project was started to vaccinate coyotes. A large number of public agencies were called upon to assist in the project. 630,000 dog food and 200,000 fix meal baits with Raboral VRG vaccine were used in a forty mile wide zone along the northernmost area of canine rabies. In addition, about 500 square miles around Laredo was vaccinated. Baits were dropped 200 feet apart along parallel lines 1/2 mile apart. The vaccination seems to be effective in stopping the progression of the disease. In one area which had a small break, 25,000 more baits were distributed and no further cases were seen. Acceptance of the fishmeal baits about 70% or twice the acceptance of the dog food baits. If the baits were not eaten within 48 hours they were subject to be consumed by imported fire ants. Although no federal money is available for next year, there are plans to bait two areas. The first will be just south of the 1995 baitings to try to push the rabies front back. The second area in a twenty-five mile wide area around the fox rabies zoonotic area. It is hoped that by 1999 or 2000, the rabies enzootic could be eradicated in Texas.

**Vesicular Stomatitis Epizootic**

Dr. Jere L. Dick, A.V.I.C., New Mexico, gave an update on the vesicular stomatitis outbreak in the Southwestern United States. The first case was reported in New Mexico on May 1, 1995 in a horse located in Las Cruces. Positive serology was received on May 9, but no virus was isolated. On May 24, another horse 13 miles north along the Rio Grande was reported. On May 30, NVSL confirmed that New Jersey strain vesicular stomatitis had been isolated from this horse. The USDA and New Mexico Livestock Board immediately established a Livestock Disease Eradication Unit in Las Cruces. On May 30 and 31, new cases appeared 100 and 200 miles respectively from Las
EPIZOOTIC ATTACK

Cruces. The number of cases increased until on June 27 all movement of horses was restricted along the Rio Grande. By July 26, no new cases had been seen for five days and movement restrictions were lifted. Concurrently, several new cases had appeared outside of the Rio Grande Corridor. On June 28, one case of VS was found in Arizona which could not be linked with the New Mexico cases. That premise was eventually released from quarantine and there was not known spread of the disease in Arizona. The only case in Texas was found on July 14 and was a horse which had just come back from Santa Fe, New Mexico. The horse was released from quarantine on August 27 and again there had been no known spread. Between July 7 and 31, animals on fourteen premises in the Cortez-Durango, Colorado area had been diagnosed with VS. By July 18, the disease had spread an additional 50 miles to Redvale. On the 29th, a case appeared in Cedaredge and in August 81 cases were seen in the Grand Junction area. To date there have only been two cases on the eastern slope of the Rockies in Colorado. The first Utah case was northeast of Moab, was seemingly unrelated to the other cases and did not spread in the area. Two cases were later seen on the Navajo Reservation near the San Juan River drainage. On October 17, a new equine case on the Green River was reported. The first case in Wyoming was on October 2. Seven cases have been reported all of them were along the Big Horn River. This basin drains north into Montana and is 400 miles from any other cases.

Avian Influenza Epizootic in Mexico

Dr. Susan Trock, Epidemiologist, APHIS/VS, Northern Region, gave a presentation of the outbreak of highly pathogenic Avian Influenza in Mexico. In October 1993, Mexican poultry producers began to experience increased morbidity and mortality in their flocks. It was not until May 1994 than an isolation of H5N2 avian influenza was reported. This virus was characterized as non-pathogenic. The government conducted a sampling survey of flocks throughout the country. It was discovered that poultry in the eleven central states of Mexico were infected with the virus. In January 1995, severely increased mortality was reported in flocks in some of the central states. Two different isolations of highly pathogenic H5N2 were made in the states of Queretaro and Puebla. As part of the control mechanism for this disease, a vaccination program was initiated in Mexico. As of September 1, there has been over 167,000 samples tested. These identified 116 flocks that were positive for virus isolation: seven were highly pathogenic AI; five were medium pathogenic; and 104 were low or non-pathogenic strains. As of September 1, there has been 286 million doses of vaccine administered on 1382 farms.

United States Perspective on Avian Influenza

Dr. Kelly Preston, Emergency Programs Staff, APHIS/VS, gave the national perspective on Avian Influenza. In early 1995, a working group was formed to look at risk factors, develop an emergency action plan, organize a
series of informational meetings, with CEAH establish a basis for information sharing and organized two on site visits in response to the isolation of highly pathogenic Avian Influenza in Mexico. APHIS has increased surveillance testing but it is still inadequate in at least two states. The focus of emergency preparedness has been on H5 and H7 infection in commercial chickens. Surveys of live bird markets in the Northeast and use of sentinel chickens in Florida will continue. Although APHIS has rescinded the restriction on the manufacture of avian influenza vaccine, its use is still being limited to official disease control program and with the permission of state officials.

National Foreign Animal Disease Surveillance and Investigation

Dr. John Williams, Director, Emergency Programs, APHIS/VS, stated that in the recent vesicular stomatitis epizootic, Veterinary Services had primarily a coordinating and oversight role. Also by working through CEAH and NVSL, timely and informative educational material was prepared and distributed. Dr. Williams then gave a summary of Foreign Animal Disease Surveillance for fiscal year 1995. Of the 270 investigations performed, 40% were for vesicular conditions (this was excluding the 1995 Vesicular Stomatitis epizootic). 15% of investigations were for Bovine Spongiform Encephalopathies (BSE); 12% for encephalitic/CNS disorders; 11% avian diseases; 6% mucosal diseases and smaller percentages for septicemia, abortions, pox, acute death, parasitic, respiratory and miscellaneous. BSE surveillance is done on foreign animal disease investigations involving encephalopathy in cattle, confirmed negative bovine submissions for rabies, brains collected at slaughter in high risk states, and brains submitted by veterinary diagnostic laboratories. To date, 2411 bovine brains have been examined without any signs of BSE. A new effort has been made to open a dialog with the Mexican authorities on ticks resistant to acaricides so that information of the status and scope of the problem is openly discussed. A temporary prohibition of Mexican slaughter animals has been established since FSIS found violative samples of coumaphos in the fat of Mexican cattle in approximately 25% of the 200 samples taken.

Screwworm Control and Eradication

Dr. John Wyss, USDA Regional Director, Laredo, TX, gave a brief history and update on the North American Screwworm Program. The screwworm has only been seen outside of the Americas once in an epizootic in Libya in 1988. In 1957 through 1959, the screwworm was eradicated from the southeastern United States. The south western United States was cleaned up between 1962 and 1966 but there were occasional recurrences in the United States. In 1984 through 1985, a binational commission pushed the screwworm front through Mexico. In 1985 to 1991 the program progressed into Central America but a large outbreak in Mexico in 1992 set the program back about two years. The last native cases in Belize and Guatemala were in 1991 and both were declared free of screwworm in 1994. Likewise, both El Salva-
EPIZOOTIC ATTACK
dor and Honduras have become free this year. Nicaragua is the key to North American eradication since it is a large country which exports livestock both north and south but imports very little. In July, 1993, the program started there and currently all screwworm cases are along the border with Costa Rica. Next year, sterile flies will begin to be released in Costa Rica. The plant which grows the screwworms is being moved from Tuxtla Gutierrez, Mexico to Panama. Panama will begin release of flies in 1997 and there will be a permanent release area between the canal and Columbia to prevent the reintroduction of the parasite. Future plans include eradication on the islands of the Caribbean.

Dr. J. L. Williams then read a recommended statement for health certificates from vesicular stomatitis affected states which Dr. R. E. Breitmeyer had given him. The committee voted that this wording should be recommended. The statement follows: "The animals represented on this health certificate have not originated from a premises or area under quarantine for vesicular stomatitis. I have examined the animals and found no signs of vesicular stomatitis."

Dr. J. J. Huse read a resolution written by Dr. J. P. Huntley which had been passed the previous day by the committee on Foreign Animal Diseases. This committee voted to forward the resolution on to the committee on resolutions and request that it be sent to both Veterinary Services and Agricultural Research Services.

The resolution follows: "USAHA requests that USDA maintain its focus on quality diagnostic capability and that adequate resources be allocated to the nation's animal disease research and diagnostic infrastructure including the training and retention of quality personnel, facility maintenance and upgrade and adequate operating funds."

The following motion was made by Dr. S. T. Wilson and passed by the committee: "That the report of this committee reflect that we missed Dr. Norvan Meyer. We hope that his health continues to improve so that he can attend our next meeting and again provide the insight and wisdom we have come to expect from Norvan."

The meeting concluded at 4:45 p.m.
K. Preston

Emergency Programs of APHIS, Veterinary Services continues to prepare for a possible introduction of Highly Pathogenic Avian Influenza (HPAI). An avian influenza working group was organized by Drs. Hueston and Williams in early 1995. This APHIS group looked at risk factors for the U.S. from Mexico (Dr. R. Crom, CEAH - Risk Assessment), developed an Action Plan to compliment the APHIS HPAI Eradication Guidelines ("Red Book"), organized a series of state/federal/industry meetings to address concerns and improve emergency preparedness, through CEAH established an AI List Server for information sharing, and organized two U.S. delegations to Mexico to study HPAI and the effectiveness of avian influenza vaccine.

This working group has been composed of Riverdale staff, regional and area field epidemiologists, NPIP, NVSL, Vet. Biologics, CEAH, Public Information, and computer automation staff. Following a formal recommendation from the 1995 NPIP National Conference, APHIS proposes to expand the working group to include industry and USAHA officials and organize it within the AI Subcommittee of the USAHA Committee on Transmissible Diseases of Poultry.

APHIS has conducted a preliminary analysis on the national AI surveillance program. The number of tests has increased in 1995 from 1994 (380K from 250K) but at least two states appear to have inadequate testing at this time.

The focus of our emergency preparedness and response will be the agents H5 and H7 and the host will be (commercial) chickens. APHIS will continue to actively survey the live-bird markets in the Northeast and use sentinel chickens in Florida. APHIS applauds the efforts of the turkey industry for their strong surveillance and control & eradication efforts. The state-wide use of an autogeneous H7 vaccine in turkeys was supported by APHIS in 1995.

APHIS made the decision in July 1995 to rescind the restriction on the manufacture of avian influenza vaccines in the U.S. This includes H5 and H7 vaccines. There has been a very high level of concern from the U.S. poultry industry on this issue. All AI vaccines for use in chickens, and all H5 and H7 vaccines, will have distribution restrictions. Limitations include permission from State officials to use the vaccine. In addition, APHIS, Veterinary Services will control the use of the vaccine(s) "as part of an official disease control program." (See APHIS Veterinary Biologics Memorandum No. 800.85.)

APHIS has supported the full licensure and study of recombinant fowl pox vectored avian influenza vaccines. Mexico has recently received a sample that will allow them to conduct their own safety and efficacy studies.
NATIONAL PERSPECTIVE ON AVIAN INFLUENZA

Summary:

1. APHIS has improved emergency preparedness for HPAI in 1995.
2. National surveillance for AI may be inadequate in some states.
3. The proposed expanded AI Working Group with USAHA will allow us to look at different scenarios of HPAI outbreaks in different regions of the US. After some “dress rehearsals” we can, hopefully, decide who does what and when - and become better prepared.
4. Advances in vaccines and new vaccine technology should provide additional tools for Mexico to eradicate HPAI.
Suspected Foreign Animal Disease (FAD) Field Investigations: During fiscal year (FY) 1995 (October 1, 1994, through September 30, 1995), veterinarians from the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) and the States conducted 270 investigations for suspected foreign animal diseases (FAD) (see Figure 1). These actions are part of the Emergency Programs (EP) approach to FAD surveillance to insure that exotic diseases do not become established in the United States or its territories.

As shown in Figure 2, the investigations included 109 (40.3%) vesicular conditions (excluding 1995 vesicular stomatitis outbreak associated investigations), 41 (15.1%) bovine spongiform encephalopathies, 33 (12.2%) encephalitic/CNS disorders, 31 (11.4%) avian diseases, 16 (5.9%) mucosal disease conditions, 11 (4%) septicemia conditions, 8 (2.9%) abortion cases, 8 (2.9%) conditions categorized as miscellaneous, 5 (1.8%) poxlike conditions, 4 (1.4%) acute deaths of unknown origin, 2 (.74%) myiasis/acariasis, and 2 (.74%) unusual respiratory conditions.
Figure 2

FAD investigations by species are shown in Figure 3.
Due to the vesicular stomatitis outbreak, a Task Force was set up in the Western States in May 1995. Vesicular investigations completed while the Task Force was in place are reported here.

Vesicular Stomatitis Surveillance: As of September 30, 1995, the Vesicular Stomatitis Task Force conducted a total of 803 premise investigations. There were a total of 315 case premises, positive premises consisting of 184 case positive premises in New Mexico, 125 case positive premises in Colorado, 1 case positive premise in Arizona, 1 case positive premise in Texas, and 4 case positive premises in Utah.

There were 39 bovine only case positive premises, 221 equine only case positive premises, 30 case positive premises with bovine and equine, and 25 case positive premises involving bovine and/or equine plus another species (llama, etc).

The New Jersey strain of the vesicular stomatitis virus was identified as the cause of the vesicular stomatitis outbreak. Surveillance and control measures were continued into FY 96.

The epidemiologic curve for the Vesicular Stomatitis 1995 Outbreak is shown in Figure 4 below.
Bovine Spongiform Encephalopathy (BSE) Surveillance:
The BSE surveillance program which started in May 1990 is continuing. Pathologists at the National Veterinary Services Laboratories (NVSL) and Iowa State University are continuing to examine bovine brains submitted to NVSL from the following sources: 1) foreign animal disease investigations where suspected encephalitic conditions in cattle are reported, 2) bovine cases confirmed negative for rabies by the Centers for Disease Control in Atlanta, Georgia, 3) brain specimens collected at slaughter from abattoirs in selected potential high risk States, and 4) brain tissues submitted by veterinary diagnostic laboratories in the United States. To enhance the surveillance process, visits have been made by State or USDA personnel to State public health and university diagnostic laboratories to arrange for the submission of suspicious specimens to NVSL in Ames, Iowa. Contacts with practicing veterinarians have also been made to increase reporting and the submission of brains from suspicious cattle. As of September 30, 1995, a total of 2,411 bovine brains have been examined (508 in 1995); none of these specimens contained characteristic lesions for BSE. Additionally, none of the traced cattle, (463 out of 499), that were imported from the United Kingdom since 1981, have shown any clinical signs of BSE. There have been no cases of BSE diagnosed in the United States. APHIS is unable to locate 36 of the 499 animals imported from the United Kingdom. Due to age, it can be assumed that a majority of these animals are dead.

Hog Cholera/African Swine Fever Surveillance:
The VS surveillance program for classical swine fever (hog cholera) and African swine fever was continued in 1995. Swine blood specimens are regularly collected at slaughter from abattoirs located in Maine, Massachusetts, New Hampshire, New Jersey, Arizona, Texas, and Puerto Rico. NVSL in Ames, Iowa, tested 8,668 samples and all were determined to be negative for the two diseases.

Highly Pathogenic Avian Influenza:
Emergency Programs of APHIS, Veterinary Services continues to prepare for a possible introduction of highly pathogenic avian influenza (HPAI). An avian influenza working group was organized in early 1995. This APHIS group looked at risk factors for the United States from Mexico (Dr. R. Crom, CEAH - Risk Assessment), developed an action plan to compliment the APHIS HPAI Eradication Guidelines, organized a series of State/Federal/industry meetings to address concerns and improve emergency preparedness, established an AI List Server for information sharing, and organized two U.S. delegations to Mexico to study HPAI and the effectiveness of avian influenza vaccine.

Following a formal recommendation from the 1995 NPIP National Conference, APHIS proposes to expand the working group to include industry and USAHA officials and organize it within the AI Subcommittee of the USAHA
Committee on Transmissible Diseases of Poultry.

A preliminary analysis on the national AI surveillance program was conducted. The number of tests has increased in 1995 from 1994 (350K from 250K) but at least two States appear to have inadequate testing at this time.

The focus of our emergency preparedness and response will be the agents H5 and H7 and the host will be (commercial) chickens. APHIS will continue to actively survey the live-bird markets in the Northeast and use sentinel chickens in selected markets in Florida. (The continuing efforts of the turkey industry in strong surveillance and control & eradication efforts must be acknowledged. The unique State-wide use of an autogenous H7 vaccine in turkeys in one Western State was supported by APHIS in 1995.)

APHIS made the decision in July 1995 to rescind the restriction on the manufacture of avian influenza vaccines in the United States. This includes H5 and H7 vaccines. There has been a very high level of concern from the U.S. poultry industry on this issue. All AI vaccines for use in chickens, and all H5 and H7 vaccines, will have distribution restrictions. Limitations include permission from State officials to use the vaccine. In addition, APHIS, VS, will control the use of the vaccine(s) "as part of an official disease control program." (See APHIS Veterinary Biologics Memorandum No. 800.85.)

APHIS has supported the full licensure and study of recombinant fowl pox vectored avian influenza vaccines. Mexico has recently received a sample that will allow them to conduct their own safety and efficacy studies.

There is a State duck viral enteritis transmission and vaccine study in domestic waterfowl being conducted. The objectives of the study are to determine the transmissibility of duck viral enteritis (DVE) from waterfowl survivors of a DVE outbreak to immunologically naive Muscovy ducks and evaluate the ability of a modified live virus vaccine to confer protective immunity to Muscovy ducks against natural challenge to DVE.

USDA, APHIS, has also agreed to perform limited tracebacks on the distribution and source of Psittacosis-infected pet birds that the Centers for Disease Control and Prevention (CDC) is currently investigating. Human psittacosis cases have been associated with shipments of pet birds to a national retail pet store chain.

Newcastle disease reappeared in double-crested cormorants in Canada this summer. Clinical neurological disease was observed only in young-of-the-year cormorants. The virus isolates appear to be similar to the viruses isolated in cormorants in 1990 and 1992. There has been no evidence of extension of infection into domestic poultry.

Acaricide resistance in populations of cattle fever ticks in Mexico:

In 1985, the Mexican authorities reported acaricide resistance in populations of Boophilus (cattle fever) ticks to coumaphos, an organophosphate (OP) acaricide. Coumaphos resistant ticks have been reported in the Gulf Coast region around Veracruz, in the Yucatan Peninsula, the state of Chiapas,
and in areas of the Southwest coast. In 1994, the Mexican authorities reported resistance in populations of *Boophilus* ticks to deltamethrin, flumethrin, and cypermethrin (all are synthetic pyrethroid (SP) acaricides).

With the increased problem of acaricide resistance in Mexican cattle fever ticks to new classes of acaricides, the probability of introduction of these ticks into the United States becomes much more likely. This year, there were two new cases of a suspected coumaphos resistant population of ticks on cattle presented at the border. This is a serious threat to the cattle fever tick prevention programs of the United States.

A new effort has been made to open a dialog with the Mexican authorities on this issue so that information on the status and scope of the acaricide resistance problem is openly discussed. How the Animal and Plant Health Inspection Service (APHIS) prepares for this problem will depend on free exchange of information.

**Coumaphos residue problems in meat of slaughter animals from Mexico:**

About 18 months ago, Food Safety and Inspection Service (FSIS) notified APHIS that they had found some horses imported from Mexico for immediate slaughter to have violative levels of coumaphos in fat tissue (kidney fat). Shortly after the notification, APHIS closed the border to all importations of horses because of the Venezuelan equine encephalomyelitis outbreak in Mexico. When the border was again opened to importation of slaughter horses in April, 1995, horses were dipped in coumaphos at 0.165 to 0.20 rather than the 0.3 normally required. These animals were held at the slaughter plant for an additional 10 days before slaughter to see if the residue problem could be corrected. The holding period does allow time for the animal to excrete the coumaphos.

In July 1995, FSIS notified APHIS that they had found violative levels of coumaphos in tissues from immediate slaughter cattle of Mexican origin. One sample was as high as 3 ppm. of coumaphos. Of approximately 200 samples taken, about 25 percent have had violative levels of coumaphos in the fat tissue.

A temporary prohibition of Mexican slaughter animals entering the United States was established until a solution to the coumaphos residue problem could be worked out with the Mexican authorities. In order to resume the importation of Mexican animals going direct to slaughter, the animals must be inspected and treated at least once for ticks in dip-vats charged with a synthetic pyrethroid, a new class of acaricide. All animals going direct to slaughter must utilize only those port of embarkation facilities with two dip-vats. The ports of embarkation where animals going direct to slaughter will be required to go for entry into the United States are located at Laredo, Texas; Del Rio, Texas; Santa Teresa, New Mexico; and Douglas, Arizona. At each of these four port of embarkation facilities, one of the dip-vats will be charged with the new acaricide, atroban, and will be used to treat only the direct to slaughter animals. Direct to slaughter animals will be rejected for entry into the United States if presented at any other port of embarkation.
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Dr. John Williams
Director
Emergency Programs, APHIS/VS

BSE Surveillance in the United States
Since May, 1990, when the BSE surveillance program began, until September 1995, 2,411 specimens have been examined for BSE. The total on September 30, 1994 was 1,903. Thus, 508 samples were examined in 1995. Cattle that would be considered as BSE suspects fit into the following categories:
- Animals that demonstrate a change in mental status;
- Animals that demonstrate a change in sensitivity to light, touch, or sound;
- Animals that demonstrate a change in posture; and
- Animals that demonstrate a change in movement.

The sources of these specimens have been:
- Foreign animal disease investigations;
- Suspected rabies cases (after testing negative for rabies they were tested for BSE);
- Submissions by private practitioners; and
- Slaughter house collections.

Thirteen slaughter plants have been targeted in five selected states to participate in a FSIS pilot project. These states are:
- California;
- Texas;
- Wisconsin;
- Michigan; and
- Iowa.

United States Import Restrictions
APHIS prohibits the importation of live cattle from countries affected with BSE. Countries recognized as being affected with BSE are listed in part 94.18, title 9 or the CFR. They are as follows:
- France;
- Great Britain;
- Northern Ireland;
- Republic of Ireland;
- Oman;
- Portugal; and
- Switzerland.

Restrictions on the importation of beef and bovine products are also cov-
BOVINE SPONGIFORM ENCEPHALOPHTY (BSE)

Bovine semen and embryos may be imported from BSE affected countries under permit and certification by the exporting country.

Cattle imported from the United Kingdom

From January, 1981 until the ban on live bovine imports from the United Kingdom in July of 1989, 499 head of cattle were imported into the United States.

As of September, 1995, 121 of the 499 animals are known to be alive in the United States, 334 are known to be dead, 8 were exported. APHIS has been unable to trace the remaining 36 animals. Efforts are still being made to locate them, however, due to age many of them can be presumed dead.

BSE in Great Britain

As of September, 1995, Great Britain has reported 152,470 cases of BSE. These cases have been distributed among 32,719 herds. 53.8% of the dairy herds have been affected while only 15% of the beef herds have been affected. This difference is most likely due to the differences in management between the two types of operations. Most of which is the types of feed fed to the animals.

According to the "Great Britain BSE Progress Report" the number of weekly reported BSE cases has been steadily going down since the peak in January of 1993. This has been attributed to the ruminant feed ban.

BSE Issues Management Team

The BSE Issues Management Team was created in January of 1995. The duties and responsibilities of the BSE Issues Management Team are as follows:

- Evaluate current information on BSE;
- Analyze and manage risks of BSE in the United States;
- Assess the BSE surveillance and preparedness programs;
- Disseminate accurate information about BSE; and
- Act as a reference source.
- Emergency Programs will manage the overall BSE program.

Activities of the BSE Issues Management Team in 1995

- A risk assessment on the importation of pet food from BSE affected countries was completed.
- A risk assessment on the importation of products of bovine origin from BSE affected countries was completed.
- A risk assessment was completed on the potential risk that one or more of the cattle imported from the United Kingdom could develop BSE.
WILLIAMS

- Decision memorandum on the importation of pet food was written.
- Decision memorandum on the importation of products of bovine origin was written.
- Decision memorandum on the management of cattle imported from the United Kingdom was written.

Activities in 1996

- Evaluate the BSE surveillance program. This will include a possible change in the targeted slaughter plants and states.
- Training for APHIS veterinarians in the collection of BSE diagnostic samples.
- Monitor the status of the cattle imported from the United Kingdom. This may include a decision to purchase and depopulate these animals. The purpose for which is to eliminate any potential for one or more of them from developing BSE. A risk assessment demonstrated that there is a 12.7% probability that one or more of the imported cattle could develop BSE in the United States. (The BSE case in Canada was in an animal imported form the United Kingdom).
- Review and rewrite the BSE emergency disease guidelines.
Dr. Don A. Franco from Animal Protein Producer Industry explained the current Hazard Analysis and Critical Control Points (HACCP) Guidelines for the rendering industry. He reviewed the basic principles of HACCP, the regulatory perspective and rationale for HACCP, the development of an action plan with detailed examples and appendices with working details for training the work force. The concept introduces the attributes of a preventative system of controls that properly applied in a rendering plant will prevent hazards and assure a quality end product. Approximately 94% of rendering plants have received copies of the guidelines. Many companies are working diligently to incorporate the HACCP principles into their managerial infrastructures. Some plants will have HACCP operational before the end of 1995, long before our planned projections for implementation.

Dr. Daniel McChesney, CVM, FSA, presented the following reports on a recent FDA survey on the presence of Salmonella Contamination of finished feed.

FDA district offices are collecting samples of complete feed and the primary animal or vegetable meal in the feed. The samples are being collected from 100 commercial feed mills and 20 on-farm mixers. The on-farm mixers were randomly selected from FDA’s Official Establishment Inventory (OEI). Each district was assigned a specific number of
commercial feed mills based on the number of registered feed mills within the district. The selection of the feed mills at which samples were collected was determined by the district. However, the district was instructed to select mills that would be representative of the feeds manufactured in the district. Medicated feeds were included in the sampling. Each sample of meal and complete feed consisted of 30 individual subsamples which were aseptically collected. Analysis followed the procedures outlined in FDA’s BAM and included serogrouping and serotyping. For the purpose of analysis, the 30 subsamples were composites into two 15 unit composites. The results I am reporting today represent data from 1980 meals subsamples and 1860 complete feed subsamples covering 66 meals and 62 complete feeds respectively.

Sixteen percent of the complete feeds and 48% of the meals were positive for salmonella. When the meals were grouped by animal and vegetable source, 82% of the animal meals and 37% of the vegetable meals were positive for salmonella. When the meal and complete feed pairs were compared, if the meal was positive, the complete feed was also positive in 30% of the samples. Alternatively, 70% of feed samples made with positive meal were negative for salmonella. There was one case in which the meal was negative and the complete feed positive (3%) and 32 cases in which both the meal and feed were negative (97%).

Robert Firth, a project engineer with California Pellet Mill Co., presented the following review of recent feed processing procedures and related equipment. The following is a quote from his presentation.

**Recent Innovations in Process and Equipment**

In the last several years some small numbers of steam-jacketed conditioners have been sold, which add about 10 to 15 degrees F to conventional conditioning temperatures; and there is increasing use of thinner dies which allow more moisturization and increased temperature before roll-slip occurs. In Europe there is the SIRT conditioning system which incorporates a long retention time holding chamber after the conditioner, to achieve positive feed sterilization. Also in Europe, double pelleting is popular (two pellet mills in series), but has not caught on in the U.S. In general the trend is toward larger, higher HP pellet mills and consolidation of small plants into fewer, larger capacity plants.

**Newest Most Promising Equipment: The Expander**

The most important new equipment introduced in the U.S. in the last two years is the annular-gap “expander,” which is like a screw extruder, but having an annular ring opening instead of a die plate. This produces an unshaped, hot, densified, kneaded product which is then pelleted by a pellet mill, usually fitted with a thin die. A conventional conditioner pre-
FEED SAFETY

cedes the expander. The feed meal passes through the expander rapidly, experiencing high pressure and temperature for a few seconds. This system affords cost savings through utilization of lower cost ingredients, increases pellet quality, and increases conversion ratios in the animals. The down side is increased energy and maintenance costs. This has been used successfully in Europe for several years.

Dr. Tom Holder reviewed the FSIS National Forum on Animal Production. He stated that ...

Many good and useful ideas came out of this forum which should be activated. (1) USDA-FSIS should not mandate federal regulations in animal production. (2) Good management practices should be used rather than HACCP. (3) More science-based research is needed. (4) USDA should coordinate and fund research. (5) USDA should serve as a forum for information sharing.

The broiler, table-egg and turkey working group passed a resolution along with the beef cattle, dairy and veal work groups. The swine group did not support the resolution.

The resolution reads—

Therefore be it resolved that a committee appointed by the USAHA president by activated and used as a mechanism through which ongoing dialogue and discussions can be held on the food safety issue. The USAHA should participate in the planning and subsequent implementation and evaluation of any proposed preharvest food safety initiative.

This committee has been appointed and had its first meeting during the current USAHA program.

Richard Sellers, American Feed Industry Association, presented comments made to FDA regarding proposed rulemaking on the development of HACCP programs for the food industry. Below, in part, is a summary which covers his presentation.

AFIA supports the voluntary use of HACCP-type approach in the feed industry for the continued minimization of microbiological contamination of animal feeds. The HACCP-type approach to minimize microbiological contamination is currently practiced through 21 C.F.R. 225, medicated feed CGMPs. Reputable feed manufacturers follow sound sanitation practices today. This voluntary approach has worked well for our industry, as AFIA is not aware of any documented U.S. cases of food-borne illnesses caused by microbial feed contamination. Not only are the hazards speculative, there is no viable and rapid testing method for pathogen detection.

Although AFIA believes a voluntary HACCP-type program has and is sufficient, if FDA mandates an HACCP program for the feed industry, such a program should focus on high risk areas of potential contamina-
REPORT OF THE COMMITTEE

tion and only those areas where risks can be defined. Any adoption of a reasonable HACCP program should result in a meaningful and cost-effective control of any microbial contamination problem.

Animal feed has not been a human safety concern for microbial contamination. There has been no cause for veterinary or human health concerns. Accordingly, FDA should focus its resources where real food safety issues can be addressed and effective HACCP programs implemented. In the case of microbial hazards, the single current intervention technique which is effective is proper cooking of product. Given this, it would seem logical for FDA to focus on the food service establishments and work with USDA to educate consumers about home food preparation practices. AFIA applauds USDA's requirement of safe handling instructions for raw meat and poultry products as a major step in home food preparation education.

Vern Moore, Chairperson of the Transportation Subcommittee, presented the following report.

On March 12, 1992, Morris Cover distributed "Charge to Committees," which suggested goals for each subcommittee of the Feed Safety Committee. The suggested charges for the Transportation Subcommittee were the following:

- Determining the percentage of feed and feed ingredients moved by truck, rail, and barge.
- Identifying all procedures now being used to control microbiological contamination and initiating scientific evaluation of one or more of these procedures.
- Proposing to the full Committee programs, methods or procedures that would reduce/prevent contamination of feed ingredients and complete feed.

Today's report is a review of progress to date on each of these suggested charges by the Transportation Subcommittee.

Relative to the first charge, during 1993 the Transportation Subcommittee used two separate surveys in an attempt to determine the percentage of feed and feed ingredients moved by truck, rail, and barge. The first survey was sent to the nine largest feed ingredient organizations. The second survey was sent to the 10 largest feed manufacturers. Neither survey yielded very many responses nor very much information, the information that was received being insufficient to reach many conclusions. No further surveys have been attempted since.

Relative to the third charge, the Transportation Subcommittee completed its work on this charge when it presented provisional guidelines for an HACCP program for the transportation industry in the 1994 USAHA 98th Annual Meeting in Grand Rapids, Michigan. No further work is planned...
FEED SAFETY

on this charge.

At that same meeting, the Microbiology Subcommittee, in order to better understand the degree to which vehicles used for transporting feed and feed ingredients might be contributing to the contamination of feed/feed ingredients, recommended sampling empty transport tanks, trailers or cars using the standard drag swab method used by the SE task force for environmental sampling to assess the frequency of salmonella contamination. No action has been taken to date on this recommendation.

Relative to the last charge (charge number 2), the Subcommittee is now formulating a plan to address this charge. We hope to be able to report back to the Committee on this charge at our next meeting.

Dr. Hans Riemann, Department of Population Health and Reproduction, University of California, Davis, presented a report on destruction of salmonella in animal feed.

Salmonella occurs frequently in animal feed and contaminated feed has been shown to cause infection in animals and ultimately in humans12.

Salmonella in feed can be destroyed by the right combination of time, temperature and moisture. In the present study, salmonella was inoculated into commercial feed which was then permitted to dry at 40°F for 3 weeks. The moisture content of the feed was adjusted to different levels and the feed was heated in thin layers in a waterbath and immediately cooled in ice water. Surviving salmonella was counted on brain heart infusion agar.

The killing of salmonella was most rapid at the beginning of the heating process, probably because some salmonella are protected by fat or particulate components of the feed. For this reason straight line survivor curves were obtained when the logs (ratio antilog colony counts) were plotted against time which, in turn, permitted statistical validation of the results.

Table 1 shows that all three factors (time, temperature and moisture) have importance for the destruction of salmonella. At optimal conditions - 180°F, 15% moisture and 40 seconds heating - 99.99% of the organisms were killed. The same degree of kill occurs at a lower temperature - 160°F - if 0.2% propionic acid is added to the feed. These results were obtained with Salmonella enteritidis and were confirmed in additional experiments with Salmonella typhimurium and Salmonella haardt.

The results of field studies, shown in table 2, support the laboratory results. The field studies were conducted with a commercial conditioner that has a capacity of 18000 pounds per hour. Fourteen to 16% moisture resulted in good pellet quality.

The heat destruction of salmonella and other non-sporeforming bacteria in animal feed is thus a fairly simple and reliable process. If this process is applied commercially, it will constitute a critical point that is
REPORT OF THE COMMITTEE

easy to control in an HACCP program. The next most important critical control point is the prevention of recontamination of the feed.

References


Table 1. Effect of time, temperature and moisture on destruction of Salmonella enteritidis in animal feed.

<table>
<thead>
<tr>
<th>Temperature: 160°F</th>
<th>Moisture</th>
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<th>10%</th>
<th>15%</th>
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<tr>
<td>20 sec.</td>
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<td>68.22% kill</td>
<td>83.44% kill</td>
<td>90.06% kill</td>
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<td>40 sec.</td>
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<td>73.5%</td>
<td>86.35%</td>
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<td>99.02%</td>
<td>99.99%</td>
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<tr>
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<td>91.62%</td>
<td>99.19%</td>
<td>99.98%</td>
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</table>

Table 2. Numbers of enteric bacteria in mash and after conditioning (185-195°F, 60-90 seconds, 14-16% moisture) and pelleting.

<table>
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<tr>
<th>Date</th>
<th>Sample</th>
<th>Enterics in 750 grams</th>
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<tr>
<td>8-Jul</td>
<td>Mash</td>
<td>18 million</td>
</tr>
<tr>
<td></td>
<td>Fresh pellets</td>
<td>3000</td>
</tr>
<tr>
<td></td>
<td>Pellets at loading</td>
<td>2000</td>
</tr>
<tr>
<td>5-Aug</td>
<td>Mash</td>
<td>10 million</td>
</tr>
<tr>
<td></td>
<td>Fresh pellets</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td>Pellets at loading</td>
<td>2</td>
</tr>
<tr>
<td>19-Aug</td>
<td>Mash</td>
<td>700000</td>
</tr>
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<td></td>
<td>Fresh pellets</td>
<td>&lt;1</td>
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Update on National Pork Producers Council’s Feed Safety Activities
Dr. Beth Lautner

In 1994, four preharvest food safety projects were funded with producer checkoff dollars that included sampling of feed for Salmonella on-farm. The projects were designed to look at a variety of on-farm production practices and their relationship to Salmonella levels on-farm. In 1995, two projects were funded that included Salmonella feed sampling as well as other environmental and animal sampling. The 1995 NAHMS Swine Survey to be conducted by APHIS will include feed sampling for Salmonella. NPPC in conjunction with the Agricultural Research Service is organizing a Swine Salmonella Symposium early next year. In addition, NPPC is supporting the development of a comprehensive literature review on Salmonella in swine feeds.

Dr. Jerry Torrison, Health Assurance Manager, PIC USA

PIC USA has been developing strategies for pre-harvest food safety programming. Among the areas being addressed are aspects of feed component, processing and delivery standards. Strategies being developed will make use of concepts and practices developed by associate companies in Europe involved in production of animal feed and breeding stock, tailoring appropriate methods to the North American market. Current European standards and practices will be discussed.

The following are summaries of two reports by Paula J. Fedorka-Cray.

1. Salmonella in Swine Feed Environment
   Sample of feed and feed ingredients were collected from 30 pig farms in eight states and cultured for the presence of Salmonella spp. At the same time, information was gathered on physical and managerial characteristics of each farm. Salmonellae were isolated from at least one feed or ingredient in 14 (47%) of the 30 herds surveyed representing five states. Of a total of 1264 samples, salmonellae were isolated from 36 (2.9%). Thirteen different serotypes and two that were untypable were isolated. The finding of Salmonella spp. in the feed had a statistically significant association with six of the herd characteristics surveyed including the lack of bird-proofing measures employed on the farm (p=0.03), using finisher feed that was prepared on the farm versus purchasing such feed (p=0.008), and housing pigs in facilities other than total confinement in the grower (p<0.025), finisher (p<0.025), gestation (OR=27, 95%CI: 1.305-555.57), and breeding (p<0.005) stages of production. These data suggest that certain management practices may be related to the occurrence of Salmonella spp. in the farm feed environment.

2. Feed Trucks as a Source of Salmonella
   Cary-Blair culture transport swabs were moistened in PBS and used to swab approximately 25 different areas of the grain box on 22 different feed trucks in 3 states. In addition, a sample of the feed type was placed into the
remaining PBS for culture. Swabs were qualitatively analyzed for the presence of *Salmonella* in both tetrathionate and GN Hajna broth followed by subculture into Rappaport Medium (R-10). Cultures were streaked onto Brilliant Green agar with sulfadiazine plates. Colonies exhibiting typical salmonellae-like morphology were transferred to Triple Sugar Iron agar and Lysine Iron agar slants for biochemical confirmation. Presumptive positive isolates were serogrouped with *Salmonella* typing sera prior to submission to the National Veterinary Services Laboratories, Ames, Iowa, for serotyping. A questionnaire was also filled out for each truck to assess environmental factors which may have impacted on the results. Trucks and/or feed were positive for 5/22 trucks for a prevalence rate of 22.7%. Four of 549 swabs were cultured for a sample prevalence of 0.7%. Three of 22 trucks were positive (13.6%) while feed was positive from 4/22 samples (18.1%). However, positive trucks and feed only matched for 2 trucks. Meat/bone meal, fish, and bone and meat meal separately and soybean meal were all positive for *Salmonella*. More trucks containing meat, bone or fish meal were positive than those containing vegetable-based feeds. Three of the 22 trucks were open to environmental contaminants. However, only 1 truck had visible signs of contamination which was identified as soybean mold. No trucks had been used to transport livestock within the past 30 days nor were any trucks cleaned or disinfected between loads. These data indicate that while sample prevalence of *Salmonella* in feed trucks is low (0.7%) the overall contamination rate for feed trucks is much higher (22%). The presence of positive feed samples suggests that this would be a source of contamination for farm animals. However, because we did not quantitate the levels of *Salmonella* within the feed, we can only speculate as to its importance. Low levels of contamination would probably be significantly reduced or destroyed following pelleting while higher levels may not. Therefore, the use of properly processed feed cannot be overemphasized. Because none of the trucks were cleaned or disinfected between loads, failure to do so would allow for the perpetuation of the contaminant to be passed to subsequent loads.

Dr. G. A. Mitchell (C.V.M.) indicated that the Feed Safety Committee USAHA was working well as a forum for discussions. He emphasized CVM's desire to work as a partner in reaching the goals of reducing the presence of pathogenic microorganisms in feed for food animals. CVM's plans for 95/96 were discussed.
REPORT OF THE COMMITTEE ON FOOD SAFETY

Chairman: Dr. Joseph L. Blair, Annandale, VA
Vice Chairman: Dr. Richard D. Willer, Phoenix, AZ

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The Committee on Food Safety was called to order by Chairman Dr. Joe Blair at 1:30 p.m., October 30, 1995. Approximately 110 persons, including thirty-five (35) Committee members, were in attendance.

Dr. Bonnie Buntain, Director, Animal Production Food Safety Program, FSIS, USDA, gave the group an update on the activities of her organization. In her update on animal production food safety (APFS), she reemphasized that the agenda for change was to establish a farm to fork strategy for the reduction/prevention of foodborne disease with risk reduction strategies being key components all along this continuum. Before specifically discussing APFS, Dr. Buntain touched briefly on the proposed Pathogen Reduction/ HACCP Regulation and its use in processing/packing plants, discussed FSIS’s efforts to work with the FDA to establish standards for the transportation component of the continuum, and mentioned FSIS’s plans to encourage states to adopt the model food code for coverage at the retail level of the continuum.

Dr. Buntain summarized the findings of the Animal Production Technical Analysis Group (AP-TAG), which was the launching pad for two national forums held the past two years on animal production food safety. She also summarized the findings of both of the forums, and distributed the proceedings of the two meetings at this USAHA meeting. Of special note are the findings that FSIS has no intention of moving toward additional regulation, or the strategy of eradication and compensation of producers, but instead intends to move toward cooperation and collaboration with producers, industry, researchers, animal health officials, and other involved entities to incorporate risk reduction strategies.

At a recent meeting of USDA and the WHO, several items were sup-
ported by the international community. These include a consensus that the responsibility is on the producers to implement good management practices to reduce pathogen risk, that industry should be encouraged to self-regulate, that the preharvest area of the farm to fork continuum is important, and that everyone along the chain needs to be educated as to their responsibilities.

Dr. Buntain concluded with a discussion of the current status of APFS relative to their mission. They have met with many groups over the past year who have provided input as to what FSIS’s responsibilities should be in this area. She stated that FSIS intends to assist with research as well as facilitate research outside the agency. She emphasized that the USAHA is a key player in facilitating dialog of the various groups involved. FSIS will promote partnerships and foster collaboration, as well as support the efforts of the private sector to develop answers to the many problems encountered. FSIS will not mandate any programs at the farm level; changes will certainly be market driven. Finally, Dr. Buntain offered a challenge to the USAHA to play a leadership role in implementing farm to table food safety strategies at the national as well as state level.

Dr. Bob Teclaw, Regional Epidemiologist, APHIS, USDA, Indianapolis, IN, updated the Committee on the National Trichinae Research Program. He reported that the project has focused attention on the development of a prototype certification program which will help to identify infected animals and herds prior to the time they are offered for slaughter. Although the incidence of human infection has dramatically decreased in the U.S. (about 1,000 cases per year) and the prevalence of infected market hogs has dropped to 0.11%, a lack of individual animal testing for trichinae is a problem in marketing fresh pork products in Europe and other countries. Efforts are being made to validate an ELISA trichina test for on farm use as well as to identify risk factors associated with herds most likely to be infected. He also reported that one estimate by a federal agency predicted a one-third increase in our exports and a $449 million increase in revenue received from export of fresh pork if irradiation were considered as a means of destroying the trichinae cysts.

Future plans for the Research Project include completion of the efficacy studies for the ELISA test, characterize herds and risk factors, working with infected herds to attain free status, conducting a national prevalence study (subject to obtaining funding), develop a prototype certification program, do an economic effects analysis, look at high risk herds not identified in the random survey, and to lay groundwork for our trading partners’ expectations for trichinae free pork.

Dr. George Lewis, Forest Resources and Aquaculture, University of Georgia reported on aquaculture in commercially raised fish. He reported on a particular project that was an outgrowth of concern for regional production of seafood (which was also addressed in the 1995 Farm Bill). Five aquaculture centers throughout the U.S. participated in the 3-year cooperative research project with objectives to define aquaculture food safety problems; design
control programs; develop HACCP concepts for processing aquacultured products; and implement HACCP projects for molluscan shellfish, catfish, crawfish and trout. Two broad areas of emphasis were identification and control of microbial contaminants and pesticide residues.

Spoilage organisms were identified as *Listeria, Clostridia, Salmonella spp.* and *E. coli*, with *Listeria* being the most prevalent. Various rinses to decrease microbial contamination as well as the effects of different packaging procedures were considered during the project. Also germane to the study was the realization that microbial contamination increased 1,000-fold during processing, 100-fold each during final marketing and distribution.

The pesticide section of the project was concerned primarily with heavy metals. An effort was made to distinguish commercially raised seafood from those raised in their natural environment. Several minor problems were found and were related to improper application of a row-crop pesticide and improper use of old transformers which had previously contained PCB's. As a result of the study, articles have been published which provide bibliographies of pertinent information as well as applicable quality assurance programs.

Dr. Fred Trout, Department of Veterinary Clinical Medicine, University of Illinois presented a paradigm, as a production medicine clinician, for teaching veterinary students food safety. Dr. Trout's paradigm called for an integrated, linear approach to be incorporated throughout the 4-year course of study rather than into a specific course. The preventive component of the practice of veterinary medicine needs to be emphasized along with the interventional component traditionally emphasized. Veterinarians are essential not only in taking care of food animals, but also in the production of wholesome food from those animals.

Freshmen and sophomore veterinary students should be introduced to food safety with the same zeal that they are introduced to anatomy and physiology. Examples of food safety concerns can be introduced during discussions in these basic classes, for instance during the study of the normal anatomy and physiology of the gastrointestinal tract. During the junior year, courses in public health and epidemiology should adopt a clinical approach to food safety with emphasis on the utilization of problem solving skills to control a food safety disease problem. Finally, during the senior year, emphasis can be placed on treating the “sick farm” just as a sick animal would be treated. The farm workup should include consideration of rule-outs for foodborne pathogens and expressions of control with reinforcement of sanitation and hygiene practices as the basis for common sense control strategies. It is during this clinical year that students should become familiar with quality assurance programs and their application to food safety problems.

Mr. Steve Krut, President of the International Meat & Poultry HACCP Alliance and Executive Director of the American Association of Meat Processors spoke to the group on HACCP in the small plant. The current idea to shift responsibility for product safety to industry is not new to the small indus-
REPORT OF THE COMMITTEE

try since it has considered itself responsible for the safety of its product for many years. After reviewing the FSIS proposed HACCP regulation, more than 80% of the small plants indicated they could not survive the new program due to the type of operations performed in their plants. Most small plants produce a notable variety of products from more than one species of food animal. The necessity for a HACCP program for each product by species would be overwhelm the small operator, thereby causing a demise of his business and livelihood. He stressed that the small plants were NOT seeking any kind of exemption but rather that standards need to be designed so that they can be equitably apply to all plants.

Small plants support the idea of product testing for microbiological contaminants but feel that it should be more product specific. Concern was also expressed regarding the frequency of microbial testing. The cost associated with the testing of a small volume of multiple products from several species is economically unfeasible for small plants.

The need for training in HACCP is great, and the speaker encouraged joint training sessions with industry and inspection personnel to foster a more cooperative approach to HACCP. Canada, Great Britain, Australia and other countries already using HACCP were cited as examples of how the standardization in training promoted successful HACCP programs. The use of existing colleges and universities to teach HACCP was also encouraged.

Other concerns raised by Mr. Krut included:

1. Near-term initiatives such as the 40 degree F. requirement for cooling products needs further assessment;
2. Lack of FSIS review/approval of tailor-made HACCP programs;
3. The compliance aspect of HACCP.
4. Industry should be allowed to retain the present system or choose HACCP;
5. An impact study is needed for small plants.

Mr. Krut also made a point critical to the general issue of food safety, regardless of anyone's affiliation. An awareness of food safety and subsequent hazards of unsafe food is needed by the general population. His recommendation to seek mandatory food safety training in the school system is noteworthy. He emphasized that all involved, including the consumer, have food safety responsibilities. Education as to those responsibilities is crucial.

Dr. Arthur Miller, Research Leader, Microbial Food Safety Research, ARS, USDA, Philadelphia, PA gave a paper entitled, "Strategies for the Elimination of Fecal Contamination on Food Animals and Carcasses." Heightened awareness of the link between the presence of fecal contamination on slaughter animals and human foodborne illness has sparked efforts to reduce bacterial pathogens on muscle foods. Enteric bacteria of most concern include: Salmonella spp., pathogenic Escherichia coli, Campylobacter jejuni/coli, and Listeria monocytogenes. Safe food production requires a hazard analysis to determine possible entry points of pathogens into the food chain. Interven-
FOOD SAFETY

tions then need to be devised to block, to limit entry, or to prevent pathogen growth at each stage of the farm-to-table continuum. In live animals, intensive management practices, crowding, and transportation stresses potentiate pathogen shedding. Such preharvest sources can cause cross-contamination from shedders to other animals via bedding and floors or direct contact by skin, hair, or feathers. Strategies for preventing fecal contamination on live animals include: avoidance by such measures as vaccines; identification and isolation of pathogen shedding animals; controlled feed withdrawal; reduction of transportation stresses; washing hauling trucks, cages, and holding pens; and washing live animals. In the slaughter environment, fecal material is spread by machinery and animal-to-animal contact. Enteric pathogens attached to the carcasses and processing surfaces form biofilms, which are difficult to remove. During slaughter operations, a variety of approaches have been attempted to reduce fecal contamination on carcasses. Prevention interventions include carcass washing and bung or vent sealing. Post-evisceration interventions include: knife trimming; steam pasteurization; carcass rinses using hot water, inorganic or organic solutes; and ionizing and non-ionizing radiation. During slaughter operations, measures need to be initiated to minimize cross-contamination by line personnel. These include: hand washing; knife sanitizing; and sanitizing of personal protection devices, such as rubber and mesh gloves. Dr. Miller described a process at Hatfield Quality Meats (Hatfield, PA) which uses an on-line, real-time continuous scoring and feedback system for the visual detection and hand trimming of fecal contamination on pork carcasses. This system is employee driven, and over a multi-year period the carcass contamination rate has dropped by over half. Using this concept, it may be possible in the future to develop sensor-based technologies for the instant detection of fecal contamination or specific pathogens. In the interest of public health, the goal of all intervention systems should be to prevent or detect and remove fecal contamination efficiently at the earliest stage in food production. In addition, multiple barriers are needed for the most effective prevention of fecal contamination on food animals and carcasses.

There was a short business session at which the day and time for future Committee meetings and miscellaneous "house-keeping" items were discussed.

The Committee on Food Safety recommends that the USAHA urge USDA to provide and/or facilitate assistance in HACCP training for small slaughter and processing plants, especially those under state inspection systems. Training for trainers, sponsorship for training of industry and inspection personnel, and financial assistance are needed. FSIS, the International Meat & Poultry HACCP Alliance and the Extension Service are urged to develop this assistance.

The meeting adjourned at 5:30 p.m.
THE CONTRIBUTION OF EXANDIS AND AAHC TO THE EVOLUTION OF ANIMAL HEALTH SERVICES IN AUSTRALIA

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Abstract/Introduction

The livestock sector of Australia's economy is highly competitive on international markets. It makes a large contribution to our national income. Australia's high standard of animal health and disease-free status are significant factors in the comparative trading advantage enjoyed by our livestock sector and, ultimately, to the economic well-being of Australia. The changing nature of demand in world and domestic markets for livestock products coupled with technological changes in animal health service delivery have produced evolutionary advances to Australia's animal health policy settings.

Over the past 5 years, strategic planning and funding of animal health services has become more inclusive of the wider financial, management and socio-political implications. This has produced a situation whereby animal health policy development has achieved a higher profile and wider base.

Traditional Structures and Processes

Australia has a federal system of Government, with six States and two Territories and a national (Commonwealth) Government. However, our Constitutional arrangements differ significantly from the USA's federal system, and this is especially so in respect of responsibilities for agriculture.

The State and Territory Governments manage the regional rural economy, have responsibility for setting domestic food standards, apply appropriate agricultural production regulations to foster industry development and to meet broader community concerns (eg land conservation, pollution control, prevention of cruelty to animals). In particular, livestock disease legislation and related control programs are issues that are solely the province of State/Territory Governments.

The Federal Government manages the national economy, particularly the import and export sectors, exercises quarantine control and provides export inspection and certification services. In general, the Australian community looks to the Federal Government to provide the leadership in issues requiring a consistent national approach by States in exercising their separate powers, and resolving problems that involve a mix of regional and national roles and...
CONTRIBUTION OF EXHANDIS TO AAHC IN AUSTRALIA

Throughout much of this century, investment in animal health services was seen as an effective means for State and Territory Governments to create regional economic growth. Healthier herds were more productive herds. The prevailing industry development policies took it for granted that increased supply could always be absorbed by international market demand. This created a solid political base for funding substantial animal health services from the 'public purses' of State and Territory Governments.

The increased production generated by regional investment in animal health infrastructures led to a greater demand for export inspection and certification services from the Federal Government. For a long time, these services were provided on a 'free of charge' or 'subsidised' basis. After the Pacific War, powerful socio-political pressures supported the creation of an import-replacement manufacturing sector under a substantial tariff-protection umbrella. This greatly impacted on the cost structure of equipment-using industries such as farming and there was general sympathy for Government funding of export services to farmers, as a tariff-compensation measure.

In more recent times, international marketplace dynamics have required Australia to take a demand-side focus to industry development, and there have been major changes to basic political and social values and priorities. This has placed major reform pressures on all of Australia's animal health service agencies and has led to a change in approach to formulating policy responses. Key issues addressed in this regard have been that:

- farmer groups were not sufficiently involved in animal health policy development;
- the larger private sector veterinary service industry was largely excluded from Government operations; and
- decision-making by individual Government agencies did not have a cohesive national planning framework.

By the late 1980s, external stakeholders were showing a strong interest in the single-issue question of Australia's foreign animal disease response capability, which led to the creation of Exandis.

Exandis

Exandis is an acronym for the Exotic Animal Disease Preparedness Consultative Council. It was established in 1990 with two basic roles:

- to augment the stream of policy advice to Governments on exotic (that is foreign) disease preparedness, by including broader management, financial and marketing expertise; and
- to manage the expenditure program for a $7.5 million fund to support innovative approaches to supplement Australia's foreign disease preparedness capability.

The Exandis initiative was put forward by the Federal Government as a pilot program. It led to significant changes to policy development in the
animal health services area, in that:

- the peak national councils of the livestock industries contributed 50% of the Exandis budget;
- industry was fully involved in the policy development activities of Exandis and was an equal partner in imposing financial accountability on animal health service providers funded by Exandis; and
- the private veterinary 'voice' was added to these policy development and program management processes.

The broadening out of the modus operandi for animal health policy formulation created early tensions. Farmers demanded strong demonstration of value for money and animal health service delivery agencies of Governments were subject to close scrutiny to ensure cost efficiency of their activities. Looking back at the end of the 5 year pilot it is fair to say that these proved to be creative developments. All the groups involved in or affected by Exandis have now publicly recorded their admiration for its achievements.

Following is a broad brush summary of the Exandis achievements:

1. revamping of compensation arrangements for animals destroyed as a consequence of disease eradication programs that fully resolved farmer and Government views as to what constitutes fair treatment. This was a rather difficult 'nut to crack';
2. the first edition of the AUSVETPLAN (uniform strategic and operational plans for the technical aspects of exotic disease emergency response in Australia) documents were prepared;
3. additional disease preparedness staff were placed in each State/Territory veterinary administration to implement new operational programs in line with the national AUSVETPLAN template;
4. disease models were developed to quantify the resource requirements for effective field delivery of AUSVETPLAN strategies, and the results were compared with an inventory compiled on actual resources available to governments;
5. to ensure there were no deficiencies in resource availability and requirements, a management policy was agreed for drawing resources from across Government agencies and from private practices to assist response to regional disease incidents. This was accompanied by special training programs for key personnel;
6. the northern Australia detection and diagnostic capability was upgraded, particularly in regard to arbovirus threats;
7. reviews of the most serious disease threats (Foot and Mouth Disease, Screw Worm Fly and Bluetongue) were conducted leading to the integration of animal health contingency planning requirements with all the related trade, social and political response implications; and
8. a national program of large scale foreign disease outbreak exercises was completed.
CONTRIBUTION OF EXHAN DIS TO AAHC IN AUSTRALIA

The Exandis pilot program provided a forum that helped implementation of institutional and structural changes to the delivery of animal health services. The importance of foreign disease freedom to Australia touches all Governments and farmer groups. Exandis provided the framework for a genuinely national approach and national ownership of cross-constituency responsibilities in the area of foreign disease preparedness.

Some problems which were hard to resolve pre-Exandis became rather more tractable post-Exandis.

AAHC

In mid-1992 or about halfway through the Exandis pilot program, an evolutionary process was initiated to look at the whole question of Australia's long term animal health service requirements. This involved a high level working group drawn from Federal and State/Territory agencies and all livestock producer interest groups.

This posed a much more complex challenge to that faced by Exandis. Exandis only dealt with the foreign disease problems. In developing the 'son of Exandis', the policy development process would need to grapple with the full gamut of animal health issues impacting on Government agencies and industry performance.

The centrepiece that arose from this policy development process was the concept of establishing an Australian Animal Health Council (AAHC), and in August 1995 there was final agreement by Government and industry shareholders on implementation arrangements. The new AAHC will:

- be a non-profit company, limited by guarantee, incorporated under Companies Law;
- be funded on a trilateral Federal, State/Territory Government and industry basis;
- have the mission of ensuring the Australian animal health service system is capable of maintaining a high level of national animal health standards which meet consumer needs and market requirements at home and overseas; and
- have a Board and small support staff which will have a number of management tools at its disposal—rolling 3 year strategic plans, annual operational plans, and a small number of strategic national projects.

In an economist's terms, the comparative advantage of the proposed AAHC will be to ensure that animal health service inputs are aligned with commercial market objectives.

The AAHC charter will not give it an operational role in Government regulatory issues. These need to be kept at arm's length from commercial enterprise, eg, the relationship between the Australian Quarantine Inspection Service and the USDA in developing and enforcing protocols for trade in livestock products will continue, and be untouched by the AAHC initiative.
Furthermore, the AAHC will not take the lead in developing programs that pursue narrow commercial interests (e.g., residue control and product quality assurance). It is envisaged, however, that in addition to addressing priorities that cut across public and private responsibilities, AAHC will facilitate a seamless interaction between public and private animal health service providers. Accordingly, Australia will have a fully responsive and consultative— but not single structure— approach to planning and funding animal health services.

The latest ‘AAHC-related’ evolution of animal health services in Australia has been motivated by changing market forces.
CONTRIBUTION OF EXHANDIS TO AAHC IN AUSTRALIA

- firstly, fundamental changes will occur in the non-tariff (eg quarantine/health status and certification) regulation of international market access in the post-GATT era. Australia's export based livestock industries need an animal health service that is systematic and consistent across all service delivery agencies, and which produces animal health information which is comprehensive, fully shared and capable of providing cost-effective results; and

- secondly, there are progressively more discerning and demanding consumer requirements in regard to food safety and wholesomeness, and the welfare of animals used for commercial production. These changes on the demand side of the marketplace are particularly strong in the higher priced niches, where Australian suppliers need to position themselves.

As a trading nation and given the significant export markets in the USA for Australian meat and wool, our animal health policy decisions also have to take account of bilateral considerations. We aim to pursue policy initiatives that are right from a domestic perspective, but which will safeguard the high regard for Australia's animal health system held by each of our export customers.
Max Appel, NY; Charles Baldwin, GA; Linda Benson, NY; Wes Bonner, TX; Philip Bradshaw, IL; Roger Breeze, NY; Jack Brooks, KY; Tom Bunting, IL; Ernesto Calderon, El Salvador; Jerry Callis, NY; Hector Campos-Lopez, Mexico; Dan Childs, FL; Wallace Deen, MO; Allen Dewald, SD; Enrique Dominguez, TX; Jaime Estupinan, DC; Peter Fernandez, Mexico; Don Franco, VA; Tom Galvin, Mexico; Marolo Garcia, MD; John George, TX; Paul Gibbs, FL; Jack Gillette, WA; Dan Goodyear, PA; John Gorham, WA; Chris Grocock, MD; Adam Grow, MD; Farouk Hamdy, FL; Jack Haslam, DC; P. R. Henry, CO; B. R. Heron, CA; Werner Heuschele, CA; Jane Homan, WI; Jim House, NY; Jack Hyde, NY; Floyd Jones, TX; Nels Konnerup, WA; David Ligda, IN; Linda Logan-Henfrey, Kenya; Don Luchsinger, VA; John Maré, AZ; Hunt McCauley, MT; H. A. McDaniel, MD; Hugh Metcalf, MD; Norvan Meyer, VA; Bob Miller, MD; M. A. Mixson, NC; Vic Nettles, GA; J. E. Novy, AA; Roger Odenweller, KY; Richard Omohundro, TX; Charles Palmer, CA; Richard Peterson, CA; Roy Peterson, OR; Kelly Preston, VA; Gerardo Quaassdorff, VT; Moe Salman, CO; E. C. Sharman, GA; Arnon Shimshony, Israel; Roxana Silva, Mexico; Malcolm Smith, ND; Bill Sterritt, Canada; David Stringfellow, AL; Paul Sutmoller, VA; Paul Taylor, MT; Kenneth Thomazin, CA; Peter Timm, CA; Lyle Vogel, IL; Tom Walton, IA; Cecelia Whetstone, NY; William White, NY; John Williams, MD; William Wilson, WY; Saul Wilson, AL; and John Wyss, Mexico.

The meeting of the Foreign Animal Diseases Committee opened with remarks by Gale Wagner about the first joint session with the Committee on Epizootic Attack, with presentations on the topic area of Emerging Diseases. The other topic areas to be covered this year include: Ticks, Risk Assessment in International Trade, and FAD and Pest Diagnostic and Research Needs. Bill Buisch discussed the upcoming revision of the Gray/White book. The following papers were presented:

**Topic Area - Ticks**

**Technological Challenges to the Tick Eradication Program in Texas.**

**John George, USDA/ARS, Kerrville.** Through September, about 68,000 cattle and 6,000 horses entered the U.S. from Mexico for immediate slaughter. The number of animals imported for this purpose this year is unusually high because of the diminished markets in Mexico. When “slaughter” livestock arrive at one of the APHIS-VS import vats they are inspected and, if free of ticks, they are dipped in a vat charged with coumaphos, loaded onto a
truck and shipped directly to a facility authorized to process livestock imported for slaughter. The discovery by FSIS of unacceptably high residues of organophosphorus (OP) pesticides in the tissues of some of these livestock raised questions about the source of the residues. Was the problem due to excessive exposure to OP in Mexico or was the problem related to the treatment in the high concentration (3,000 ppm) of coumaphos in an import vat immediately before animals were shipped? The possible options: (1) livestock could be kept long enough post-treatment for the pesticide residues to be metabolized or excreted before slaughter; (2) the import of livestock for slaughter could be stopped; or (3) import of slaughter cattle could be restricted to a single port and the acaricide used in that import vat changed to permethrin, the only non-OP available. The latter option would determine if the OP residues were attributable to pesticide exposure of livestock prior to treatment in the import vat, but would be a departure from the historical zero risk model for operating the Boophilus eradication program in Texas. APHIS-VS decided to use Atroban® 42.5% EC in a single import vat, and asked ARS to test the efficacy of a 500 ppm Atroban treatment in a dipping vat. Results indicate that the performance of Atroban is too poor to meet standards for an eradication program. In anticipation of these results, ARS planned a vat test of zetacypermentrin, a pyrethroid known to be very effective against Boophilus ticks. However, because of recent reports from Mexico that B. microplus populations throughout much of the species range are cross-resistant to the available pyrethroids (deltamethrin, cypermethrin, and flumethrin), the use of a pyrethroid acaricide in import vats or in Texas would be imprudent. Amitraz, an amidine acaricide, is the only product that will control OP and pyrethroid resistant ticks and that can be used in a dipping vat under the conditions required by the needs of the Tick Eradication Program. One of the major difficulties in monitoring and managing resistance of ticks to acaricides is the lack of a method that can be used to estimate the frequency of resistance genes in a population. Cooperative research is underway to develop probes to detect resistance in B. microplus to OP, pyrethroid, and amidine acaricides. Such probes will be used to assess the susceptibility of ticks from outbreaks, and to monitor progress once suitable management strategies are implemented. In other work, ARS scientists have devised a method for degrading coumaphos with anaerobic bacteria by circulating the vat contents through a tank equipped with a filter system on which the bacteria aggregate and multiply. In the recent trial, the initial concentration of 1,100 ppm in 15,000 liters of vat fluid was reduced to 10 ppm in 15 days. This system should enable VS to satisfy pending new state and EPA requirements for the disposal of coumaphos.

**Topic Area - Risk Assessment in International Trade**

*Constructing Risk Assessment Under GATT: A Blueprint.* Ken Forsythe and Dan Sheesley, USDA/APHIS, Washington. The documentation and
FOREIGN ANIMAL DISEASES

transparency of the General Agreement on Tariffs and Trade (GATT) in 1994 requires a clear understanding of the formal risk analysis process that underlies decision-making. An added Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures proposes a generic SPS trade risk analysis process consisting of 5 parts: (1) process management steps (including decisions on the level and type of analysis); (2) an analysis of origin factors; (3) an analysis of destination factors; (4) option prioritization steps; and (5) decision/action steps. Embedded in each are the essential procedures in risk analysis, such as the methods from various disciplines (biology, epidemiology, economics, etc.), as well as hazard identification, risk assessment, risk management, and risk communication. Frequently overlooked in risk analysis is an assessment of the benefits to both the importing and exporting countries of the trade being evaluated. Such an assessment of trade benefits is a key component of the risk analysis process designed to address the question “Should trade in a particular commodity take place between specific trading partners, and if so, under what conditions?” This combination of methods provides estimates within a benefit cost framework for evaluating the SPS risk associated with internationally traded commodities. The key feature of the framework is that it allows for an objective evaluation that can help determine a tolerable level of SPS risk when making decisions regarding international trade.

FMD Risk Regionalization and Risk Assessment for South America. Vicente Astudillo and Paul Sutmoller, PAHO, Rio de Janeiro. Under the rules of the WTO and/or such agreements as NAFTA, trading policies for animals and animal products will depend on risk management and a concept of regionalization. The Continental Animal Disease Surveillance and Information System in South America, operated out of the PAHO, FMD Center in Rio de Janeiro, compiles weekly information reports from a network of field units, diagnostic labs, the national and regional management units of the FMD control and eradication programs, and the livestock industry. Based on the epidemiological information obtained, veterinary authorities receive timely information on the behavior of FMD in the field, the development of higher risk situations and emerging problems, and evaluation of management strategies. Importantly, the information base also allows for the regionalization of South America with regard to FMD risk for an importing country. The classifications are dynamic and consider such factors as the frequency of FMD (sporadic, endemic, etc.), the results of serological and virological surveys, the presence of natural or man-made barriers, the use of vaccination, and the FMD condition of adjacent regions. It should be noted that this risk regionalization is meant to show the levels of risk for international trade in animals and animal products, not to substitute for the regionalization of FMD ecosystems. The latter is based on epidemiologic and livestock production systems, and is intended to improve the strategies for FMD control and eradication pro-
REPORT OF THE COMMITTEE

grams. It is clear that, as a regional ecosystem changes from endemic to sporadic and eventually to FMD free, the risk posed by products from that region will tend to approach zero. Data were presented that compared information from 1985 to 1995. The low risk areas have increased over the decade. In 1985, about 4 million cattle in 250,000 herds were in regions without FMD. Currently, it is estimated that there are 93 million cattle in 1 million herds and 40 million sheep in regions that have been free of FMD for at least a year. If this favorable trend continues, important regions of the continent will be in low FMD risk for export.

The Mexico-U.S. Exotic Animal Disease Commission: Transition to the Future. Peter Fernández, APHIS, Mexico City. The Mexico-U.S. Commission for the Eradication of Foot-and-Mouth Disease was formed in 1947 to carry out the FMD eradication campaign in Mexico. Once accomplished, the name was changed in 1952 to the Mexico-U.S. Commission for the Prevention of Foot-and-Mouth Disease. The Commission was restructured again in 1985 to include surveillance and diagnosis of other exotic animal diseases, and was designated the Mexico-U.S. Commission for the Prevention of Foot-and-Mouth Disease and other Exotic Animal Diseases. APHIS has referred it as the Exotic Animal Disease Commission or EADC. EADC efforts are principally dedicated to: 1) surveillance and outbreak investigations for prevention of FMD and other FAD entering Mexico; 2) diagnostic capabilities for rapid detection of FMD and other FAD throughout Mexico; and 3) training and public education to communicate animal disease prevention measures. In 1992, APHIS reviewed the current and future role of EADC within the context of the increasing opportunity for the movement of animals and animal products across national boundaries; the increased risk of disease/pest introductions; the increasing need for quality and timely animal health information; the increased industry presence and involvement in animal health issues and trade; increasing environmental and consumer concerns; and the level of financial support that the U.S. can provide to the EADC. Mexico maintained that exotic animal disease outbreak management was their responsibility and that the EADC should be reorganized to reflect that capability. The resulting transition plan includes: (1) a bi-national cooperative agreement; (2) an electronic bulletin boardsystem on applications of new technologies to FAD management; (3) a bi-national animal disease diagnostics forum; and (4) training and education. The decision was also made to include Canada in future discussions. A trilateral group reviewed the transition plan in mid-1995 and recommended that the U.S. formally agree to continued financial (per Article 12) and functional participation, that past support of both U.S. and Mexican industry be publically acknowledged and that those ties be strengthened, that addenda be added to the existing agreement to begin the process of legal change (as opposed to re-drafting a new agreement), and that a network for the exchange of animal health information be established between appropriate agencies in
the U.S., Mexico and Canada. The group also recommended that a trilateral READEO test exercise be organized with particular attention to testing new technologies (including the new READ1 system) by predetermined teams, cooperative efforts in training, education and electronic information exchange, and that regular meetings be held to discuss issues of mutual interest. Since the transition plan was implemented, APHIS financial support is now directed at improving the FAD diagnostic laboratory at Palo Alto, near Mexico City, including support for technology transfer and joint projects. A course on the ELISA diagnosis of vesicular diseases was presented in 1995 to diagnosticians from Mexico, Panama and Colombia. Proposals for upgrading biosecurity and expanding working areas at Palo Alto, and for data management equipment for field applications have been submitted.

FMD Risk Analysis. John Wyss, APHIS, Panama City The risk assessment of a future FMD outbreak in the U.S., Mexico and Central America was discussed. A "fault tree" for assigning risk includes pathogenicity in the target species (cattle, sheep, goats and horses), the many natural domestic and wildlife hosts of the virus, fomites, livestock movement, biologics, etc. The risk analysis suggests that an initial outbreak might not be detected before rapid spread would occur. Costs to eradicate would be about $1500 per animal. If only 1% of the U.S. cattle population were involved (about 1 million head) the cost of the eradication would be about $1.5 billion. Similar figures were presented for hypothetical outbreaks in Mexico and Central America.

Update on Risk Assessment of Embryo Transfer: FMD, BT and VS. Paul Sutmoller, PAHO, Rio de Janeiro. A quantitative risk assessment was conducted for an area of Brazil, Uruguay and Argentina, a region that offers animal health conditions that may qualify for "regionalization" and the subsequent export of frozen embryos. The preliminary results indicate that the probability is exceedingly small (about 1 in 100 million or less) that frozen embryos would contain FMD or VS virus. The chance for embryo transfer to transmit BT virus is greater (about 1 in 100,000 or less) although still small. Clearly, the risk is less with diseases that are easily recognizable, such as FMD and VS. Quantitative risk assessment provides veterinary authorities with a more complete assessment than the classification system being used by certain groups.
ditions (excluding the investigations associated with the 1995 vesicular stomatitis outbreak), 41 (15.1%) bovine spongiform encephalopathies, 33 (12.2%) encephalitic/CNS disorders, 31 (11.4%) avian diseases, 16 (5.9%) mucosal disease conditions, 11 (4%) septicemia conditions, 8 (2.9%) abortion cases, 8 (2.9%) conditions categorized as miscellaneous, 5 (1.8%) poxlike conditions, 4 (1.4%) acute deaths of unknown origin, 2 (.74%) myiasis/acariasis, and 2 (.74%) unusual respiratory conditions. Vesicular Stomatitis Surveillance: As of September 30, 1995, the VS Task Force conducted a total of 803 premise investigations. The 315 case positive premises comprised 184 in New Mexico, 125 in Colorado, 1 each in Arizona and Texas, and 4 in Utah. There were 39 bovine only case positive premises, 221 equine only premises, 30 with bovine and equine, and 25 case positive premises involving bovine and/or equine plus another species (llama, etc). The New Jersey strain of the VS virus was identified as the cause of the outbreak. Surveillance and control measures were continued into FY 96. Bovine Spongiform Encephalopathy (BSE) Surveillance: The BSE surveillance program that started in May, 1990 is continuing. Pathologists at the NVSL and Iowa State University examine bovine brains submitted to NVSL from the following sources: (1) FAD investigations where suspected encephalitic conditions in cattle are reported; (2) bovine cases confirmed negative for rabies by the CDC in Atlanta, Georgia; (3) brain specimens collected at slaughter from abattoirs in selected potential high risk States; and (4) brain tissues submitted by veterinary diagnostic laboratories in the U.S. To enhance the surveillance process, visits have been made by State or USDA personnel to State public health and university diagnostic laboratories to arrange for the submission of suspicious specimens to NVSL. Contacts with practicing veterinarians have also been made to increase reporting and the submission of brains from suspicious cattle. As of September 30, 1995, a total of 2,411 bovine brains have been examined (508 in 1995); none of these specimens contained characteristic lesions for BSE. Additionally, none of the traced cattle, (463 out of 499), that were imported from the U.K. since 1981, have shown any clinical signs of BSE. There have been no cases of BSE diagnosed in the U.S. APHIS is unable to locate 36 of the 499 animals imported from the U.K. Due to age, it can be assumed that a majority of these animals are dead. Hog Cholera/African Swine Fever Surveillance: The VS surveillance program for classical swine fever (hog cholera) and African swine fever was continued in 1995. Swine blood specimens are regularly collected at slaughter from abattoirs located in Maine, Massachusetts, New Hampshire, New Jersey, Arizona, Texas, and Puerto Rico. NVSL in Ames, Iowa, tested 8,668 samples and all were negative for the two diseases. Highly Pathogenic Avian Influenza: APHIS-VS Emergency Programs continues to prepare for a possible introduction of highly pathogenic avian influenza (HPAI). An APHIS avian influenza working group organized in early 1995 evaluated risk factors for the U.S. from Mexico, developed an action plan to
compliment the APHIS HPAI Eradication Guidelines, organized a series of State/Federal/industry meetings to address concerns and improve emergency preparedness, established an AI List Server for information sharing, and organized two U.S. delegations to Mexico to study HPAI and the effectiveness of avian influenza vaccine. Following a formal recommendation from the 1995 NPIP National Conference, APHIS proposes to expand the working group to include industry and USAHA officials and to include it within the AI Subcommittee of the USAHA Committee on Transmissible Diseases of Poultry. A preliminary analysis on the national AI surveillance program was conducted. The number of tests increased in 1995 from 1994 (350K from 250K) but at least two States appear to have inadequate testing. The focus of our emergency preparedness and response will be the agents H5 and H7 in commercial chickens. APHIS will continue to actively survey the live-bird markets in the northeast and use sentinel chickens in selected markets in Florida. The continuing efforts of the turkey industry in strong surveillance and control and eradication efforts is also an advantage. The unique State-wide use of an autogenous H7 vaccine in turkeys in one western State was supported by APHIS in 1995. APHIS rescinded the restriction in July, 1995 on the manufacture of AI vaccines in the U.S., including H5 and H7 vaccines. There has been a very high level of concern from the U.S. poultry industry on this issue. All AI vaccines for use in chickens, and all H5 and H7 vaccines, will have distribution restrictions. Limitations include permission from State officials to use the vaccine. In addition, APHIS-VS will control the use of the vaccine(s) "as part of an official disease control program." (See APHIS Veterinary Biologics Memorandum No. 800.85.) APHIS has also supported the full licensure and study of recombinant fowl pox vectored AI vaccines. Mexico has recently received a sample of the vaccine for safety and efficacy studies. Duck Viral Enteritis: A State duck viral enteritis (DVE) transmission and vaccine study in domestic waterfowl being conducted. The objectives are to determine the transmissibility of DVE from waterfowl survivors of a DVE outbreak to immunologically naive Muscovy ducks, and to evaluate the ability of a modified live virus vaccine to confer protective immunity to Muscovy ducks against natural DVE challenge. Psittacosis: Human psittacosis cases have been associated with shipments of pet birds to a national retail pet store chain. APHIS has agreed to perform limited tracebacks on the distribution and source of Psittacosis-infected pet birds that the CDC is currently investigating. Newcastle Disease: Newcastle disease reappeared in double-crested cormorants in Canada this summer. Clinical neurological disease was observed only in young-of-the-year cormorants. The virus isolates appear to be similar to the viruses isolated in cormorants in 1990 and 1992. There has been no evidence of extension of infection into domestic poultry. Acaricide resistance in populations of cattle fever ticks in Mexico: In 1985, Mexican authorities reported acaricide resistance in populations of Boophilus (cattle fever) ticks to coumaphos, an organophosphate (OP) acaricide. OP resistant
ticks have been reported in the Gulf Coast region around Veracruz, in the Yucatan Peninsula, the State of Chiapas, and in areas of the southwest coast. In 1994, resistance in populations of Boophilus ticks to deltamethrin, flumethrin, and cypermethrin (all are synthetic pyrethroid (SP) acaricides) was reported. With the increased problem of acaricide resistance of cattle fever ticks to new classes of acaricides, the probability of introduction of these ticks into the U.S. becomes much more likely. This year, there were two new cases of suspected OP resistant ticks on cattle presented at the border. This is a serious threat to the cattle fever tick prevention programs of the U.S. A new effort has been made to obtain up to date information on the status and scope of the acaricide resistance problem in Mexico. Coumaphos residue problems in meat of slaughter animals from Mexico: About 18 months ago, FSIS notified APHIS that they had found some horses imported from Mexico for immediate slaughter with unacceptably high levels of OP residues in fat tissue (kidney fat). Shortly after the notification, APHIS closed the border to all importations of horses because of the Venezuelan Equine Encephalomyelitis outbreak in Mexico. When the border was again opened to importation of slaughter horses in April, 1995, horses were treated with coumaphos at 0.165 to 0.20 rather than the 0.3 normally required. These animals were held at the slaughter plant for an additional 10 days before slaughter to see if the residue problem could be corrected. The holding period does allow time for the animal to excrete the OP. FSIS notified APHIS in July, 1995 that they had found unacceptably high levels of OP residues in fat tissue from about 25% of 200 samples taken from immediate slaughter cattle of Mexican origin. One sample was as high as 3 ppm of coumaphos. A temporary prohibition of Mexican slaughter animals entering the U.S. was established until a solution to the OP residue problem could be worked out with Mexican authorities. Now, Mexican animals going direct to slaughter must be inspected and treated at least once for ticks in vats charged with Atroban, an SP. The ports of embarkation where animals going direct to slaughter will be required to go for entry into the U.S. are at Laredo and Del Rio, Texas; Santa Teresa, New Mexico; and Douglas, Arizona. At each of these port facilities, one of the dipping vats will be charged with Atroban, and will be used to treat only slaughter animals. Such animals will be rejected for entry into the U.S. if presented at any other port of embarkation.

World Animal Disease Distribution. William White, APHIS, Riverdale. Foot-and-Mouth Disease (FMD): Significant advances in FMD eradication continued in Argentina, with its last outbreak reported in April 1994, and Uruguay, which completed one year without vaccination in June 1995, and meets OIE requirements for FMD free status. The comment period for a proposed APHIS rule to recognize Uruguay free of FMD and RP ended October 4, 1995. In Paraguay, where a FMD eradication program has been active since 1992, the northwestern region is considered "FMD-free with vaccination". In contrast Brazil experienced a 70% increase in outbreaks in 1994, the seventh
successive year with an increase in outbreaks. But no outbreaks occurred in the southern States of Rio Grande do Sul and Santa Catarina. In 1995 Bolivia, Brazil, Colombia, Ecuador, Peru and Venezuela reported Type O1 outbreaks, while Colombia struggled with several Type A24 outbreaks in Cordoba Department. Brazil and Venezuela also reported Type A24 outbreaks. North America, Central America, the West Indies, the Guyanas (Guyana, Suriname and French Guiana) and Chile remained "FMD-free without vaccination" in 1994 and 1995. The Uraba Chocoano region of Colombia and the Patagonia region of Argentina south of parallel 42 remained free from FMD. The Mesopotamic Region of Argentina has reported no outbreaks for three years. An epizootic of FMD Type O with 95 outbreaks occurred in Greece from July to September 1994. Ninety outbreaks were caused by illegal movement of sheep from Turkey to Lesbos Island with subsequent movement to the mainland in Thrace. An additional five outbreaks in Evros prefecture were probably introduced from eastern Turkey by Pakastani immigrants. All clinically affected herds were depopulated, and no vaccination was used. In March 1995 an outbreak of Type O occurred in the Thrace region of Turkey by illegal importation from the Anatolian region. Thrace was previously free of FMD, and the 13 western provinces of Anatolia form a FMD vaccination buffer zone for Europe. Only the eleven affected cattle in the affected village were destroyed, while vaccination of 10,500 cattle, sheep and goats in six nearby villages was performed. No further outbreaks have been reported, but the episode underlies the threat that the Asian portion of Turkey presents to Europe. **Vesicular Stomatitis (VS):** In 1994, as in previous years, VS was diagnosed only in the Western Hemisphere, with the highest frequency again recorded in Colombia (199 isolations). The New Jersey serotype predominated. In 1995, the distribution was similar, except for the epizootic of VS-New Jersey in the western U.S. that began in April. The virus may have been introduced from an enzootic focus south of the U.S., or may have escaped a silent enzootic cycle pre-existing in the western U.S., although proof of such a cycle is still lacking. Mexico reported VS-NJ cases from seven south central States in mainly September 1995. **Swine Vesicular Disease (SVD):** Only Italy and the Netherlands reported SVD in 1994. In the Netherlands two outbreaks occurred in February after having been absent for 18 months, probably introduced by a truck used for international transport. After stamping out and three negative serosurveys of pigs in the affected regions, control measures were lifted in April. After no further incidents, The Netherlands declared itself free in November, 1994. Italy has reported sporadic SVD outbreaks in 1995 in north and central municipalities. In October, 1995 Portugal reported SVD in a quarantined imported herd, and all 4,960 swine were destroyed. SVD had never been reported previously in Portugal. The USDA recognized Austria (June 1994) and Spain (May 1995) as free of SVD, and published a proposed rule (August 1995) to recognize Germany as free. **Rinderpest (RP):** Uganda, Ethiopia and Eritrea had RP outbreaks in 1994, and the dis-
ease is reportedly enzootic in southern Sudan. In December 1994 and January 1995, an outbreak in buffalo in Tsavo West National Park in southern Kenya occurred, with 200 animals of all ages dying. Cattle grazing in nearby areas were unaffected. In August 1995 Kenya reported outbreaks in 13 cattle herds (20 dead animals of 480 exposed), introduced by cattle smuggled from a neighboring country. Iran and Turkey reported outbreaks in 1994 for the first time since 1989 and 1991, respectively. RP also circulated in four southern states of India, in Pakistan and in Sri Lanka. Peste des Petits Ruminants (PPR): PPR outbreaks were reported from West and East Africa, the Middle East and India in 1994. Gambia reported an exceptionally high incidence. PPR was reported in India for the first time in three northern States, having previously only been identified in the south. Contagious Bovine Pleuropneumonia (CBPP): All regions of Africa, with the exception of North Africa, are affected by CBPP. From August 1994 to February 1995, Tanzania experienced a large epizootic in three villages, where 3,000 deaths and 9,000 cases occurred in 30,000 cattle sharing common grazing areas. Quarantine, slaughter of clinically affected cattle, and ring vaccination were performed. Botswana experienced two outbreaks involving 2,112 cattle in March, 1995, the first outbreaks since 1939, followed by six more outbreaks in October. In Europe, only Spain (two outbreaks) and Portugal (63 outbreaks) reported CBPP. The Spanish outbreaks occurred in Santander Province in March and Guipuzcoa province in April. The number of outbreaks in Portugal fell 62% from 1993 (165 outbreaks). Lumpy Skin Disease (LSD): In 1994, LSD was only reported in Africa. Egypt and Mali had outbreaks, after being absent since 1990 and 1989, respectively. Senegal, Guinea, Ethiopia, Namibia, South Africa and Botswana also reported outbreaks. Outbreaks in Africa were generally more virulent and greater in number than in previous years, probably as a result of increased rainfall and insect vectors. Outbreaks were reported from several Subsaharan countries in 1995. Rift Valley Fever (RVF): After a brief RVF episode in July 1993, all ruminants in Egypt were revaccinated in January 1994. There have been no further animal abortions or human cases since July 1993. Outbreaks have been reported in Malawi, Mozambique and Zimbabwe in 1995. Bluetongue (BT): Japan reported clinical signs of BT in indigenous cattle and a few sheep for the first time in 1994. Australia continues to have viral activity but only within the range of Culicoides brevitarsis, which extends along the northern and eastern rim of the country. Activity is greatest in northern Australia during the wet season (December to May). In 1993-94 there was limited infection in sheep with Type 1, but no reports of disease. New Zealand has never reported BT. In the Middle East, Israel and the Israeli Controlled Territories and Lebanon reported clinical disease, and Iran, Jordan and Cyprus reported viral or serological activity. The U.S. continues to be enzootic for BT in the southern portions of the country. A serosurvey performed during FY 1995 on slaughter cattle in 18 northeastern and north central States, Alaska and Hawaii using the competitive ELISA had only 31
positive samples out of 8,004 (0.4%). **Sheep and Goat Pox (SGP):** Algeria and Morocco had significant increases in outbreaks in 1994, and Russia reported 10 outbreaks after being free of SGP since 1977. In November 1994, Greece had one outbreak in sheep near the borders with Turkey and Bulgaria, and in May 1995 sought disease free status according to OIE guidelines. In August and October 1995 Bulgaria reported its first outbreaks since 1954 with sheep in three villages affected. **African Horse Sickness (AHS):** Morocco decided to repeat vaccination against AHS in 1994 despite the absence of cases since October 1991. Over 1.5 million horses were vaccinated, about 90% of Morocco’s equine population. Morocco declared itself free of AHS in July, 1995, after meeting OIE requirements of two years with no cases and 12 months without vaccination. Egypt stopped vaccinating in the South in 1994, after stopping in the North in 1984. Portugal, Spain and the United Arab Emirates were recognized free of AHS by the USDA in March 1994, March 1995 and April 1995, respectively. AHS has been reported from five Subsaharan countries so far in 1995. **African Swine Fever (ASF):** Four outbreaks occurred in South Africa in 1994 and 1995 in ASF control zones where domestic pigs have contact with warthogs. Single outbreaks were reported in Mozambique in 1994 and 1995, and in Namibia in October, 1995. In Kenya, 4 outbreaks were reported in 1994, the first since 1964. The incidence of ASF in 1994 continued to fall in Spain (13 outbreaks compared to 37 in 1993), with only 3 provinces still affected: Cordoba, Seville and Huelva. A surveillance zone, incorporating 100 municipalities in the above three provinces and in Cadiz and Malaga Provinces, was established. In Sardinia, Italy, the number of outbreaks remained similar to 1993 (91 compared to 96 in 1993), but outbreaks occurred only in Nuoro Province (compared to outbreaks in 3 provinces in 1993). Nuoro continues to have ASF and HC outbreaks in 1995. Regionalization by the EU has allowed a 17-year-old ban to be lifted on fresh pork, ham and cured pork from all provinces of Sardinia except Nuoro effective March 1995. After instituting control measures and experiencing no further outbreaks for 12 months (last case August 1993), Portugal declared itself free of ASF in May 1995 following EU and OIE guidelines. **Hog Cholera (HC):** HC remains limited to two island countries in Africa: Madagascar and Mauritius. HC recurred in Costa Rica in February 1994 after illegal importation of pigs and was stamped out in early 1995. The State of Baja California Sur in Mexico lost its HC free status after a single outbreak in November 1994 and multiple outbreaks in October 1995. Mexico still recognizes Baja California, Sonora, Sinaloa, Chihuahua, Coahuila, Nuevo Leon, Tamaulipas, and Yucatan States as free. Vaccination continues in selected areas of the infected zones in central and southern Mexico. HC continued to be a major problem in Europe. In 1994 Estonia reported its first outbreak of HC since 1958, and recrudescence occurred in Austria, Belarus, Belgium, FRY (Serbia and Montenegro), Germany, Italy, Poland, Russia and Slovakia. In the Czech Republic, two outbreaks occurred in wild boar and one in fattening pigs in a
region enzootic for wild boars. In Germany and Belgium, more than 120,000 and 510,000 pigs were destroyed in 1994, respectively, to control the disease. In 1995 outbreaks have been reported in Germany, Croatia, Austria and Northern Italy, and HC continues to circulate on Sardinia. The control of HC in continental Europe is especially difficult because of the high swine densities, the high volume and rapidity of trade in live pigs and pork products, the feeding of contaminated swill, and the ability of the virus to circulate in wild boar populations. Switzerland, however, declared itself free from HC in July, 1994, following OIE guidelines. After experiencing outbreaks in 1993, it performed nationwide serosurveys in piggeries feeding swill in September 1993 and April 1994, and tested wild boar samples collected during hunting, all with negative results. Fowl Plague (FP)/Highly Pathogenic Avian Influenza (HPAI): An outbreak of HPAI (H7N3) occurred in Australia in December 1994 on a remote layer farm near Brisbane, Queensland. All birds were slaughtered, and an extensive surveillance program revealed no further cases. The outbreak likely resulted from an unusual concentration of wild birds under drought conditions on a watercourse used by the farm. In June, 1995, after six months without an outbreak and meeting OIE guidelines, Australia declared itself free of the disease. In Mexico, a mild form of AI was first observed in October 1993, and in May 1994 was characterized by the NVSL as an H5N2 isolate similar to the one occurring in Pennsylvania in 1983-84. A control and surveillance program was initiated, and virus was isolated from 11 (eventually 14) of 32 Mexican States, but not in States adjoining the U.S. In late December 1994 and early January 1995, HPAI emerged to cause serious losses in chickens in the States of Puebla (14 premises, mostly layers) and Queretaro (55 premises, 90% broilers). Nationwide control measures have included quarantine, biosecurity, testing, slaughter without indemnities, and vaccination with an inactivated non-pathogenic H5N2 strain. Vaccine efficacy has been questionable. In August 1995, Puebla was elevated to Zone 2 (antibody or low PAI isolated), but Queretaro maintained its Zone 3 (medium or HPAI isolated) status. Mexican states bordering the U.S. are classified as free or Zone 1 (no evidence of AI). Velogenic Newcastle Disease (ND): Serious outbreaks were reported in 1994 in South Africa (industrial, backyard and ostrich farms), Swaziland (backyard) and Zimbabwe (backyard). In 1995, large outbreaks occurred in Namibia (backyard and ostrich farms) and Reunion Island (backyard and hobby fowl). In September and October 1995 Canada reported 3 ND outbreaks in cormorants: a single cormorant on the Ottawa River 20 km east of Ottawa, 3 breeding colonies with 20,000 birds on Dore lake in central Saskatchewan province, and 2 breeding colonies with 500 birds on Lake Ontario near Presqu'ile Point in Ontario province. In the third location 1% of birds displayed clinical signs suggestive of ND. No domestic poultry have so far been affected. Taipei, China declared itself free of VVND in August 1994, having had no further outbreaks since May 1991. However, 12 outbreaks of a less virulent disease occurred from January through
FOREIGN ANIMAL DISEASES

March 1995 on small chicken farms along coastal areas having possible contacts with migrating wildfowl. The incidence of ND in Germany in 1994 remained similar to 1993, with 180 outbreaks affecting mainly farms in the east with less than 200 birds. The widespread outbreaks in small flocks caused Germany to mandate vaccination of all flocks with less than 200 chickens or turkeys against both ND and AI. Previous regulations mandated vaccination only in flocks with over 200 birds. The Netherlands reported only 8 outbreaks in 1994, 3 in industrial units and 5 in hobby fowl. In March 1994, Switzerland reported its first outbreak since 1989, in 6 hens on a remote farm affected. Belgium reported the disease in psittacine birds imported from Asia and placed in a quarantine station at an airport. In 1995 ND was reported in Germany (small broiler flocks), the Netherlands (hobby fowl) and Luxembourg (backyard hens and turkeys).

Heartwater (HW): The cooperative CARICOM-IICA-FAO-USDA Amblyomma Tick Eradication Program began officially on the island of Anguilla in May, 1995, Nevis in October, 1995, St. Kitts in October, 1995, and will begin activities on Montserrat in January 1996. Amblyomma variegatum is established on 14 islands and reported from 5 more. The eradication program on CARICOM member islands will consist of a 5 year eradication phase with treatment of all livestock every 2 weeks. The eradication phase will be coordinated with the French islands, which began eradication activities in April 1994. A. variegatum is an important host for HW (confirmed on Antigua, Guadeloupe and Marie Galante) and is associated with large losses from dermatophilosis.

Screwworm (SW): Cuba reported outbreaks of SW from March through October 1995. All provinces (except Juventud Island) and mainly cattle have been affected. About 60% of 385 samples were positive. Control has been mainly public information campaigns and treatment of individual animals. As a result of the Host Country-USDA Screwworm Eradication Program, SW has been eradicated in Mexico (1991), Belize (1991), Guatemala (1993) and El Salvador (1993). Honduras was declared "technically free" in October, 1995, and the last confirmed case was in January, 1995. Nicaragua is averaging fewer than 20 cases per week, mainly in the southern one third of the country. The goal of the program is to extend eradication activities to Costa Rica and Panama, and form a permanent sterile fly barrier at the Isthmus of Panama.

Bovine Spongiform Encephalopathy (BSE): Native cases have only been recorded in Europe, and were first reported in the United Kingdom in 1986, Ireland in 1989, Switzerland in 1990, France in 1991, and Portugal for the first time in 1994. In the U.K., the number of laboratory confirmed cases from January to September 1994 totalled 26,087, a decrease of 26% from the same period during 1993. From December, 1994 to September, 1995, there were 12,461 confirmed cases. The peak of the epidemic appears to have occurred in January 1993. Through September, 1995, the U.K. has confirmed a total of 152,470 cases. Up to April 14, 1995, 18,421 cases of BSE had been confirmed in animals born after the ruminant feed ban in July 1988, most occurring soon after the ban. The majority of these cases
had probably been exposed to contaminated feed still in the feed chain after
the ban. The normal range of the incubation period (2.5 to 8 years or more)
will ensure more cases in the future. The other affected countries have expe-
rienced only sporadic native cases. In 1994, and the first nine months of
1995, Switzerland had 64 and 52 cases, Ireland had 19 and 3 cases, Portugal
had 12 and 10 cases, and France had 4 and 2 cases, respectively. Transmis-
sion probably occurred by feeding contaminated meat and bone meal pro-
duced in the U.K. to native cattle before importation was prohibited. Seven
countries imported cattle from the U.K. that later developed BSE: Falkland
Islands (1 case in 1989), Oman (2 cases in 1989), Portugal (6 cases in 1990-
1993), Germany (4 cases total in 1992 and 1994), Denmark (1 case in 1992),
Canada (1 case in 1993) and Italy (2 cases in 1994). Dourine: In April 1995
a lot of 60 horses for export to the U.S. was tested for dourine at the NVSL.
Six tested positive serologically by the complement fixation test, and were
slaughtered and rendered. During traceback investigations in May, an addi-
tional 10 horses from Chihuahua state tested positive and were slaughtered.
A large survey of horses from all 14 rural districts of Chihuahua is being
planned. Although Mexican officials reported the episode to the OIE in July
as dourine, all seropositive horses have been clinically normal and cross re-
action to other trypanosomes is suspected. Mexico has been free of dourine
of VEE began in northwestern Venezuela (VE) in April 1995 and by August
had spread west to La Guajira state of Colombia (CO). There have been over
12,000 patient visits for VEE in La Guajira (surveys estimate over 45,000
people infected), and an undetermined number of horses infected. The cur-
rent epidemic is the largest in the region since 1962-1971, when outbreaks
eventually spread to Central America, Mexico and Texas. Closely related 1C
epizootic strains have been isolated in both VE and CO. The outbreak is
believed to be associated with heavy rains and flooding in arid rural areas, a
subsequent increase in the mosquito population, and an unprotected equine
population serving as amplifiers of the virus. Because of the lower number of
horses relative to 1971, human and other animal infections may have helped
to sustain the epizootic. Mosquito control programs are credited with limiting
the spread to the northern part of La Guajira state. About 5000 equines in La
Guajira, 20,000 in Magdalena and 70,000 in Cesar States have been vacci-
nated with TC-83 (live attenuated) vaccine in advance of the outbreak. Spo-
radic equine deaths from eastern equine encephalomyelitis have also been
confirmed in Cordoba, Cesar and Magdalena States of CO. Viral Hemor-
rhagic Disease of Rabbits (VHD): Cuba declared itself free of VHD in March,
1994, after experiencing outbreaks from May to August 1993 and implement-
ing an eradication and surveillance program. VHD is enzootic in parts of
Europe and China. In Australia VHD that was being assessed in experimen-
tal trials on Wardang Island off South Australia for its potential as a biological
control agent in wild rabbits, escaped experimental pens in October 1995 to
two nearby warrens on the island. From Wardang Island it spread to the mainland near Port Pearce 4 km away, where two dead rabbits were confirmed positive by electron microscopy. Surveillance and eradication programs have been implemented to prevent further spread on the mainland.

Overview of Animal Health Activities in Israel. Arnon Shimshony, VSAH, Beit Dagan, presented by Bill Buisch, APHIS, Scotia. Data on a 1993-94 outbreak of Bluetongue type 16 in sheep in Israel was presented. Cases were identified in exotic European sheep breed. Most were unvaccinated animals, with 23 foci in 1993 and 61 in 1994. In 1994 there were 547 cases with mortality in 177 animals. From 1975-1992, there were no cases of Bluetongue type 16. The attenuated vaccine developed at the Onderstepoort Vaccine Laboratory (containing types 2, 4, 6, and 10) also incorporates type 16 in the vaccine used in Israel. There were no cases in 1995 until October, when 2 suspect clinical cases were reported. So far, no virus has been identified or typed.

Status of Foreign Animal Diseases in Australia. Jack Haslam, Embassy of Australia, Washington. The challenge of trying to make timely reports to the OIE and put out responsible information to the public, while also dealing with the sometimes less than responsible reports that appear on the internet was briefly discussed. Australian authorities investigated 6 FAD outbreaks: Japanese Encephalitis: Two human cases on islands in the Torres Straits, between Australia and New Guinea were reported. This is a special quarantine area monitored by Australia. A serologic survey of livestock in the area showed Australia to be free. Parasitic Mite of Bees: An outbreak of the mite Verona jacobsoni was reported in a honey bee colony in the Torres Straits surveillance area. The colony was destroyed. Continuous surveillance of the mainland shows Australia to be free. Avian Influenza: One outbreak of type A H7N3 was reported in 1994. The flock was depopulated and clinical and serological surveillance pursued. Australia was declared AI free in 1995. Kangaroo Blindness Syndrome: Surveillance and laboratory testing continues on this elusive disease. No etiologic agent, reservoir or possible vector has been definitively identified. Rabbit Calicivirus (Viral Hemorrhagic Disease of Rabbits): Field trials are underway on Warding Island to evaluate the virus as a biological control agent of wild, European rabbits. The virus spread to the mainland, where infection of 2 rabbits was confirmed. Surveillance continues on the mainland while the field trials are completed. Additional details were reported by White, above Equine Morbillivirus: In 1994 an outbreak of equine morbillivirus resulted in the deaths of 13 horses and the trainer of the horses. Seven horses and 1 animal caretaker recovered from illness. A clinical and serologic survey of surrounding premises and horses was negative. A possible conclusion is that the morbillivirus escaped its natural host to cause disease in an unnatural one. Another human death was reported in late October, 1995. The man had been involved in a necropsy of a
REPORT OF THE COMMITTEE

horse that had died of similar symptoms earlier and some miles away from the original outbreak in 1994. The morbillivirus was suspected in the human death, and subsequent testing of preserved material from the horse he had worked on showed antibody activity to the virus.

EXANDIS and AAHC: The Evolution of Animal Health Services in Australia. Steve Hoare, DPIE, Canberra. This paper was discussed as presented in the General Session. The full text is included elsewhere in these proceedings.

Status of the Screwworm Program in Central America. John Wyss, APHIS, Panama City. Mexico has been free of screwworm since June 1993. A recent earthquake damaged the plant at Tuxla, but no wild-type flies were thought to have escaped. 20 million sterile flies were released in the vicinity as a precaution. The last case in Belize was in 1991; the country was declared free in 1994. Guatemala was also declared free in 1994. El Salvador was declared free in June, 1995. Honduras has had no cases since January, 1995. Nicaragua continues to have 15 to 20 cases per week along the border with Costa Rica, down from about 3800 per week a year ago. Sterile flies are only being dispersed in Nicaragua at this time. The program is being organized in Costa Rica, with the first releases anticipated in July, 1996. Discussions on the eradication program in Panama, and the construction of the new plant, are underway in Panama City. The land for the site of the new plant has been given to the program by the Government of Panama. The matching funds from the Government of Panama are also available. Additional details were reported by White, above.

Planning the Next Edition of the Gray Book. Bill Buisch presided over a spirited discussion on the proposed revision to the Gray/White Book. A subcommittee to organize the revision process was proposed and approved. Bill Buisch will chair the sub-committee, with Werner Heuschele as Co-Chair. Members are: Hector Campos-Lopez, Jim House, Jack Hyde, David Ligda, Chuck Mebus, Al Smith, Bill Sterritt, and John Williams. Discussion included the need for an internet version, revision of the supplemental manuals, marketing the new edition, keeping the current field orientation of the book, etc.
JOINT SESSION:
THE COMMITTEE ON EPIZOOTIC ATTACK, AND
THE COMMITTEE ON FOREIGN ANIMAL DISEASES

Topic Area - Emerging Diseases II

The first joint meeting of the 2 committees was opened with remarks by Gale Wagner about the intent of the session to take advantage of the topics of interest to both committees. John Maré (Univ. Arizona, Tucson) was introduced as the moderator of the joint session. The following papers were presented:

Diagnosis of FAD and the National Veterinary Services Laboratory (NVSL). Jim Pearson, APHIS, Ames. The highest priority for the NVSL is to provide support for the prevention of the introduction of FAD. The NVSL laboratory whose primary mission is to diagnose foreign animal diseases is the Foreign Animal Disease Diagnostic Laboratory (FADDL), located at the Plum Island Animal Disease Center, which is a part of the USDA-ARS. The central laboratory for the NVSL is located in Ames, Iowa. Three laboratories at NVSL perform FAD diagnosis. The Diagnostic Bacteriology Laboratory (DBL) and the Pathobiology Laboratory (PL) have most of their space in a strip mall, with a small amount of space in the NVSL Central building and the NADC. The portion of the DBL and PL where the FAD diagnosis is performed is a biosafety level 2 facility. The Diagnostic Virology Laboratory (DVL), located in the NADC, is a biosafety level 3 facility. The NVSL in Ames has a staff of 231 and has a full service diagnostic laboratory that receives about 45,000 accessions in a year. The diagnostic capability for selected FAD’s is located in Ames. These diseases are the ones that have less potential for spread and do not require to be worked on in a high containment facility on an island. The DBL has the capability to diagnose five FAD’s: equine piroplasmosis, bovine babesiosis, dourine, contagious equine metritis, and glanders. The DBL has a staff of 42 people, including 6 veterinarians. The PL is called upon to conduct FAD field investigations and is the reference laboratory for identification of foreign and domestic ticks, for screwworm identification, and for the diagnosis of bovine spongiform encephalopathy. The PL has a staff of 28 people, including 10 veterinarians. The DVL has diagnostic capability for hog cholera, blue eye of pigs, Venezuelan equine encephalitis, Geath, exotic strains of bluetongue and epizootic hemorrhagic disease, Aino, Akabane, and all the avian viruses. The avian viruses include velogenic Newcastle disease, highly pathogenic avian influenza, turkey rhinotracheitis, egg drop syndrome, and others. The VS diagnostic work is done in Ames as well as the FADDL; this is not an FAD, but the clinical signs are almost identical to FMD, so it is treated like an FAD. The DVL has a staff of 40, including 7 veterinarians. The FADDL has the capability to diagnose all of the other FAD’s. An emphasis is put on the
diagnosis of vesicular diseases because foot-and-mouth disease is so infectious and economically devastating. The NVSL has a building plan to consolidate the laboratories in the strip mall and NADC into NVSL Central. This would provide a facility with better biosecurity that is more appropriate for the diagnostic work being conducted at the NVSL. Funding has been requested for this consolidation.

Review of FADDL Diagnostic Capabilities. Alfonso Torres, APHIS, Plum Island. The elements of a 1993 review of APHIS-NVSL and FADDL diagnostic capabilities were described within the context of what the NVSL considers as its number one priority, the diagnosis of FAD. Staffing appears to be adequate with 25 at FADDL directly involved in FAD work. The main functions of FADDL include FAD diagnosis, development of tests, preparation of reagents, training and animal welfare. Most of the day to day activity involves work on samples from imported animals. FADDL participates in about 300 FAD investigations a year, involving the field diagnosticians trained at Plum Island. Training activities also include university professors, veterinary students, state diagnostic lab personnel, and diagnosticians from other countries. The evolution of diagnostic test development was described, including the collaborative evaluation of tests, reagents and vaccines with laboratories in other countries. FADDL also maintains the North American FMD vaccine bank. Animal welfare work includes the vigorous efforts to reduce the use of experimental animals.

Integration of Foreign Animal Disease Missions between ARS and APHIS. Harley Moon, ARS, Plum Island. The ARS/APHIS consolidation of activities into one building at Plum Island was very much a team effort and has been completed. The final stages of the consolidation were completed during the early stages of the VS outbreak in September, 1995. The results in terms of coordination, collaboration and cooperation highlighted the intent of the consolidation, to fully integrate ARS and APHIS efforts on FAD research and diagnosis. The directorship of the center will now rotate every 5 year between ARS and APHIS. The level of communication has been intensified to assure that all personnel at Plum Island understand the mission of the laboratory and how to optimize all resources available. The renovations begun 10 years ago will continue, with the goal of improving animal rooms and then the remaining laboratory space. Scientific goals are being set by all scientists involved.

Collaborative Research on Vesicular Stomatitis. John Mare, Univ Arizona, Tucson. Many questions about the epidemiology of VS remain unanswered, including vector transmission, mechanical transmission, and the reservoir. Laboratory experiments with black flies (Simulium spp) suggest that several species may be efficient vectors of VSV, while others may have midgut and/or salivary gland barriers to virus transmission. Field work has con-
centrated on role of rodents and sandflies (*Lutzomyia* spp) in maintaining reservoirs during quiescent periods between epizootics.

**ARS Research Program on Vesicular Stomatitis.** Walter Tabachnick, ARS, Laramie. The ARS effort has concentrated on the analysis of old and new outbreaks in terms of animal movements, biological transmission, contact transmission, and the role of inapparent reservoirs of infection (only about 10% of infected animals show clinical signs). In the 1982 and 85 outbreaks, virus was recovered from *Culicoides* spp. In the current outbreak in New Mexico, virus was recovered from *Simulium* spp. Future research must include a risk analysis and assessment of control strategies.

**APHIS Surveillance of the Vesicular Stomatitis Outbreak in New Mexico, Utah and Colorado.** Jerry Dick, APHIS, Riverdale. The APHIS activities during the recent outbreak were described. The details were similar to the earlier report of FAD surveillance activities (see Williams report, above). Any case investigated was considered positive if VSV was isolated from any tissue sample, or if the serum sample had antibody activity detected by the CF test.

**Vesicular Stomatitis in Mexico, A 15-year Review (1981-1995).** Cristóbal Zepeda, SARH, Mexico City. Vesicular stomatitis is an American disease, endemic in Mexico, Central America and parts of South America. It is sporadic in the U.S., with outbreaks occurring roughly every ten years. Surveillance for a disease like VS in Mexico relies on trained FAD diagnosticians in 8 regions of the country. The organization includes an Animal Health Emergency Group in each state to serve as the basis for surveillance and action when an FAD is confirmed. Data on VS has been collected since early 1981. Positive cases were defined as a herd or group of animals clinically affected with vesicles and confirmed by the CF test. VS is endemic in Mexico, particularly in the states of Veracruz, Chiapas and Tabasco. Sporadic cases occur in the northern part of the country. Generally VS is not considered a significant threat for animal health, its main importance lies that it must be differentiated from FMD in the laboratory. VS cases were detected in each year of the study. Every year Mexico exports more than 1 million cattle to the US, but VS outbreaks in that country occur only every 8 to 10 years. The lack of scientific research in the epidemiology of the disease does not allow to explain the origin of the 1995 outbreak in the U.S. and its explosive spread. In Mexico in 1995, the few cases reported were confined to the south of the country.

**Avian Influenza Eradication Program in Mexico.** Eduardo Rivera-Cruz, SARH, Mexico City. Last year at this meeting, Al isolates of low pathogenicity were reported in flocks in 11 Mexican states. Then, in Jalisco in December, 1994, medium and highly pathogenic isolates were collected in cen-
tral Mexico. Quarantine, biosecurity and vaccination procedures were initiated. The vaccine consists of an inactivated H5N2 virus in oil emulsion. Concurrent laboratory studies showed, however, that while vaccination would prevent clinical AI, it would not prevent the spread of virus when vaccinates were challenged. Thus, the vaccine is used by permit only, restricting its use to defined epidemiological situations. Since late 1994, about 286 million doses of vaccine have been used. Currently several states in the Yucatan peninsula and in the north have been declared AI free. Some farms in the endemic area have been certified free. Vaccination will continue through the winter, with followup serosurveillance and, when possible, reduced vaccination. It is hoped that all but the central states will be declared free by 1997. A recombinant vaccine product is currently being tested. Additional details were reported by White, above.

Bill Buisch led the discussion on a joint resolution calling for enhanced funding for USDA research and diagnosis on FAD. The resolution passed. The joint session was adjourned.

**Topic Area - Foreign Animal Disease and Pest Diagnosis and Research**

**Molecular Approaches to Disease Diagnosis - the State Laboratory Experience.** Lloyd Lauerman, AVDL, Auburn. The shift of development work on new diagnostic tests to PCR based methods was described. Multiplex assays using primers for conserved 16S ssRNA gene sequences are being used for avian mycoplasma cases. A combination of PCR and RFLP is available for avian, porcine, bovine and most small ruminant mycoplasmosis suspects. A multiplex PCR protocol for differentiating clostridial toxins is available. Training in the use of the PCR has been presented in Brazil and Mongolia.

**Molecular studies of ASF Infection.** Dan Rock, ARS, Plum Island. The molecular basis for virulence may include a gene that enables the virus to invade and replicate in highly differentiated cells such as neurons. Deletion mutants of the virus still replicated in cell culture, so the effect of the gene may be to define host range. The deletion mutant may be a live virus vaccine candidate.

**Molecular Diagnosis of AHS Infection.** Will Laegreid, ARS, Clay Center. Effective diagnosis of any FAD depends on the match of a technique or test to the sample or problem at hand. Current diagnosis requires 5 to 7 days to complete, the use of either suckling mice or egg inoculation, and biocontainment to accomplish. A molecular approach to diagnosis should be group specific, provide results in 24 hours (reducing time and cost), offer a sensitivity greater than or equal to isolation procedures, and apply to any sample with need for biocontainment (reduces cost and increases the num-
MARE, et al

The approach was tested with primers for a sequence on a structural gene of the virus. The test protocol was rapid (results in 24 hrs), specific (group specific with all 9 serotypes amplified), and sensitive (as few as 10 copies of the genome could be detected). The PCR based test performed better than culture when samples were subjected to the rigors of shipping and handling.

Molecular Diagnosis of FMD Infection. Rich Meyer, APHIS, Plum Island. Simultaneous detection and serotype determination of FMD virus from infected porcine and bovine tissue has been developed. A high degree of conservation exists in the genomic region coding for the viral RNA polymerase among the seven FMDV serotypes. An oligomeric primer and probe were constructed from consensus sequence data within this region and utilized in a modified PCR technique. All seven serotypes of FMDV RNA were amplified and PCR product detected in a few hours. The sensitivity of the enzymatic amplification of FMDV was 10 TCID50 by gel electrophoresis and less than 1 TCID50 by hybridization to a labeled probe or HPLC analysis. The technique was specific as determined by examination of at least 12 other viruses, including enteroviruses and other agents of vesicular disease. Serotype designation for FMDV’s type A, O C and Asia-I was determined by utilizing oligomeric primer pairs constructed from VP1 sequence data. The PCR product was directly sequenced and subtype designation determined by sequence comparison to a FMDV database. This procedure allows more accurate FMDV identification from field cases without introducing selective process resulting from laboratory isolation in cell culture. In vitro enzymatic amplification of FMDV RNA using the modified PCR technique is a highly specific, sensitive and rapid procedure for FMDV laboratory diagnosis.

Detection of FMD: Needs and Current Prospects. Cecelia Whetstone, ARS, Plum Island. The single most important element in the control of FMD is the ability to detect it rapidly. Currently, diagnosis of FMD is carried out in laboratories with facilities to work with the virus in biocontainment. Using methods such as ELISA, AGID, CF, virus isolation, virus neutralization, and PCR, it is possible to identify and subtype a virus from a field outbreak within a few hours of the sample reaching such a specialized laboratory. What is still lacking in the current arsenal of FMD diagnostics is a test to make a diagnosis in the field. In the current world economic culture of opening and expanding trade and free trade markets, it is also very important to be able to differentiate vaccinated from convalescent animals. New tests for the detection of FMD virus need to be: rapid and capable of being done on site; specific, being able to diagnose FMDV and differentiate it from the other vesicular diseases; safe, made from non-infectious material; and sensitive, for on-the-spot identification of FMDV contaminated products. New tests for the detection of FMDV antibodies that can differentiate vaccinated from convalescent animals should be capable of using a sample of blood. Recently, two
ARS/PIADC scientists, Juan Lubroth and Fred Brown, showed antibodies to an FMDV nonstructural protein, called 2C, are present only in animals that have been infected with live FMDV and are not present in animals that have only received vaccine. Antibodies to another nonstructural protein called 3D, also known as the polymerase or the VIA antigen, are present in all animals which have experienced either infection; vaccination. The reason vaccinated animals apparently do not have antibodies to 2C is because it is very tightly bound to membranes, and, during the procedures used to make FMDV vaccines, membrane materials are not incorporated into the final product. Thus, when animals are vaccinated with the currently used killed virus vaccines, their immune systems never “see” the 2C protein. It is only when an animal is infected with live virus, and the virus undergoes replication, that antibodies are then produced against 2C. If, after extensive testing, this observation remains true, the development of a diagnostic test to differentiate vaccinated from convalescent animals will be possible. Rich Meyer, FADDL/PIADC, is currently expressing both 2C and 3D in a baculovirus expression system for the purpose of developing such a differential diagnostic. This work is a collaborative effort between ARS and APHIS scientists in the PIADC FMD program, and with International Services at PANAFTOSA..

Bill Buisch presented several draft resolutions for discussion. Resolutions approved called for early construction of the new screwworm rearing facility in Panama, enhanced USDA research and diagnostic efforts on VSV, and the organization of a joint READEO exercise with Mexico and Canada. The meeting was adjourned.
The Government Relations Committee of the United States Animal Health Association met on February 27, 1995 and the morning of February 28, 1995, in the United States Department of Agriculture south building in Washington, D.C., with representatives of the United States Department of Agriculture. On the afternoon of February 28, 1995, we also met with representatives of the Allied Industries at the National Cattlemen's Association Office, 1301 Pennsylvania Avenue, Washington, D.C. On the afternoon of March 1, 1995, we met with Dr. Luchsinger and the senior management staff of Veterinary Services at their new Riverdale, MD facility.

The efforts of Dr. Don Luchsinger and his staff in making this meeting very open and informative were greatly appreciated. The continued opportunity to keep this meeting as a direct and open line of communication between APHIS and USAHA is viewed by our organization as being of the utmost importance.

**USDA-APHIS-VS - Dr. Don Luchsinger**

Dr. Don Luchsinger, Acting Deputy Administrator, Veterinary Services, greeted the Government Relations Committee and introduced VS staff attending. In his introductory remarks, he indicated that an agency attorney had challenged the relationship between APHIS and USAHA. He indicated that this was an area needing some discussion, but that he had rationalized the relationship and was not all that concerned about it. He remarked that the trade workshop (NAFTA/GATT) on March 2, 1995 was the first workshop of its kind and that there would be more to follow. He indicated that APHIS has finally been authorized to fill open positions.

**OPERATIONAL SUPPORT - Dr. William Hueston**

Dr. Hueston, Veterinary Services Operational Support, stated that operational support is divided as follows: 1) cattle diseases and surveillance; 2) information systems; 3) national center for import/export; 4) emergency dis-
REPORT OF THE COMMITTEE

eases; 5) national animal health programs (swine, sheep, goats, aquaculture, equine, poultry).

There are four main blocks making up Veterinary Services: 1) field infrastructure; 2) NVSL; 3) operational support; 4) center for epidemiology and animal health. The move from Hyattsville to Riverdale has been completed and the new building has been specifically designed for APHIS and is adjacent to the University of Maryland campus. There is a full range of ongoing training (including computers) and day care facilities.

NATIONAL ANIMAL HEALTH PROGRAMS - Dr. Joe Annelli

The National Poultry Improvement Plan (NPIP) has been moved to Georgia in order to place the agency closer to the poultry industry. This is being utilized as a prototype for possible further moves of this type to place the agency in closer proximity to those being served. The NPIP move was at the request of the NPIP General Conference Committee.

The voluntary certification program for fish eggs is working well. The aquaculture industry will meet in March with APHIS in Maryland to develop information on the needs for a national aquaculture animal health program. A follow-up meeting with state/federal agencies will be held.

The announcement for a change in the EIA reporting system was a cause of concern for the accuracy of the data due to the fact that some states require the testing of equine twice per year.

The pseudorabies program is going well. The concern is that we are now entering a more difficult stage of the program. A key component of the program is the large number of contiguous states in the northwest and north central (WA, MT, ND, WY, ID, OR, NV, UT) which are Stage 5 and which may help in regionalization and trade. If California were free, this would help exports.

The recycled commodity feeding program risk assessment for feeding recycled commodities to domestic swine in the U.S. has been distributed for review and feedback.

As of February 22, 1995, there were 91 sheep flocks enrolled in the National Scrapie Program. There are still 71 infected flocks and 6 source flocks left in the U.S.

As of February 23, 1995, there were four new herds (infection) in the U.S. and all will be depopulated. By March 1, 1995 we may be at "zero" infected herds, except for feral swine.

The national trichina research project goals are: 1) determine validity of the ELISA test; 2) determine characteristics of high risk herds; 3) determine efficacy of control programs to clear infection. The infection rate is thought to be about 0.02 percent.

CATTLE DISEASE SURVEILLANCE STAFF - Dr. Granville Frye

Colorado is now brucellosis free—making a total of 33 free states, plus
GOVERNMENT RELATIONS

Puerto Rico and the Virgin Islands. The goal is to have infected herds under 100 and as of the end of January were at 129. A lot of herds are being depopulated and the concern now is the number of new infected herds. Last year there were 20 as of January 31, 1994; this year, 21.

More bison are leaving the Yellowstone National Park, about 389 as of the week of February 20, 1995. Most of the meat is going to native Americans. A cooperative agreement between USDI and USDA has been signed with the goal to eliminate brucellosis in the park. There is good agreement at the top administrative level, but many disagreements at lower levels. A memorandum of understanding ("Greater Yellowstone Interagency Bison Agency") has been signed by the governors of Montana, Wyoming and Idaho. This may or may not be in harmony with the USDI/USDA cooperative agreement. Its goal is eradication by 2010. There is some question whether the USDI/USDA cooperative agreement is in harmony with 1994 USAHA Resolution No. 9 and the APHIS response. APHIS feels there are only three ways bison should be released to native Americans: 1) for meat; 2) neutered; 3) rigid testing requirements to ensure negative status. Also, they must have concurrence of state officials.

Humane organizations have been active in opposing face branding. We have to abandon "old ways" if they are not the only way. The department has received 12,000 letters in opposition to face branding. Many were generated as the result of the effort of two individuals. Also, there is concern that TB tail branding might be missed by inspectors at slaughter.

IMPORT-EXPORT STAFF - Dr. Robert Kahrs

In order to represent U.S. trade negotiations, we need personnel trained with portfolios for four regions of the world. This requires individuals with a broad outlook and will require cross training.

NAFTA/GATT represent a new world trade paradigm and will require revision of five sections of the Code of Regulations regarding animals. Veterinary Services will shift from an outlook based on:

1) countries to one based on regions and;
2) "free" status to degrees of risk. In terms of risk, there will be three levels of risk for "infection" and three levels of risk for "free", for a total of six levels of risk.

PETA has been active in bringing about change in the procedure for spaying of heifers.

EMERGENCY PROGRAMS - Dr. John Williams

Dr. Williams discussed the organizational structure of emergency programs, including: 1) emergency preparedness team; 2) field operational support team; 3) technical services.

As of December 1994, there were 140,000 cases of BSE in the United Kingdom involving 30,000 herds—52 percent were dairy and 14 percent beef. There has been a ban on import of cattle to the U.S. from the U.K. since July 1989. Of the 489 animals that had been imported prior to that date (as of
January 24, 1995), 135 are still known to be alive, 307 dead, 39 still being traced and 8 have been exported. From May 1990 to January 1995, a total of 1,996 specimens have been examined for BSE in the U.S. These were from a variety of sources, including FAD investigations, rabies negative cases, slaughterhouse collections and veterinary laboratories. FSIS has a pilot project which involves slaughterhouses in five high risk states.

INTERNATIONAL SERVICES - Dr. Kelly Preston

International Services has one regional office with 300 employees and operates on a $50 million annual budget. Their staff includes 24 veterinarians. They have a heavy presence in Latin America, with only three veterinarians in other parts of the world.

Their budget supports four major program areas: 1) screw worm; 2) foot and mouth disease; 3) tropical bont tick; 4) international programs. A handout of the table of organization was provided.

They have recently closed the Asia/Pacific office in order to upgrade their trade mission to China.

Screw worm--This is the major program area, expending some $30 million per year. In 1995, they plan to be almost through all of Nicaragua. The program needs a new fly production plant at the Panama barrier, but there is no federal funding for this. IS, by agreement, will be out of Mexico by December 1996.

Foot and mouth disease (and other foreign animal diseases)—This takes $3 million per year, with most of this aimed at the Colombian barrier. The European nations support the Turkey barrier.

Avian influenza in Mexico--In December 1994, the H5N2 AI in Mexico turned high path (HP) and is widespread in a belt across the central part of the country. There is no support in Mexico to buy HP flocks; the poultry marketing system is quite convoluted, there is little integration of the industry, and it is a chaotic situation. They are putting their faith in vaccination and are encouraging U.S. biologic firms to conduct field trials in Mexico; they have decided to live with it. USDA is not contemplating any activity itself in Mexico and feels it is too widespread to do anything about it.

Tropical bont tick--This takes about $500 thousand per year. Progress has been very slow, due to the complexity introduced by so many global agencies and countries being involved (death by committee). It is part of a regional program directed by FAO. The U.S. will concentrate on islands that have Heartwater disease.

Mexico TB--The Mexican cattlemen have not come through with agreed upon dollar support to fund a coordinator position. For this reason, the cooperative program has stopped. Texas is not waiting and has gone ahead with adoption of regulations following the Border States Veterinarian alternative proposal to the USDA regulation.
In 1994, BBEP licensed 131 new products (vaccines and diagnostics) produced by 117 licensed biologic facilities. There currently are over 2,000 licensed products, with a total of 130-150 new products a year. Because of personnel limitations (due to resignations and retirements), BBEP is experiencing increased workload, with no increase of work force. They are currently recruiting for three of four positions vacated last year. They have a total of 60 authorized positions.

The approval process length varies with the product under consideration. It may be as long as 3-1/2 years for a vaccine, where duration of immunity is involved, or one year for a diagnostic test. Major product growth areas are: 1) diagnostics; 2) products for further manufacturing; 3) biotechnology (52 biotech products now, including diagnostics and vaccines).

The veterinary biologics program has undergone a revamping to improve the approval process. This involves the following points: 1) licensing considerations; 2) coordinated review process; 3) reducing response time; 4) streamlining the label approval process; 5) licensing philosophy changes. A new procedure for risk assessment has been incorporated into the review process and is considered important for such things as release of a live vaccine into the environment.

Harmonization of licensing is important because of international ownership of biologic companies, political interest in free trade, and decrease of redundancy and exchange of information on regulation. It will reduce costs and regulations, improve research and facilitate trade. Europe has a long way to go to harmonize within the European community of nations before a lot of progress can be made between the U.S. and Europe. A neutral international office is needed for coordination and OIE has established the "International Committee for Harmonization."

BBEP has proposed a new regulation on repackaging of biologics after they leave the manufacturer. Distributors have objected, as there is no provision for single dose sales—primarily for companion animals. Implementation of the regulation has been delayed until August to address this issue.

In response to a question regarding concern of the poultry industry that bursa-derived vaccines may be removed from the market because of possible contamination with chicken anemia agent (CAA), Dr. Espeseth stated the agency was flexible and would not take these products off the market, but they were concerned about CAA. Testing has shown bulk vaccine to be contaminated with CAA, indicating that the inactivation process is not working. To solve this, they have asked firms to validate the inactivation process or demonstrate there is no contamination of the bulk vaccine. As of July 1994, the firms were given a year to respond; a letter was sent in November as a reminder. If there is no data by July, they can renegotiate additional time.
In response to a question regarding the development of a vectored vaccine for avian influenza, Dr. Espeseth stated that some companies may be working on this, but that there had been no talk with them about the need for this type of product. Such a product might be good for eradication if it could be differentiated from the field isolate.

In response to a question, Dr. Espeseth stated it was for a licensed veterinarian to manufacture an autogenous bacterin in one state and use it in another, as long as the practitioner had visited the farm and animals involved and was personally aware of the problem.

APHIS UPDATE - Dr. Lonnie King; Mrs. Patricia Jensen

Dr. Lonnie King, Acting Administrator of APHIS, commented on the reorganization. The FSIS food safety initiative field work continues to be done by APHIS-VS on a reimbursable basis. The Salmonella enteriditis program transfer to FSIS is taking form.

On May 24-26, 1995, VS will host a meeting to address the industry concerns on food safety.

Dr. King envisioned a potential role for USAHA as the official feedback mechanism from industry and state programs on global trade issues.

The major focuses for VS are to finish commitments in brucellosis, pseudorabies and tuberculosis; and in herd certification where quality is emphasized, using quality assurance programs.

The next phase—referred to as Reinvention II—will identify future roles, what to do and what not to do, which roles to send to states, and what functions can be privatized.

A “future search” conference met in February to identify the vision, competency of staff, work environment, and ten-year mission. An implementation conference will be planned for the first week of April.

The next year’s budget includes 25-30 percent of revenue from user fees. The largest area of concern was in Emergency Preparedness; OMB will not provide funds for future emergencies. Some portion of the budget must be set aside annually to develop a fund to take care of emergencies. Every effort will be made to protect the AVIC and VMO field positions and regional offices will be reduced. The current attitude about funding will prevent spending of funds in other countries to protect our borders.

APHIS placed $1.2 million in the rabies initiative in Texas to provide vaccination by baiting in coyotes.

Acting Assistant Secretary of Marketing and Regulatory Programs, Mrs. Patricia Jensen, cited the political atmosphere as impacting regulatory programs. The definitive impact of the “moratorium on regulations” on APHIS will be followed with much concern. She expressed cautious optimism on support for APHIS regulatory needs being met.

The signing of an agreement with the other involved agencies on the principles of the approach to rid Yellowstone National Park of brucellosis, was a
GOVERNMENT RELATIONS

recent highlight of APHIS activity. She assured us that no movement of diseased bison would be allowed.

Assistant Secretary Jensen feels that USAHA must play a large role in educating legislators that funding for emergency preparedness is essential. She stated, "APHIS programs make agriculture strong and independent." Congressional leaders like that concept.

USDA received over 20,000 letters of complaint on face branding of cattle. She urged us to utilize the opportunities to show humanitarian concerns in dealing with this situation.

In closing, she stated that we couldn't do our job without USAHA support and need your input and direction.

AGRICULTURE RESEARCH SERVICE (ARS) - Dr. Robert Oltjen et al.

Dr. Robert Oltjen, Associate Deputy Administrator for Animal Sciences of the ARS, and members of the staff reported on ARS activities.

Dr. Oltjen gave us an update on the ARS budget—mentioned several ARS programs that will suffer as a result of a reduced budget; he shared information on changes in program staff.

ARS, which receives less than five percent of its budget from outside sources, suffered a four percent reduction in fiscal year 1996 from its current $700 million budget; this represents a reduction of $28 million. In addition, Congress has put a hold on the $12.6 million National Swine Research Center building in Ames. In order to meet this budget reduction, ARS will have to terminate operation of over twenty of its 120 program locations. In addition, a number of ARS programs have been eliminated—including the Animal Health Consortium and research on lyme disease, aquaculture, and turkey gene expression.

Dr. Oltjen, who firmly believes that animal health research is a Federal role, mentioned that although he has been successful in the past in protecting ARS programs from the budget ax, the new political climate is such that ARS could use our support. In view of the fact that APHIS doesn't have its own research arm, support from the USAHA cannot be overemphasized.

Dr. Don Knowels, who is on special detail to ARS from the Animal Disease Research Unit at Pullman, Washington, discussed several diseases that ARS is currently working on. Brucellosis—research on a new attenuated vaccine, RB51, appears to induce titers that can be distinguished from field infection; tuberculosis—$1 million has been redirected in the ARS budget to the NADC for research in the areas of diagnostics and traceback of TB outbreaks; paratuberculosis—research on the diagnosis of the preclinical carrier state and the potential for causing disease in people; bovine spongiform encephalopathy and scrapie—research on the development of a preclinical diagnostic assay and reproduction of the disease in calves inoculated with tissue from scrapie-infected sheep (the disease was reproduced clinically, but it did not appear the same histologically); anaplasmosis—research on the
REPORT OF THE COMMITTEE

diagnosis of the carrier state where a competitive ELISA test has been developed that appears to work well; avian influenza--research on the current AI problem in Mexico, with the idea of developing a vaccine.

Although ARS conducts research on mycotoxins, tissue residues and poisonous plants, Dr. Jane Robens, ARS national program leader for food safety, discussed the microbiological research area, including a number of ARS research programs directed toward improving food safety. ARS has dedicated $16 million into pathogen reduction research, with over three-fourths being spent on post-harvest. Some of the research projects mentioned include showing that the rumen supports the growth of E. coli 0157:H7 better when cattle are starved (with possible application to using a feed additive in animals transported to slaughter); the use of an E. coli vaccine using a swine model; additional methods for E. coli diagnosis; rapid E. coli diagnostics that may have application to HACCP programs; various cryptosporidiosis projects, including defining resistance to heat, cold and chlorination; an improved Salmonella vaccine and diagnostic techniques; and finally, whether Salmonella enteritides phage type IV (recently found in a California flock) is really more pathogenic than other types.

FOOD SAFETY

A meeting with Dr. Mike Taylor, J.D., Undersecretary for Food Safety, was scheduled for Monday afternoon; Dr. Taylor failed to appear at the designated time. After some delay, Dr. Michael Marshall made a phone call to Dr. Taylor's office; Dr. Taylor was out of the office and could not be reached. Dr. Taylor's secretary regretfully indicated that an apparent misunderstanding of scheduling resulted in the unfortunate circumstance of Dr. Taylor not being able to meet with the Committee at the designated time.

COOPERATIVE STATE RESEARCH, EDUCATION AND EXTENSION SERVICE (CSREES) - Dr William Carlson et al.

Dr. William Carlson is Acting Administrator of the newly formed CSREES. This agency is part of the USDA's reorganization and includes part of the old cooperative research service, seventy-four land grant colleges, experiment stations, and other such agencies. CSREES has a current budget of $932 million and has a staff of 400, of which five are veterinarians.

Dr. Carlson introduced Dr. Peter Johnson who briefed the group on the National Research Initiative (NRI) Competitive Grants program. He stated NRI is allotted approximately 6-1/2 percent of USDA's research appropriation ($97 million). Dr. Johnson stated a research grant was awarded because of its merit and content (not because of species) and a quota system on funding per species does not exist. The deadline for grant applications is January and approximately 75-80 percent of those approved goes to institutions. Most address sustaining animal health and well being, average $60,000 per year and have 2.75 years before completion. The low grant last year was $85,000 for a two-year program and $300,000 for a three-year program. Dr. Carlson
GOVERNMENT RELATIONS

stated food safety grant proposals would receive priority in the next few years and estimated 70 percent would be approved for post-harvest and 20 percent for pre-harvest food safety work.

FOOD AND DRUG ADMINISTRATION (FDA) - Dr. Bert Mitchell

Dr. Bert Mitchell, representing the FDA, spoke to the Committee. Dr. Mitchell discussed the availability of euthanasia drugs to non-veterinarians and stated the Center would appreciate USAHA's input for direction on this issue. Dr. Mitchell explained the mechanics of the Veterinary Feed Order (VFO) and what criteria has to be met before the VFO can be used. He stated it was FDA's position not to approve a VFO if it were written by a veterinarian not licensed in the state the VFO is to be used (this differs from the AVMA position).

There was a discussion on the illegal use of Clenbuterol in show animals. Dr. Mitchell said FDA has been involved in several livestock exhibitions monitoring for this drug. There was a short discussion on the new "Animal Medical Drug Use Clarification Act of 1994."

Tuesday afternoon
February 28, 1995
National Cattlemen's Association Headquarters

ALLIED INDUSTRY

The Committee met with representatives of several allied industry groups at the NCA headquarters. The status of the proposed legislation for the "Humane Transportation of Horses to Slaughter" was discussed. Representatives from the North American Elk Association presented a list of issues regarding disease control programs and the marketing of live animals and meat products of cervidae. The Committee assured them that these issues would be presented to the appropriate USAHA committees and APHIS officials.

The National Broiler Council reported its deep concern regarding the Mexican avian influenza situation and the lack of national plans to deal with the potential introduction of the disease into the United States.

A round table discussion regarding a number of issues of concern followed:

1. TB and brucellosis program funding.
2. Coordinated effort in the paratuberculosis situation.
3. Emergency preparedness.
4. Need for industry and organizations such as USAHA and the AVMA to communicate their concerns directly to Congress.
5. Concern for the free trade agreements and the potential impact on the animal health programs of the U.S.

Dr. Robert Whitlock, University of Pennsylvania School of Veterinary
REPORT OF THE COMMITTEE

Medicine and Chairman of the USAHA Committee on Johne's Disease, met with the Governmental Relations Committee and Allied Industry representatives in response to an invitation from USAHA President, Wes Towers. Meaningful discussion was held regarding the possible association of paratuberculosis in animals and Crohn's disease in humans. It was the unanimous consent of the group that USAHA should provide the forum for evaluating current information to determine the potential threat of this disease.

The Governmental Relations Committee encouraged and endorsed a proposal presented by Dr. Whitlock to form a working group. The working group will be made up of affected industries and scientific and regulatory representatives. The group will submit a report to the USAHA Committee on Johne's Disease for consideration at the 1995 annual meeting.

Wednesday afternoon
March 1, 1995
Riverdale, Maryland

VETERINARY SERVICES - SENIOR MANAGEMENT - Dr. Don Luchsinger et al.

Dr. Don Luchsinger opened the meeting by stating that he had a list of things to put on the table and they could be taken up in any order along, with any items the group may have.

Will Hueston was asked to bring the group up to date on avian influenza in Mexico. He stated that a team was sent to Mexico about two weeks ago with the following mission:

1. Assess risks to U.S.
   a. Address most likely areas of risk
   b. Develop cost estimates of risk
   c. Evaluate adequacy of surveillance program
2. Evaluate options available
   a. Revisit emergency response guidelines
3. Active communications
   a. Press releases, update fact sheets, videos, etc.

The team has returned and the reports will be forthcoming; all three areas are being developed simultaneously.

Will Hueston also updated the group on the status of the BSE exposed cattle remaining in the U.S.

Dr. Luchsinger updated the group on VS budget and staff positions. $6.2 million has been taken from the budget and given to FSIS for the food safety initiative; along with this funding goes 26 positions, with a potential for 41 additional positions to be transferred out. The entire SE field group in Pennsylvania was moved as a block.

VS will be involved in food safety in quality assurance aspects of pre-harvest.
The current swine rule says that certificates of veterinary inspection must be issued within seven days from the time of inspection. The new proposal is to extend that time period to 30 days.

Wes Towers explained the working group concept for Johne’s/Crohn’s disease, how the committee will be formulated, and what its charges are.

Dr. Luchsinger explained the Federal Advisory Committee Act (FACA) and how it will affect USDA/VS relationships; he foresees very little impact.

Bob Nervig discussed VS’s frustrations with the Greater Yellowstone brucellosis situation and emphasized their determination to try to get positive action from the various interests involved.

Much time was devoted to the concerns of States and commodity groups regarding emergency response capabilities. We were assured that despite cutbacks there are core people trained and prepared to implement updated plans when outbreaks occur, as well as in epidemiology, technical services, surveillance, etc. There are a group of people who can be mobilized quickly to be the first line of offense for a disease outbreak, but replacements will have to be trained on the job. States may be asked to help in larger outbreaks.

Joan Arnoldi outlined that AAVLD and NVSL is conducting a listing of the various state laboratory capabilities and developing a strategic plan for their utilization in the case of a serious disease outbreak.

There may be no funds for depopulation and plans need to be made to address that possibility, as well as environmental concerns.

Thursday
March 2, 1995
Riverdale, Maryland

FREE TRADE: IMPLICATIONS AND OPPORTUNITIES—A USDA/APHIS WORKSHOP ON NAFTA AND GATT - Dr. Don Luchsinger et al.

Forty three individuals, representing various APHIS constituencies, including the United States Animal Health Association (Government Relations Committee), AVMA, animal owners and industry organizations, and several state and federal animal health agencies, gathered at the new APHIS headquarters building in Riverdale, Maryland on March 2, 1995 for a one day workshop involving the NAFTA and GATT trade agreements, entitled Free Trade: Implications and Opportunities sponsored by USDA-APHIS. The format of the meetings was general session informational sessions, midmorning and early afternoon small group breakout discussion sessions addressing a variety of trade issues, followed by group reports and a feedback and wrap-up session.

Don Luchsinger, APHIS Acting Deputy Administrator for Veterinary Services, enthusiastically greeted the participants and stated that this workshop represented another of a series of workshops addressing new directions and responsibilities for APHIS. He stated that the March 2 meeting was a new
prototype and forum which was intended to stretch the envelope of our ability
to respond to the new world of trade ushered in by the NAFTA and GATT
agreements. The workshop was planned to address what these agreements
mean for industries and regulatory officials and to address concerns of allied
industry groups. Additional meetings and workshops will be held.

As a result of the recent USDA reorganization, APHIS has a new mission
to support marketing in the newly formed USDA Marketing and Regulatory
Programs section it is now a part of. Many lack familiarity of the trade agree-
ments and this workshop was planned to fill those gaps of information. APHIS
wanted to gain insights from individuals, industries and agencies who make
decisions pertaining to trade and felt the small group discussions would as-
sist in this objective.

William Hueston--Director of the Center for Animal Health and Monitor-
ing, Program Leader for NAHMS, and Acting Director of the Operational Sup-
port staff--reviewed a recent needs assessment survey of the USAHA Gov-
ernment Relations Committee and the APHIS management team regarding
the NAFTA and GATT trade agreements and what should be addressed by
the workshop. He stated that the objective of the workshop would be a proactive
effort to position American agriculture to take advantage of the trade agree-
ments. Specifically, it would address: 1) how do NAFTA and GATT effect agriculture;
2) listen to participants ideas to form strategies and articulate risks.

John Greifer, Policy Analyst with the APHIS' Trade Support Team, stated
that the signed trade agreements contained the principles of agreement be-
tween nations, that now was the time to develop the details. He stressed that
everyone has the opportunity to shape the agreement details now. He re-
viewed the history of NAFTA and GATT and stated there is an explicit right of
every country to protect itself and to adopt more stringent regulations, with
three caveats: 1) must be based on science-based risk assessment; 2) must
chose the option that is least trade distorting; 3) not arbitrarily discriminate
against similar products. He then discussed the six principles of the agree-
ments: 1) science-based; 2) international standards; 3) equivalence;
4) regionalization; 5) transparency and; 6) dispute resolution.

Dr. Luchsinger stated that at the agency level APHIS formally created the
"Trade Support Team" (TST) in November 1994 to support implementation of
the agreements; Dr. Dan Sheesley is the Director. The TST is assigned to
International Services of APHIS, under Dr. Alex Thiermann, and at the agency
level relates to Veterinary Services, International Services, BBEP and PPQ.
At the department level, the TST relates to the U.S. Trade Representative, the
Food Safety Inspection Service and FAS. The function of the TST is to pro-
vide analytical services, internal communication and representa-tional ser-
vices.

Dr. Luchsinger continued by stating that in the international arena, the
World Trade Commission recognizes OIE as the standard setting agency for
animal health matters. APHIS has been a leader in feeding into OIE in recent
GOVERNMENT RELATIONS

years as a result of GATT. In the last three to four years, quadrilateral meet-
ings between New Zealand, Australia, Canada and the U.S. have been provid-
ing policy proposals to OIE pertaining to: 1) regionalization; 2) risk assess-
ment; 3) veterinary infrastructure. These have been accepted in the GATT
code. The current area of interest is monitoring and surveillance. At the
present time, the U.S. has four people in critical positions within OIE: Drs.
King, Thiermann, Strating and Pearson.

Dr. Luchsinger stated that to handle the vast increase in trade related
issues, Veterinary Services has formed the National Center for Import/Export
headed up by Dr. Robert Kahrs. This unit is addressing the question, how do
we accommodate to the new world of trade? New skills are needed in the
agency, such as negotiating skills, cultural sensitivity and language skills. In
addition, the agency has to adjust to the new paradigm shift from “free or not
free to risk assessment and regionalization. NAFTA and GATT are a done
deal and animals are going to move and standards are going to be set; APHIS
will lead in this area. There are 8-10,000 permit requests per year and the
agency used to do “intuitive” risk assessment while considering them. This
will be changed to a more qualitative risk assessment now and eventually will
shift to a more difficult, quantitative assessment system. A proposed rule on
risk assessment will be available in about four to six weeks.

The participants broke up into five groups to address the subjects of:
1) role of OIE; 2) regionalization; 3) risk assessment and transparency in
decision making; 4) impacts on animal health officials; 5) dispute resolution
process. The groups rotated every 20-30 minutes, with each participant hav-
ing the opportunity to sit in on each of the five groups. Reports were given by
each small group chairperson.

Dr. Will Hueston provided the feedback and wrap-up for the day-long work-
shop. He stated we understand more and have raised new questions not yet
assessed. In relation to monitoring and surveillance—we have to determine
how to evaluate and answer the question, “Where’s the trust”? In terms of
veterinary infra-structure—we have to determine how to measure and in terms
dispute resolution; we have to determine where the dollars and resources
come from to bring about settlement. In terms of U.S. resources—we have to
identify regions and measure risk assessment for both imports and exports.
In terms of reciprocity—if we open up, how do we assure ourselves of the
same level of trust with others? This requires careful thought to the risk
assessment techniques, communications and documentation. In other words,
where is the data, how reliable is it and how do we validate it?

Friday morning
March 3, 1995
USDA Building

FSIS - PRE-HARVEST FOOD SAFETY INITIATIVE - Dr. Bonnie Buntain;
Mr. Thomas Billy
REPORT OF THE COMMITTEE

The Committee very much appreciated the opportunity to talk with Mr. Thomas Billy, Associate Administrator for FSIS, and Dr. Bonnie Buntain, Director of the Animal Production Food Safety Program, concerning the important new issue of pre-harvest food safety.

Mr. Billy presented his views on the need for an FSIS reorganization, explaining the expected efficiency of having all functions of USDA which have to do with food safety now under one Undersecretary. The Committee was very pleased to hear that isolated production units where pathogens had been isolated would not be the sole target of this new initiative. We believe, as well, that the whole animal production marketing system—including transportation, the slaughter facility, meat processor and retail store—should be comprehensively reviewed using the HACCP approach to pathogen reduction.

Dr. Buntain told the Committee about the personnel who had already been transferred from APHIS to FSIS and those who still could be transferred in the future. She explained the possibility of a plan being negotiated with APHIS to keep the remaining personnel in place, yet would provide FSIS with needed epidemiological and laboratory data. The Committee sincerely hopes that the best agreement, with the least disruptive consequences, can be worked out to the benefit of both agencies. Dr. Buntain and her staff are to be commended for recognizing the fact that other agencies such as APHIS NAHMS can collect much needed baseline data and ARS can conduct significant research that will provide some essential new information for this initiative.

The Committee was pleased to hear that the new program would be non-regulatory in nature, instead focusing on the area of quality assurance driven by marketplace acceptance. The concern was expressed, however, that there must be a significant amount of research completed on the presence and duration of specific pathogens in animals before punitive measures can be applied to production units where transient pathogens are found.

The Committee was extremely supportive of the plans and format of the upcoming Animal Production Food Safety Forum and welcomes the opportunity to provide our input. We look forward to working with both Mr. Thomas Billy and Dr. Buntain in the future, especially at our meeting in Reno, and pledge our organization's total support in helping them formulate a well-rounded, comprehensive approach to the reduction of pathogens in our nation's livestock and poultry being offered for food.
REPORT OF THE COMMITTEE ON
HEMOPARASITIC DISEASES

Chairman: Dr. Rube Harrington, Jr., Arlington, TX
Vice Chairman: Dr. Robert L. Hartin, Oklahoma City, OK

J.L. Alley, AL; R.D. Anderson, IL; G.M. Buening, MO; D.B. Childs, FL; A.A. Cuthbertson, NV; W.C. Davis, WA; C.A. Gipson, FL; W.L. Goff, ID; T.J. Holt, NY; O. James, MT; M. Lea, Jr., LA; D.L. Notter, KY; J.O. Pearce, FL; M. Ristic, IL; G.P. Shibley, KS; C.E. Starkey, AR; J.E. Strickland, GA; G.G. Wagner, TX; J.M. Williams, CO

The Hemoparasitic Diseases Committee met on Thursday, November 2, 1995, at 1:30 pm in the Bonanza B Room. There were 11 members and 11 guests present. Four presentations were made to the committee.

Dr. C. J. Holland, Protatex International Inc., St. Paul, MN, reported on the “Epidemiologic and Zoonotic Implications of Equine Granulocytic Ehrlichiosis.” She pointed out that recent reports indicate that the rickettsial agent, *Ehrlichia equi*, the causative agent of equine ehrlichiosis, infects dogs and that this organism is also the etiologic agent of a newly-recognized disease, human granulocytic ehrlichiosis (HGE). Aside from genetic and immunological identification of the organism in the tissues of people who died as a result of infection, the blood from an affected person caused typical equine ehrlichiosis when injected into susceptible horses. Most of the members of the genus *Ehrlichia*, are related antigenically, but the two equine pathogens, *E. equi* and *Ehrlichia risticii* are antigenically distinct. Although the vector responsible for transmitting *E. equi* in horses has not been established, recent evidence suggests that the tick, *Ixodes scapularis* (formerly *Ixodes dammini*) the deer tick, transmits this agent to dogs and human beings. The same tick is known to transmit Lyme disease. The ability of one tick species to transmit this agent to humans and other species of animals should warrant classification of equine ehrlichiosis as a zoonotic disease.

Dr. G. G. Wagner reported on three studies in progress at Texas A&M University, College Station, TX. They were as follows:

1. “Preliminary studies on *Theileria* infections of cattle.” *Theileria* spp. from domestic U.S. cattle (*Bos taurus*) with high circulating parasitemias and clinical signs consistent with theileriosis are being compared with *Theileria* isolates from Korea and Japan. DNA sequences of the complete srRNA genes are being aligned with srRNA gene sequences available through GenBank for various *Theileria* spp., *T. parva*, and others. The complete srRNA genes of 2 Korean, 1 Japanese, and 2 U.S. *Theileria* isolates have been sequenced. The Korean, Japanese and 1 U.S. isolate appear indistinguishable from
the GenBank sequence of *T. buffeli*. The second U.S. isolate shows considerable variation in the V-4 region of the srRNA gene, however the overall sequence is most closely related to that of *T. buffeli* of the sequences available for *Theileria* spp.

2. “Exoantigens of *Babesia bovis*.” Exoantigens of *Babesia bovis* (Tamaulipas isolate) were prepared from microaerophilous stationary phase cultures in HL-1 medium supplemented with 5% normal bovine serum. The exoantigens were evaluated by PAGE and Western blots using monoclonal antibodies and monospecific antisera from cattle in babesiosis endemic areas of Mexico. Five antigens (152, 58, 28, 18 and 12 KDa) were identified and isolated. Two antigens (58 and 12 KDa) were common to another *B. bovis* strain (Huesteca isolate). The antigens will be evaluated for immunogenecity in cattle in endemic areas in Mexico.

3. “Uncharacterized *Ehrlichia* spp. may contribute to clinical heartwater.” A lymph node suspension (Germishuys isolate) prepared from a sheep that died of symptoms typical of heartwater was used to infect a susceptible sheep. Infected blood from that sheep was then used to infect other sheep, including 3 that had been immunized with *Cowdria ruminantium* (Kumm isolate). Almost all recipients, including the 3 immunized sheep, died of apparent heartwater. The few sheep that reacted and recovered developed antibody activity (IFA) to *C. ruminantium*. From the srRNA gene sequence of *C. ruminantium* (Crystal Springs isolate), primers were used to amplify the hypervariable V1 loop of the srRNA gene of the Germishuys isolate. Subsequent analysis of the full sequence showed 98% identity with the sequences of *Ehrlichia canis* but not *C. ruminantium*.
Introduction

Equine ehrlichiosis is caused by the rickettsia *Ehrlichia equi* and is presumed to be transmitted by a tick vector. The disease was first recognized to affect horses in northern California in 1969. Since that time, the disease has been sporadically reported from several other states in the U.S., and from Sweden and Switzerland. Experimentally, a number of different animal hosts, including non-human primates, dogs and cats, have been found to be susceptible to infection by *E. equi* (1). Recently however, *E. equi*, or a very closely related agent, has expanded its epidemiologic spectrum. Naturally occurring infections with *E. equi* are now more frequently detected in dogs. More importantly, this organism, or a very closely related ehrlichia, is now implicated as the etiologic agent of a newly recognized disease, human granulocytic ehrlichiosis (HGE).

This paper describes some pertinent biologic properties and zoonotic aspects of major select members of the genus *Ehrlichia* with special emphasis on emerging diseases of dogs and humans caused by *E. equi*, a known natural pathogen of horses.

**BRIEF BACKGROUND OF THE GENUS EHRLICHIA**

**Historic Review**

While *Ehrlichia canis*, the causative agent of canine ehrlichiosis, was first described in 1935, the full pathogenic potential of this organism for its canine host was not realized until 1968 during the war in Vietnam where a severe epizootic of ehrlichiosis occurred among U.S. military working dogs, resulting in hundreds of cases of morbidity and mortality among these animals (2). It is the blood and other tissue material obtained from these diseased dogs that was used to accomplish the very first *in vitro* propagation of *E. canis* by a team of scientists at the University of Illinois (3). The *in vitro* cultivation of *E. canis* made possible the generation of sufficient quantities of antigen for use in the development of a serologic test [indirect fluorescent antibody (IFA) test] for confirmatory diagnosis of canine ehrlichiosis and various other studies on the disease (4). Some of the accomplishments made possible by use of the IFA test are: information on the geographic distribution of *E. canis*; recognition of the antigenic relationship between *E. canis* and *Rickettsia sennetsu* (5,6), which resulted in the latter agent’s reclassification to the genus *Ehrlichia* (7,8); evidence for the existence of infection with
EQUINE GRANULOCYTIC EHRLICHIOSIS

*E. sennetsu* outside Japan (9); the isolation and identification of the causative agent of equine monocytic ehrlichiosis (synonym, Potomac horse fever), named *Ehrlichia risticii* (10); specific diagnosis of the first human case of ehrlichiosis (11), and subsequent serologic studies, conducted by the University of Illinois, Centers for Disease Control (CDC) and departments of health in various states, resulting in the detection of hundreds of cases of human ehrlichiosis throughout the U.S. (12).

Subsequent studies on the relationship between species of the genus *Ehrlichia* revealed a good degree of antigenic relatedness among most agents (Table I). However, the two equine agents, *E. equi* and *E. risticii*, lack such an antigenic relationship. Antigenic studies on *E. equi* and *E. phagocytophila* revealed a lack of genetic distinction between the two, suggesting that *E. equi* and *E. phagocytophila* may be strain variants of the same species (13).

**Infectious and Pathogenic Properties**

Aside from *E. phagocytophila*, which is a natural pathogen of sheep, cattle and bison, all other ehrlichiae originally limited their natural pathogenic potential to humans or a single animal species. However, with the exception of *E. canis*, all other ehrlichiae were subsequently found to be infectious for a variety of animal hosts following experimental exposure. Wild and domestic canids are currently considered the only natural or experimental hosts for *E. canis*. In view of the fact that ticks remain infected only through transstadial rather than transovarial means, and because ticks most likely acquire *E. canis* during feeding on an affected animal in the acute phase of the disease, it is reasonable to suggest that other unknown reservoirs of *E. canis* may exist in nature. However, all efforts to experimentally infect other animal species, including sub-human primates (*Macacca mulatta*) with *E. canis*-infected canine monocyte cultures, did not produce any evidence of infection or survival of the organism in any animal species other than canine (14).

*Ehrlichia sennetsu*, a known human pathogen, has been shown to induce experimental infections in Rhesus and Cynomolgus monkeys. Infected monkeys developed a clinical syndrome characterized by lymphadenopathy, lethargy and transient leukocytosis. Dogs and mice are also susceptible to experimental infection (15).
### Table I. Antigenic Relationship Among Major Members of the Genus Ehrlichia using Indirect Fluorescent Antibody (IFA) Test.

<table>
<thead>
<tr>
<th>Antigens</th>
<th>E. risticii</th>
<th>E. equi</th>
<th>E. phagocytophila</th>
<th>E. sennetsu</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. canis</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>E. risticii</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

+++ = strong reactivity, ++ = moderate reactivity, + = weak reactivity, - = no reactivity
EQUINE GRANULOCYTIC EHRLICHIOSIS

The natural host of *E. risticii* is the horse, but mice, dogs, cats and Rhesus monkeys are susceptible to experimental infection with this organism, with mice showing the most severe clinical signs. Serologic evidence indicates that dogs, cats, foxes and wild rabbits are also susceptible to natural field exposure with clinical disease being noted in some dogs and cats (16).

*Ehrlichia equi*, the natural pathogen of horses and ponies, has exhibited a broad experimental host range which includes burros, goats, sheep, dogs, cats and sub-human primates (17). Both Rhesus monkeys (*Macaca mulatta*) and baboons (*Papio anubis*) were successfully infected with *E. equi* after intravenous inoculation of whole blood collected from acutely-infected horses. Pyrexia, increased sedimentation rate, mild anemia and the presence of inclusion bodies (morulae) in the granulocytes were major disease manifestations in infected sub-human primates (17). All clinicopathologic parameters returned to base levels within one week of the disappearance of morulae. Inoculation of a splenectomized horse, with pooled blood from two infected rhesus macaques, induced severe clinical signs of equine ehrlichiosis, thus showing that the virulence for the horse had not been altered with the passage in sub-human primates. Finally, when recovered monkeys were again challenge-exposed with *E. equi*-infected blood, they fully resisted the infection, indicating that a protective immune status, similar to that observed in horses, had been established. Pertinent characteristics of species of the genus *Ehrlichia* are shown in Table 2.

Susceptibility of sub-human primates to infection with *E. risticii* and *E. equi* provides a definitive basis for consideration that these ehrlichial agents may constitute human pathogens. The establishment of the zoonotic potential of the various species of ehrlichiae was evidenced during the last decade. Very recently, at least one ehrlichia species, *E. equi*, the causative agent of equine ehrlichiosis, has been found to also be the etiologic agent of a disease affecting dogs and humans.

Equine Ehrlichiosis

The causative agent of equine ehrlichiosis, *Ehrlichia equi*, preferably invades the cytoplasm of host neutrophils and eosinophils. Individual organisms are surrounded by a cell wall and plasma membrane and are contained either singly or as inclusions (morulae) by a vacuole of host cell origin (18). The appearance of the organism at microscopic and electron microscopic levels is shown in Figure 1. Because of the reported frequent presence of ticks on infected animals and the seasonal occurrence of the disease, tick transmission is strongly suspected.

Clinical manifestations of the acute phase of the disease are: fever (101° - 107°F), depression, anorexia, ataxia, edema of the limbs and abdomen, and icterus (1). Affected animals are usually reluctant to move and may develop CNS signs. Specific diagnosis of equine ehrlichiosis may be confirmed by microscopic detection of *E. equi*-infected granulocytes upon exami-
Table 2. Differential Characteristics of Species of the Genus *Ehrlichia*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th><em>E. canis</em></th>
<th><em>E. sennetsu</em></th>
<th><em>E. risticil</em></th>
<th><em>E. equi</em></th>
<th><em>E. phagocytophila</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural host</td>
<td>Domestic and wild canidae</td>
<td>Man</td>
<td>Horse</td>
<td>Horse</td>
<td>Sheep, cattle, bison</td>
</tr>
<tr>
<td>Leukocytes infected</td>
<td>Mononuclear cells</td>
<td>Mononuclear cells</td>
<td>Mononuclear cells</td>
<td>Granulocytes</td>
<td>Primarily granulocytes</td>
</tr>
<tr>
<td>Invertebrate vectors</td>
<td><em>Rhipicephalus sanguineus</em></td>
<td>Not known</td>
<td>Tick suspected</td>
<td>Tick suspected</td>
<td><em>Ixodes ricinus</em></td>
</tr>
<tr>
<td>Experimental hosts</td>
<td>None</td>
<td>Mouse, dog, monkey</td>
<td>Mouse, dog, cat, monkey</td>
<td>Donkey, sheep, goat, dog, monkey, cat</td>
<td>Guinea pig, mouse, goat</td>
</tr>
<tr>
<td>Geographic distribution</td>
<td>Worldwide</td>
<td>Japan, Malaysia</td>
<td>USA, Canada</td>
<td>USA, Sweden, Switzerland</td>
<td>Great Britain, Europe</td>
</tr>
</tbody>
</table>
EQUINE GRANULOCYTIC EHRlichiosis

nation of Giemsa-stained peripheral blood smears prepared during the acute phase of illness. An indirect fluorescent antibody (IFA) test is also available for the confirmatory serologic diagnosis of the disease. Treatment with intravenous administration of oxytetracycline at the rate of 7 mg/kg daily for 5-10 days is highly effective. The immunity following recovery seems to be sterile in nature. Tetracycline-treated or naturally recovered animals are fully resistant to reinfection for at least two years.

Figure 1. Ehrlichia equi. A) Ultrathin section of an infected equine blood granulocyte with an intracytoplasmic inclusion body. Several single organisms bound by a rippled cell wall and plasma membrane are evident (x 51,000). B) An intragranulocytic inclusion body stained by the Giemsa method (x 900).
Dogs were first determined to be susceptible to experimentally induced infection by *E. equi* in a study conducted by Lewis, *et al.* (17). In this study, infection was confirmed in 8 out of 10 Beagles inoculated with *E. equi*-infected equine blood. *Ehrlichia equi* inclusions were observed in the peripheral blood neutrophils and eosinophils beginning at 3 to 7 days post-infection. Subinoculation of 13 other dogs, using whole blood derived from the primary dogs during the patent phase of infection, resulted in successful infection of 3 out of 7 Beagles and 6 out of 6 German shepherd dogs.

Clinical signs in each of the experimentally-infected dogs were mild to inapparent in nature. In general, affected dogs developed a mild fever, transient thrombocytopenia and a mild transient anemia. Only a few dogs developed leukopenia. Hematologic parameters returned to normal values within 2 weeks following the disappearance of detectable parasitemia.

The first evidence that dogs may become naturally infected by *E. equi* was reported by Madewell and Gribble (19). Each of the 2 dogs in which *E. equi* infection was documented resided in a region of California in which *E. equi* infections in horses are known to be endemic (1). Clinical signs associated with the *E. equi* infection in each of the 2 dogs were difficult to define since both dogs were receiving immunosuppressive therapy for unrelated conditions (19). However, both dogs were anemic, thrombocytopenic and hypoglobulinemic. Leukocyte counts were either normal or elevated, but a differential count revealed a lymphopenia and monocytosis in each of the 2 dogs. Both dogs were negative for antibodies to *E. canis* by the IFA test. Whole heparinized blood derived from one of the affected dogs was inoculated intravenously into 2 horses, 2 dogs and 2 cats. *Ehrlichia equi* infection was established in each of the 6 inoculated animals; however, only the 2 horses and 1 cat developed clinical signs. The cat became febrile and depressed between days 9-14 post-infection, during which time *E. equi*-infected neutrophils and eosinophils were observed on examination of peripheral blood smears. Each of the 2 inoculated horses was mildly febrile during the parasitemia phase. However, subinoculation of blood from 1 horse into 4 additional horses (2 yearlings and 2 adult horses) resulted in mild clinical signs in the yearlings and severe clinical equine ehrlichiosis in the 2 adult horses. The greater severity of clinical disease in mature, adult horses as opposed to young horses (< 2 years) is also commonly observed under natural field conditions (1).

Over the past 5 years, there has been an increasing number of confirmed clinical cases of naturally-acquired *E. equi* infections in dogs (20,21,22). In the majority of documented cases, there was a history of fever, depression and anorexia. Thrombocytopenia was the most notable hematologic abnormality. In some cases there was a leukocytosis with an associated neutrophilia and lymphopenia and a decreased hematocrit level. Serum chemistry profiles were generally unremarkable, with the exception of el-
EQUINE GRANULOCYTIC EHRlichiosis

Elevated levels of alkaline phosphatase. Examination of Giemsa-stained peripheral blood smears during the acute phase of illness revealed the presence of typical *E. equi* inclusion bodies (morulae) within neutrophils and eosinophils. While the percentage of infected cells varied, it was, in general, a small percentage and considerably less than that observed in *E. equi*-infected horses, in which up to 60% of granulocytes may contain morulae during the acute phase of disease. Serology, using the IFA test, confirmed infection by the detection of antibodies specific for *E. equi* in the sera of affected dogs. Antibody titers were usually at relatively low levels during the early acute phase but increase significantly during the late acute-early convalescent phase. Dogs infected with *E. equi* responded rapidly to a 14-21 day course of tetracycline (66 mg/kg divided t.i.d.) or doxycycline (5-10 mg/kg divided b.i.d.) with complete recovery being uneventful.

Cases of canine ehrlichiosis caused by *E. equi* are no longer limited to the Sacramento foothills region of California. A number of cases have now been confirmed in the state of Washington (20). In most cases, the affected dogs have no travel history outside of that state. In addition to dogs, there have been a few cases of *E. equi*-associated equine ehrlichiosis in the state of Washington. All of the recent evidence, most not yet published, strongly suggests that *E. equi* infections in dogs residing in various regions of the U.S. are more prevalent and widespread than that which is known to date (22).

A history of tick infestation appears to be a common finding among the cases of *E. equi* infections in dogs. Experimental studies on Lyme disease in Connecticut, in which ticks (Ixodes scapularis) local to that region were allowed to feed on experimental research dogs, revealed that the majority of these dogs seroconverted for antibodies to *E. equi* by the IFA test beginning 10 days post-tick exposure (22). Although, to date, there have been no confirmed cases of naturally-acquired *E. equi* infections in dogs from that region, there have been several cases of equine ehrlichiosis caused by *E. equi* in both Connecticut and New York (22). This study strongly suggests that naturally-acquired *E. equi* infections in dogs, as well as horses, are occurring in the northeastern U.S., but are undetected or misdiagnosed. The study further suggests that the tick, *Ixodes* spp. in particular, is indeed the biological vector of *E. equi*. Since this species of tick is known to feed on horses, dogs and humans, as well as other mammalian species, it is most likely the common vector of *E. equi* infections in horses and dogs, as well as humans. The section below provides evidence that *E. equi* is apparently the actual causative agent of the newly recognized human granulocytic ehrlichiosis.

**Human Ehrlichiosis**

**Early Studies**

Prior to 1980, *Ehrlichia sennetsu*, causative agent of sennetsu fever,
was the only species of *Ehrlichia* known to be infectious for humans (23) and was believed to be geographically limited to certain regions of Japan (5).

The development of methods for more efficient *in vitro* propagation of *E. sennetsu* provided sufficient quantities of antigen for a large-scale seroepidemiologic study (24). Between 1980 and 1983 more than 3000 sera from regions of Southeast Asia, other than Japan, were examined by the IFA test for anti-*E. sennetsu* antibodies. Approximately one-third of the sera, the majority originating from Malaysian patients with febrile illness of undetermined etiology, contained *E. sennetsu*-specific antibodies. At least three *E. sennetsu*-like agents were then isolated from the blood of some of the above-mentioned individuals (24,25). These studies concluded that either *E. sennetsu*, or an agent which shares a dominant antigen with *E. sennetsu*, is present in Malaysia and possibly other regions of Southeastern Asia (9).

**Recognition of the First Case of Human Ehrlichiosis in the United States**

In 1986, the first case of human ehrlichiosis in the United States was documented (11). Ten days prior to the onset of clinical signs, the Michigan patient had been bitten by ticks while in Arkansas. The patient was hospitalized with an acute illness characterized by fever, headache, myalgia, confusion, pancytopenia, abnormal liver function tests and renal failure.

The differential diagnosis included Rocky Mountain spotted fever, leptospirosis and tularemia. Initial therapy with chloramphenicol resulted in no clinical improvement. A week after the onset of illness, microscopic examination of the patient's peripheral blood revealed the presence of cytoplasmic inclusions in the leukocytes. The inclusion bodies were most notable in lymphocytes, but neutrophils and monocytes were also affected. Therapy was then changed to doxycycline. The patient gradually recovered and was released from the hospital 12 weeks later.

Serological tests on this patient were negative for *Rickettsia rickettsii*, *R. typhi*, *Coxiella burnetii*, *Leptospira icterohaemorhagiae*, *Francisella tularensis*, hepatitis A virus and hepatitis B virus. However, serum obtained from the patient on the fourth day of hospitalization was submitted to Ristic's laboratory at the University of Illinois and found to be seropositive against four species of ehrlichiae, with the IFA titer to *E. canis* being the most prominent. Following successful treatment, the patient's antibody titers to *E. canis* and related species showed a gradual decline over a period of five months (Table 3).
**Table 3.** First Documented Case of Human Ehrlichiosis: Indirect Fluorescent Antibody Titers to Various Species of Ehrlichia.

<table>
<thead>
<tr>
<th>Date of Serum Collection</th>
<th>Species of Ehrlichia and their Titers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>E. canis</em></td>
</tr>
<tr>
<td>April 18, 1986</td>
<td>1:640</td>
</tr>
<tr>
<td>May 13, 1986</td>
<td>1:640</td>
</tr>
<tr>
<td>June 2, 1986</td>
<td>1:80</td>
</tr>
<tr>
<td>Sept. 5, 1986</td>
<td>1:40</td>
</tr>
</tbody>
</table>

**Initial Surveillance for Human Ehrlichiosis in the United States**

Following the recognition of the first human case of ehrlichiosis in the U.S., CDC contacted Ristic's group at the University of Illinois for technical information and reagents needed to jointly initiate seroepidemiologic studies of human ehrlichiosis in the U.S. (12). The study involved patients that were hospitalized during October 1, 1985 and September 30, 1986, for Rocky Mountain spotted fever (RMSF)-like illness but where serologically negative for *R. rickettsii* as well as for *R. typhi*, *C. burnetii*, *Borrelia burgdorferi*, and *F. tularensis*. A four-fold rise or fall in serum antibody titers to *E. canis* in some of these patients provided confirmatory evidence of ehrlichiosis (12,13,26). In this, and subsequent studies between CDC and certain state departments of health, more than four hundred cases of human ehrlichiosis have been identified in 16 states of the southeastern and central regions of the country, with the majority of the clinical cases recognized from late spring through the early fall (27). The cases varied from asymptomatic infection to a serious life-threatening and occasionally fatal illness (28,29). The most common signs and symptoms include: fever, anorexia, headache, myalgia, chills, nausea, weight loss and, occasionally, vomiting and confusion. Hematologic abnormalities consist of leukopenia and thrombocytopenia (27,30). Signs of recovery and a subsiding fever were usually noted within 24 to 48 hours after the start of tetracycline treatment (31).

Following the isolation of an *E. canis*-like agent from the blood of a patient with human ehrlichiosis, studies using 16S rDNA gene sequencing indicate that this agent is a unique *Ehrlichia spp.* and has been named *Ehrlichia chaffeensis* (32,33). This putative causative agent of human ehrlichiosis appears to be very closely related to *E. canis*, having a 98.2% 16S rDNA homology, and less related to *E. equi*, *E. phagocytophila*, *E. sennetsu* and *E. risticii*, respectively. *Ehrlichia chaffeensis* is currently used as the antigen in the IFA test for the serologic diagnosis of human ehrlichiosis. However,
cross-serologic studies have shown that antibody titers of human patients using either *E. canis* or *E. chaffeensis* as the substrate antigen were, with few exceptions, either identical or differed by only a 2-fold dilution (32).

While the majority of cases of *E. chaffeensis*-related ehrlichiosis are sporadic, a recent outbreak of ehrlichiosis occurred within a golf-oriented retirement community in Tennessee (34). *Ehrlichia chaffeensis* was used for serologic and PCR testing of the patients. Of the 3000 retirees evaluated, 12.5% showed evidence of infection. Eleven of these residents developed fulminating disease and most required long hospitalization. The high rate of infection in this community resulted from its proximity to a wildlife reserve where deer are numerous and the tick infestation very high. Based on a survey of the participants in the study, it was found that the golfers who searched for errant balls off the fairway were four times more likely to show evidence of the infection than those who played new balls. The lonestar tick, *Amblyomma americanum*, was identified as the putative principal disease vector in this outbreak as well as in other previous cases of human ehrlichiosis caused by mononuclear leukocytic ehrlichiae.

**Emergence of Human Granulocytic Ehrlichiosis (HGE)**

During 1994-95 a new form of tick-borne human ehrlichiosis emerged that is currently known as Human Granulocytic Ehrlichiosis (HGE). About 60 cases of the disease have been confirmed and several dozens of other cases of illness from tick bites fit the pattern. While the majority of confirmed cases were patients residing on the east coast, six patients, two of which died, were from Northern Minnesota and Wisconsin. Nationwide, four people have died from the new disease. The blood granulocytes of one patient which died contained intracytoplasmic vacuoles with organisms ultrastructurally characteristic of ehrlichiae (35). From this patient, a 1.5 Kb DNA product was amplified by PCR technique using universal eubacterial primers of 16s rDNA. The analysis of the nucleotide sequence of the amplified product revealed 99.9% and 99.8% similarities with *E. phagocytophila* and *E. equi*, respectively. Further genetic studies demonstrated that the granulocytic human ehrlichia has only 92.5% 16s rDNA homology with the mononuclear *E. chaffeensis*.

The results of the above-mentioned genetic studies were confirmed by cross-serologic studies using the IFA test. All convalescent phase sera from human patients with HGE and from animals infected with *E. equi* or *E. phagocytophila* had antibodies which reacted strongly against *E. equi* antigen. None of these sera reacted with the mononuclear *E. chaffeensis*. This antigenic relationship, coupled with the nearly identical nucleotide sequences of 16s rDNA genes, strongly indicates that *E. equi*, *E. phagocytophila* and the HGE agent are very closely related or variant strains of the same species (36). The identity of the HGE agent was further substantiated in subsequent studies conducted by these investigators in
which they transfused blood from a patient with HGE to a horse, resulting in infection and clinical disease typical of equine ehrlichiosis (36). Based on genetic and antigenic similarities, ehrlichiae are currently classified into three distinct groups (Table 4).

Table 4. Current Grouping of Ehrlichiae Based on Their Genetic and Antigenic Similarities.

<table>
<thead>
<tr>
<th>GROUP 1</th>
<th>GROUP 2</th>
<th>GROUP 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ehrlichia canis</td>
<td>Ehrlichia equi</td>
<td>Ehrlichia risticii</td>
</tr>
<tr>
<td>Ehrlichia chaffeensis</td>
<td>Ehrlichia phagocytophila</td>
<td>Ehrlichia sennetsu</td>
</tr>
</tbody>
</table>

Concluding Remarks

Studies of the most recent outbreaks of human ehrlichiosis revealed that *E. equi*, a known equine pathogen, is most likely the causative agent of a fatal human disease known as Human Granulocytic Ehrlichiosis (HGE). While, earlier sero-epidemiologic studies indicated that certain ehrlichiae might be possible etiologic agents of human ehrlichiosis, these very recent findings identify *E. equi* as the first proven zoonotic member of the genus *Ehrlichia*. Nationwide, more than 60 cases of HGE have been confirmed and four affected people died.

Aside from humans, dogs are also now included as natural hosts of *E. equi*. Evidence that, in one study, dogs contracted infection with *E. equi* following their exposure to the *Ixodes scapularis* (formerly *Ixodes dammini*), the deer tick, suggests that this tick may be the natural vector of *E. equi*. Most recent studies by Magnarelli, et al. (37) revealed that hemolymph preparations, derived from various species of ticks collected from Connecticut, Massachusetts, Missouri, Pennsylvania, Rhode Island and British Columbia, reacted positively with *E. canis* and *E. equi* antisera, including sera from patients with HGE. In a related study using PCR analysis, DNA of the HGE agent was detected in 59 (50%) of 118 adult *I. scapularis* ticks, however, there was no evidence of *E. chaffeensis* DNA in these ticks. Thus, preliminary investigation of the tick vector responsible for HGE strongly suggests that an *Ixodes* species tick is involved (37).

The etiologic agent of human sennetsu ehrlichiosis, *E. sennetsu*, and *E. equi*, now recognized to cause disease in humans, are each known to experimentally infect subhuman primates in addition to a variety of other ani-
mal species. Evidence of certain pathogenic properties, i.e., infectivity for subhuman primates, is, thus far, not available for the mononuclear human isolate, *E. chaffeensis*. In addition, unlike the above two ehrlichiae, *E. chaffeensis* has not been specifically identified in the blood monocytes or tissues of affected human patients since its isolation. Until such pathogenic and microscopic evidence becomes available, and because of the very close genetic and antigenic similarities between *E. chaffeensis* and *E. canis*, the question is raised as to whether *E. chaffeensis* is a unique human pathogen or a variant strain of *E. canis*.

References


25. Ristic, M. 1986. Pertinent characteristics of leukocytic rickettsiae of


Mr. W. L. Adams, GA; Mr. Duncan Alexander, IL; Ms. Linda T. Benson, NY; Dr. Bob H. Bokma, PR; Mr. Jess Burner, Jr., TX; Dr. Ronald B. Caffey, MD; Dr. Richard A. Carmichael, IA; Mr. James L. Copper, MA; Dr. Michael David, MD; Dr. Linda A. Detwiler, NJ; Dr. William H. Fales, MO; Dr. Robert Fetzner, VA; Dr. Warren C. Foote, UT; Mr. Robert Frost, CA; Mr. Frank H. Harding, IL; Dr. Rube Harrington, TX; Dr. Jack Haslam, DC; Dr. Werner P. Heuschele, CA; Dr. G. Reed Holyoak, UT; Dr. James L. Hourrigan, VA; Dr. Thomas H. Howard, WI; Mr. Tom J. Hunt, MI; Dr. Robert F. Kahrs, MD; Dr. Ralph C. Knowles, DE; Dr. Nels Konnerup, WA; Dr. Donald W. Luchsinger, DC; Mrs. Amy Mann, DC; Dr. Andrea M. Morgan, MD; Dr. Claude J. Nelson, TX; Dr. Patrick E. Phillips, WI; Dr. Gerardo Quaassdorff, VT; Dr. Glenn B. Rea, OR; Dr. David A. Stringfellow, AL; Dr. Paul Sutmoller, VA; Dr. Paul J. Taylor, MT; Dr. Lynn Anne Tesar, SD; Mr. Shelby V. Timberlake, NY; Mrs. Michele C. Turner, TX; Dr. William Utterback, CA; Dr. Charles D. Vail, CO; Mr. Willard H. Waldo, NE; Dr. Jerry S. Walker, MD; Dr. Gary M. Weber, DC; Dr. Kay W. Wheeler, NY; Dr. William White, NY; Mr. David Winters, TX; Mr. Fred Wise, IN.

The Import/Export Committee of USAHA met November 1, 1995, in the Southern Pacific Room of the Nugget Hotel, Sparks, Nevada. Mr. Jay C. Lemmermen presided. Thirty-one members and seventeen guests were in attendance. After a welcome and introductory remarks by the Chairman, the committee took time to thank Mr. Dan Childs for many years of service as chairman.

Mr. John Williams, USDA-APHIS Emergency Programs, presented brief update on the Vesicular Stomatitis outbreak and outlined reorganization of USDA, APHIS, VS, Emergency Program Staff, and aimed at improving emergency preparedness.

Dr. Robin Bell, UK, was asked to voice the concerns of the EU about the VS outbreak. He stated that they were at first happy with the notification process but were concerned that in September:

1. The origin of the outbreak was still unknown.
2. Isolated cases were spreading. Why?
3. The lack of epidemiological studies in the face of the outbreak.
4. Movement controls were inadequate for a "Class A" disease. Animals were allowed to move within the affected states except to shows and fairs.
5. Variable approach to restrictions imposed by other states.

APHIS will respond to these concerns at our next meeting.
Dr. Robert Teclaw, USDA, APHIS, VS, reported on the National Trichinae Research Project, a collaborative effort among NPPC, APHIS, ARS, FSIS, state veterinarians and state pork producers. He presented the research project in view of how the results will affect the export markets for U.S. pork. The preliminary results of the project indicate that U.S. pork has a much lower incidence of Trichinae than has been previously assumed. Future project activities include expanding the prevalence study nationally, developing a prototype herd-based certification system, conducting an economic analysis of the advantages of achieving Trichinae-free states in all or part of the national swine herd and working with U.S. trading partners to establish an acceptable Trichinae certification program that would allow importation of fresh pork from the U.S. into previously restricted markets.

Dr. David Vogt, USDA, APHIS, discussed the proposed use of equine passports. USDA has agreed to use equine passports to facilitate the movement of horses for import and export. The document would be used mainly for identification to supplement a health certificate.

USDA would expect various equine registries and other interested groups to issue passports based on a certain minimum criteria. There are some equine groups already doing this in the United States.

Dr. Ernest Zirkle commented on a "smart card" system being evaluated in cooperation with the Jockey Club, as a passport system for thoroughbreds. This card has all pertinent information about health status, and identification in a computer chip that can be read by an inexpensive reader and updated as necessary.

Dr. Robert Kahrs, DVM, PhD, USDA, APHIS, moderated the presentation of the 1995 report of the National Center for Import and Export.

Dr. David Vogt presented the report on import animals activities. Highlights included: the Harry S. Truman Import facility was fully occupied during FY 1995. This is a first for the facility. APHIS has removed the seven day equine quarantine requirements for horses from Mexico that was in place because of Venezuelan Equine Encephalitis. No VEE has been diagnosed in Mexico for over twelve months. The seven day requirement has been reduced to three days.

Twenty import protocols were finalized for germplasm and animals during the past year.

Dr. Andrea Morgan presented the Animal Export Activities Report. Forty-two protocols were established or updated for exporting animals and germplasm to other countries. The EU agreed to allow semen from bulls resident in Certified Semen Services participating centers to be used to inseminate cows for embryo production and export to its 15 member states. Prior to this the semen itself had to be qualified to be exported to the EU prior to its use in embryo production.

Dr. Kahrs presented the Avian Import/Export Report. Over 7.5 million poultry were imported into U.S., a significant increase from FY 1994. Impor-
IMPORT/EXPORT

tation of commercial birds continues at much lower levels than the 1980's. Two shipments totaling over 6,000 birds were refused entry because they were infected with Newcastle Disease.

No live ratites were imported. However, 22,092 ostrich eggs were placed in quarantine facilities. Of these, 6,992 (31.6%) chicks were released at the end of quarantine.

Plant Protection and Quarantine Animal Disease Exclusion activities were related by Dr. Althea Langston. PPQ continues to expand the use of x-rays as a screening tool. PPQ in partnership with the U.S. Army are developing a prototype x-ray system. Detector dog teams operate at twenty airports. The program will expand to 108 teams in the next four years. Ninety-eight percent of commercial shipment data is now entered into automated commercial systems.

Dr. Kahrs, explained the upcoming proposed regulation to incorporate regionalization and risk assessment into U.S. Sanitary and Phytosanitary (SPS) measures. This major change, predicted by U.S. participation in international trade agreements, involves abandonment of country-by-country free-not-free, approaches to import requirements in favor of assessing levels of risk to regions which may be countries, parts of countries or groups of countries. He urged industry groups to study carefully the regulation when published for public comment and try to achieve member consensus for response.

Under actions taken on requests by foreign governments to be recognized free of specified disease, Dr. Morgan told us that Spain and the United Arab Emirates were recognized free of African horse sickness. Spain was also recognized as free of swine vesicular disease. Switzerland was recognized free of FMD, rinderpest, and Exotic New Castle disease.

The full text of these reports accompany this report.

Ms. Connie Greig, NCA, Animal Health and Inspection Committee related NCA's concern about the U.S. Emergency Response capability. They have recommended an External Audit of the system to include where money to pay for depopulation, indemnity, and disposal would come from if we experienced a foreign animal disease outbreak.

Ms. Greig also brought a resolution and recommendation pertaining to the Northwest Pilot Project.

Shelby V. Timberlake, Chairman of the Subcommittee on Embryo Movement, presented the minutes and highlights of the subcommittee meeting held October 30, 1995. They included a resolution pertaining to 9 CFR Part 98. The full text of the minutes accompanies this report.

Dr. Kahrs commented on USDA's response to the resolution passed in the 1994 meeting pertaining to antibiotic treatment of, or culture on bovine semen intended for import to the U.S. He stated that USDA was reluctant to develop import regulations for ubiquitous organisms for which no domestic Federal programs exist and USDA would continue discussion with Certified Semen Services on the issue.
REPORT OF THE COMMITTEE

The chair asked for comments about the recent decision to change chemicals used in border crossing dip vets. It was related that a letter was sent to Dr. Campos in Mexico with a copy to the Texas State authorities that said the border would be closed September 15 to October 15 and a different chemical would be used in the vats to control fever ticks. Texas authorities were given no prior notice and were not consulted as to which chemicals would be used. The chair commented that actions of this sort tend to promote distrust between agencies that need to work together and communicate to protect the health of our U.S. animal industries.

The committee took up the Resolutions and Recommendations presented.

Resolution #1 and Recommendation #1 pertaining to the Northwest Pilot Project was presented and passed.

Dr. Cleon Kimberling brought a resolution (#2) from the Sheep and Goat Committee concerning scrapie in exported sheep and goats. The resolution was moved, discussed, and passed.

Another resolution (#3) from the Sheep and Goat Committee concerning funding of the U.S. portion of a collaborative research project with Scotland and New Zealand was presented, discussed, and passed.

The Committee next took up two related resolutions. One was a resolution brought by the Sub-Committee on Embryo Movement (#4) concerning 9 CFR part 98. The other was a resolution forwarded by USAHA District at Large pertaining to the same subject. After a lively debate the Subcommittee's resolution was passed. The other failed.

Dr. Ernest Zirkle asked for a vote of support for a resolution passed in the Infectious Diseases of Horses Committee pertaining to the request to waive testing requirements for piroplasmosis in horses coming to compete in the Olympics in Georgia. The resolution asks that the Secretary stand firm on the requirement for a negative test to piroplasmosis to enter this country. The Import/Export Committee voted to support the committee on Infectious Diseases of Horses.

There being no further business, the meeting was adjourned at 5:50 p.m.

Respectfully submitted,

Jay C. Lemmermen
IMPORT/EXPORT

This recommendation was not presented as a resolution or included in the committee report but was added by action of the Executive Committee.

Recommendation from the Import/Export Committee

The North West Pilot Project was first conceived and proposed as the Montana Pilot Project in May 1995; and

The project calls for the implementation of three components by October 1996:

I. In the U.S., recognition of Canada's disease-free status for brucellosis and tuberculosis, and elimination of the test and vaccination requirements from U.S. states and federal regulations; and

II. In Canada, the creation of special feedlots which could import U.S. feeders without test for anaplasmosis, brucellosis, or tuberculosis, subject to strict requirements for identification and records ensuring all sales are to packers only; and

III. In both countries, streamlining of operational procedures used to implement the regulations, using modern information technologies such as facsimiles and electronic mail to reduce the cost and shorten the certification process of moving livestock from one country to another; and

The Montana Stockgrower's Association, the North Dakota Stockmen's Association, the National Cattlemen's Association and the Canadian Cattlemen's Association have endorsed the North West Pilot; and

The existing import regulations are no longer in accordance with current recognized science or risk analysis; and

The existing regulations are restricting the development of regional trade.

Recommendation:

That USAHA encourage USDA to work with Agriculture and Agri-Food Canada as they assess the special feedlot concept and in the implementation of other components of the North West Pilot Project.
Chairman: Mr. Shelby V. Timberlake, Jr., Pelham Manor, NY

Dr. Richard A. Carmichael, IA; Mr. Jay Lemmerman, FL; Dr. Jack Haslam, DC; Dr. Nels Konnerup, WA; Dr. Donald Luchsinger, DC; Dr. Patrick Phillips, WI; Dr. Paul Sutmoller, VA; Dr. Paul Taylor, MT.

The meeting was called to order by Chairman Timberlake at 1:40 P.M., October 30, 1995. There were twenty-one in attendance including committee members Carmichael, Haslam, Konnerup, Lemmerman, Luchsinger, Phillips, Sutmoller, Taylor, and Timberlake.

Dr. Michael Thibier, Director General, National Veterinary and Food Research Center, in France, speaking as a citizen of one on the countries of the EEC, gave us an update on the EEC and OIE:

Embryo transfer in Europe:
- 22,500 donors flushed in Europe in 1994 (represents 75 percent increase over 1993) (21 countries)
- France, The Netherlands, Germany, United Kingdom, and Belgium report the most activity.
- 115,000 viable embryos collected in Europe (In 1994 represents a 26 percent increase over 1993.)
- Mean numbers of embryos per flushed donor has increased to 5.1.
- Number of bovine embryos transferred in Europe in 1994 = 102,800. This is a 6.6 percent increase over 1993.
- European commission - Embryo control 92.65 Directive - (May and June 1995 published on porcine, ovine, caprine movement of embryos (intra community and extra community movement guidelines included.)
- OIE - received appendix from I. E. T. S. on handling of lab animal embryos was circulated and first comments will be received and discussed in January 1996.

Dr. A. E. Wrathall, Central Vet Lab Ministry of Agriculture, New Haw, Addleston, Surrey, UK, gave his United Kingdom update:
- Also update on BSE project.

Update on BSE situation (as of October 1, 1995)

251
MINUTES ON EMBRYO MOVEMENT SUBCOMMITTEE

<table>
<thead>
<tr>
<th></th>
<th>1994</th>
<th>1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>143,000</td>
<td>153,000</td>
</tr>
<tr>
<td>Herds</td>
<td>31,911</td>
<td>32,254</td>
</tr>
<tr>
<td>Percent Dairy Herds</td>
<td>52.3 percent</td>
<td>53.9 percent</td>
</tr>
<tr>
<td>Cow/Calf</td>
<td>13.9 percent</td>
<td>15.1 percent</td>
</tr>
</tbody>
</table>

question - on source of new herds
note - ban April 1988 on feeding of animal protein to cows (ruminants)
- conclusion from figures
- epidemic clearly on decline
- cases born after 1988 - likely due to accidental consumption - so future ban on "specified bovine offal" (e.g., brain)

Tissue Lymphati -
- Maternal transmission of BSE considered very unlikely.
- BSE embryo project update
- described experimental design as in previous years.
- Results to date:
  - Donor/mouse/recipient
  - Mouse assays so far negative
- total ETS 587/347
  - Report pregnancy at 90 day - 48.7 percent
- Conclusions
  - sufficient embryos were recovered
  - No BSE so far
- Recipient - no evidence of BSE
  - Some died from other causes
  - Final results after year 2000
- Animal welfare considerations
  - Some groups in UK have looked at advanced reproductive techniques
    - have made recommendations to government which on whole are realistic.

Canada Update - Dr. Brian Evans, Director, Animal Health Division and Chief Veterinary Officer, Canada
- see typed report attached
- Biggest change in Canada - has gone from being one of the top exporters of embryos to being the top importer of embryos in 1994, largely due to the import of 8 - 10,000 Boer goat embryos from South Africa.
TIMBERLAKE

Embryo Importation and Cryobanking Strategies for Lab Animals and Wildlife Species - Dr. M.C Schiewe, Director, IVP and Embryology, California Fertility Associates, Santa Monica, CA.

- Most guidelines based on previous guidelines for domestic livestock (esp. cattle)- variations inserted based on species and husbandry dictated changes. Incentives for guidelines for "nonconventional" species are variable including agricultural (farmed wildlife species), humanitarians (endangered species) and scientific (valuable lab animal strains, e.g. transgenic).
- Primary disadvantage; with many of these species is a lack of embryo - pathogen interaction studies.
- There is a need for regulatory requirements to protect all positives of use of advanced reproductive.
- Advantages in lab animals
  - One or can be closed colonies
  - Combination of requirements such as so called "conventional" testing and embryo processing.
  - Wild or free-ranging zoo or tamed wild specie.
  - ET Technology can be applied in some of these species so need health certification guidelines.
- Strategy = combination.
- OIE defined OIC health lab procedures
- Strict sanitation
- Testing donor
- Another strategy = PPEQ (Permanent Post Entry Quarantine)
- IVF Systems provide great opportunity for salvage of genetic material from wildlife species (e.g. culled animals); however little research to help devise health assurance guidelines.

Australia Update - Dr. Jack Haslam, Veterinary Counselor, Embassy of Australia

- About to issue guidelines for accreditation of embryo collection teams. Hope to have framework in place by end of year, 1995.
- Bovine embryo imports totaled 4,654; export 1,723
- Ovine exports 338; imports 17
- Seven year drought has lead to serious decline.
- Quality assurance for embryo collection and transfer -
  [a] all procedures at a registered center or by an accredited ET vet.
  [b] demonstration of competence by virtue of AES certification.
  [c] renew every three years.
  [d] approved quality assurance (AQA) arrangement with AQIS.
- Objective:
  [a] competence in ET technology

253
MINUTES ON EMBRYO MOVEMENT SUBCOMMITTEE

[b] AETS certification  
[c] Processing labs and storage meet standards.  
[d] Compliance with certification documents.  
[e] Embryo ID and record keeping procedures.  

- Development of an AQA arrangement to assure that correct procedures will be followed.  
- Australian inspection and quarantine agency.  
- Audit and supervisory visit.  

- Use of representative samples of flush fluids, washing fluid, degenerative ova and embryo - save for official examination - Teams will hold material until end of a successful audit.  
- Other  
- Anticipate quantitative risk assessment on:  
  - semen imports  
  - sheep/goat imports  
  - Trying to conform to OIE documents as much as possible regarding protocols for importation of semen embryos and live animals.

Scrapie Update - Dr. Reed Holyoak - Utah State University  
Update on continuing project  
- vertical transmission of scrapie in sheep and goats AJVR - 54: 1863-1868  
- Results of collecting and transfer of embryos published by Dr. Warren Foote.  
- Project with embryo transfer from naturally scrapie infected sheep is continuing — results indicate no transfer of scrapie to date.  
- Other studies trying to produce IVF on scrapie ewes but without funding will lose source flock and work will stop in general due to lack of funding. Several programs have been suspended.  
- International effort UK/US/New Zealand  
- UK will fund  
- NZ will fund  
- US - waffling - no funds available at current time

Horse Embryo Imports - Dr. Reed Holyoak  
- Still working on a proposed appendix but very little research on equine embryo pathogen interactions so have to fall back on traditional means (which are more restrictive.)

Llama Update - Dr. Paul Taylor - Taylor Llamas  
Three ET young born  
Twenty plus recipients pregnant  
- Current success 50-70 percent pregnancy on fresh transfer of hatched blastocysts- can’t be frozen - have produced pregnancies - can hold
embryos up to 48 hours in culture medium.
Summary - feasible to achieve pregnancy via ET in llamas - they must be transferred fresh (won’t cryopreserve) and after hatching.
- wants help in developing an import protocol.

USDA, APHIS Comments - Part 98 Revision
- Dr. David Vogt (APHIS) - comment that proposed rule published - APHIS has received considerable number of comments and the agency is in process of evaluating these comments. There may or not be changes made and the agency may not discuss publicly at this time.
- An APHIS representative did say that anyone can get the flavor of these comments by requesting to see them (they are available to the public)
- Dr. Pat Phillips commented AETA applauds the USDA for taking on revision of Part 98, however, we concerned that the research is not available to support the multiple species included in the proposed revision. AETA suggest that each specie be addressed separately.

Jay Lemmerman, Chairman, USAHA Import-Export Committee, read statement (as attached)
- considerable discussion followed.
- A. E. Wrathall said that research to back up document not adequate in his opinion.
- Dick Carmichael commented from an historical perspective (see AETA 1993 statement attached)
- Chairman Timberlake asked Drs. Carmichael and Phillips to draw up a resolution for this committee based on our verbal rejection of Part 98 revision as published in 1995.

IETS Report of Meetings held in Reno on Oct 28 and 29
Research- Dr. Stringfellow made group aware of availability of research update from IETS.
- Commented that IVF embryos should not be considered the same as in vitro derived embryos.

Import -Export - Dr. A. E. Wrathall
Commented on behalf of Dick Nelson that in the “forms” chapter of third edition of the manual will include written definitions for embryo grades.

Regulatory- Dr. Brian Evans
Commented on the viability and value (his confidence) in the work of his regulatory committee.

Administrative - Dr. Michael Thibler, President of IETS
Thanked Chairman Timberlake for his reception of IETS members and IETS committee into this meeting every year.

**Update on Quarantine Risk Assessment - Dr. Paul Sutmoller**

[a] Dr. Sutmoller gave a general description of the process of QRA.
[b] Gave a general description how the process is applied in assessing risk of transmitting infectious diseases through embryo transfer.
[c] Concluded - QRA provides veterinary authorities with more complete information than disease categorization.

(See report attached.)

Dr. Thibier questioned that there was so much difference between risk of B1 and FMD transmissions.

Prior to the end of the meeting, Drs. Phillips and Carmichael presented their resolution to the embryo movement committee members and the resolution was approved by a vote of 7 to 1. It will now be passed on for approval by the Import-Export Committee of the USAHA. (see copy attached)

As there was no additional business to come before the committee, the meeting was adjourned at 5:40 P.M.
Animal Import Activities

The Harry S Truman Animal Import Facility (HSTAIC) was fully occupied during FY 1995.

A shipment of approximately 460 boer goats and sheep from the Republic of South Africa was released from HSTAIC in the spring of 1995 and placed in 5-year observation programs in the Voluntary Scrapie Flock Certification Program (VSFCP).

A shipment of 560 alpacas and llamas from Peru was released at the end of September 1995 for placement in VSFCP's.

An importation of llamas and alpacas from Bolivia will arrive at HSTAIC during the last part of November.

Veterinary Services is working with the Agricultural Research Service to import bovine embryos from Venezuela.

APHIS continues to work with the 1996 Olympic Committee and Georgia State officials concerning the equine piroplasmosis test requirement. APHIS will be waiving the user fees for its support and monitoring activities for the Olympic Games.

During FY 1995, 142,942 spayed heifers were imported from Mexico. These heifers were spayed under direct VS supervision. In response to humane concerns, all spay operations must be performed under local anesthesia, and heifers must be M branded high on the tailhead rather than on the face. The M brand on the tailhead is also required for feeder steers.

There were 68,415 direct-to-slaughter cattle imported from Mexico to approved establishments in FY 1995. The increase is due to the devaluation of the peso. In spite of the large increase in direct-to-slaughter cattle, the number of Mexican cattle found to have tuberculosis lesions continues to drop.

In other actions concerning Mexico, APHIS removed provisions from the Code of Federal Regulations that allowed the temporary importation of Mexican cattle for feeding purposes. These cattle had been imported "in bond" temporarily and then returned to Mexico. A waiver was granted allowing the in bond cattle in the United States to be slaughtered in the United States. The waiver was granted in response to the devaluation of the peso.

APHIS also removed the 7-day equine quarantine requirement for horses from Mexico that was in place because of Venezuelan Equine Encephalitis. No VEE had been diagnosed in Mexico for over 12 months when the 7-day requirement was reduced to 3 days.
Our Import-Export staff veterinarians continued meeting with their Mexican counterparts to discuss animal health issues of mutual concern and implementation of the animal health provisions of NAFTA.

APHIS finalized a requirement for import permits for sheep and goats from Canada. One condition specified on the import permit is that the importer’s flock/herd must be enrolled in the VSFCP if the imported animals or germ plasm have been been in a third country (other than New Zealand and Australia) within the past 60 months.

Six groups of small ruminants held in 5-year research quarantines were enrolled in the Voluntary Scrapie Certification Program (VSCP). Additionally, two herds were released from quarantine as they completed a 5-year observation period for scrapie.

We have completed our review of the Contagious Equine Metritis regulations. The regulation changes that were recommended by the work group are currently being drafted. During the past year New Hampshire and Texas were added to the list of States that are approved to receive CEM horses for culture and test breeding.

Baudette, Minnesota was added to the list of full service ports along the U.S.-Canadian border.

APHIS published a proposed rule concerning the importation of non bovine embryos from foot-and-mouth disease affected countries. The comment period ended on August 7. The comments are currently under review.

Our regionalization docket has been drafted and is currently being reviewed by the Office of the General Counsel.

The following import protocols were finalized during the past year:

**United Kingdom**
1. Cervid embryos
2. Cervid semen
3. Porcine semen

**The Netherlands**
1. Bovine semen
2. Bovine embryos
3. Sheep and goat semen
4. Sheep and goat embryos

**Germany**
1. Bovine embryos
2. Bovine semen
3. Bovine
4. Sheep and goat semen
5. Sheep and goat embryos
6. Porcine semen

**France**
1. Sheep and goat semen
2. Sheep and goat embryos

**Australia**
1. Bovine semen

**Belgium**
1. Bovine
2. Sheep and goat embryos
3. Sheep and goat semen
4. Porcine
AVIAN IMPORT ACTIVITIES

A. Poultry and Hatching Eggs

There were 7,539,037 poultry, 375,955 including day old chicks, and 12,544,134 hatching eggs imported into the United States during fiscal year (FY) 1995. This is a significant increase from FY 94. There were 10,500 goose eggs imported as well as 510 exhibition game fowl.

B. Commercial Birds

Importation of commercial birds continues to be at much lower levels than in the mid 1980’s. The Wild Bird Conservation Act restricts the importation of most species of birds. This resulted in the importation of many of the non-prohibited species such as finches and other song birds. There were 84,618 commercial birds released during FY 95.

Two shipments totalling 6,236 birds were refused entry because they were infected with exotic Newcastle disease. One lot was also refused entry because of an isolate of H7N1 that was potentially pathogenic.

C. Pet Birds

There were 589 pet birds imported into the United States during FY 95. All pet birds covered under the Wild Bird Conservation Act were required to have a U.S. Fish and Wildlife exemption prior to importation.

D. Confiscated Birds

A total of 105 birds were smuggled/abandoned at the New York Animal Import Center and 364 birds were confiscated at the Mission, Texas Quarantine Facility. The Miami Animal Import Center quarantined 145 confiscated birds. One lot of two Amazon parrots was destroyed because an exotic Newcastle disease virus isolation. The USDA quarantine station in San Ysidro, California, quarantined 268 seized/abandoned birds.

E. Ratite Importation

Currently, there is only one foreign ratite farm approved by USDA to export ratites and ratite hatching eggs to the United States. No requests have been made to approve farms in Africa. During FY 1995, 75 farms were inspected in Africa by USDA-APHIS officials.

A total of 22,092 ostrich eggs were placed in privately owned bird quarantine facilities. From these imported eggs, 6,992 (31.6%) chicks were released at the end of quarantine.

During FY 1995 there were no ostrich chicks quarantined at the New York or Miami Animal Import Centers. Two shipments of cassowaries, totalling 13 were quarantined and released from the Hawaii Animal Import Center.
APHIS REPORT TO IMPORT AND EXPORT COMMITTEE


<table>
<thead>
<tr>
<th>AVIAN</th>
<th>FY 1993</th>
<th>FY 1994</th>
<th>FY 1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poultry and day old chicks</td>
<td>6,282,363</td>
<td>2,725,542</td>
<td>7,914,992</td>
</tr>
<tr>
<td>Poultry hatching eggs</td>
<td>17,593,184</td>
<td>10,048,120</td>
<td>12,544,134</td>
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<tr>
<td>Commercial Birds</td>
<td>133,435</td>
<td>110,570</td>
<td>84,618</td>
</tr>
</tbody>
</table>

Ratites

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<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hatched ostrich chicks</td>
<td>15,556</td>
<td>16,509</td>
<td>6,992</td>
</tr>
<tr>
<td>Ostrich chicks</td>
<td>1,322</td>
<td>643</td>
<td>0</td>
</tr>
<tr>
<td>Emu</td>
<td>1,238</td>
<td>776</td>
<td>0</td>
</tr>
<tr>
<td>Cassowaries</td>
<td>0</td>
<td>0</td>
<td>13</td>
</tr>
</tbody>
</table>

TOTAL: 24,027,098 12,902,160 20,570,649

ANIMAL EXPORT ACTIVITIES

During FY 1995, APHIS continued negotiations with various countries to update current animal health protocols or establish new ones.

New protocols were established or were updated for exporting bovine semen to Argentina, Switzerland, Vietnam, the European Union (EU), Kazakhstan, Turkmenistan, and Uzbekistan; bovine embryos to Poland, the People’s Republic of China, the EU, Indonesia, Kazakhstan, and Turkmenistan; cattle to Canada, Ecuador, Turkey, Vietnam, Mexico, Lebanon, Kazakhstan, Uzbekistan, Turkmenistan; poultry to Mexico and the United Kingdom; sheep to India, Peru, Kazakhstan, Turkmenistan, and Uzbekistan; swine to Vietnam and Peru; porcine semen to Vietnam; horses to the EU, Chile, Switzerland, Norway, and Hungary; equine semen to Sweden; canine semen to the United Kingdom; and ostriches to the United Kingdom and the People’s Republic of China.

These and many other import health requirements for various countries and other species are available through the computerized International Regulations Retrieval System.

After approximately 2 years of negotiations, the EU has agreed to revise its import requirements as they relate to equine viral arteritis (EVA) for U.S.-origin horses exported to the Community for temporary and permanent purposes. In previous years, the EU would only accept uncastrated male horses if they were negative serologically or by a virus isolation test on a semen sample for EVA.

This requirement, for the most part, prohibited EVA vaccinated animals
Effective October 1, 1995, uncastrated males may (in addition to the previous requirements for EVA) be qualified for export to the EU under the following conditions if they are less than 180 days old (no test required); if they are vaccinated for EVA within 15 days of a negative serum neutralization (SN) test result at the 1:4 dilution; or (provided they are between the ages of 180 and 270 days) if they are vaccinated for EVA after having undergone two SN tests for the disease at an interval of at least 10 days with the results demonstrating a stable or decreasing titer.

The EU agreed, after discussions with APHIS, to allow semen from bulls resident in Certified Semen Services participating centers to be used to inseminate donor cows for embryo production and export to the 15 Member States. Previous to this change, only semen from bulls resident in the 18 artificial insemination centers approved to export bovine semen to the EU could be used. The semen itself also had to be qualified to be exported to the EU prior to its use for embryo production.

ANIMAL, POULTRY, GERM PLASM EXPORTS - FY 1995
(Partial Data Totals, October 1995)

Livestock (including slaughter)
- Bovine: 111,672
- Equine: 53,437
- Ovine: 402,767
- Caprine: 16,325
- Porcine: 121,032

TOTAL LIVESTOCK: 705,233

Poultry
- Day-old chicks: 27,706,347
- Hatching eggs (dozens): 49,253,864

Germ Plasm
- Bovine semen: 6,945,333
- Equine semen: 1,491
- Porcine semen: 2,952
- Caprine semen: 486
- Bovine embryos: 13,873

Other animals ( cervids, camels, zoo, etc.) 731,083

Animal Product and By-Product Activities
A total of 5,510 permits were issued in FY 1995 by the National Center for
Import-Export, Products Program Staff, authorizing the importation of organisms, vectors, biological materials, and animal products and by-products. Fewer actual permits were issued in FY 1995 than in FY 1994. This may be in part due to alternative methods developed for importing certain materials that have been determined to be of low risk or of little agricultural concern. Additionally, there were 7,676 applications processed this fiscal year, compared to 8,746 applications processed in FY 1994. This decreasing trend in application numbers was noted all through FY 1995 and would account for the greatest differences in the number of permits issued.

The Products Program continues to implement alternative methods to provide for importing low agricultural risk materials. These include non-live-stock species not susceptible to epizootic livestock and poultry diseases. They also include recombinantly engineered laboratory organisms produced without involvement of animal products or disease agent derivatives. For materials to qualify, there must be sufficient description or identification at the time of entry, such as by certification from the export facility or country.

User fees are no longer having a negative effect on establishments approved to import restricted animal products. The number of approved establishments have stabilized and many past establishments have re-applied.

Requests for export certification continue to increase. Export problems associated with international trade continue to increase as well. Plans are well underway for providing a data base for export conditions. Additional bi-lingual health certificates will eventually be available as well.

Dry, cured pork products from Spain have been approved for importation. Spain is preparing a list of plants to be designated for approval to export to the United States. However, the Spanish meat packers are having difficulty meeting the requirements of the Spanish Ministry of Public Health.

The Products Program Staff have finished its technical review of the regulation changes being developed for regionalization and risk assessment. The legal review is now being conducted.

**ACTION TAKEN ON REQUESTS BY FOREIGN GOVERNMENTS TO BE RECOGNIZED FREE OF SPECIFIED DISEASE**

Spain and the United Arab Emirates were recognized free of African horse sickness; Spain was also recognized free of swine vesicular disease; Switzerland was recognized free of foot-and-mouth disease, rinderpest and exotic Newcastle disease.

Proposed rules to recognize Germany free of swine vesicular disease and Uruguay free of foot-and-mouth disease and rinderpest were published late in FY 1995. Also published was a proposed rule to add the Mexican State of Chihuahua to those approved to transit pork products through the United States.
PLANT PROTECTION AND QUARANTINE -- PORT OPERATIONS

X-RAY Baggage Inspection

Plant Protection and Quarantine (PPQ) continues to expand the use of "x-ray" as a screening tool in passenger baggage clearance at major international airports. There are x-ray scanning machines located at all foreign-arrival and predeparture sites. Such machines for predeparture clearance are at Ponce, Roosevelt Roads, Aguadilla, and San Juan, Puerto Rico, and four islands of Hawaii, where passengers bound for the U.S. mainland are inspected because of plant pest concerns, such as the Mediterranean fruit fly. The international airports are San Juan, Miami, Honolulu, Chicago, Kennedy (New York), Houston, Dallas, Boston, Atlanta, Dulles (Washington, DC), Los Angeles, San Francisco, Seattle-Tacoma, Philadelphia, Orlando, and Newark. San Ysidro, Otay Mesa, and Nogales on the Mexican border, are land border ports with such equipment. X-ray Machines are used in two postal facilities.

PPQ in partnership with the U.S. Army, Picatinny Arsenal, New Jersey, are developing a prototype x-ray system. This system will:
- Detect quantities weighing 10 grams.
- Throughput of 120 ft/min as required for "check-in" baggage inspection.
- Accommodate baggage dimensions allowed for check-in items.
- Store scanned images for unlimited length of time; be capable of retrieving and displaying them at will.
- Barcode the baggage having detected product.
- Neural net analysis with continuous learning.

DETECTOR DOG PROGRAM

Forty eight trained dog teams at 20 major airports are used in clearing passenger baggage. The airports are: Atlanta, Orlando, Miami, Houston, Dulles, Dallas, Charlotte, Philadelphia, San Juan, Newark, Kennedy, Boston, Charleston, Chicago, Los Angeles, San Francisco, Seattle-Tacoma, Detroit, Bangor, Honolulu. Los Angeles, Honolulu, San Francisco (Oakland mail facility), and Miami have dog teams in their post offices.

The program will expand in the next 4 years to 108 teams.

AUTOMATED COMMERCIAL SYSTEMS (ACS)

As of October 1, 1995, there are 431 sea carriers operating in 38 ports and 99 airlines operating in 27 airports on the Automated Commercial System (ACS). Ninety eight percent of commercial shipment data is entered into ACS.

To facilitate trade and reduce the paperwork burden on industry, the National Performance Review (NPR) tasked the U.S. Government to establish an integrated database for the collection and dissemination of all international
trade data through the expansion and redesign of the U.S. Customs Service Automated Commercial System.

APHIS, PPQ is now in the process of developing an Automatic Targeting System that will automatically place holds on regulated cargoes. This system looks at both entry and manifest information and uses developed criteria to place holds. Inspectors will only need to look at a list of holds and not scroll manifests. It will aid in the facilitation of trade and yet uphold the enforcement and tracking of regulated agricultural commodities.

REGULATED GARBAGE, MARPOL ANNEX V

The U.S. Coast Guard is the enforcement Agency for Annex V of the International Convention to Prevent Pollution of the Seas (MARPOL 73/78). This Annex prohibits discharge into the sea of “all plastics including, but not limited to, synthetic ropes, fishing nets, and plastic garbage bags.” It also prohibits discharge of food wastes and other floating materials within specified distances of land. These regulations became effective December 31, 1988. USDA-regulated garbage handling requirements have not changed. All food or food-contaminated materials, such as plastics contaminated by galley waste, must be retained aboard the vessel in covered, leakproof containers. If offloaded, such garbage must be incinerated or heated to an internal temperature of 212 °F for 30 minutes. There continue to be increasing interest in the strict enforcement of MARPOL Annex V requirements. APHIS PPQ continues to play a major role because of their vessel inspection and garbage control requirements.

During the period of October 1994 to October 1995, APHIS generated percent (80 reports) of the MARPOL V violations.

AIRPORT 1990’s

Processing the increasing number of international travelers continues to present many challenges to all Federal clearance agencies. As reported last year Customs has adopted a new plan, “Airport 1990’s,” which calls for Customs to be more selective and examine reduced numbers of passengers and bags. In response, APHIS is using “rovers” and “choke points” to control passenger movement.

IBIS, Interagency Border Inspection System, is used by approximately 20 agencies to focus on the individual person and any past violation history. Thus, past violators of APHIS programs can be “electronically” listed. IBIS is being expanded to more effectively identify passengers requiring personal inspection by the FIS agencies including APHIS. This system, designated Advance Passenger Inspection System (APIS), is being implemented to expedite passenger clearance but more effectively protect American Agriculture.
This summer USDA, APHIS, PPQ participated with the U.S. Customs Service, the Immigration and Naturalization Service, and the State Department in a reengineering government initiative. This Border Passenger Processing Reengineering consisted of three multiagency teams (Northern Border - Canada, Southern Border - Mexico, and international airports) which examined processing of passengers and their baggage as they entered the United States. The teams were initially directed to look for ways that passenger processing could be expedited, while at the same time compliance with U.S. laws and regulations remained the same or was increased. Alternative methods already being tested or slated for test implementation were included in the study, as well as more cross-agency passenger processing methods, and methods depending on intensive use of technology now in relatively early stages of development or availability.

All agencies agreed that base-line measurements of enforcement effectiveness were either minimal or lacking, and agreed to coordinate studies to maximize usefulness and minimize multiple intrusions on passenger processing. Plant Protection and Quarantine is entering the second year of a random sampling study to determine what agricultural products are being carried by passengers entering the United States, and is compiling results from and continuing other studies.

Planning for implementation of test passenger processing expediting methods at several different land border and international airports is now in process. Rapid implementation is expected.

PLANT PROTECTION AND QUARANTINE PORT ACTIVITIES REPORT OF ANIMAL PRODUCTS IMPORTED/EXPORTED
September 1994—August 31, 1995

Vessels and Aircraft Arrivals

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessels arrived</td>
<td>65,909</td>
</tr>
<tr>
<td>Vessels boarded</td>
<td>59,582</td>
</tr>
<tr>
<td>Vessels monitored for garbage violations</td>
<td>9,997</td>
</tr>
<tr>
<td>Lots consisting of 8,909,505 kilograms of garbage were removed from these vessels</td>
<td>9,843</td>
</tr>
<tr>
<td>Aircraft arrived from foreign locations</td>
<td>427,055</td>
</tr>
<tr>
<td>Kilograms of garbage removed from these aircraft</td>
<td>21,861,092</td>
</tr>
</tbody>
</table>

Meat and Other Animal Products Confiscated/Refused Entry

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ship passenger baggage</td>
<td>1,226 Lots</td>
</tr>
<tr>
<td>Aircraft passenger baggage</td>
<td>198,541 Lots</td>
</tr>
<tr>
<td>Border crossing</td>
<td>33,593 Lots</td>
</tr>
<tr>
<td>Post offices</td>
<td>8,792 Lots</td>
</tr>
</tbody>
</table>
APHIS REPORT TO IMPORT AND EXPORT COMMITTEE

Footwear Cleaned and Disinfected 6,223 Pair
Maritime Garbage Civil Penalties 300 $56,950
Baggage Civil Penalties 22,164 $1,186,310
Notification Violations 157 $46,700
Predeparture Baggage Violations 56 $3,115


<table>
<thead>
<tr>
<th>SPECIES</th>
<th>FY 1993</th>
<th>FY 1994</th>
<th>FY 1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bison</td>
<td>**</td>
<td>**</td>
<td>1,058</td>
</tr>
<tr>
<td>Bovine</td>
<td>2,528,537</td>
<td>2,248,842</td>
<td>2,526,966</td>
</tr>
<tr>
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**IMPORT ANIMALS**

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SUMMARY – BI-WEEKLY ANIMAL IMPORTS
CANADIAN AND MEXICAN BORDER PORTS

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| EQUINE                     |          |          |          |          |
| Breeding                   | 31       |          |          |          |
| Commercial                 | 290      |          |          |          |
| Competition                | 225      |          |          |          |
| Feeder                     | 96       |          |          |          |
| Other                      | 4,513    |          |          |          |
| Pet                        | 2,422    |          |          |          |
| Racing                     | 4        |          |          |          |
| Slaughter                  | 7,745    |          |          |          |
| TOTAL                      | 15,326   |          |          |          |

| OVINE                      |          |          |          |          |
| Feeder                     | 1,661    |          |          |          |
| TOTAL                      | 1,661    |          |          |          |

| CANADIAN BORDER PORTS      |          |          |          |          |
| BOVINE                     |          |          |          |          |
| Breeding                   | 42,375   |          |          |          |
| Competition                | 1,193    |          |          |          |
| Commercial                 | 7,850    |          |          |          |
| Feeder                     | 44,160   |          |          |          |
| In-bond                    | 7,647    |          |          |          |
| Other                      | 857      |          |          |          |
| Research                   | 34       |          |          |          |
| Slaughter                  | 966,599  |          |          |          |
| Transit                    | 852      |          |          |          |
| TOTAL                      | 1,071,567|          |          |          |

<p>| CAPRINE                    |          |          |          |          |
| Breeding                   | 752      |          |          |          |
| Commercial                 | 74       |          |          |          |
| Competition                | 9        |          |          |          |
| Feeder                     | 22       |          |          |          |
| In-bond                    | 12       |          |          |          |
| Other                      | 7        |          |          |          |
| Slaughter                  | 4        |          |          |          |
| TOTAL                      | 880      |          |          |          |</p>
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272
POTENTIATION OF BOVINE RESPIRATORY SYNCYTIAL VIRUS INFECTION IN CALVES BY BOVINE VIRAL DIARRHEA VIRUS

Clayton L. Kelling, Bruce W. Brodersen, Louis J. Perino, Vickie L. Cooper, Alan R. Doster, John H. Pollreisz

Department of Veterinary and Biomedical Sciences, University of Nebraska-Lincoln, Lincoln, NE 68583. (Kelling and Brodersen) and Pfizer Animal Health, Exton, PA 19341 (Pollreisz)

Summary

Bovine viral diarrhea virus potentiated BRSV infection of pulmonary airway epithelial cells and caused exacerbation of lung injury leading to augmentation of respiratory disease in conventional 450 pound feeder calves. Clinical signs of BRD (depression, serous to mucopurulent nasal discharge, and dyspnea) were more severe and extent of lung injury was greater in calves inoculated with both BRSV and BVDV than in calves inoculated with either virus alone. Clinical condition of the dual virus-infected calves deteriorated daily after inoculation. Dual viral infection caused development of macroscopic pulmonary lesions consisting of dark red firm areas in the cranial lungs, as well as microscopic lesions consisting of multifocal areas of bronchiolar epithelial necrosis with occasional syncytia. Bovine respiratory syncytial virus was isolated from nasal secretions and lung tissues of infected calves. Immunohistochemical procedures were used to localize BRSV antigen in the cytoplasm of airway epithelial cells. Macroscopic and microscopic lesions and antigen deposition in the lungs of the dual-infected calves indicated that BVDV potentiated BRSV infection of airway epithelial cells and clinical signs when compared to calves exposed with BVDV or BRSV individually.

Introduction

Bovine respiratory disease (BRD), a major health problem of cattle in the United States, causes greater economic loss than all other feedlot diseases of cattle combined. Complex interactions between viruses, bacteria, mycoplasmas and various environmental stressors of calves cause clinically-severe BRD. Severe pneumonia in feeder cattle is frequently associated with mixed bacterial and viral infections. Pathogenic bacteria are frequently carried in the nasopharynx of normal cattle where they reside as commensals. The respiratory system of normal cattle is highly resistant to bacterial colonization. When the mucociliary apparatus becomes impaired by viruses such as bovine respiratory syncytial virus (BRSV), respiratory secretions increase in amount and viscosity which reduces the efficiency of this defense mechanism. Degeneration and necrosis of ciliated epithelial cells caused by BRSV
or other viral infection follows and further inhibits the ability of the tracheobronchial tree to remove foreign material including bacterial pathogens. Subsequently, efficiency of pulmonary macrophages to clear the lung of bacterial pathogens is suppressed resulting in colonization and proliferation of bacterial pathogens such as *Pasteurella haemolytic*, *Pasteurella multocida*, *Haemophilus somnus*, or *Actinomyces pyogenes*. Mixed bacterial and BRSV infections have been shown experimentally to cause more severe respiratory disease. It has also been demonstrated that mixed viral infections play a role in BRD both in natural and experimental infections. There is serologic evidence of naturally-occurring mixed viral infections in BRD where seroconversion to BRSV was associated with an increased rate of seroconversion to infectious bovine rhinotracheitis virus (IBR), parainfluenza type 3 virus, bovine adenovirus type 3, and BVDV. Bovine virus diarrhea virus infection has been shown to result in increased distribution of IBR virus in experimentally inoculated calves. The etiologic role of BVDV in BRD has been attributed to its immunosuppressive effects in the host animal since there is limited or no evidence for lung injury due to BVDV infection. Bovine viral diarrhea virus has a tropism for lymphoid cells of the primary and secondary organs of the immune system. The virus causes decreases in populations of those cells in vivo as well as down-regulating cell functions in vitro. Immunosuppression has been associated with increased susceptibility of cattle to bacterial infections. Bovine respiratory syncytial virus causes bronchitis, bronchiolitis and pneumonia. While individual effects of BVDV and BRSV on the host animal are well documented, synergistic effects of simultaneous BVDV and BRSV infections have not been defined. The objective of the present study was to determine the pathologic effects of concurrent BRSV and BVDV infections in calves to determine if disease-potentiation occurred during simultaneous infections.

**Experimental Methods**

Fourteen yearling Hereford beef calves, serologically and virus isolation negative for BVDV and BRSV, weighing approximately 450 pounds were obtained from a privately-owned range herd. The calves were transported to the Animal Research Facility at UNL and were housed in BL2 isolation rooms (2 calves per room). Animals were fed a commercial complete pelleted ration with continuous free access to fresh water. The calves were acclimated for 7 days before initiating the study.

The calves were randomly-assigned to 1 of 4 treatment groups: group 1, calf Nos. 1, 2, 3, 4; group 2, calf Nos. 5, 6, 7, 8; and group 3, calf Nos. 9, 10, 11 12; group 4, calf Nos. 13, 14. Calves in group 1 were exposed to BVDV and calves in group 2 to BRSV. Calves in group 3 were exposed to both BRSV and BVDV and calves in group 4 were non-inoculated controls. Calves were euthanatized and necropsied as follows: Day 3: Calf Nos. 1, 5 and 9; Day 6: Calf Nos. 2, 6, 10 and 13; Day 9: Calf Nos. 3, 7 and 11; and, Day 12:
Calf Nos. 4, 8, 12 and 14.

Calves were inoculated intranasally with $2 \times 10^8$ tissue culture infective doses 50% (TCID$_{50}$) of New York-I BVDV on Day 0. Bovine respiratory syncytial virus challenge virus (Isolate No. 165, $1 \times 10^5$ TCID$_{50}$/ml provided by M. O'Hara and L. Nelson, SmithKline Beecham Animal Health) was administered intranasally (5 ml) and intratracheally (5 ml) in the morning, and intranasally (5 ml) in the afternoon on Days 0, 1 and 2.

Each calf was evaluated clinically and the body temperature of each calf was determined twice daily. The following clinical parameters were evaluated and scored: (1) The amount and character of the nasal discharge (2) Respiratory rate and character (3) Consistency of feces (4) Appetite and (5) Condition.

Calves were euthanatized, necropsied and tissues were collected for virus isolation, bacteriologic, histologic and immunohistochemical examination.

Discussion

Bovine viral diarrhea virus potentiated BRSV infection of pulmonary airway epithelial cells causing exacerbation of lung injury leading to augmentation of clinical signs of respiratory disease in 450-pound feeder calves in the present study. Clinical signs of BRD (depression, serous to mucopurulent nasal discharge, and dyspnea) were more severe and extent of lung injury was greater in calves inoculated with BRSV and BVDV than in calves inoculated with either virus alone. Magnitude and character of clinical responses of calves to single viral infections in the present study were equivalent to earlier reports of clinical responses of calves of the same age to experimental infections with BVDV$^8$ or BRSV$^{19}$. All 4 calves infected with BRSV and BVDV developed mild signs of upper respiratory tract infection after inoculation consisting of moderate depression, and serous to mucopurulent nasal discharge. The condition of the dual virus infected calves progressed to signs of lower respiratory tract disease which was manifested by dyspnea. Clinical condition of the dual virus-infected calves continued to deteriorate daily until they were severely depressed or recumbent. Dual virus-infection did not affect the onset or duration of viral shedding in nasal secretions since both viruses were present from only Day 2 to 7 after viral inoculation in calves infected with either virus alone or in combination. This 7 day duration of BRSV shedding is consistent with BRSV shedding patterns in experimentally-inoculated calves$^{19}$ or sheep$^{20}$. Similarly, neither the onset nor duration of BVDV viremia was affected by concurrent BRSV infection since BVDV was usually present in buffy coats from 2 days after inoculation until the animals were euthanitized (Table 1).

Potentiation of pathogenic effects and clinical signs of BRSV by BVDV during dual BRSV/BVDV infections in calves, resulted in more extensive lesions in the respiratory tract compared to BRSV alone. Dual viral infection
induced development of macroscopic pulmonary lesions consisting of dark red firm areas in the cranial lungs. Microscopic lesions consisting of multifocal areas of bronchiolar epithelial necrosis with occasional syncytia were associated with BRSV infection in calves inoculated with BRSV alone or in combination with BVDV. Results from immunohistochemical tests showed that bronchiolar epithelial necrosis was due to BRSV based on localization of BRSV antigen in the cytoplasm of airway epithelial cells (Figures 6 and 7). BRSV was reisolated from lung tissues of calves killed 6 days after being inoculated with BRSV alone or in combination with BVDV and from the calf euthanitized 3 days after inoculation with BRSV and BVDV. The presence of BRSV in postmortem lung tissues corresponded with onset of bronchopneumonia in the calf of the same treatment group which was killed 3 days later (Table 2).

Increased severity of clinical signs and extension of gross pulmonary lesions in dual virus-infected calves over calves infected with BVDV or BRSV individually, indicated that BVDV potentiated BRSV-induced lung injury. Increased severity and expanded distribution of microscopic lesions consisting of lymphoid depletion in tracheobronchial, mesenteric and cecal lymph nodes of dual virus-infected calves compared to BRSV-infected calves (Table 2) indicated an immunosuppressive role for BVDV which resulted in potentiation of disease. The presence of BVDV antigen in the thymus and Peyer's patch of 3 of the 8 calves inoculated with BVDV was supporting evidence of the negative effects of BVDV on the immune system which culminated in augmented BRSV pulmonary infection. These results led us to conclude that potentiation of BRSV infection by BVDV in the present study was due to the immunosuppressive properties of BVDV. Immunosuppression can be attributed to the lymphotrophic properties of BVDV. Bovine virus diarrhea virus infection causes decreases in the absolute numbers of B and T lymphocytes in acute infections and decreases in immunoglobulin secretions. Neutrophil function is down-regulated and bacterial clearance is impaired by BVDV. Collectively, these immunosuppressive properties of BVDV could account for the potentiation of BRSV infection by BVDV observed in the present study. It has been shown that T cell mediated immune response plays a role in protection against BRSV. Decreases in T cell numbers as a result of BVDV infection could be a specific cause for enhanced disease due to dual viral infection.

An apparent potentiation of BVDV infection of the digestive tract by BRSV also occurred and was manifested by intensification of enteric clinical signs in calves dually-infected with BRSV and BVDV compared to calves infected with only BVDV. This is supported by the fact dual virus-infected calves were moderately depressed and developed nonformed feces by Day 3 which progressed to severe watery diarrhea on Day 7. Calves inoculated with BVDV, in contrast, became only moderately-depressed and diarrheic on Day 3 and remained in that condition until necropsy. Only 2 of the 4 calves inoculated with BRSV developed mild depression (without diarrhea) which was evident
for one day. BVDV's role in causing moderate diarrhea in BVDV-infected calves and severe diarrhea in the dual BRSV/BVDV-infected calves was confirmed by localization of BVDV-specific antigen. Antigen was present in cells in areas of multifocal lymphoid necrosis within mesenteric lymph nodes and Peyer's patches. Virus isolation from the affected organs also confirmed the presence of BVDV.

Potentiation of BRSV infection and pulmonary injury by BVDV supports the generally accepted hypothesis for the pathogenesis of classical, naturally-occurring, clinically-severe BRD which is typically due to mixed viral and bacterial infections. This study supports findings of a serologic study in which BVDV was associated with initiation of BRD and it was concluded that multiple viruses concomitantly infect animals and could be important in pathogenesis of naturally-occurring, pneumonia in feeder cattle. Our results indicate that BRSV and BVDV, together, are important causes of naturally-occurring BRD. This conclusion is further supported by a serological study of feedlot cattle in Canada in which BRSV, BVDV and Pasteurella spp. were associated with 60% of BRD occurrence.

References


REPORT OF THE COMMITTEE OF INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA

Chairperson: Dr. C. Seymour Card, Harrisburg, PA
Vice Chairperson: Dr. Lynne Siegfried, Harrisburg, PA

H. Acland, PA; F. Bauer, CA; S.R. Bolin, IA; J. Brooks, KY; H.M. Chaddock, MI; D. Christ, OR; T. Conner, IN; R. Crandell, TX; G. Crenshaw, CA; A. Dewald, SD; K. Dowling, SD; M. Fowler, CA; L. Harrison, KY; D. Hensel, CO; S. Holland, SD; J. Hunt, MO; J.A. Jarvinen, IA; A. Kennel, MN; P. Lee, IN; P. Lies, ND; A.J. Luedke, CO; D. Mattson, OR; P. McDonough, NY; J. Miller, IA; P. O’Berry, IA; B. Osburn, CA; D. Schlafer, NY; J. Schmitz, NE; C. Siroky, MT; J. Strickland, GA; D. Suther, CA; G. Teagarden, KS; R. Temple, OH; C. Thoen, IA; W. Wren, IA.

The Committee on Infectious Diseases of Cattle, Bison and Llama met from 1:30 to 5:30 pm on October 31, and from 1:30 TO 5:30 on November 1, 1995 at John Ascuaga’s Nugget Hotel, Reno, Nevada. Dr. C. Seymour Card, Chairman, conducted the meetings.

Committee members present included: H. Acland, PA; D. Christ, OR; T. Conner, IN; R. Crandell, TX; G. Crenshaw, CA; A. Dewald, SD; K. Dowling, SD; CA; L. Harrison, KY; D. Hensel, CO; S. Holland, SD; J. Hunt, MO; A. Kennel, MN; P. Lee, IN; P. Lies, ND; D. Mattson, OR; P. McDonough, NY; J. Miller, IA; P. O’Berry, IA; B. Osburn, CA; D. Schlafer, NY; J. Schmitz, NE; C. Siroky, MT; J. Strickland, GA; D. Suther, CA; G. Teagarden, KS; R. Temple, OH; C. Thoen, IA; W. Wren, IA.

Dr. Clayton L. Kelling discussed the potentiating capability of the Bovine Viral Diarrhea Virus on the Bovine Respiratory Syncytial Virus infection in calves. In this study BVDV potentiated BRSV infection in of pulmonary airway epithelial cells and caused exacerbation of lung injury leading to augmentation of respiratory disease in conventional 450 pound feeder calves. Clinical signs of BRD (depression, serous to mucopurulent nasal discharge, and dyspnea) were more severe and extent of lung injury greater in calves inoculated with both BRSV and BVDV than in calves inoculated with either virus alone. Clinical condition of the dual virus-infected calves deteriorated daily after inoculation. Dual viral infection caused a development of macroscopic pulmonary lesions consisting of dark red firm areas in the cranial lungs, as well as microscopic lesions consisting of multifocal areas of bronchiolar epithelial necrosis with occasional syncytia. Bovine respiratory syncytial virus was isolated from nasal secretions and lung tissues of infected calves. Immunohistochemical procedure were used to localize BRSV antigen in the cytoplasm of airway epithelial cells. Macroscopic and microscopic lesions and antigen deposition in the lungs of dual-infected calves indicated that BVDV
REPORT OF THE COMMITTEE

potentiated BRSV infection of airway epithelial cells and clinical signs when compared to calves exposed with BVDV or BRSV individually.

Dr. Brad Barr and co-workers of the California Diagnostic Laboratory discussed the current status of Neospora caninum abortion in California cattle. Neospora was first identified in 1988 as a new genus of pathogenic Toxoplasma-like apicomplexan protozoan associated with congenital encephalomyelitis in puppies. Fetal and neonatal infections caused by Neospora species have since been described in cattle, sheep, goats and horses. Neospora caninum, isolated from dogs, and the Neospora species isolated from cattle are very similar, and may represent a single protozoan species. However, until complete identity between these parasites can be proven either through identification of identical life cycles with a single definitive host, or through molecular characterization studies, the bovine protozoan should be referred to as a Neospora species.

Bovine fetal neosporosis, is now considered to be a major cause of bovine abortion in select regions in the United States, New Zealand, and possibly in the Netherlands and Great Britain. In addition, bovine Neospora abortions have been recognized throughout North America, Australia, Japan, South Africa, Great Britain, and Denmark. With increased awareness and availability of new methodologies, Neospora, like Toxoplasma, may eventually be recognized worldwide, perhaps as a major cause of currently undiagnosed bovine abortions.

The diagnosis of bovine Neospora abortion currently relies on fetal histopathology, and the identification of Neospora parasites in fetal tissues by immunohistochemistry. Detection of Neospora antibody titres in aborting cows establishes maternal exposure, but cannot confirm the cause for individual abortions within a herd. Currently there is no information on whether specific Neospora antibodies are produced or detected in fetuses as a result of Neospora infection. Detection of fetal antibody production to specific abortifacients in ruminants, such as Toxoplasma indicates fetal exposure and is often used to confirm the cause for abortion. The objective of this study was to determine whether specific Neospora fetal antibodies could be detected in the fetal fluids and/or fetuses with Neospora infections using the indirect fluorescent antibody test (IFAT).

Fetal fluids from 138 spontaneously aborted bovine fetuses were examined for the presence of antibodies against Neospora antigens using an indirect fluorescent antibody test (IFAT). The fetuses were divided into Group 1 consisting of 74 fetuses with confirmed or presumptive fetal neosporosis, and Group 2 consisting of 64 fetuses with either no aetiologic diagnosis, presumptive diagnoses of non-Neospora infectious or noninfectious diseases, or fetuses with confirmed diagnoses of other fetal diseases. Thirty-seven of 74 fetuses in Group 1 with a diagnosis of neosporosis had detectable Neospora antibody titres. In Group 1 approximately 21% of fetuses between 3 and 5 months gestation, 56% between 6 and 7 months gestation, and 93% be-
between 8 and 9 months gestation had detectable *Neospora* antibody titres. Only 1 of 64 fetuses from Group 2 had a detectable *Neospora* antibody titre. The results suggest that the *Neospora* IFAT is specific for detection of fetal antibodies against *Neospora* and that this test may be a useful adjunct to histopathology/immunohistochemistry in the diagnosis of fetal neosporosis, especially in late term aborted fetuses.

Dr. Jim Cullor of the University of California at Davis discussed the problem of endotoxins in cattle vaccines. In the Code of Federal Regulations (9 CFR) the testing terminology for safety in vaccine approval is defined as the "freedom from properties causing undue local or systemic reactions when used as recommended or suggested by the manufacturer." Unfavorable reactions are defined as "overt adverse changes which occur in healthy test animals subsequent to initiation of a test and manifested during the observation period prescribed in the test protocol which are attributable either to the biological product being testing or to factors unrelated to such product as determined by the responsible individual conducting the test."

Even though USDA, APHIS attempts to evaluate the safety of veterinary biologicals prior to their release for sale to animal agriculture, deaths, illness, and adverse reactions due to vaccine administration continue to be a daily event in the United States and elsewhere. Safe or Tolerance levels for endotoxin(s) in vaccines are not known for any species. No pyrogenic threshold has been established for bovine or other food animal biologicals.

Traditional Gram-negative vaccine preparations have been plagued by problems of adverse reactions in the host species, thus earning the distrust of many veterinarians and producers. Commercial Gram-negative immunogens contain thousands of EU/ml of vaccine, and may contain up to millions of EU/ml of free endotoxin as measured by the Limulus Amebocyte Lysate assay. When one considers that the pyrogenic threshold for pharmaceutical compounds is 5 EU/kg body weight, a 700 Kg cow would have 3,500 EU as the maximum target amount. There are no pyrogenic thresholds established for food animals related to vaccine administration; however, the vast majority of the immunization schedules employed today in food animals far exceed the target amount set in the pharmaceutical compound example. As producers become more aware of the possible adverse reactions that can result from immunization protocols the veterinarian in charge of herd health programs must be aware of the endotoxin levels present in the vaccines being administered to the animals. For example, veterinarians may need the products tested and then weigh safety and efficacy considerations in selecting which immunogen is to be administered, or alter the frequency of vaccine administration. There are no published research studies, at this time, that assess either of these strategies using commercial vaccine preparations.

Dr. Cullor continued with a discussion of testing for antibiotics in milk. Our nation's milk supply is to be monitored on a daily basis for the presence of antibiotic residues. Appendix N of the Pasteurized Milk Ordinance is the
section that deals with drug residue monitoring and farm surveillance. It was "established to reference safe levels and/or establish tolerance and to assure that milk supplies are in compliance with these safe levels or established tolerance for drug residues in milk." This appendix to the PMO clearly states that "drug residue detection methods shall be evaluated at the safe level or tolerance." It appears that it was never the intent, either expressed or implied, that residue testing methods should be "accepted" when they are assay positive at several times below the established safe or tolerance level or safe concentration. Unless the producers or veterinarians are able to submit a problem at the biennial NCIMS conference and get it approved, they have little or no input on the important regulatory document.

Since mid-1994 there have been antibiotic residue assays that are Center of Veterinary Medicine/Food and Drug Administration (CVM/FDA) "accepted", Association of Official Analytical Chemists (AOAC) International "performance tested", and National Conference On Interstate Milk Shipments (NCIMS) "recommended" that: a) are used for tanker milk and have never been scientifically field tested on tanker loads of milk, b) are used for trace back on bulk tank milk and have never been field tested on bulk tank milk, and c) are routinely used on individual animal milk samples and have not gone through an appropriate epidemiological individual animal validation protocol. The use of antibiotic residue assays in everyday settings and the consequences of current assay performance is already adversely impacting dairy producers and food animal practices around the United States and elsewhere.

Antibiotic residue test performance in "Real World" scientific studies has been one of the more revealing stories of test kit performance from individual animals samples to tanker truck loads of milk. Problems associated with the tanker truck screening assays are found in the National Drug Residue Milk Monitoring Program (NDRMMP) conducted by the Food and Drug Administration Center for Food Safety and Nutrition. An FDA summary of NDRMMP for FY'94 revealed that of 33 screening assay positive samples of tanker milk, only 8 were verified as containing violative residues. This translates into approximately a 75% false positive rate. In a FY '95 Quarterly Report NDRMMP (Draft report)- 1 January to 31 March 1995, of the 48 screening assay positive tanker milk samples, only 3 were verified as containing violative residues. This translates into approximately a 94% false positive rate. Similar problems have been reported around the world when these assays have been used to test individual animal milk samples; thus, leading to unwarranted dumping of milk and culling of cows. In addition, companies that insure dairy producers against the loss of milk due to antibiotic residues are reporting that they a currently paying claims at a rate up to 10 times above that of previous years. This is in the face of reduced antibiotic use by producers and veterinarians in treating dairy cattle.

Dr.'s David Hird, Deryck Read and Richard Walker of the University of California, Davis, presented information on the epidemiology of foot warts in
INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA

California cattle. In the last two decades, papillomatous digital dermatitis (PDD), or foot warts, has become an increasingly important cause of lameness in dairy cattle throughout the world, including Europe, and North and South America. In California, one southern California hoof trimmer reported occasionally seeing typical lesions as long ago as 1968. The disease first began to draw attention in southern California in the early '90's when many herds became affected, and the disease spread rapidly within affected herds. Currently, little is known about the cause and epidemiology of PDD.

In the Spring of 1994 the authors conducted a mail survey of dairy managers in California in order to describe the occurrence and dates of appearance of PDD in California dairies, as well as seasonal occurrence and reported success of various treatments.

The earliest reports of PDD in California were from southern California in the early to mid-1980's. Later it was reported on the north coast, northern California and the central valley. Growing numbers of dairies reported seeing the disease in the early 1990's as mentioned previously. Over three-quarters of reporting southern California dairies have seen foot warts, and nearly one-half have reported outbreaks. The situation in central California was not much different. Far fewer north coast and northern dairies reported foot warts, and fewer outbreaks were reported in these regions.

Almost 10% of cows were reported to be affected by foot warts in the southern and central regions during 1993. In southern California there was a clear tendency for highest activity during the summer months; for central California there was no definite seasonal pattern. Most managers considered that topical tetracycline was the most successful treatment for PDD.

In the late summer of 1994 the authors conducted a case-control study in 57 dairies in the Chino Valley, to determine why some dairies were severely affected by foot warts while others were not. Dairies with muddier corrals were 19 times more likely to have high PDD prevalence, as compared to those with dryer corrals. Dairies buying replacement heifers were 6 times more likely to be high-prevalence PDD dairies, compared to dairies that did not.

Dr. Tom Drake of the Pennsylvania Animal Diagnostic Laboratory System discussed a case of parasitism in a bison. A recently assembled herd of bison in central PA began to show reduced weight gains and in some cases weight loss. A yearling calf that died in early October was submitted to ADL at Penn State University for Necropsy. Gross observations included poor body condition, diarrhea or liquid feces in the colon and rectum, and severe thickening of the abomasal mucosa with a dense concentration of small nodules visible on the surface.

On histologic exam the intestinal tract was negative for Johne's Disease, and nematode larvae were observed in the abomasal nodules. This lesion is compatible with type II Ostertagiadue to hypobiotis ostertagia larvae.

A recommendation was made to worm the herd with Ivomeca, and begin
a preventive worming program during the following grazing season in 1996.

Dr. Don Mattson of Oregon State University discussed the possible impact of vesicular stomatitis in llamas. During the recent disease epizootic with vesicular stomatitis in the Southwestern United State, llama producers were concerned with the potential threat of the virus to their animals. The virus is believed to be transmitted both by direct contact and arthropod transmission will allow its continued dissemination.

Different species of animals vary with their sensitivity to infection. Horses are more severely affected followed by cattle; sheep and camelids appear to be quite resistant. During the 1982 outbreak, there were numerous reports of llamas in close contact with infected cattle and horses but none of the llamas showed signs of disease. Some years ago, researchers in South American showed that it was difficult to infect llamas with VS and, when signs of infection appeared, they were comparatively mild. Lesions could only be reproduced by direct inoculation of the virus in the epithelium of the tongue.

During the 1995 epizootic, one case of VS was described in a llama. Vesicles developed on the tongue during a 10-day period. The vesicle quickly ulcerated and healing proceeded without complications. The animal developed a fever and was hesitant to eat because of the painful lesion. The authors and co-workers conclude that llamas can become infected with the virus but there is little threat of devastating losses.

Dr. John Kopec, USDA/APHIS/VS discussed the progress that has been made in reducing the number of quarantined Brucellosis herds in the country. State and federal disease regulatory workers, cattle associations and other agencies have carried out a long term and successful programs throughout the country to eliminate this disease. The one remaining problem is the infected population of buffalo in the greater Yellowstone Park (YNP) area that threatens livestock herds in the contiguous states of Montana, Idaho and Wyoming. Cattle from these three states are sold all over the United States and thus poise a threat of reinfection. The final stage of the elimination of Brucellosis will depend on the successful resolution of the disease problem in the YNP herd.

Dr. Clarence Siroky, State Veterinarian for Montana discussed the programs that Montana has initiated to control the movement Bison from the YNP into contiguous Montana grazing land. The substance of both Dr.'s Kopec and Siroky presentations are included in the Report of the Brucellosis Committee, and need not be included in this Committee report.

Dr. Mike Gilisdorf, USDA,APHIS/VS discussed the continued efforts of USDA and the International Llama Association (ILA) to provide uniform codes for both Brucellosis and TB.

Dr. William Davis, Washington State University discussed research that is supported by the Lama Medical Research Foundation, on the investigation of the Lama immune system using contemporary technologies that have provided similar knowledge for other animal species and humans. A brief de-
description is included in the following discussion by Dr. Artur Kennel, ILA and Chair of the Lama Medical Research Group.

Dr. Kennel provided an informative discussion on the maturing Lama research programs. The first major funding of llama medical research in North America was in 1987. Subsequently, multiple llama and alpaca associations funded research on request of the scientific merit or appropriateness of budget, and there was no consistent method of administration and accountability. Some valuable research was done in that era, but unfortunately, money was wasted, reporting was erratic, and there was duplication of effort. In 1993 several llama organizations met in “Llama Assembly” and the Llama Medical Research Group (LMRG) was appointed to coordinate the research funding of the several organizations. The LMRG developed priorities, a long range plan, and partnerships. The LMRG makes recommendations to Llama Assembly annually and to components throughout the year.

Many llama and alpaca associations are now following the LMRG’s recommendations. Fruitful partnerships have also been developed by LMRG on behalf of the industry with the Morris Animal Foundation (MAF) and with official agencies such as Ag Canada and U.S. Department of Agriculture (USDA). The Morris Animal Foundation is the largest sponsor of companion animal research in U.S. having funded $1,200,000 for research into horses, cats, dogs, llamas, and mountain gorillas in the last fiscal year. The MAF evaluates proposals for scientific merit, relevancy, appropriateness of budget, and it administers the funds holding recipients accountable. Official agencies are interested in research that has implications for the larger livestock industry and has regulatory application.

Llama Medical Research at Veterinary Schools Supported by the Industry
1. Sustained release ivermectin to prevent meningeal worm, Iowa State Univ  $24,158
2. Epidemiology of juvenile llama immunodeficiency, Colorado State Univ  $19,993
3. Pharmacokinetics of gentamicin in llamas, Colorado State Univ  $13,666
4. The minute chromosome in llamas, Univ of Minnesota  $10,500
5. Choanal atresia in llamas, Oregon State Univ  $24,741
6. Serologic response of llamas to rabies vaccination, Auburn Univ  $3,800

Total to academic institutions  $96,858

Llama Medical Research by Official Agencies (USDA, APHIS, VS)
1. Tuberculosis testing of llamas, done in U.S. and Argentina (by INTA)  $105,000
2. Brucellosis testing in llamas, done in Ohio and Ames, Iowa  $50,000

Total of official agencies  $155,000
REPORT OF THE COMMITTEE

Donated animals, transportation and veterinary services
Includes 46 llamas donated by individuals and services valued at $40,000

Grand Total $2,921,858

Discussion:
The North American lama industry can be proud of its support of medical research. Thirteen associations, one insurance company, and numerous individuals contributed. As a result of this voluntary cooperation, all proposals that met scientific merit and relevancy criteria were funded. About four dollars were invested in research for each llama and alpaca in North America. The industry has demonstrated that they are responsible members of the larger livestock industry. The industry will reap benefits of improved health of animals, an attractive product for the marketplace, and financial and emotional rewards for owners.

Llama and alpaca (lama) medical research is in its infancy in North America. In the past decade it has grown significantly, reaching record levels of support in 1994-95. Most of the work is being done in universities and supported by the industry, more recently major research has been done by official agencies such as Ag Canada and the U.S. Department of Agriculture with some support from the industry. We summarize most of the work in progress or completed in 1994-95.

Projects supported by Industry at Veterinary Schools
1. Efficacy of Sustained Release Ivermectin in the Prevention of Meningeal Worm Infection by Dr. Julie A. Jarvinen at Iowa State University and associates. There is no known safe and effective preventive medication for llamas to protect against meningeal worm. The investigators will test a sustained release formula the drug ivermectin to prevent the infection.

2. Epidemiologic Characterization of Juvenile Llama Immunodeficiency by Dr. Franklin B. Garry, et al, at Colorado State University. Juvenile lama immunodeficiency affects young llamas and is usually fatal. The cause is unknown. This epidemiological study will examine whether the disease is heritable or acquired and whether there are risk factors in the environment that predispose to it.

3. Pharmacokinetics of Gentamicin in Lamas by Dr. Ellen B. Belknap, et al, at Colorado State University. Gentamicin, a widely used antibiotic, predisposes animals to kidney failure. It is unknown how llamas handle gentamicin and doses are extrapolated from other species. Disposition and elimination kinetics are being determined, thus providing safer and more accurate dosage regimens.

4. The Minute Chromosome in Lamas: Relation to Embryo Death and Genetic Defects by Dr. Alvin F. Weber of University of Minnesota, et
al. A minute chromosome, an undersized mate of the smallest autosome (non-sex chromosome) was found in about 1/3 of blood samples from lamas with reproductive problems and anatomic defects. The investigators wish to determine the possible effects of this minute chromosome on infertility (early embryonic or fetal death) and/or malformations.

5. **Choanal Atresia in the Llama: Heritability and Identification of Carriers** by Dr. Bradford B. Smith, et al. of Oregon State University. Choanal atresia (CA) is the most common congenital defect in llamas, thought by most to be genetically inherited. It affects the animal's ability to breathe properly. The investigators are developing a herd of true breeding CA llamas, seeking to establish that CA is genetically based, and hope to develop a diagnostic test to identify carriers.

6. **The Serologic Response of Llamas Vaccinated with a Killed Rabies Vaccine** by Dr. J. C. Wright, et al. of Auburn University. A female llama died of rabies in a research herd at Auburn University. She had inflicted a wound on her cria. Three groups will be vaccinated using 3 different schedules of administration of a killed vaccine. The serologic response will be determined at intervals for one year following the last dose.

### Projects supported by the U.S. Dept. Of Agriculture and by Industry

1. **Evaluation of Diagnostic Methods for Detection of Brucellosis Infection in Llamas** by Dr. Michael Gilsdorf, et al. of USDA, APHIS, VS. In Phase I, donated male llamas were vaccinated with *Brucella abortus* and periodic serologic responses were determined. In Phase II, donated female llamas were inoculated with live virulent *Brucella abortus*. Periodic serologic responses were determined, and necropsies were performed.

2. **Evaluation of Different Intradermal Tests for the Diagnosis of Tuberculosis in Llamas** by Dr. M. C. Antognoli, et al. of INTA, Argentina sponsored by USDA, APHIS, VS. Llamas were infected with *Mycobacterium bovis* and responses to skin testing in the axillary site for pinna were determined. Animals were necropsied and correlations made with the skin test results.

### Vitamin D Deficiency Induced Hypophosphatemic Rickets in Camelids

by Drs. Robert Van Saun and Bradford Smith of Oregon State University. Budget: 1 year, $18,508

Metabolic bone disease with resultant angular limb deformities is a significant clinical problem in the young rapidly growing llama and alpaca. The hypothesis being tested is: **American camelids are incapable of synthesizing sufficient vitamin D to meet daily requirements for maintenance and growth during the winter months, resulting in a vitamin D-respon-**
sive hypophosphatemic rickets syndrome in neonatal animals. A preliminary study has demonstrated significantly lower serum concentrations of vitamin D and phosphorus in clinical rickets-affected animals compared to nonclinical herdmates and a strong association between low serum vitamin D and phosphorus concentrations. Significant effects of month of birth on serum vitamin D concentrations suggested a seasonal susceptibility phenomenon. Given the suggestion of a seasonal incidence with this syndrome, a relationship between light availability (seasonal influences) and serum vitamin D, calcium, and phosphorus concentrations is currently in progress. The final aspect of the investigation will determine the relationship between exogenous vitamin D administration and changes in serum calcium and phosphorus concentrations as the first step in the development of therapeutic and preventive strategies.

Development and Use of Monoclonal Antibodies to Characterize the Immune System in Lamas by William C. Davis, PhD, and associates at Washington State University. 1 year, $19,200

White blood cells (leukocytes) are an important part of resistance to many diseases. Very little is known about them and their function in lamas. This study will use laboratory methods established in other animal species and humans to identify the various leukocyte types and characterize the immune system in lamas. This basic knowledge will provide information necessary to understanding how the lama fights infection, develops immune deficiencies, responds to immunization, and may lead to more specific tests for diseases such as tuberculosis. It may also provide a more rational basis for vaccinations.

Choanal Atresia in the Llama: Heritability and Identification of Identification of Carriers by Dr. Bradford Smith and associates at Oregon State University, and Drs. Garry Adams and Joe Templeton of Texas A&M University. Three years $39,999 Yr. 1 $22,530, 2 $7,725, 3 $9,744

Choanal atresia is the most common significant developmental defect encountered in the North American camelid population. This study will test the hypothesis that choanal atresia is a genetically based disorder that can be identified in clinically normal llamas using DNA analysis techniques. Successful conclusion of this study will permit identification of carrier animals and facilitate their removal from the gene pool. This project is a continuation of a currently funded 3-year MAF study and will expand the use of techniques developed and refined during the initial 3-year period.

Robert Frost, also from the ILA discussed the current status of Tuberculosis testing for Lamas.

There is no evidence that any herds of llama or alpaca in North America have bovine tuberculosis. The "Assessment of Risk Factor for M. bovis in the U.S." published in 1992 by USDA, APHIS, VS states, the "current evidence
INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA

indicates that camelids have not been a factor in the spread of *M. bovis*.” Currently reports from APHIS and state regulators are that all is quiet in regards to *M. bovis* and camelids.

**Diagnostics**

The axillary space is the USDA recommended tuberculin skin test site for detection of bovinetuberculosis in camelids. To date the axillary tuberculin test has been administered in a few thousand farmed llama and alpacas in North and South America. There have been no reactors.

**Research Continues**

The International Llama Association has been proactive since the late 1980's in its cooperative efforts with governments, states, and provinces in researching diagnostic methods for the detection of *M. bovis* in camelids. The largest ever and most recent research project to be completed was the cooperative agreement between USDA and Argentina's INTA (National Institute of Agricultural Technology). Also, NVSL (National Veterinary Services Laboratories) currently finished a diagnostic project on llamas. The results of both projects are under evaluation. The preliminary data suggests that the axillary site for the tuberculin skin test is a good choice. Other skin test sites are being evaluated for backup testing in the future. Serologic tests are being evaluated from these research projects and will provide diagnostic methodology for *M. bovis* detection in camelids.

The International Llama Association again takes this opportunity to thank USDA, Agriculture Canada, and USAHA committee personnel for implementing research projects, evaluating protocols and regulations, and assisting the llama/alpaca industry as we continue to expand.

The Committee agreed to recommend a statement from Dr. Don Lein, “that the USAHA recommend that the research community focus resources on developing live animal diagnostic tests for salmonella species which are sensitive, specific, rapid and cost-effective and can help predict the public health status of animals and poultry”.

The Committee Chair read a resolution from the Committee on Transmissible Diseases of Swine, urging the APHIS to develop, in cooperation the subcommittee on health monitoring, an ongoing surveillance program for diseases of high priority to the pork industry, report on their national incidence, prevalence, geographic distribution and trends, and develop economic models based on optional level of diseases. A second resolution by the Committee urged APHIS to work with OIE to develop methods that uniformly enforce disease reporting, surveillance and monitoring. The Infectious Disease Committee agreed with the intent of the resolutions and supported the acceptance by the USAHA Executive Committee.
attachment:

This information was not in proper form when presented to the Resolutions Committee. Because of the importance of this information the Executive Committee unanimously approved the amendment of the Report of the Infectious Diseases of Cattle, Bison, and Llama to include this information.

Source: Committee on the Infectious Diseases of Cattle, Bison, and Llama

subject matter: Antibiotic Residue Testing in Milk

background information:

Our nation's milk supply is to be monitored on a daily basis for the presence of antibiotic residues. Appendix N of the Pasteurized Milk Ordinance is the section that deals with drug residue monitoring and farm surveillance. It was "established to reference safe levels and/or establish tolerances and to assure that milk supplies are in compliance with these safe levels or established tolerances for drug residues in milk." This appendix to the PMO clearly states that "drug residue detection methods shall be evaluated at the safe level or tolerance." It appears that it was never the intent, either expressed or implied, that residue testing methods should be "accepted" when they are assay positive at several times below the established safe or tolerance level or safe concentration. Unless the producers or veterinarians are able to submit a problem at the biennial NCIMS conference and get it approved, they have little or no input on this important regulatory document.

Since mid-1994 there have been antibiotic residue assays that are Center of Veterinary Medicine/Food and Drug Administration (CVM/FDA) "accepted," Association of Official Analytical Chemists (AOAC) International "performance tested," and National Conference on Interstate Milk Shipments (NCIMS) "recommended" that: a) are used for tanker milk and have never been scientifically field tested on tanker loads of milk, b) are used for traceback on bulk tank milk and have never been field tested on bulk tank milk, and c) are routinely used on individual animal milk samples and have not gone through an appropriate epidemiological individual animal validation protocol. The use of antibiotic residue assays in everyday settings and the consequences of current assay performance is already adversely impacting dairy producers and food animal practices around the United States and elsewhere.

Antibiotic residue test performance in "real world" scientific studies has been one of the more revealing stories of test kit performance from individual animal samples to tanker truck loads of milk. Problems associated with the tanker truck screening assays are found in the National Drug Residue Milk Monitoring Program (NDRMMP) conducted by the Food and Drug Administration Center for Food Safety and Nutrition. An FDA summary of NDRMMP for FY 94 revealed that of 33 screening assay positive samples of tanker milk, only 8 were verified ass containing violative residues. This translates into approximately a 75% false positive rate. In an FY 95 Quarterly Report,
NDRMMP (draft report)- 1 January to 31 March 1995, of the 48 screening assay positive tanker milk samples, only 3 were verified as containing violative residues. This translates into approximately a 94% false positive rate. Similar problems have been reported around the work when these assays have used to test individual animal milk samples; thus, leading to unwarranted dumping of milk and culling of cows. In addition, companies that insure dairy producers against the loss of milk due to antibiotic residues are reporting that they are currently paying claims at a rate up to 10 times above that of previous years. This is in the face of reduced antibiotic use by producers and veterinarians in treating dairy cattle.

Resolution:

The surveillance of the nation's milk supply for the presence of antibiotic residues continues to be an important food safety issue and should be maintained on a continuous basis. However the methods employed to assess the residue status of the milk must be approved according to sound epidemiologic scientific principles.

The residue assays should be accepted only if they perform at no more than 25% below FDA established safe and tolerance levels.

Validation of the kits must include appropriate field evaluation of the assays on samples of milk from tanker trucks, bulk tanks, and individual animals known to be free of antibiotic residues. All assays must be evaluated in such a manner that final calculations of epidemiological sensitivity, specificity, and predictive value (positive and negative) can be performed and published in refereed journals. These assays should perform at the 95% Se, Sp level with a 95% Confidence Interval.

Because none of the assays have been properly validated for individual animals or bulk tanks according to sound biomedical principles, it is in the best interests of the consumer, regulatory personnel, and the producer, for the NCIMS Executive Committee to not recommend the acceptance of the residue test for these purposes until additional appropriate testing is completed. There is a scientifically appropriate four phase residue test kit validation program available as proposed by the National Mastitis Council Research Committee in 1993.

The prevalence of antibiotic-positive tanker truck loads is low. Therefore, it is appropriate diagnostic methodology to implement a screening system that has a high Predictive value negative. Then if the sample is assay positive, it can be subjected to a testing system that has a high predictive value positive. In this system, a quantitative assay such as High Performance Liquid Chromatography (HPLC) could be used as the true "confirmatory assay" because it should have a high PV (+) if performed properly.

Since many people have complete faith in the screening assays, the current ones could remain in place with the provision that any "screening assay positive samples" are handled through the proper chain of custody in
REPORT OF THE COMMITTEE

tamper-proof vials and subjected to HPLC testing at the FDA Denver Labora-
tory. If the sample is determined not to contain a violative residue: a) no
violation is reported against the producer, b) the producer is reimbursed by
the processing plant for the tanker milk and the charges for performing the
HPLC assay are paid for by the processing plant as well. Of course, if the
sample is found to contain a violative residue, then standard procedures are
implemented. This system would: a) serve as a more scientifically appropri-
ate manner to implement regulatory guidelines and b) share the responsibility
of "residue positive" loads that are currently being dumped. Remember, regu-
laratory agency data already indicates that greater than 60% of the screening
assay positives are not being verified as containing violative antibiotic resi-
dues. Although some view this as "erring on the safe side," it will not be long
until insurance companies will begin refusing to insure tanker load of milk
against antibiotic residues, because milk is being dumped via assays that
reportedly have been calibrated below the FDA safe/tolerance/safe concen-
tration levels. Once again, the producer and/or veterinarian must pay the
price for a test system that have not been validated according to sound epide-
miological principles.
A project to compare various diagnostic tests in the diagnosis of tuberculosis was conducted in experimentally infected llamas. Seven llamas were divided in groups: 4 received 400 colony forming units each of *M. bovis* by intratracheal injection, one llama received a subcutaneous injection of killed *M. bovis* in oil, and 2 were negative control animals. Serum was collected at 0, 7, 14, 21, 28, 35, 42, and 51 days post-infection (p.i.). The serum was frozen for future serologic testing. An intradermal tuberculin test was done at a site on the midear on day 42 p.i. An ophthalmic test was conducted by administering PPD to the conjunctival sac on day 46 p.i. A comparative axillary test was done on day 48 p.i. Llamas were euthanized on day 51 p.i. and necropsied. Disseminated gross and microscopic lesions were present in two of the infected llamas. *Mycobacterium bovis* was isolated from multiple tissues from three of the infected llamas. The fourth exposed llama was negative for *M. bovis* infection by histopathology and culture. The low numbers of animals included in this study preclude test sensitivity values within acceptable confidence limits, but suggest comparative antigen tests may have value in differentiating skin sensitivity resulting from infection with *M. bovis*.
REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES OF HORSES

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Vice Chairman: Dr. Ernest W. Zirkle, Trenton, NJ (Acting)

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EQUINE ENCEPHALITIS

Dr. J. E. Pearson reported the following:

Summary of Equine Encephalitis Surveillance, 1995
A. D. Alstad and J. E. Pearson,
National Veterinary Services Laboratories,
Ames, Iowa

Since the 1971 epizootic of Venezuelan equine encephalitis (VEE), the National Veterinary Services Laboratories (NVSL) has been testing samples for the equine encephalitides as part of the VEE surveillance program. The majority of the samples are submitted by State veterinary diagnostic laboratories. Samples were also submitted by Veterinary Services, U.S. Department of Agriculture veterinarians and veterinarians in private practice. The testing is done at the NVSL at no charge.

Most of the positive cases are based on the results of tests on a single serum sample. A single sample was reported positive if it had a neutralizing antibody titer of ≥1:10 and hemagglutination inhibition antibody titer of ≥1:40 against only eastern equine encephalitis (EEE) or western equine encephalitis (WEE). Some of the EEE and WEE results have been confirmed by a diagnostic increase in antibody titer or virus isolatlin, and most positive EEE serology results have been confirmed by EEE IgM capture enzyme-linked immunosorbent assay (ELISA). The results shown in Tables 1 through 3 are composites of reports submitted to the Centers for Disease Control (CDC), Fort Collins, Colorado, from NVSL test results and from several State veterinary diagnostic laboratories.

294
REPORT OF THE COMMITTEE

January - December 31, 1994

From January 1 through December 31, 1994, there were 340 U.S. submissions and 1 foreign submission for equine encephalitis at the NVSL. Of the domestic submissions, there were 252 horses, 81 avian (the majority of which were ratites), and 8 other species including cattle, goats, pigs, elk, and a zebra.

There were 36 horse, 4 emu, 2 pheasant, and 1 duck EEE positive cases and 4 horse, 2 emu, and 1 pigeon WEE positive cases at the NVSL (Tables 1 and 2).

During this time period, there were 137 additional cases of EEE in horses, 13 in emu, 3 in dogs, 2 in geese, 2 in pigs, and 1 in a deer and 1 additional case of WEE in a horse reported to the CDC from public health and State diagnostic laboratories.

There were two human cases of WEE reported in Wyoming in 1994 and 1 human EEE case reported in Louisiana.

January - October 1995

For this period, there were a total of 229 submissions received at the NVSL: 181 equine diagnostic submissions, 47 avian (the majority of which were ratites), and 1 porcine. There were 35 positive equine EEE cases and 4 avian (4 emu) (Table 3). There was one positive foreign EEE equine submission from Panama. There have been no WEE cases diagnosed in horses during this time period.

There were 4 human EEE cases in 1995 with 1 each in Florida, Indiana, Massachusetts, and Michigan. The Indiana case was fatal. There have been no human WEE cases reported for this time period.

In 1995, 1 horse had antibody against VEE. It was a stable antibody titer, its vaccination history was vague, and there was no apparent explanation for the VEE antibody titer.
## Table 1. Eastern equine encephalitis positive cases
January 1 - December 31, 1994

<table>
<thead>
<tr>
<th>State</th>
<th>NVSL Positive Cases</th>
<th>CDC and Other Sources</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>0</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Florida</td>
<td>1 (duck)</td>
<td>101 (2 geese, 2 pigs, 3 emu, 1 deer)</td>
<td>102</td>
</tr>
<tr>
<td>Georgia</td>
<td>0</td>
<td>14 (3 canine, 2 emu)</td>
<td>14</td>
</tr>
<tr>
<td>Indiana</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Louisiana</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Michigan</td>
<td>7 (2 pheasant)</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>New Jersey</td>
<td>3 (all emu)</td>
<td>14 (7 emu)</td>
<td>17</td>
</tr>
<tr>
<td>North Carolina</td>
<td>16 (1 emu)</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td>Ohio</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>South Carolina</td>
<td>7</td>
<td>15 (1 emu)</td>
<td>22</td>
</tr>
<tr>
<td>Virginia</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>43 (4 emu, 2 pheasant, 1 duck)</td>
<td>158 (13 emu, 3 canine, 2 geese, 2 pigs, 1 deer)</td>
<td>201</td>
</tr>
</tbody>
</table>

1 human case - Louisiana
REPORT OF THE COMMITTEE

Table 2. Western equine encephalitis positive cases  
January 1 - December 31, 1994

<table>
<thead>
<tr>
<th>State</th>
<th>NVSL Positive Cases</th>
<th>CDC and Other Sources</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>1 (pigeon)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Colorado</td>
<td>1 (emu)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Idaho</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Nebraska</td>
<td>1 (emu)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Texas</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wyoming</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Totals</td>
<td>7 (2 emu, 1 pigeon)</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

2 human cases - Wyoming

Table 3. Eastern equine encephalitis positive cases  
January 1 - October 15, 1995

<table>
<thead>
<tr>
<th>State</th>
<th>NVSL Positive Cases</th>
<th>CDC and Other Sources</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arkansas</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Florida</td>
<td>0</td>
<td>41 (1 parrot, 1 crane, 1 emu, 1 rhea)</td>
<td>10</td>
</tr>
<tr>
<td>Georgia</td>
<td>0</td>
<td>5 (3 emu, 1 canine)</td>
<td>5</td>
</tr>
<tr>
<td>Illinois</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Indiana</td>
<td>10 (1 emu)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Kentucky</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Michigan</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Mississippi</td>
<td>2 (1 emu)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>North Carolina</td>
<td>10 (1 emu)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>South Carolina</td>
<td>3 (1 emu)</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Tennessee</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Texas</td>
<td>0</td>
<td>9 (1 emu)</td>
<td>9</td>
</tr>
<tr>
<td>Totals</td>
<td>39 (4 emu)</td>
<td>56 (1 parrot, 1 crane, 4 emu, 1 rhea, 1 canine)</td>
<td>95</td>
</tr>
</tbody>
</table>

4 human cases - Florida, Indiana, Massachusetts, and Michigan
There is an ongoing, major epizootic of Venezuelan equine encephalitis (VEE) which began in northwestern Venezuela in April 1995 and has spread westward to the Guajira peninsula and to Columbia. This is the largest outbreak of VEE in the region since the 1962-1971 epizootic. The actual number of human cases estimated from epidemiological surveys in Columbia may exceed 45,000 with an undetermined number of equine deaths.

Some of the areas involved in both Venezuela and Columbia have limited numbers of equines, although vaccination and restrictions of movement of equines have been initiated in control programs. Approximately 95,000 horses have been vaccinated in 3 states in Columbia in an area beyond the advancing epidemic front, and insect control programs have also been initiated.

The subtype 1C of VEE is the virus involved in this outbreak as it was in the 1992 VEE epizootic in Venezuela.

CDCMMWR 10-6-95 Vol. 44, No. 39, 769-772.

SUMMARY OF EQUINE INFECTIOUS ANEMIA (EIA) TESTING IN THE U.S. AND OTHER EIA CONSIDERATIONS

Obviously, this year the big change is in the reporting format from tests reported to horses tested from Oct. 1, 1994 to Sept. 30, 1995.

See the map on page . . .

Three Year Implementation Plan To Strengthen the EIA National Control Program

Participants include, James E. Pearson, D.V.M., M.S., Charles J. Issel, D.V.M., Ph.D., Ralph C. Knowles, D.V.M., Tim Cordes, D.V.M.

This year Drs. Pearson, Issel and Cordes would like to announce the new University of Kentucky/USDA EIA video and information brochure; the completion date is April 1996 and copies will be sent to all committee members. Today I would like to briefly review the results of the “States EIA Uniform-Policy Program Survey,” answer questions, and persuade Dr. Knowles to entertain a resolution to form a subcommittee to review the development of a STATES EIA UNIFORM-POLICY PROGRAM. The subcommittee’s findings could provide the basis for a booklet entitled “National Program Standards for Equine Infectious Anemia,” authored by Dr. Ralph Knowles and Dr. Tim Cordes, and produced by National Animal Health Programs (NAHP) APHIS/USDA.

For FY 95-96, Dr. Pearson and Dr. Issel will collaborate on all equivocal
Equine Infectious Anemia

Tests Reported from 10/1/94 - 9/30/95

Horses Positive 1,804
Horses Tested 1,116,396

\[
\text{Horses Positive} = \frac{1,804}{1,116,396} = 0.16\%
\]
INFECTIONOUS DISEASES OF HORSES

serum samples. Support to the National Veterinary Service Laboratory will be provided through NAHP. Dr. Issel will meet with the state veterinarians and heads of testing labs that have signed onto his Southern Animal Health Association EIA HOT ZONE project.

FY 96-97 will pull all of these projects together in open meetings with industry groups and both scientific and lay publications.

Follow-up on State’s EIA Uniform-Policy Program Survey

I have had a year to discuss the results of this survey with many of you-reported to this group last year. You may recall the survey was divided into four categories, and there was remarkable uniformity or agreement amongst states in the first three.

Testing
All states are on the same ground with the old concepts, but express an interest in the new testing.

Identification
Again, states are very much in line with interest in the new permanent, electronic ID. The industry will drive this directly to our doorstep as Dr. Zirkle will report today.

Regulations
Those regulations that were CFR-related provided for a 75% or better agreement amongst states, and those not CFR-related provided for split amongst states.

Movement
Aside from the fact that 47 states have entry or interstate regulations, this area is a complete assortment of rules, ideas and comments.

Before I present examples from the survey, allow me to introduce Dr. Chuck Issel’s concept of the HOT ZONE. The highest proportion of EIA reservoirs, and thus new cases, are in states bordering the Gulf of Mexico and the Mississippi River. Last year, I reported 83% of the positive tests from this area; if the state of Oklahoma is added to this list, the percentage climbs to 92%. This year’s numbers are virtually unchanged from last year.

Now consider a few example questions to demonstrate perceived national norms:

...from category ONE (Testing)

What Serologic Tests For EIA Do You Use?
Fifty-two states or 100% responded AGID and comments were basically
REPORT OF THE COMMITTEE

that AGID was the standard or tiebreaker with increasing interest in both ELISAs.

Use Of the Official Lab Form VS 10-11?

Of 52 states, only six had modifications or "improved" versions, often used in conjunction with the standard VS 10-11.

...from category THREE (Regulations)

Identification Of Reactors Following USDA’S CODE OF FEDERAL REGULATIONS?

The category "closely" provided for extremely minor differences in the comments describing assorted combinations of hot, freeze, tattoo, locations and numerals, etc. Thus, 44 states or 84% closely conformed here. On the other hand, where there were no CFR-related guidelines . . .

State's Definition Of Exposed Equine?

There were 55 responses because nine defined both as same premises and within 200 yards. Twenty-seven states or 55% simply had no definitions with most comments indicating epidemiologic investigation determines exposure usually per state veterinarian’s discretion). This slide shows the 27 states with no definition for exposed equine. Now if we overlay the HOT ZONE, we see that there is no uniformity, with a 7/8 split. If we overlay the four states that significantly lead the horse industry in Gross National Product figures (CA, NY, TX, FL) again we see a split 2/2. Consider another important example dealing with reactors . . .

Provisions For Quarantine Of a Farm Following the Removal Of a Reactor?

This was an interesting split. Twenty "No" responses were generally followed by comments reflecting no specific regulations other than the State’s given authority to quarantine. "Yes" responses averaged 30-60 days, with a mean of 45 days. This slide shows the 20 states with no provisions for quarantine. Again, if we overlay the HOT ZONE, we see a 8/7 split. Also, if we overlay the big four, we again see a 2/2 split. If we overlay the big 4 states by numbers of horses, only Oklahoma pushes into the top four, with no marked statistical difference.

MORBILLIVIRUS OF HORSES AND HUMANS IN AUSTRALIA:

AN OVERVIEW AND UPDATE

This was reported by Drs. Tim Cordes, Riverdale, Maryland, and Peter Hooper, CSIRO-Australia.
INFECTIOUS DISEASES OF HORSES

ACUTE EQUINE RESPIRATORY SYNDROME IN BRISBANE, AUSTRALIA

Summary
An outbreak of what is now known as Acute Equine Respiratory Syndrome or AERS occurred in thoroughbred horses on two premises in the Brisbane area of Queensland, Australia, during the period September 7-26, 1994. Fourteen horses died or were euthanized in extremis with high temperatures, ataxia and bloody nasal discharge. In addition, the trainer of the diseased horses, died of an identical respiratory condition.

Equine Cases
On September 7, two horses had been moved to the Hendra (suburb of Brisbane) stable from a paddock (Figure 1). One of these, a pregnant mare, was noted to be ill and died two days later, no necropsy was performed. A companion horse in the paddock had also died several days earlier but was not examined. The other horse was subsequently moved and never became sick.

By September 26, 14 horses had died of an acute respiratory syndrome—one in the paddock, 11 at the Hendra stables, one in the adjoining stable and one on a property north of Brisbane after relocation from the Hendra stable. Seven other horses were later considered to have been exposed (seropositive for the agent) and recovered from the illness—3 of these were asymptomatic.

Clinical signs
The clinical features of the affected horses included inappetence, pyrexia, and dyspnea in most cases with a frothy nasal discharge varying from clear to blood-tinged. Mucous membranes were usually dark to cyanotic. Several horses developed marked dependent edema, ataxia, and head-pressing. Terminal patients usually died in extremis with a copious frothy, bloody nasal discharge.

Pathology
Pathological findings were consistent grossly with severe pulmonary edema and blood-stained froth in the major airways; and consistent microscopically with acute interstitial pneumonia including damage to the endothelial lining of small blood vessels, hemorrhage and foci of early necrosis. Additional pathology was not consistent.

Human Cases
Five days after the death of the index mare, a 40-year-old male stablehand from the Hendra stable who had close contact with the mare developed an influenza-like illness(Figure 1). His symptoms were myalgia, headaches, lethargy, and vertigo. He did not develop respiratory symptoms or require
hospitalization and his physical examination was unremarkable. His illness persisted for six weeks and he gradually recovered.

Six days after the death of the index mare, a 49-year-old male horse trainer from the Hendra stable became ill with symptoms similar to those of the stablehand (Figure 1). He had had considerable exposure to fluids from the dying mare in attempting to hand-feed her while he had abrasions on his hands and arms—no cellulitis was noted.² Four days after the onset of symptoms he developed nausea and vomiting, was hospitalized on day five and transferred to the Intensive Care Unit on day six for ventilation. The trainer died after seven days in ICU and found at postmortem to have had severe interstitial pneumonia.

Etiology

Australian animal and public health officials are to be commended for their extensive investigations of this outbreak. The Commonwealth Scientific and Industry Research Organization's (CSIRO) Australian Animal Health Laboratory (AAHL) isolated a previously undescribed morbillivirus from the lungs of five of the six horses tested and from the kidney of the trainer. Evidence that a new morbillivirus was responsible for the outbreak included the following: 1. No bacterial pathogen or toxin could be demonstrated. 2. In horses, African horse sickness, equine influenza, equine rhinopneumonitis, equine viral arteritis, hantavirus, Legionaire's disease, and the equine viral encephalitis were ruled out. 3. The virus was isolated from the lungs of 5 horses tested and from the kidney of one human. 4. In horses, antibody to the virus was present in 4 recovered cases and in 3 contact cases which suffered mild and transient illness, but not in other horses. 5. Serologic tests (serum neutralization and immunofluorescence) were positive in both human patients. 6. Positive transmission studies were completed in 4 horses, with recovery of the virus at necropsy.

Control Measures

Five premises were placed under quarantine in the Brisbane area due to movement of horses from the 2 affected premises. Restrictions were also instituted prohibiting the movement of horses, donkeys, and mules in a 5-km zone around the quarantined premises. Horse movement, race meets, and other equestrian competitions continued outside the restricted area. The Australian Government provided certification stating that exported horses had not been in the quarantined zone for 30 days prior to export. In September, 1994, the USDA implemented a temporary requirement for statement of certification that imported horses had not resided in the State of Queensland for a 60-day period immediately prior to export. It was lifted in January, 1995.

Epidemiology

The incubation period in natural horse cases was 8 to 11 days. The AAHL transmission studies incubation period ranged from 3 to 12 days. The 2 hu-
INFECTIOUS DISEASES OF HORSES

man cases had an assumed incubation period of 5 to 8 days. All of the equine cases and the human cases can be linked to the original index case; it was first determined to be ill on September 7, and died on September 9, 1994. Epidemiology suggests that, although highly virulent, the virus does not spread easily among horses as evidenced by its limited spread to only two premises; natural transmission is most likely by direct contact with nasal discharges. Aerosol transmission seems less likely as the upper respiratory tract of affected horses did not demonstrate pathology and coughing was not a part of the clinical picture. By September 29, 1994, all additional sick horses had recovered, and to date, no new cases have been reported. One thousand nine hundred and sixty-four horses from over 630 premises throughout Queensland tested negative to the virus on the serum neutralization test (Table 1). It is not considered highly infectious to humans. There was no serologic evidence of infection in 157 humans who had some association with the sick horses or humans (Table 2).2

Discussion

Virologic, serologic and transmission studies definitively showed that a new morbillivirus was responsible for this limited respiratory outbreak in horses and humans. No other infected humans or horses were found, despite widespread publicity, active case-finding in humans, and a wide serologic survey of human and horse contacts.2 The source of the virus at this time is still unknown. Studies are underway to identify the original host species.

The Genus Morbillivirus includes canine distemper, seal plague, rinderpest, peste des petits-ruminants, and measles—the only one previously known to infect humans. The specific factors precipitating the emergence of the equine Morbillivirus in this outbreak and the circumstances under which the virus changed hosts are yet to be identified. However, the “zoonotic pool” is an important and potentially rich source of emerging diseases; periodic discoveries of “new” zoonoses suggest (such as equine morbillivirus) that the zoonotic pool appears by no means exhausted.3

References

Table 2. Results of serological testing (virus neutralization and immunofluorescence) for the equine respiratory virus in potentially exposed humans

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Total</th>
<th>Positive test</th>
<th>Negative test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close contact with index horse case</td>
<td>4</td>
<td>2*</td>
<td>2</td>
</tr>
<tr>
<td>Close contact with other sick horses</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Postmortem contact with infected horses</td>
<td>15</td>
<td>0</td>
<td>15'</td>
</tr>
<tr>
<td>Association with affected stables or lived in the vicinity of the affected stables</td>
<td>70</td>
<td>0</td>
<td>70&quot;</td>
</tr>
<tr>
<td>Nursing/medical care of sick humans</td>
<td>64</td>
<td>0</td>
<td>64</td>
</tr>
<tr>
<td>People with adult respiratory distress syndrome in the intensive care unit with Patient 2</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

* The two cases described in the text
' Tests were repeated for six people: all were negative
" Tests were repeated for 19 people: all were negative

Table 1. The premises and horses surveyed by serologic testing for equine morbillivirus, after the disease outbreak

<table>
<thead>
<tr>
<th>Premises</th>
<th>Premises</th>
<th>Horses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarantine Premises</td>
<td>13</td>
<td>107</td>
</tr>
<tr>
<td>1 (within 100 m of Hendra stables)</td>
<td>7</td>
<td>54</td>
</tr>
<tr>
<td>2 (100 m to 200 m of Hendra stables)</td>
<td>21</td>
<td>122</td>
</tr>
<tr>
<td>3 (200 m to 1 km of Hendra stables)</td>
<td>93</td>
<td>730</td>
</tr>
<tr>
<td>4/5 (reminder of Queensland)</td>
<td>&gt;500</td>
<td>963</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>&gt;630</strong></td>
<td><strong>1,964</strong></td>
</tr>
</tbody>
</table>

Quarantine premises included those with clinical cases, holding properties associated with the Herndra stables, and other premises where horses under investigation were kept.


1995 VESICULAR STOMATITIS SUMMARY

Dr. Karen James (USDA, APHIS, VS, EP) reported the following:

VESICULAR STOMATITIS VIRUS (VSV)

Background:

VSV is an economically important epizootic viral disease that primarily affects cattle, equine, and swine in the Americas and is a differential diagnosis for foot-and-mouth disease (FMD). Because VSV clinically resembles FMD in cattle much effort is required by Veterinary Services authorities during the early stages of an epizootic to investigate and determine the specific etiology. (See slide)

VSV is not considered to be a foreign animal disease. It is considered to be endemic and enzootic in the Southern US. Epizootic VSV occurs sporadically in the United States approximately at 10-15 year intervals. VSV occurs epidemically in temperate regions and endemically in warm areas. A persistent phase of the virus is probable. Climatic factors and unusual patterns of rainfall have been suggested to be responsible for its spread. (See Slide)

VSV is classified as a vesiculovirus of the family Rhabdoviridae. There are 7 serotypes recognized. The two primary serotypes in the United States
REPORT OF THE COMMITTEE

are New Jersey & Indiana. (See slide)

The Incubation period is thought to be 2-8 days (OIE 21 days). The eco-

logy of VSV is not well understood; the reservoir of the virus in unknown, and

the origins and methods of spread are controversial. However, the spread of

VSV has been attributed to movements of animals, insect vectors (biting and

non-biting flies), and mechanical transmission.

Clinically the disease starts with a fever. Cellular necrosis results in the

formation of vesicles which develop into ulcers. Salivation, anorexia, and

lameness are seen secondary to oral lesions (See Slides)

VSV must be differentiated from other vesicular diseases (e.g., FMD).

Laboratory test for VSV include virus isolation, complement fixation, virus

neutralization, and ELISA. (See Slides)

Measures to control the spread of the disease include isolation of in-

fected animal, insect vector control, movement restrictions, and use of proper

disinfectants. (See Slide)

History:
Previous VSV epizootics involving horses occurred in 1982-83 and again in

1985: (See Slides)

- In May 1982 the first case of VSV was diagnosed in cattle in Camp

Verde, Arizona. Extensive epidemiologic studies were conducted. Isola-

tion of New Jersey-VSV was identified by immunofluorescence from

flies (Culicoides variipennis (biting gnat), Musca domestica (house

fly), Musca autumnalis (face fly), Chloropidae spp. (eye gnat),

Anthomyiidae spp. (a muscoid fly) and Simuliidae spp.(black fly).

- 1st case of a major epizootic involving over 1,045 premise investiga-

tions, with 617 positive premises.

- Followed the Rio Grand & Colorado river valleys.

- By the end of September 1983 the disease spread North Northwest

through 14 States (Arizona, New Mexico, Colorado, Utah, Wyoming,

Idaho, Montana, Nebraska, California, Oregon, Washington, Missouri,

Kansas, South Dakota).

- Animal contact played a major role in the spread of the disease.

- The greatest number of equine cases were reported in Colorado.

- In January 1983 - Western States Animal Health Association recom-

mended the use of quarantines on affected premises for a minimum

of 30 days. Soon other states implemented such quarantines

- Economic loss was severe due to drop in production and secondary

infections.

- In 1985 - Southern New Mexico, Arizona, & Colorado reported VSV.

1995 Time Line Summary: (See Slides)

Vesicular Stomatitis Virus - New Jersey Epizootic has been going on since

INFECTIOUS DISEASES OF HORSES

There were 617 confirmed cases positive premises in that epizootic in 15 primarily Western states; 1,045 investigations were conducted during that epizootic.

The 1995 epizootic has had a more narrow geographic distribution. The first positive premises was identified in Las Cruces, New Mexico. The disease then moved north/northwest to Colorado, Arizona, Utah, Texas, and Wyoming. The majority of the disease has been in New Mexico and Colorado (See Slides)

As of October 27, 1995, (26th week of outbreak) a total of 989 premises have been investigated for VSV. There have been a total of 340 case positive premises. Currently positive premises refers to the number of premises that have a positive field diagnosis and serologic confirmation from the laboratory or positive virus isolation. Of the positive premises, New Mexico had 186 (181 have been released from quarantine); Colorado had 139 (88 released from quarantine); Arizona had 1 case positive premise (released from quarantine); Texas had 1 case positive premise (released from quarantine); Utah had 7 (2 released from quarantine) and Wyoming had 7 case positive premises.

There have been 42 bovine only case positive premises, 242 equine only case positive premises, 31 bovine and equine case positive premises, and 25 bovine and/or equine plus another species case positive premises.

Control measures have consisted of quarantining affected premises until 30 days after the lesions have healed, placement of a 10 mile radius restriction zones around affected premises with cancellation of some livestock events, and placement of movement of restrictions within these zones, spraying and insect vector control, and restricted use of an autogenous vaccine to affected states. Only a few premises in Colorado and Utah have used the vaccine to date.

Trade Restrictions:

- Canada - Certification that horses, ruminants, and swine have not been in a VSV-affected state for the past 30 days. All horses entering must be inspected. Animals from previous affected states (Texas and Arizona) are required to meet the previous requirements as well as test negative to serum neutralization, certify that animals resided in a vector proof facility, and have not resided on a premises for the past 30 days where VSV had been diagnosed.
- Russia - No US. beef from VSV-affected states
- Romania & South Africa - No US beef
- Chile - No animals from VSV-affected states.
- European Union - Health certification that the horse(s) has not resided in a VSV affected state for the past 30 days and negative serological test on all horses originating from the United States.

International Concerns:

On August 27-Sept 2, 1995, the European Unions’ European Commis-
REPORT OF THE COMMITTEE

sion Team visited the US to conduct a site visit. This visit provided the EU with an opportunity to see first hand the VSV situation in the US.

The EU report:

1. Concerned and disappointed that more resources had not been put into studying the epidemiology of the disease in its acute phase.
2. Concerned about the level of controls being applied to restrict the spread of an outbreak of an OIE List A disease.
3. The restricted 10 mile zone are not comparable to those put in place in the EU in similar circumstances.

Because of the above findings the EU does not think it is possible to regionalize anything other than a whole State. Basically due to lack of legal authority to control movements within a State.

Highly likely that within the framework of OIE rules, the EU will reinforce the EC's import requirements regarding horses originating in or coming from third countries with VSV.

Research and Epidemiology

- Epidemiologic Case Investigations - Develop a detailed picture of each infected premise and intra-herd epidemiology. Identify potential risk factors in disease spread. The Center for Epidemiology and Animal Health (CEAH) is coordinating an intensive epidemiological studies of affected premises in the Grand Junction, CO area.
- Insect Vector Study and Other Possible Vectors (rodents) - Determine the role of vectors in maintaining virus presence during epizootic and non-epizootic periods. (Collections of biting and flying insects).
- Case Control Study - Evaluate management factors that may predispose herds to infection. (Study of a VSV-affected dairy in La Plata, NM).
- VSV Seroprevalence in Wildlife - Study to assess the presence of antibodies in wildlife species.
- Vaccine Field Studies - Evaluate the general efficacy of vaccination in dairy herds.
- Geographical Information System (GIS) Study - Identify geographical features that put premises at risk.

Vaccine Usage:

To date approximately 6,400 Equine doses and 18,000 Bovine doses of the vaccine have been sold. Each state is responsible for maintaining current, accurate vaccination records in their respective state.

DOURINE-MEXICO-SEROLOGIC TESTING

Dr. Jose M. Irastorz (Mexican Government) reported the following:

In April 1995, 60 horses were serologically tested in Mexico for export for dourine. Among these animals, 6 tested positive for dourine at the National
INFECTIOUS DISEASES OF HORSES

Veterinary Services Laboratories (NVSL), Ames, Iowa. Traceback was done. Ten animals were seropositive among 187 animals in 3 municipalities. All horses were clinically healthy.

Subsequently, all horses from the suspicious herds are tested prior to movement.

An ongoing serological survey is being conducted among 231,859 equids in the State of Chihuahua.

All seropositive horses remain clinically healthy.

The literature reports possible cross reactions with other trypanosomes, such as T. evans and T. cruzi. Is this a cross reaction?

HORSE PASSPORT FIELD TRIAL

Dr. E. W. Zirkle reported on a horse passport field trial conducted in the summer of 1995 at three thoroughbred racetracks in New Jersey (2) and Pennsylvania (1).

This trial uses a Smartcard®, a computerized card the size of a credit card. This card can replace certificates of veterinary inspection and other pertinent papers that need to accompany horses in transit. This ongoing trial will be reported on in the future.

Three resolutions are offered regarding:
1. EIA control program uniformity.
2. U.S. quarantine stations for import horses.
3. Equine "piro" requirements for horses at the 1996 Olympic Games.
Paratuberculosis (Johne's disease) is a chronic, progressive enteric disease of ruminants caused by infection with *Mycobacterium paratuberculosis*. Clinical disease is characterized by chronic or intermittent diarrhea, emaciation, and death. Further economic losses in affected cattle are caused by reduced milk production and poor reproductive performance. Although the economic impact of paratuberculosis on the national cattle industry has not been determined, it is estimated to exceed $1.5 billion/year.

Diagnosis of subclinical paratuberculosis is difficult. Diagnostic tests based upon evaluation of humoral or cell-mediated immune responses to *M. paratuberculosis* antigens, bacteriologic culture of feces or tissue specimens, and most recently a nucleic acid probe and a polymerase chain reaction (PCR) assay for identification of *M. paratuberculosis* in fecal and tissue samples have been developed. Immunological diagnostic tests suffer disadvantages from false positive and false negative results caused by the lack of specificity of antigens used to elicit or detect responses. Bacteriologic culture is the most definitive method of diagnosis but is time consuming and labor intensive. A nucleic acid probe developed from an insertion sequence of *M. paratuberculosis* has been used in conjunction with amplification of the target sequence using polymerase chain reaction to detect *M. paratuberculosis* in fecal samples. Unfortunately, in our laboratory the probe test is only 60% as sensitive as fecal culture. Therefore, the need of more sensitive diagnostic tests to detect subclinical shedders is immediate.

Recent evidence has linked Crohn's disease in humans to infection with *M. paratuberculosis*. Although not characterized as a zoonotic agent, *M. paratuberculosis* has been identified in intestinal biopsy tissue from patients with Crohn’s disease, an inflammatory enteritis in humans. One possible source of human exposure to *M. paratuberculosis* is the consumption of milk or dairy products since presence of paratuberculosis DNA has been documented in cow’s milk obtained from retail markets in Great Britain. It is not certain at present whether current pasteurization and processing procedures in the United States are adequate to destroy high numbers of paratuberculosis in the milk, creating a possible health hazard for consumers.

Current objectives for research at the NADC are: 1) to develop new and modify existing diagnostic procedures for the detection of subclinical paratuberculosis; 2) determine a possible etiological role for *M. paratuberculosis* in Crohn’s disease in humans and potential exposure to this pathogen through contaminated dairy products; 3) isolate and characterize
JOHNE'S RESEARCH AT NATIONAL ANIMAL DISEASE CENTER

*M. paratuberculosis*-specific proteins which can be used as diagnostic tools; and 4) investigate genetic association between resistance/susceptibility to *M. paratuberculosis* and disease state of the animal.

Cultivation of *M. paratuberculosis* from fecal specimens is considered to be the definitive diagnostic test for bovine paratuberculosis. We have recently modified the fecal culture method to include a centrifugation step which aids in concentration of bacteria. This method improves detection of *M. paratuberculosis* in fecal samples 10-fold without contamination problems associated with previously used techniques. We have also evaluated the use of -interferon production of paratuberculosis. When stimulated with preparations of *M. paratuberculosis* in vitro, peripheral blood mononuclear cells isolated from animals with subclinical paratuberculosis produced significantly greater amounts of -interferon compared to noninfected control animals.

A possible role of *M. paratuberculosis* in the etiology of Crohn's disease in humans has lead to studies evaluating milk pasteurization conditions and potential survivability of this pathogen in dairy products. It is unknown whether current standard conditions of milk pasteurization are adequate to kill contaminating *M. paratuberculosis*. Experiments are being conducted to determine optimal times and/or temperatures for maximal killing of *M. paratuberculosis* in milk. A small-scale pasteurization unit purchased from a commercial vendor is being utilized to conduct these experiments. These experiments are evaluating various field and laboratory strains of *M. paratuberculosis*, including isolates from Crohn's patients.

Due to the high degree of similarity in their genetic makeup, cross-reactivity between *M. paratuberculosis* and *M. avium* in diagnostic tests is a major problem. Identification of *M. paratuberculosis*-specific antigens would circumvent this problem, however, there is currently very little information available in this area. At the NADC, two *M. paratuberculosis*-specific proteins were recently identified which do not cross-react with *M. avium*. Genetic cloning and expression systems were developed for *M. paratuberculosis* and affinity-purified antisera for screening clones was prepared. With this methodology, an *M. paratuberculosis*-specific gene was isolated and found to be immunogenic.

There is a significant association between the major histocompatibility complex in cattle (BoLA) and host immunity. The BoLA class I and class II genes encode for cell-surface proteins which are important in the regulation of immune responses. There is currently no information available describing the relationship between paratuberculosis in cattle and expression of BoLA class II genes. We have initiated studies to screen herds for paratuberculosis and correlate expression of specific alleles within the gene locus with infection status of cows as determined by fecal shedding of *M. paratuberculosis*. 

312
Why is it of interest to assess the global prevalence of Johne’s disease? With agriculture, as with any aspect of modern life, neighbors’ conditions affect one another. As the definition of “neighbor” is no longer limited to geographic proximity but includes those with whom we work and trade, unaffected by distance, it behooves us to appreciate circumstances beyond our borders.

In all likelihood, Johne’s disease is to be found in every country. Being free of the disease is probably more a function of how hard one has looked than a true lack of incidence. Knowing that paratuberculosis is at least a potential if not actual concern for every country should promote a realistic, useful international perspective of the disease. A complete grasp of the extent of paratuberculosis will assist all those affected in the many ways possible by the disease, whether through regulatory activities, livestock management or medicine, research, and public health. This assistance will take the form of developing practical management, regulatory and economic policies. These policies, having been based on actual conditions, vs. abstract extrapolations, will support a uniform global arena for agricultural endeavors.

Specific realms to consider when assessing the international impact of Johne’s disease include:

1. **Trade barriers**

   As illustrated by the situation in Australia (see below), having *M. paratuberculosis* test positive herds can affect all aspects of trade. Prices can slide, demand drop, export regulations be required, etc. Additionally, dissimilar barriers between different countries can make trade more cumbersome and costly. In all probability, barriers will soon also address products made from animals with Johne’s disease. These products currently are free of restrictions in all international markets.

2. **Slowed global genetic improvement**

   Dissemination of genetically superior livestock can be hindered by the perception that the buyer is free of disease and the seller has some degree of prevalence. Actual genetic improvement will be prevented through the purchase, often with scarce resources, of untested and infected animals that then infect the recipient herd. Zoological parks exist on every continent: Johne’s disease is a threat to the continued health and propagation of these rare collections.

3. **Policies based on inconsistent testing methodologies**

   Conclusions based on interpretations of different tests applied in varying
JOHNE’S DISEASE, AN INTERNATIONAL PERSPECTIVE

matters can be more expensive and unproductive than having made no conclusions at all. Testing methodology, results interpretation and the successes and failures in management application of test results should be shared among countries.

4. Costs

The direct and indirect costs of Johne’s disease stem from many realms. Losses with which we are most familiar include reduced milk production and weight loss due to poor feed conversion and clinical/subclinical disease, increased culling rate, time and labor both complying with and managing regulatory programs, testing expenses and research. An additional loss for developing nations is an impairment of economic development programs, as investments in livestock are wasted. Development of ecotourism programs (such as photo-safaris) can also be hampered by the threat of cross-infection between wildlife in national parks and surrounding domestic livestock. Impediments to tourism can curtail a major component of the GNP and the country’s only source of foreign exchange.

5. Zoonosis

The continued investigation of the possible association between Crohn’s disease and M. paratuberculosis could benefit from a thorough global analysis of the incidence of both diseases.

6. Research and control

An assessment of the international prevalence of Johne’s disease can help prioritize research efforts and funding, support the establishment of effective global disease control programs and better determine the cost-effectiveness of efforts intended to control and/or prevent the spread of paratuberculosis worldwide.

Methodology

To gain an impression of the prevalence of Johne’s disease internationally, a short survey was developed and faxed to a subset of the IAP membership. A literature review was conducted as well, and government publications were canvassed for any information pertaining to the disease.

It goes without saying that the topic of this paper, “the international perspective”, is in fact a compilation of general impressions given the testing and interpretation difficulties inherent with Johne’s disease. The most common impression received was the lack of information on any basis, be it local, national or international. As a Canadian respondent put it “There is an amazing paucity of information on the prevalence of Johne’s disease.”

Given this “paucity”, we will give a brief description of the world’s exposure to Johne’s disease. In most cases, the data is bimodal - either a country has it or it doesn’t.

JOHNE’S DISEASE POSITIVE LOCALES

Africa

In countries on the African continent, testing for M. paratuberculosis runs the gamut from never being done to gene probe confirmation of BACTEC cul-
tures. We were able to find information about 12% or 6 of the continent's 49 countries: Kenya, Nigeria, Sudan, Tunisia, Zambia and South Africa. (Only the Sudan and Kenya are contiguous, and that minimally: Kenya shares only 1/20th of Sudan's border.) In this case, "finding information" meant discovering that at least one case had been reported in recent years. In South Africa the disease has been reported in both sheep and cattle with a focus of isolated herds in the wetter regions of the country (Natal, E. Transvaal). The disease is believed to be neither highly prevalent nor of major significance in this country. In Zambia paratuberculosis is reported to be a greater problem in sheep than in cattle and Tunisia's reports dealt only with camels. No information has been found to date on the other 43 African countries, and therefore no conclusions can be drawn about Johne's disease prevalence in those areas.

**Australia**

New Zealand reports that paratuberculosis is widespread in dairy cattle and goats plus is of concern in sheep and beef cattle as well. The number of recorded infected dairy properties has jumped dramatically over the last 4 years, and it is believed that this registry of infected premises understates actual prevalence. In concert with an increase in the extent of the disease (also evidenced by a doubling in vaccine sales in a year), all research was stopped.

**Lesson from Australia - Potential trade barriers**

Each of the 7 Australian states manages and monitors its own agricultural activities. Of the 7, Johne's disease is endemic in one state, positive herds are found in two others (at a reported prevalence of 17% and 1.4%) and the remaining 4 states report themselves free of the disease. Sheep and cattle trade among the states is stymied, with demand, marketing and prices affected by the perception, as well as the certainty, of Johne's disease prevalence.

**Asia**

China, Japan, India, Korea, Kazakhstan, Nepal and the Philippines are countries in Asia with contemporary, albeit infrequent, reports of Johne's disease. Japan's information was the most extensive for the region, reporting an annual average of 212 cases of clinical bovine paratuberculosis over the last five years. These cases were confirmed at slaughter. As the United States government continues its efforts through USAID to develop dairy industries in Pacific Rim countries, the need for Johne's disease testing for the new industries should provide a sense of the prevalence in this region.

**Europe**

Incidence of Johne's disease is reported to be increasing in the Netherlands, Finland, Italy and Scotland. In other parts of the European continent, no change in incidence has been noted over recent years. Countries belong-
ing to the constant incidence category are Norway, Denmark, Portugal and Belgium. France, Cyprus, the Czech Republic, Greece, Hungary, Iceland, Slovakia, Spain, Switzerland and Turkey report that cases of paratuberculosis have been found within their borders but offer no guess about the direction in which incidence is moving.

Lesson from Sweden - If you look, you will find it

From 1989 to 1994, only seven cases of Johne’s disease were identified. Found in six herds, they all were traced to imports from Denmark. A July 1994 publication stated that “Swedish livestock are free of paratuberculosis”. In March 1995 however, a Swedish herd was found to be positive and was slaughtered. Seventy contact herds are now under investigation. Sweden’s continued testing of its livestock after its having been deemed paratuberculosis-free was valuable.

Central and South America

We found information about only three countries in this region - Mexico and Brazil which report test positive cases and Argentina which believes incidence is increasing.

Summary

We close with another quotation from a survey respondent: “The incidence of Johne’s disease appears to be increasing due to the veterinarian’s interest and attention”. With greater scrutiny comes increased appreciation of the extent of problem. We believe no region in the world is free of *M. paratuberculosis* infection in its ruminant livestock and that every region’s agricultural sector therefore is hampered to some extent by Johne’s disease. We also believe that the resources to address paratuberculosis-related problems on a state-wide and national basis will continue to shrink as financial constraints are felt in government and other sectors. More extensive pooling of resources and efforts on an international basis may be one of the few remaining ways of continuing efforts to improve diagnosis and management of this disease.

References

The committee meeting began at 1:30 p.m. on October 31, 1995 and included 19 reports and presentations and vigorous discussions and concluded at 6:15 p.m. Attendance included 24 of the 42 committee members and 44 guests for a registered total of 68 (some attendees did not sign the register).

The purpose of the Johne's Disease Committee as written in Article II of the USAHA was read aloud to remind committee members of the tasks set forth for the committee.

"The purpose of the Committee on Johne's Disease is to facilitate control and eventual eradication of paratuberculosis by providing information and guidance on diagnosis and control of infection to appropriate federal, state, and industry personnel.

The committee also provides the latest information to animal diagnostic and regulatory agencies concerning diagnostic methods for Johne's disease, assists in helping identify the most sensitive and specific tests available for paratuberculosis diagnosis, and fosters the establishment of standardized diagnostic tests including culture and serologic tests for the detection of M. paratuberculosis.

The committee identifies the prevalence and economic losses associated with paratuberculosis infection in ruminants and promulgates distribution of information on how to best to control and manage
Formation of National Johne's Working Group (NJWG):

The committee chair described actions taken on the recommendations and resolutions from the last Johne's committee meeting. A letter was sent on November 18, 1994 to each Johne's committee member requesting input concerning the establishment of a task force on the relationship of *M. paratuberculosis* to Crohn's disease. This letter outlined a draft of the charge to the task force and listed potential constituent groups as participants on the task force. Several responders provided additional insight about the formation of the task force. With many important ramifications for both the USAHA and producer groups, the chair of the Johne's Committee and the president of the USAHA, Dr. Wes Towers, agreed it would be prudent to have the task force, later to be called the National Johne's Working Group (NJWG) appointed by the President of the USAHA. During a meeting of the USAHA executive committee in Washington, DC at the NCA office on February 28, 1994, Dr. Wes Towers, President USAHA appointed John Adams (National Milk Producer's Federation), Gary Weber (National Cattleman's Association) and Robert Whitlock (Chair Johne's Committee) as co-chairs of the National Johne's Working Group (NJWG). They in conjunction with Dr. Towers and the USAHA executive committee, identified the following individuals (organizations) to serve on the NJWG: Members of the NJWG with organizational affiliation:

Adams, John B., Director - Milk Safety and Animal Health for National Milk Producers Federation; Arnoldi, Joan, Director, National Veterinary Services Laboratory, Ames, Iowa; Byrne, Robert D. Jr., Assistant Director, Product Safety & Technology, International Dairy Foods Association, Washington, DC; Bulaga, Leslie, Epidemiology Officer, USDA APHIS Veterinary Services, Trenton, NJ; Bursey, R.G. Sr., Vice President, Dairy Management Inc., Arlington, VA; Collins, Michael, University of Wisconsin, Madison, WI; Essay, Mitch USDA - Cattle Diseases, Riverdale, MD, Hansen, Donald, American Association of Bovine Practitioners, Oregon State University, Corvallis, OR; Luchsinger, Donald, USDA, APHIS, VS, Washington, DC; Nelson, Richard, Exec. Assistant - Domestic Affairs, Holstein Association, Brattleboro, VT; Olson, Kenneth, E., American Farm Bureau Federation, Director, Dairy Department, Park Ridge, IL; Rossiter, Christine, Cornell University, Ithaca, NY; Sayler, Allan, R. Senior Milk Specialist, Food and Drug Administration, Washington, DC 20204, Slack, Glenn N., Executive Director, Livestock Conservation Institute, Bowling Green, KY; Stabel, Judith, USDA/ARS/NADC, Ames, Iowa; Thorpe, Daryl K., Representing the AVMA Council on Public Health and Regulatory Medicine, Pierre, South Dakota; Thoen, Charles, representing the AAVLD Mycobacterial committee, Ames, Iowa; Towers, H. Wesley, representing the USAHA, Dover, DE; Van Kruiningen, Herbert J., College of Agriculture & Natural Resources, University of Connecticut, Storrs, Ct., Vogel,
JOHNE'S DISEASE


John Adams, Co-chair NJWG, presented an update on the activities of the NJWG. He stated that the first meeting of the NJWG was held April 4, 1995 in Kansas City, MO, at the LCI meeting with 14 members and 15 guests present. The following four subcommittees were formed: Economics—Chair Ken Olson, Johne's Control Programs—Chair Mitch Essey, Research—Co-chairs Judith Stabel and Tom Walton, Diagnostics—Chair Joan Arnoldi. Several objectives were outlined for each of the sub-committees. The second meeting of the NJWG was held during the AVMA meeting in Pittsburgh on July 12, 1995 at the Hilton Towers Hotel. Each subcommittee presented a report with brisk, energetic discussion on several issues including the CFR, the upcoming NAHMS' Dairy '96 program, milk pasteurization studies and the agreement of USDA/APHIS/NVSL to conduct Johne's check tests for diagnostic laboratories that may be participating in the Johne's certification program.

Mr. Adams reviewed a draft of the mission statement and objectives for the NJWG.

NJWG Subcommittee of the report summary:

Ken Olson, Chair
Subcommittee on the Economic Impacts of Paratuberculosis.
Members of economics subcommittee: Michael Collins, Kenneth E. Olson, Steven Ott, Christine Rossiter, Michael Westendorf.

Economics subcommittee objectives:
1. Review the literature and summarize studies evaluating the economic impact on the of Johne's Disease for producers.
2. Compile other information relative to economic impacts on the industry.
   - Possible consumer reaction
   - International trade implications
   - Interstate trade impacts
3. Compile listing of reported incidence of Johne's:
   - By state
   - By country
4. Provide input on the NAHMS' dairy survey relative to Johne's...
REPORT OF THE COMMITTEE

Dr. Collins reported that his review of the literature and a recent international FAX survey he conducted indicated that no country is free of Johne’s disease.

Dr. Mitch Essey, Chair
Subcommittee to review State Control Programs for Johne’s Disease
Members of subcommittee: Chris Rossiter, Don Sockeyt, Leslie Bulaga, Lee McPhail, Mike Westendorf, Debbie Donch, and Elizabeth Chandler Porter.

Objectives:
1. To review all state Johne’s control and certification programs
2. To recommend a unified approach to controlling Johne’s disease
3. To minimize regulatory barriers to Johne’s disease control
4. To amend the regulations to fulfill the need for a workable, acceptable effective Johne’s control initiative.
5. To develop a strategic plan for an industry-led voluntary National Johne’s control program, supported by industry and acceptable to state and federal animal health regulatory entities.

Regulatory issues about paratuberculosis included in CFR Part 80 and Part 71 were reviewed. The final rule to retain Johne’s Disease (paratuberculosis) in the CFR and to specifically change the location of the brand from the jaw to the left hip was passed September 19, 1995. At this time, as has been the case for many years, there is no “official Johne’s test” approved by the Secretary of Agriculture. Thus part 80 of the CFR has not been invoked but remains on the books.

Dr. Judith Stabel, Co-Chair
Subcommittee on “Research Status and Priorities”

Members of subcommittee: Thomas Walton Co-chair, Ray Sweeney, Michael Collins, John Kreeger

Objectives:
1. Determine and prioritize research objectives for Johne’s disease,
2. Update on current (state-of-the-art) techniques for the diagnosis of Johne’s disease
3. Report on most current research publications.

Responses to a letter sent to 15 investigators requesting their input about priorities for Johne’s disease research were tabulated by Dr. Stabel and are listed:
JOHNE'S DISEASE

Main Priorities:
A. DIAGNOSTICS—Need for a more sensitive tool for detection of subclinical infection; improved fecal detection.
B. CROHN’S DISEASE and M. paratuberculosis - Detection/diagnosis; pasteurization; epidemiology.
C. VACCINATION—Need for a better vaccine; subunit vaccine.
D. EPIDEMIOLOGY—Study of transmission of disease (animal to animal, animal to human; contaminated resources to animals/humans) regional occurrence.

Lesser Priorities:
E. ANTIGENS—Isolate and characterize M. paratuberculosis specific antigens.
F. IMMUNE RESPONSE—Evaluate the host immune response at various stages of infection and pathogenesis.
G. CONTROL/EDUCATION PROGRAMS—Implement management systems to reduce incidence of Johne’s.

Data from three pasteurization studies being conducted at this time are not complete.

Preliminary results from the milk pasteurization studies suggest:
1. The number of organisms added (often $10^8$ per ml) to the milk are artificially high and may not be in the same form as occurs naturally (intracellular and in clumps).
2. Pasteurization at $72^\circ$ C for 30 minutes may kill most M. paratuberculosis but short pasteurization times at higher temperature may not kill most of the organisms.
3. Some strains of M. paratuberculosis may vary in their sensitivity to pasteurization time and temperatures. The strains isolated from patients with Crohn’s disease were more heat susceptible than bovine strains.
4. The preliminary results of the three studies suggest that some M. paratuberculosis organisms may survive normal pasteurization processes. However no data exists to suggest that viable M. paratuberculosis have been isolated from pasteurized milk in the marketplace. Reports from England indicate M. paratuberculosis DNA to be present in marketed milk, but viable organisms were not found in that milk.

Dr. Joan Arnoldi NVSL, Chair
Subcommittee on “Diagnostic Issues”.
Members of subcommittee: Janet Payeur, Howard Whitford and Pat McDonough
USDA/NVSL will be conducting Johne's check tests for both fecal culture and antibody detection systems in the near future. The samples (30 sera and 20 fecals) will be submitted to participating laboratories in November 1995. Approximately 14 laboratories will participate in the first check test.

A poll of laboratories conducting tests for Johne’s indicated the following:

<table>
<thead>
<tr>
<th>Diagnostic Test</th>
<th>Number of laboratories performing the test</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGID</td>
<td>26</td>
</tr>
<tr>
<td>CF</td>
<td>22</td>
</tr>
<tr>
<td>IDEXX ELISA</td>
<td>16</td>
</tr>
<tr>
<td>Gamma Interferon</td>
<td>1</td>
</tr>
<tr>
<td>Fecal Culture</td>
<td>35</td>
</tr>
<tr>
<td>DNA probe</td>
<td>7</td>
</tr>
<tr>
<td>DNA probe (in house)</td>
<td>2</td>
</tr>
</tbody>
</table>

**Pasteurization of milk report—M. Collins.**

A report on scientific studies done at the University of Wisconsin, funded by the Wisconsin Milk Marketing Board, to evaluate the ability of *M. paratuberculosis* to withstand pasteurization was presented by M.T. Collins. Both human and animal strains of *M. paratuberculosis*, suspended in lactate buffer or raw milk, were tested at five different temperatures and a minimum of five different heat exposure times. The results were shown graphically as thermal death curves. Comparison of these thermal death curves to present pasteurization methods suggests that *M. paratuberculosis*, if found in raw milk, would be killed by the low temperature, long time (vat method) of pasteurization but not by the high temperature, short time (HTST) method. Dr. Judy Stabel, NADC, indicated that these findings are in agreement with similar studies done at her laboratory.

Dr. Stabel, NADC, described research to evaluate the gamma interferon test to detect clinical and preclinical *M. paratuberculosis* infected cattle. The data are encouraging and suggest that this test will be useful to detect infected animals earlier than by other diagnostic methods.

Mr. Ken Smith, IDEXX Laboratories, Inc., described several modifications to the *M. paratuberculosis* Antibody Test Kit sold by his company. In December a kit will be available in "strip well format" to permit laboratories with a smaller volume of Johne’s testing to use the test more easily. Also, it will be packaged in units with fewer tests per package to make the kit more affordable for small volume laboratories. Modifications in antibody conjugate to permit use of the assay on multiple species of animals and development of software to make data management and reporting of results easier are potential improvements under study.
JOHNE'S DISEASE

NAHMS Dairy '96 project was outlined by Dr. Scott Wells.

The basis for the NAHMS' program is found in the Animal Industry Act of 1884 which directed the predecessor of Animal Health Inspection Services' (APHIS), the Bureau of Animal Industry, to "collect such information...as shall be valuable to the agricultural and commercial interests of the country". Presently NAHMS's activities are led by the Fort Collins, Colorado staff, with fifteen members to carry out their mission with broad cooperation from producers, veterinarians, Universities, State Departments of Agriculture and others. The Objectives for the Dairy '96 Study are:

1. Estimate the national and regional prevalence of specific pathogens in dairy cattle, including \textit{M. paratuberculosis} (Johne's disease), bovine leukosis virus, and Neospora sp. A further objective is to provide information on factors associated with \textit{M. paratuberculosis} in cattle to support the development of herd certification programs. The resulting information is intended to support preventative efforts directed toward these key bovine pathogens. Disease pathogens were identified as a priority by focus groups representing dairy producer groups, veterinary/dairy scientist groups, and USDA:APHIS.

2. Describe baseline dairy cattle health and management practices used on U.S. dairy operations.

3. Describe management practices used to assure the production of quality dairy products on U.S. dairy operations.

4. Describe the incidence of digital dermatitis (hairy heel warts) on U.S. dairy operations.

5. Evaluate factors related to Salmonella in dairy cattle.

6. Provide a profile of animal waste handling systems used on U.S. dairy operations.

Twenty states, which contain approximately 83% of the U.S. dairy cattle will be given the opportunity to participate in the study. Approximately 4500 initial contacts will be made in these 20 states. The estimated response rate to the first phase of the study is 50%. An estimated 700 producers will voluntarily participate in the second phase of the study which includes a current assessment of Johne's disease. An estimated 30 adult cattle will be randomly chosen from each herd for blood samples to be tested using the IDEXX absorbed Johne's ELISA test. NVSL has agreed to do the serologic testing on the 18,000 to 20,000 sera to be collected. The sampling scheme should detect at least one infected cow in a herd with a true prevalence of 10%, with 95% confidence, if the test used is 100% sensitive and specific. This will help define the herd prevalence of Johne's disease in the nation's dairy herd.

This study should determine:

1. The proportion of dairy herds infected with \textit{M. paratuberculosis}

2. Producer awareness of Johne's disease.
REPORT OF THE COMMITTEE

4. An initial assessment of the economic losses attributable to Johne's disease.

The time line for the Dairy '96 is:
January 1996: Phase I- NASS conducts first interview with producers to collect baseline management information and obtain permission to give their names to APHIS-VS/State-VMO for second phase of the study.
February to May 1996: Phase II. APHIS-VS/State-VMO administers second health questionnaires and conducts biological sampling.

Report of subcommittee on changes to CFR part 80, Dr. Max Van Buskirk.
The primary changes needed to update the CFR part 80 that pertains to Johne's disease are referable to the designation of an official test (currently the US secretary of Agriculture has no designated official test), substituting "Johne's disease" for "paratuberculosis" and elimination of the necessity for branding. Discussions with state veterinarians indicated little support for the designation of an official test, such as the fecal culture, at this time.

Update on State Programs.
Brief reports were made by representatives from New York, Michigan, Ohio, Pennsylvania, Wisconsin, Texas, New Jersey, Maryland, Kentucky, Minnesota, and South Dakota. Each state program is somewhat unique and all are frustrated by a lack of resources to meet the needs of herd owners wanting to try and rid their herds of Johne's disease. The cost of testing is subsidized totally in some states, partially in others and not at all in a few. District veterinarians in most states try and visit owners of infected herds to help educate them about Johne's control practices. The impression by all states is that Johne's disease is increasing in incidence. The rate of testing for Johne's is also increasing.

M.T. Collins announced that the next international meeting dedicated to research on Johne's disease, called the Fifth International Colloquium on Paratuberculosis, will be held in Madison, Wisconsin, September 29 - October 4, 1996. The meeting occurs at the same time as the World Dairy Expo in Madison providing an interesting opportunity for persons interested in dairy cattle and the dairy industry.

Mission statement and objectives for the NJWG: Drafts of both were reviewed by the committee.
A motion to support the draft mission statement for the NJWG was made and not passed. A second motion to table further action on the mission statement until next years meeting was passed. Several suggestions were
made to improve the mission statement. The draft mission statement was as follows:

The National Johne's Working Group (NJWG) will serve as a resource for animal agriculture in assessing any potential association between Johne's and human health. Recognizing that Johne's disease has major economic implications for producers, the NJWG will develop and coordinate implementation of a national Johne's program. This program will be designed to protect the public and animal health, reduce the economic burden upon producers and bring about a uniform approach for control, herd certification, and eventual eradication of this insidious and costly disease in the United States.

A motion was made and passed to endorse the objectives for the NJWG. The objectives are as follows:

1. NJWG will evaluate information suggesting *M. paratuberculosis* is a zoonotic pathogen and assess the likelihood that animals serve as a reservoir of infection.
2. NJWG will evaluate the potential for the organism to contaminate foods of animal origin.
3. NJWG will identify and encourage research needed to develop a strategy for a control and herd certification program.
4. NJWG will evaluate the domestic and international economic impacts of Johne's disease and develop recommendations for updating currently suggested good management practices which can be employed by producers to prevent entry and spread of the infection in livestock populations.
5. NJWG will develop a set of policy objectives and goals to enhance development and implementation of the strategy for a Johne's disease control and herd certification program.

Function of the working group with the Johne's Committee:

Discussion centered around the expanded role of the NJWG and the Johne's Committee. Many members believed the NJWG with their broadly based objectives has assumed many objectives of the Johne's committee as described in the purpose statement for the committee. To facilitate the goals of both the committee and the NJWG, committee members and others, both the NJWG and the NJWG subcommittees will be expanded to include additional committee members and others interested persons.

The meeting was adjourned at 6:15 pm.
The USAHA Committee on Leptospirosis met at 1:30 PM on Tuesday, October 31, 1995 with 12 members and guests present.

Dr. Carole Bolin of the Research Branch (USDA, ARS, NADC) of the National Leptospirosis Reference Center reported on the areas of research conducted during the past year. The primary research focus remains on the development of improved procedures for the diagnosis and control of leptospirosis in livestock. Studies were conducted to compare existing PCR assays for detection of leptospires in bovine urine. The optimum assay and sample preparation method were determined and these methods were found to be more sensitive than fluorescent antibody testing, but somewhat less sensitive than a rigorous culture procedure. A new PCR test was developed which allows for the detection and and serovar identification of leptospires directly from clinical specimens. Commercial leptospiral culture medium was evaluated and found to vary somewhat from lot to lot but was generally satisfactory for primary isolation of leptospires. The reference center has been officially requested to serve as a serology reference center for CDC.

Antibiotics were evaluated for the elimination of chronic hardjo infections from cattle. Oxytetracycline, ceftiofur, and tilmicosin were found to effectively clear the infection and may be useful to replace dihydrostreptomycin for treatment of chronic leptospirosis in cattle. Infection with serovar hardjo was found to provide protection against reinfection with homologous or heterologous strains of serovar hardjo. This indicates that regional or local approaches to hardjo vaccine development may not be required. Six experimental hardjo vaccines incorporating different antigens and adjuvants were evaluated for protection of cattle from hardjo infection. Unlike previous trials some of these vaccines showed some promise in protecting cattle against infection.

Dr. Lee Ann Thomas of the Diagnostic Branch of the National Leptospirosis Reference Center gave a report on the activities of the section. Dr. Thomas reported that the National Veterinary Services Laboratories provided the following reagents to diagnostic laboratories: 91 vials of Leptospira multivalent conjugate, 182 vials of reference antisera and 218 Leptospira cultures (19 serovars). The NVSL also performed over 3000 microscopic agglutination
REPORT OF THE COMMITTEE

tests. In addition, an import permit for the MAT check test produced by the Center for Reference and Research on Leptospirosis in the Netherlands has been obtained. Further information may be obtained from the Import Export Staff for those laboratories that are interested in obtaining a permit. Finally, a MAT training course was held at the NVSL in September. Evaluations of the course were highly favorable.

Plans to produce a MAT check test are proceeding. A batch of equine antiserum has been provided by Dr. Mike Donahue. The check test will be a collaborative effort between Dr. Carole Bolin at the National Animal Disease Center and personnel at the NVSL. It is hoped that the check test will be available by the fall of 1996.

Kevin W. Ruby of the Aerobic Bacteriology Section, Veterinary Biologies Laboratory, National Veterinary Services Laboratories prepared a presentation Status of Leptospiral ELISA's: An update which was presented by Dr. Lee Ann Thomas. They reported that 4 ELISA's have been developed for measuring the relative potency of leptospiral bacterins. The pomona and canicola ELISA's have been evaluated by the biologics industry and were not described in this presentation. The ELISA's for icterohaemorrhagiae and grippotyphosa have recently been developed. The monoclonal antibody and procedure for each of these assays were described. In the near future a letter of invitation will be sent to all firms marketing leptospiral products inviting them to participate in the evaluation of the 2 ELISA's. Data submitted by participating companies and the NVSL will be forwarded to licensing staff in support of incorporation of these assays into the Code of Federal Regulations.
The purpose of the Committee on Livestock Identification is to centralize, and evaluate methods of livestock identification and to make recommendations to USAHA for the adoption or rejection of individual identification systems.

The goal of the committee is to meet the expanding needs in livestock identification, both national and international, and be prepared to reach conclusions that are not only reasonable to the livestock industry, but fulfill the purposes for which each livestock identification system is designed.

The committee met Wednesday, November 1, 1995, at 1:30 PM in the Southern Pacific ABG, John Ascuaga's Nugget Casino Resort, Reno, Nevada. There were 15 members and 17 guests present. Two papers were presented as follows:

1. Mr. Keith Myhre, a representative of the International Standards Organization (ISO), discussed the standards that have been established with regards to the standards dealing with the number and configuration of the characters utilized in electronic identification devices (text included).

2. Ms. Nancy Robinson, Livestock Conservation Institute (LCI) Committee Chairperson Livestock Marketing Association, gave a progress report on where her committee is on identification issues to include the proposed LCI/USAHA joint working groups on animal identification (text included).

Representatives from the following segments of the livestock industry (beef cattle, dairy cattle, equine, feedlots, packers, sheep and goat, stockyards and swine), and State and Federal Regulatory personnel, gave reports (provided texts included) addressing several issues including the standardization
and structure of identification, how a standard system could apply to or be utilized by the regulatory agencies and industry segments, and what type of data base could or should be maintained regarding identification of premises or animals. Three major issues were identified. They were: 1. Standardization of Animal Identification, 2. Animal Identification Data Management, and 3. Animal production and Industry/Government/Regulatory Interface. The committee acted to approve the following motion made by Ms. Nancy Robinson and seconded by Dr. Robert Brewer: The livestock Identification Committee recommends USAHA address the three major issues identified by appointing USAHA Livestock Identification Committee members to working groups. The motion was passed. The working groups will be comprised of identification committee members from USAHA and LCI. The working groups will be assigned to address each of the three major issues. The chair for each group will then provide an update and/or recommendations of their working group at the LCI meeting being held in Colorado Springs, Colorado April 10-12, 1996.

The committee passed the following resolution proposed by Mr. Gary Simpson and seconded by Dr. Robert Brewer:

BACKGROUND INFORMATION:

The current system of backtags for identification of sows and boars in marketing channels is inadequate. In addressing this concern, stakeholders recognized the need for a National Premises Identification system for sows and boars.

RESOLUTION:

The USAHA Identification Committee supports a National Premises Identification system for use in the identification of sows and boars. USAHA urges USDA, APHIS, and state animal health officials to coordinate the development and implementation of this system in cooperation with the stakeholders. USDA, APHIS should work with state animal health officials to develop guidelines for assigning the premises numbers by January 1, 1996. In addition, USDA, APHIS should coordinate changes in regulations, notices, and memoranda to allow the system to proceed by April 1, 1996.

Mr. Ray Findley, President & Chief Operating Officer, American Card Technology, Inc., demonstrated the use of a "Smart Card" in a pilot project with horses.

There being no further business to come before the committee, the meeting was adjourned at 5:30 PM.
LIVESTOCK IDENTIFICATION

PRESENTATIONS TO THE UNITED STATES ANIMAL HEALTH ASSOCIATION LIVESTOCK IDENTIFICATION COMMITTEE MEETING

Mr Keith Myhre
ANIMAL ELECTRONIC ID STANDARDIZATION
VICE PRESIDENT OF BUSINESS DEVELOPMENT
InfoPET IDENTIFICATION SYSTEMS, INC.

The International Organization for Standardization (ISO) began the development of an international standard for the electronic identification of animals in February 1991. Based upon the current status, it is anticipated that the two documents defining the standard will be published in mid to late 1996. Implementation of this standard for transponders and readers will facilitate universality of electronic animal identification across state and national boundaries.

The technical work of ISO is carried out through Technical Committees (TC). Each Technical Committee may, in turn, establish Sub-Committees (SC) and Working Groups (WG) to cover different aspects of its work. As of the end of 1990, ISO had 72 member countries, 172 Technical Committees, 653 Sub-Committees, 1,764 Working Groups, and published 7,778 ISO standards. In February 1991, SC 19 (responsible for "Animal Identification") of TC 23 (responsible for "Tractors and Machinery for Agriculture and Forestry") established WG 3 (responsible for "Animal Identification") to "define an electronic identification system for animals in agriculture. It shall describe a numbering system and the necessary technical specifications for the identification."

The eleven meetings of ISO TC 23/SC 19/WG 3 held since June 1991 have resulted in the drafting of two electronic ID standards. ISO/DIS (Draft International Standard) 11784 defines the code structure while ISO/DIS 11785 defines the technical concept. Consensus was reached in September 1994 to extend the electronic identification standards to encompass all categories of animals, not just agricultural animals. Revised versions of ISO/DIS 11784 and ISO/DIS 11785 were released to the 23 member nations of TC 23/SC 19 in July 1995 for a six month voting period. Seventy-five percent of the votes cast must be in favor of approval in order to be published as an ISO standard.

The American National Standards Institute (ANSI) is the U.S. member body of ISO. The Equipment Manufacturers Institute (EMI) coordinates inputs for agricultural equipment standardization on behalf of ANSI. A Technical Advisory Group (TAG) was established by EMI in 1992 to recommend U.S. positions on agricultural animal electronic identification standardization. The U.S. ISO TC 23/SC 19/WG 3 TAG comprises interested companies and organizations, including the National Holstein Association, the National Dairy Herd Improvement Association, and the American Veterinary Medical
ISO/DIS 11784 defines a transponder code structure of 64 data bits:

1 bit = Animal or Non-Animal
10 bits = Country Code (0 - 899) or Manufacturer's Code (900 - 999)
38 bits = Unique ID Code (275 billion per country or manufacturer)
1 bit = Flag indicating additional data block(s)
14 bits = Reserved for future use

Each nation using the country code scheme will be responsible for issuing blocks of the 275 billion unique ID numbers to manufacturers. Nations utilizing the manufacturer's code scheme will have to rely on manufacturers voluntarily adhering to the manufacturer's code registration procedures that are currently being established.

ISO/DIS 11785 "specifies how a transponder is activated and how the information stored is transferred to a transceiver". Defined characteristics include transponder activation and response frequencies and timing, data encoding and modulation, bit rate, and error detection code. ISO/DIS 11785 defines two technical approaches. A Half Duplex system operates by having the reader (transceiver) charge up a capacitor, which acts as a battery to power the transponder which begins transmitting its data once the reader switches off. A Full Duplex transponder simultaneously transmits its data while the reader energizes the transponder.

ISO/DIS 11785 accommodates much of the current installed base of transponders by defining a backward compatible reader which, in addition to reading both Full Duplex and Half Duplex ISO transponders, can also read one or more of the following manufacturers' transponders: Datamars, Destron, and Trovan. Backward compatible readers will be permitted for as long as users need such readers. Considering the 30 year life span of horses and 50+ year life span of parrots and other birds, backward compatible readers will likely be in use for a long time. Recognizing that ISO standard transponders won't be readily available immediately following the publication of ISO 11785, a two year transition period for Datamars, Destron, and Trovan transponders will be authorized by the standard.

It is equally insightful to understand what the ISO standards don't define. They don't specify whether the transponder is implantable or external, the construction (such as size and shape) of either the transponder or the reader, nor computer database format/content. The ID code structure does not specifically define a premise (i.e., farm, ranch, or producer) identifier. Such a definition is the responsibility of each nation through a sub-definition of the 38 unique ID code bits.

In February 1993, the U.S. industry trade association for automatic identification, AIM USA, established a Small Animal RFID Task Force to define a standard for the electronic identification of companion animals (i.e., any animal kept predominately for pleasure) in the U.S. since ISO standardization efforts were limited to agricultural animals. Task Force participants include
manufacturers, distributors, the American Veterinary Medical Association, the American Kennel Club, the National Animal Control Association, and other interested organizations. Based upon the results of a user survey of the companion animal industry, the Task Force drafted a User Requirements Document which has been published by AIM USA. Among other requirements, this document specifies an implantable transponder, constructed of non-toxic materials and hermetically sealed in biocompatible glass, with a maximum length of 12 mm that can be injected with a 12 gauge, or smaller needle. Two types of readers are specified: a Hand-Held Reader and a Hands-Free Reader (such as a pass-by panel reader), both of which must be backward compatible to accommodate the U.S. installed bases of AVID, Destron, and Trovan transponders in pets. Based upon the current plans of the Small Animal RFID Task Force, the AIM USA electronic ID standard for companion animals will be based upon the ISO standard, but will not be identical.

Since ISO standards are voluntary and the ISO has no enforcement authority, implementation of the ISO animal electronic identification standards will hinge on a number of issues. Which nations will edict use of the ISO standards via regulatory authority? Those that can't or don't will have to depend upon market economics to determine the rate of implementation. When will ISO standard readers and transponder be available? And how many manufacturers will there be to select from? How much will transponders and readers cost? Interested manufacturers will evaluate production costs and risks versus projected sales and potential profits to determine if and when to begin production. How can a user be assured that a transponder number will be unique considering multiple manufacturers? Manufacturers must voluntarily cooperate and institute a quality control system to help ensure transponder number uniqueness. Will there be incentives for unscrupulous manufacturers to intentionally duplicate transponder numbers (such as insurance claim fraud with valuable animals)? Will all "ISO standard" readers be able to read both Full Duplex and Half Duplex ISO transponders? Will users become disillusioned with electronic ID due to varying, and perhaps inadequate, performance (such as reading distance) of different manufacturers' systems?

Despite all of these issues, the ISO standards will provide a tremendous boost to animal industry acceptance and use of electronic identification. Electronic identification is a tool which will help automate herd health management and regulatory controls. However, it is incumbent upon prospective users to understand that electronic identification, in and of itself, is not a panacea.
REPORT OF THE COMMITTEE

Ms. Nancy Robinson
REPORT ON THE LCI'S LIVESTOCK IDENTIFICATION EFFORTS
U.S. ANIMAL HEALTH ASSOCIATION/
COMMITTEE ON ANIMAL IDENTIFICATION
CHAIRPERSON OF THE
LIVESTOCK CONSERVATION INSTITUTE'S
LIVESTOCK IDENTIFICATION COMMITTEE

Thank you Dr. Lindstrom and Dr. Bridgewater for including me in your program today. As Chairman of the Livestock Conservation Institute's Livestock Identification Committee, one of my top priorities has been to encourage better coordination between LCI, the USAHA and other interested groups on livestock ID issues. As livestock ID becomes a larger issue in food safety programs, production management systems and international trade, we can ill afford to go a hundred different directions in responding to the many issues that animal ID presents to us now and in the future. Happily Dr. Lindstrom and Dr. Bridgewater agree with me on this point thus bringing together two significant animal health groups representing virtually the whole of the animal industry in a common effort to move livestock ID forward in the United States.

Nearly a year ago, the Livestock Conservation Institute held a National Livestock ID Symposium in St. Louis, Missouri. That symposium, entitled, "The Challenge Before Us", was to be a significant first step in building a consensus on the various elements of the ID equation.

The ID Symposium brought together more than 30 different speakers talking on four major ID topics: (1) technical and performance requirements of electronic ID, (2) the Federal regulatory perspective, (3) ID in the international arena, (4) database management, (5) current applications and experiences in livestock ID, and (6) advancements in electronic ID technology.

So what did we learn from all these learned sources. Well, we learned that standardization of electronic ID (EID) technical and performance requirements is as equally important to users as it is to the manufacturer. EID standardization minimizes costs, provides compatibility of equipment from one user to another and removes technical and performance barriers to the widespread use of EID in the livestock industry.

We also learned from a panel of Federal regulators that livestock ID is critical to their mission of protecting the meat supply, facilitating their identification of critical control points in voluntary and mandated HAACP programs, controlling animal disease in the domestic herd, carrying out human epidemiological investigations and strengthening financial accountability between buyers and sellers of livestock.

Our international speakers brought home the message that livestock ID within the international community is no less a mixed bag of successes and failures than we have experienced here in the United States. The Netherlands and Denmark have sophisticated mandatory national livestock ID and registry
LIVESTOCK IDENTIFICATION

systems that seem to be working well for them. Our Canadian neighbors however are struggling, much as we are, to find the right mix of private and government incentives to develop cost effective, workable ID systems nation-wide.

Not too surprisingly, as we progressed through the symposium program, database management became a core issue. Who collects the information and for what purpose; what, how and where the information is stored; centralized versus decentralized databases; protecting the confidentiality of the information; and utilizing ID information for production management, regulatory and trade purposes without compromising the information all were critical database management issues raised by the symposium participants.

Fortunately, we have the experiences of individuals in the swine breeding industry, an integrated beef production and processing company and designers of cattle management systems to give us some guidance in this area. However, it has also become abundantly clear from our discussions on the issue of database management that a great deal more input and commonality of thought among all livestock ID stakeholders is needed if we ever hope to make progress in adopting livestock ID on a universal scale.

Whenever you hold a symposium of this nature, you hope besides imparting some valuable information on the group that you will leave with some consensus on where you are, where you hope to be and how you hope to get there. I think we had a fairly clear sense, once the meeting came to a close, as to where we are currently in the livestock ID continuum. Where we hope to be in the not so distant future on this issue was, as you can imagine, much harder to attain. We were able however to agree on a few basic precepts, such as: (1) national ID systems should be largely driven by economics, (2) ID systems must be easy to use, (3) minimum uniform standards must be developed which also meet regulatory needs, (4) ID systems must provide the capability for unique animal ID, and (5) current ID systems are not adequate.

For every point of consensus reached however there were a like number of issues that remained unresolved. For instance, whether ID databases should be centralized or decentralized, what the best injection sites were for electronic implantable devices, how to incorporate worker safety, food safety and environmental concerns into ID systems, insuring flexibility in ID information gathering and dissemination, how to implement the ISO standards to assure the industry of compatible ID equipment and systems were all substantial issues requiring greater in-depth discussion than our two day symposium would permit.

It was these unresolved issues that presented us with our greatest challenge. At the close of the symposium we had begun to ask ourselves: how could the symposium be considered even a modest success with so many outstanding issues unresolved? How could we initiate a major effort to take action on livestock identification only to walk away from it after a two day symposium? And, how were we ever to make strides in developing universal
livestock identification if we simply let the subject slide into oblivion once the symposium came to a close? The answer is—we couldn’t.

That is why the Livestock Identification Committees of LCI and the USAHA—the two organizations most capable of building consensus on issues of common concern within the animal health and production community—have come together in a joint effort to resolve these ID issues. We intend to continue the work of the symposium and our respective ID committees through the formation of three smaller ID work groups. These three work groups will review and make recommendations in three principal areas: (1) standardization of livestock ID systems and technology, (2) database management, and (3) animal production and industry/government/regulatory interface.

You have in the handout I provided to you a basic outline for these three work groups. As you can see this is no small task we will be asking these groups to undertake. Regardless of the difficulty of that task however I hope those members of the LCI and USAHA ID committees who have the interest, knowledge and desire to see universal livestock ID become a reality will step up to the plate and serve on one of these work groups. Because we hope to keep these groups down to a workable size of 8-10 people, we ask that you submit your name and business affiliation and the group on which you would like to serve to Dr. Lindstrom or myself on the attached sign up sheet to the work group outline. We will also be contacting by mail all the members of the LCI and USAHA ID committees who were not able to be here today to enlist their participation as well. Once we have a body of people interested in serving on these work groups, we will attempt to try and accommodate as many of you wishing to work on this project as possible while also assuring that all animal ID interest are served. So please, if you wish to help in the effort to move livestock ID forward, sign up for these work groups today so we can begin the work soon.

Thank you and I look forward to working with many of you in the future on these important ID issues.

LIVESTOCK CONSERVATION INSTITUTE/U.S. ANIMAL HEALTH ASSOCIATION JOINT WORKING GROUPS ON LIVESTOCK IDENTIFICATION

I. WORKING GROUP ON STANDARDIZATION OF LIVESTOCK IDENTIFICATION SYSTEMS

This working group will review and make recommendations on livestock identification (ID) issues related to standardization of animal ID systems in achieving compatibility of ID systems and devices to promote widespread use of animal ID in the animal industry, such as but not limited to:

* The ID code/numbering structure and what works for the various spe-
LIVESTOCK IDENTIFICATION

cies, ID manufacturers, different ID devices, and for traceback and data retrieval.
* Incorporating new technology or trends into current ID standards.
* National standards for application to, retention by, and retrieval from the various species.

II. WORKING GROUP ON LIVESTOCK ID DATA MANAGEMENT

This working group will review and make recommendations on livestock identification issues related to the management of information derived from the identification of livestock, such as but not limited to:
* Centralized versus decentralized information management systems.
* Security of information derived from identified animals.
* Database linkages for regulatory purposes, breed registration, health and value information exchange.
* Where the transfer of ownership fits into maintaining traceability of the animal.
* Purposes for which information from the ID would be used and who the responsible parties will be for collecting the information and inputting it.

III. WORKING GROUP ON ANIMAL PRODUCTION AND INDUSTRY / GOVERNMENT / REGULATORY INTERFACE

This working group will review and make recommendations on livestock ID issues related to animal production and the interface between the animal industry and the government/regulatory sectors, such as but not limited to:
* FDA approval requirements for implantable electronic ID devices.
* Traceback of identified animals, where it begins and ends.
* Individual animal ID and/or premise ID for interstate movement, regulatory traceback and marketing purposes.
* The roles of the various production, marketing and processing sectors in the application of ID devices, maintenance of records, retrieval and transfer of information, removal and disposal of ID devices, etc. in meeting industry and regulatory requirements.
* Federal and State inter-agency ID coordination.
* Field application of ID systems and devices.

REPORTS TO THE COMMITTEE ON LIVESTOCK IDENTIFICATION

PROSPECTIVES FROM INDUSTRIES VIEW
Dr. Gary Cowman
National Cattlemen’s Association

Dr. Cowman discussed the viewpoints of the beef cattle producers and feedlot industries (text not provided).
The U.S. dairy industry has had significant success in animal identification. Much of this has been driven by the desire of producers to advance the performance level of the U.S. dairy herd. Programs for milk recording and breed registration have provided valuable services, that as a prerequisite, require identification. Over 50% of the U.S. dairy herd is identified on the databases of such service providers. This is not to say the we are content with the level of animal identification. Increasing accuracy and obtaining a higher percentage of animals identified remains an objective for the industry.

Many of our ID programs have had “special interest” objectives versus a “national” focus with the capability of having all segments of the industry cooperating for the establishment of one system. For example, much of the Holstein Association’s focus regarding the administration of animal ID has been performance related. The need to consolidate efforts across user application: genetics, animal health, disease control/eradication and food safety is important and warrants the development of a national program.

National Identification Systems

The merit and value of a national system is greatly supported in the dairy sector. In the past, reference to a “national” system may have been confused with “mandatory” identification. Therefore, defining the expectations of a national program is appropriate. Some suggestions are listed below:

National animal identification systems must harmonize the permissive identification of farm animals across the United States. The systems must provide animal information that meets the demands of various applications while standardizing common fundamentals used for each. A unique and permanent identification number for the life of dairy animals is the primary basis for the National Dairy Identification System.

“Applications” define the reason animals are identified; that is, the use for the animal identification records (tracking lineage, genetic evaluations, ownership, disease control and eradication, food safety, etc.). The specifications for each application need to be defined by various industry segments involved in farm animal production and processors of farm animal food products.

“Means of identification” are practices that “physically” identify animals and are specifically defined for each application. Common on-farm practices used for each application need to be standardized, i.e., tagging, branding, implant locations for transponders, etc.

Common issues across species can then be identified and standardized when possible. For example, if EID transponders are used as a means of
Identification (attached or implanted), the code structure and technical communication protocol would be standardized across all species and applications to insure the most cost effective technology is available for all segments of the production and processing chain.

The current utilization of different numbering systems in the dairy industry has created considerable problems. The “grade” population is identified with a USDA uniform series tag while the registered sector has a nine digit numeric number. Often, calves eligible for registration are first identified with a USDA number, then later with a number assigned by the Holstein Association. This often results in having the same animal identified on our systems two times, each with a different number. We realize that change within our industry is needed to more effectively identify our cattle.

The permanent number assigned to an animal can be compared to the serial number (VIN) of a vehicle. That is, the owner does not use the serial number on a day-to-day basis, but it is required for significant transactions, i.e., when the car is sold to another person. The vehicle’s serial number is a permanent number. The license plate number, however, is used frequently as the car’s ID. For example, if the driver buys gas and charges the cost to a credit card, the station attendant often requires a license plate number. The license plate number may change over the life of the vehicle; for example when the car is sold to another person.

Numbering cattle can have similarities. For example, a permanent lifetime number that provides unique identification across the United States can be compared to a vehicle’s serial number. Another level of the animal’s identification used for herd management purposes, like bangle ear tags, can be compared to the vehicle’s license plate. Since many animals change locations, the herd management number (number on the bangle tag) may change over the life of the animal. The current herd management number, however, is always cross referenced to the lifetime number when needed by the producer.

Since the basis of a national dairy identification number is to establish unique identification for the life of the animal, it is advantageous if the numbering scheme does not attempt to provide meaning to the animal’s record. Too often, information like premises location, registry status, ownership, etc. is desired to be part of the numbering method or series. Any “piece of information” subject to change should be administered as separate fields on the animals record within the databases. Administering this information as separate fields allows the “national” number to be permanent for the animal’s entire life.

Some animal identification applications do not require individual ID. In such applications, another source of information on the animals database record is appropriate. This, in some cases, will be the animal’s premise location rather than the animal’s unique ID. However, the database should probably allow for individual ID as it is likely that another application within the same species will require some type of unique animal ID.
REPORT OF THE COMMITTEE

The establishment of a universal identification system has been successful. However, minimal implementation has been achieved due to a lack of commitment and/or agreement of its importance across all users in the industry.

The American Dairy Identification System

Recent efforts by the Council on Dairy Cattle Breeding (CDCB) have established the American Dairy Identification System. The CDCB is made up of National DHIA, National Association of Animal Breeders, Purebred Dairy Cattle Association (breed registry organizations) and USD/AIPL. USDA/APHIS was also represented in the discussions for the development of the American Dairy Identification System.

The American Dairy Identification System, in principle, is a scaled down version of the universal identification format. The numbering system is being distributed for comments throughout the industry with plans to implement the system in early 1997. This time allows for the administrators of databases to revise their file structures and programs.

In essence, this plan will provide for a national identification system for the dairy sector. The **American Dairy Identification System** is described in the following:

1. Allows all dairy cattle in the U.S. to have a unique number whereby all breeds utilize the same numbering series and the Council on Dairy Cattle Breeding allocates unique ID numbers in “blocks” to appropriate organizations that provide identification programs and/or services. An agreement between the CDCB and the participating ID organizations would establish guidelines for the efficient and cooperative administration of animal identification.

2. Provides a unique lifetime number with the following specifications:

   **American Dairy Number:**
   - Country code Alpha (3)
   - Unique ID # Alpha numeric (12)

   **Additional Fields:**
   - Species Alpha (1)
   - Breed Alpha (2)
   - Sex Alpha (1)
   - Status * Alpha numeric (2)

   * Status designates breed program.

   The attachment of the “additional” fields allows for the presentation of the universal identification number when required or appropriate.
3. Supports the early identification of calves and their recording* on off-farm databases. The dairy industry, in order to promote early identification and to document its merit relative to accuracy, must track the date the animal's ID is recorded on the “off-farm systems”. The weighting of records used for genetic evaluations, given substantiating research data, could be correlated to the age the animal was recorded. Therefore, a field for “date recorded” must be part of each animal's record.

*Receipt of the animal’s ID record on off-farm databases, e.g., DHIA/DRPC, breed associations, etc.

4. Supports administration procedures and producer requirements that support accurate identification by:
   - requiring the American Dairy Number be attached to the calf by an approved means unless a permanent form of ID (color diagrams, tattoos, freeze brands, etc.) is used with ID certificates.
   - providing, to the extent possible, for the electronic tracking and submission of the American Dairy Number. This is of value to minimize manual recording error and to lessen the “burden” placed on the dairy producer.
   - having a herd ID number (equivalent of premises designation) cross referenced to the dairy producer’s name, address, etc., to avoid having systems that process and rely on producer names directly.
   - providing replacement ID Tags with the animal’s original American Dairy Number or other ID means.
   - establishing a logo for the American Dairy Identification System for use on ID Tags. The presentation of this logo on ID Tags would signify that the animal is recorded in the American Identification System.

5. Allows for consideration of a National Identification Database, given economic justification, where all segments of the industry agree to provide pertinent information to the database, e.g., American Dairy Number, species, breed, sex, status, sire, dam, date recorded, and herd number.

Electronic Identification

The incorporation of electronic transponders has, for many years, been of interest to many segments of the dairy industry. Radio Frequency identification (RFID), the most common form of electronic identification (EID), must be considered as one of several “means of” identification. The benefit of RFID over the “traditional” forms of ID is having an ID method that can be used for automation of herd management systems as well as providing an ID system for off-farm programs.
Implementation of RFID has been minimal, however, two of the obstacles that have slowed the adoption of RFID and its integration in dairy systems are nearing resolution.

**Standardization**

Compatibility of RFID systems among manufacturers of the equipment is essential. The standards being finalized by the International Standards Organization (ISO) will provide this compatibility.

- **Code Structure**

  ISO 11784 which defines the code structure of the electronic number should meet the needs for the identification of farm animals as well as other animal species.

  Each country is responsible for ensuring the uniqueness of the identification codes allocated within their country. Thus, having a national administrator of the code number would be beneficial for the United States. Since the United does not have such an organization, the use of a manufacturer code will be used instead of the country code. Manufacturers will then be responsible for producing transponders with unique numbers.

  The code or number of the electronic transponder may have, in the past, been confused with the "national number". While the number contained in the transponder may be the same as the animal's permanent (national) number, it should not be a requirement at this time. The efficiency and practicality of administering the national number in the transponder is not known at this time. Thus, databases should be developed that allow for the administration of the animal's "national ID" number as well as an "electronic" number.

- **Technical Standards**

  ISO/DIS 11785 specifies how a transponder is activated and how the information stored is transferred to a transceiver (reader). Having this standard is essential for the successful integration of RFID technology in the farm animal industry.

Now that standards are becoming reality, it is critical that the industry assume responsibility for implementation of such standards. Integrators of RFID systems need to use equipment that meets the specifications of the ISO technical standards. Other allied segments must also support and require the implementation of the standards.

**Implants**

Initially, most efforts were in the development of the implant transponder. The labelling of the transponder as a feed additive by the FDA and the challenge of obtaining approval created interest in the transponder attachments. The success of field trials with RFID tag attachments has lessened the need
LIVESTOCK IDENTIFICATION

for transponder implants. In actuality, the attachments have advantages such that we (Holstein Association) have approved RFID Tag as an official form of identification.

Premises Identification
The need for premises location is acknowledged and supported. While the format of the number for premises location has not been determined, it is agreed that this information must be handled as a separate field on the animal's record.

Developing a system for assigning numbers to "production" units with respect to location is needed. Our current DHIA numbers with a two digit state code, a two digit county code and a four digit producer number may be a viable system. However, producers that do not participate in DHIA would not have such a number. Therefore, a plan for administering numbers for production units remains unresolved in the dairy sector.

Premise records need to be administered as part of the animals record on the database. That is, the national number provides access to the animal's record. Which, when accessed may contain the premise information of the animal.

Database Administration
The development of sophisticated on-farm computer systems increases the capabilities of producers and lessens the need for off-farm processing of data. The decentralization of the data, or lack of access to it, is a concern for the future.

Having several service providers is "healthy" for a competitively stimulated business. The industry's ability to centralize or link the database is a significant challenge. The centralization of the animal's "primary" identifiers (national number, date of birth, sex) should be made available to initiate or allow access to the animal's record on all databases. The centralization of such data is critical. This initial access, could then provide the link to the proper database based on the additional information being requested (pedigree, performance, health, ownership, etc.). The national number, therefore, becomes a critical component of the administration of the database.

Developing systems for the electronic submission of information from the production units to the database (off-sight entry) and the exchange of data is essential for greatest efficiency. Since more and more on-farm records are being computerized, the standardization of field definitions is essential to allow for accurate exchange of data.

The cost of administering the databases must be considered. Producers that benefit from the end results need to provide financial support; possibly with initial enrollment fees. However, all users must be willing to support the financial requirements of administering the database. Considering an access charge for specific information on the animal's record is appropriate.

Many details must be worked out for the administration and release of
data before the development of such systems. Producers must be provided with options that allow them to define the release of their records. The availability of technology and the need of the industry warrant further efforts to move ahead with such projects.

Ms. Amy Mann
Equine Industry Viewpoints on Identification
Director For Health and Regulatory Affairs
American Horse Council

To date the American Horse Council has not taken a position on electronic identification pending the outcome of FDA's consideration of the issues. We have no answers, therefore, to the questions we were asked to address here today. This does not mean we have not had discussions of these issues. We are very aware of the need to improve identification methods, especially in the area of animal health. However, the issue is not a priority across the industry, but rather has been taken up by individual segments of the industry, primarily the breed registries.

We can say that our industry will not support anything that is mandatory. It must be driven by industry desire.

Our indications of the industry's concern about a centralized database comes from our experience in the requirements being placed on horses traveling internationally in terms of developing a passport system. How our breed registries have handled this is to provide the passports only to those horses that will travel internationally, specifically to the European Union, rather than to issue passports to all registered animals.

When we began to look at developing a passport system the main concern expressed by the breed registries was how to ensure the proprietary information they collect on their registered horses. We can be relatively certain that this will remain a concern as we examine this issue.

I'm sorry we don't have more to offer but we are pleased to be included in the continuing discussion on animal identification.

Mr. Steven Krut, Executive Director
American Association of Meat Processors

Mr. Krut provided comments from the industry members.

Al Reicks, AAMP: Keeps his own "traveling bookkeeping" system, says many people do not. Thousands of hogs are shipped to East and West Coasts, for example, and where scalding goes on. So it might be ok. The idea of a national system scares him a little.

Tom Leidy, Leidy's Inc.: We have a grade and yield system, lots have to be kept separate. Every hog is paid for by value. Our system works, a national
LIVESTOCK IDENTIFICATION

system would be government interference. We don't buy hogs without place of origin. One reason we got away from sales, is we need to know where they're coming from. When a direct producer comes in here, we apply a tattoo. Yet I can see the need. The problem (in hogs) exists in sale barns or stations where the animals are unidentified. In that case, a number system would be justified.

John Reininger, Hatfield Meats: Our identification is done with a slap tattoo on the shoulder. Our people ink the carcass where it can be noticed. Most of the animals we deal with are 245 pounds or below. Cull females are done at the point of purchase through the auction. The number is physically tattooed on.

(Most of our people seem to have set up their own system, which works fine, and don't get into the situations that would require National Premises ID Numbers).

Cleon V. Kimberling, D.V.M.
Sheep and Goat Extension Veterinarian
Colorado State University
Ft. Collins, Colorado

Introduction

The initial emphasis on electronic identification (EID) of sheep came about during the scrapie negotiated rule making process. The committee defined the ideal form of identification as one that is easily applied, easily read, permanent, individually unique, and affordable. Other methods of identification, i.e. ear tags and tattoos, fulfill only portions of this criteria. Ear tags are easily applied and reasonably priced but are not permanent and are subject to about a 10% error rate when numbers are recorded. Tattoos are permanent but can be difficult to apply and are frequently plagued with errors in reading and transcribing. EID is the only method of identification currently available that meets all of the desired criteria.

The initial recommendation of the negotiated rule making committee was to adopt EID as the official form of identification. This recommendation was later modified to accept flank tattoos as an alternative method until standards for EID had been adopted. Acceptance of EID has met with some reluctance on the part of producers. This reluctance has been, to a large extent, due to cost. However, those that have applied flank tattoos tend to have a different appreciation for the amount of time and labor involved and hesitation over the cost of EID becomes less of a concern. Producers have also expressed the concern that the brand of EID they apply today may not be the brand eventually selected for use in scrapie program thus necessitating reimplantation and incurring additional expense. In an effort to alleviate some of these concerns, encourage the use of EID, and to stimulate enrollment in the scrapie
program, an incentive program is being developed by the USDA which will make EID available to scrapie program participants.

Identification for the voluntary scrapie certification program can be accomplished with a simple 10-digit alphanumeric transponder and a central database. The program can be written to accommodate flock of origin, changes in ownership, production measurements or any conceivable data deemed necessary. **Keep the chip simple!!** It is much easier to modify a software program than to dream up everything that any portion of the industry could possibly want and encode all of these items into a single chip.

"A good plan today is better than a perfect plan tomorrow.” George S. Patton

**Industry Needs**

The potential benefits of EID to the sheep industry extend far beyond its application to the voluntary scrapie certification program. A major need of the industry is to identify and document superior genetics. To accomplish this goal, there needs to be a system that will provide permanent, individually unique identification that can incorporate production, health, and slaughter records. This information can then be used for management decisions and flock improvement. Electronic identification provides such a tool. Only the basic EID equipment is necessary: 1. a medium size transponder (15-18mm x 2.5mm) that is highly resistant to breakage, 2. a reader that is compatible with a sheep production software program, 3. compatibility between readers and transponders of different manufacturers, and 4. in cases of national health programs, transfer of ownership, and animal registry, a national database.

**Ms. Nancy Robinson**

"The Livestock Markets' View of Livestock ID"

Associate Manager
Government and Industry Affairs
Livestock Marketing Association

* LMA was recently asked by Dr. John Weimers of the APHIS Swine ID staff to identify what livestock markets need from a swine ID system.
* While our reply was more specific to swine, I think our list of parameters for swine ID works equally well for all forms of livestock ID.
* It will be no surprise to most of you here that the markets strongly feel that ID should begin at the production site—the farm, ranch or feedlot. It just makes good sense. On-farm identification facilitates proper application, retention, product control and marketing of the animal.
* As well as a valuable management tool for the producer, point of origin identification will be important for traceback purposes in responding to value-based marketing programs, residue and microbiological control programs, etc.
* Also, to the greatest extent possible, any new or modified identification system or requirements should be easily incorporated into the market's ex-
LIVESTOCK IDENTIFICATION

isting management practices. Otherwise, any major departure from those current practices will likely be met by considerable resistance.
* Another large question for the markets, as we look at future developments in livestock identification, is what our responsibilities will be when handling livestock that reaches our facilities without legally mandated ID. For instance, would the markets apply a new ID device with the same or a different number, who will supply the numbers and devices, who will pay for application of the ID and so on.
* Identification if applied at the markets must be simple to apply, simple to retrieve and simple to record.
* Likewise, ID devices will need to withstand the rigors of differing market conditions in different regions of the country, such as differing weather conditions, types of animals, modes of transportation, etc.
* Obviously we would want to keep administrative, technical, facility and personnel cost to a minimum in adopting any ID system.
* And, accepted ID systems should facilitate not obstruct the movement of livestock in and out of our facilities. Nor should ID systems put auction and terminal markets in a competitive disadvantage to other forms of marketing such as direct marketing.
* Lastly, ID data management systems will need to be compatible with computer and non-computerized information and recordkeeping systems currently in place in the markets or at least to the greatest extent possible.
* So you see, we don't ask much from livestock ID systems or at least no more that other sectors of the livestock industry would expect.
* I think the Joint LCII/USAHA ID Work Groups will be very helpful in working out some of these issues for the markets as well as the other sectors of the livestock industry.

Dr. Beth Lautner
Swine Identification Update
National Pork Producers Council

It is critical for food safety, disease control and product improvement to have the ability to identify swine and provide the appropriate information back to their source. The pork industry has a history of interest in swine identification. In 1984, a National Pork Producers Council (NPPC) Task Force was formed to study identification and develop a proposal for a national swine identification program. In 1985, the NPPC delegate body approved the identification standards presented by the Task Force. In 1986, the NPPC delegates supported mandatory identification of all slaughter hogs back to the last farm of ownership. NPPC supported mandatory identification for several reasons. First, the ability to improve product quality depends on the availability to the producer of information on the composition and merit of market hogs. Second, disease control programs such as the Pseudorabies Eradication Program need identification to be successful. And in the area of food
safety, accurate identification has been critical in the National Residue Program to correct problems. Currently, all hogs bought and sold into interstate commerce have to be identified in some manner.

The current slap tattoo system for market hogs is viewed as working well. However, the current system of back tags for identification of sows and boars is inadequate. Retention of the back tags through the marketing channels is poor. In April 1993, NPPC requested that APHIS allocate additional resources to improve sow and boar identification. APHIS responded to this request and designated Dr. John Wiemers to work with the industry to address industry and regulatory needs. Efforts at improving retention through the development of a better glue, different methods of application and enforced compliance at the markets have had little permanent impact on the overall level of identification.

At the 1995 Pork Industry Forum, the delegate body supported a resolution on identification that 1) NPPC continue to support improvements in swine identification systems for the long term benefit of the pork industry; 2) the identification systems must provide the capability for unique animal identification and when necessary, the system should allow this identification to be associated with a premises; 3) minimum uniform standards for identification systems, including electronic identification, should be jointly developed by the industry, manufacturers and the U.S. Department of Agriculture; 4) these standards should allow communication across industry segments for product improvement, provide an option, if needed, to meet appropriate regulatory requirements and be compatible with international identification efforts; and 5) use of electronic identification should be voluntary and based on the economic and management benefits it offers producers.

On October 19, 1995, NPPC in cooperation with the Livestock Conservation Institute sponsored a Swine Identification Stakeholder Meeting to discuss the design and implementation of a national premises identification system. The basic concept consists of a premises identification number that would be included on producer tags.

USDA would have the responsibility to coordinate the development and implementation of this system, coordinate changes in regulations, notices and memoranda to allow the system to be developed and coordinate the identification needs of other federal agencies. Producers would have the responsibility to apply to their state animal health officials for a premises identification number, order production tags with the premises identification number and to make sure breeding swine leaving the farm have been identified. The state animal health officials would have the responsibility to provide application forms to producers, assign the numbers and maintain the database of all numbers assigned within the state. The minimum information needed to assign a premises identification number would be the producer name, address, phone number and geographic location. The premises identification numbers would begin with the postal code abbreviation for that state. The livestock
markets would have the responsibility to recognize the swine arriving with premises identification numbers, apply identification devices to any swine not arriving with identification and to maintain records of identified swine. The packing industry would have the responsibility to facilitate the collection of samples and identification devices.

The potential benefits of a national premises identification system include fewer false tracebacks due to inaccurate identification, the ability to rapidly trace animals to premises for foreign animal diseases, Program diseases and residues, good identification device retention, and its adaptability to electronic identification systems.

The premises identification system is still under development. There are many questions that remain to be resolved at this time. Some of these include what are the costs of this type of identification system, how are the costs distributed throughout the pork chain, what is the impact for markets and packers, what changes are needed in the CFR to accommodate this system, is there a need for a central database, what is the ability of states to maintain databases and is this system voluntary.

The pork industry looks forward to the continued development of a national premises identification system that will meet industry and regulatory needs and ultimately benefit the consumer.

PROSPECTIVES FROM A STATE REGULATORY VIEW

Leroy M. Coffman, D.V.M.
Electronic Identification
State Veterinarian
Oregon Department of Agriculture
Salem, Oregon

Standards for electronic identification are being established by the international community, ISO. While progress on these standards is slow, the process is necessary to achieve acceptable harmonization of an international system. Those standards have now progressed to a point where existing or new data bases can be functionally linked in the future, to the final process, through a bar code. Finalization of international standards will involve considerable more time, followed by clarification in the application process. The importance of starting a system to utilize the present technology is paramount in order to provide direction, avoid fragmentation and build data bases with the potential to be linked to national and international networks. The essential component of the data bases we have today is the premise identification. This component already exists in our national disease control data bases (ie. Brucellosis and Tuberculosis) providing us with the vision to establish the data base system at this time. Other data bases already exist in varying degrees of compatibility and are continually growing. The time has come to use premise identification to allow for the first phase of the national/
Communication and credibility are the essential components of any system. While many animal related private, corporate, university, research and individual identification systems vary, the one thing they have in common is premises.

State regulatory agencies can use premise identification to provide the basis for disease control, identifying ownership and monitoring animal movements. Premise identification can be incorporated into a state geographical information system (GIS) for a number of purposes including Emergency Response.

GIS systems typically use latitude/longitude designations to establish location for mapping. These locations can then be tied in the database to premise identification and other useful information (ie. zip codes and bar codes) to expand their application to other databases (ie. national or international). The same could be true for our already present National Disease Control Programs (ie. Brucellosis and TB). Two standards need to be established. The ISO (standard) is linked by the bar code to the state (standard) premise ID. The individual ID is left up to the premise owner. If you want to ship internationally, you will have the choice to meet that requirement when it is established. Mean while we can use the data bases created to accomplish the varied tasks of the producer, regulator, investigator, Quality Assurance Program, Emergency Management, survey, analysis, animal registry, breed association etc.

The present TB and Brucellosis data bases have 10 spaces for premise and 9 spaces for julian record. Suppose we use these data entry spaces for premise and individual animal ID. We now need to standardize how the premise ID is designated. Everybody recognizes state abbreviation codes. OR—Oregon etc. We can use nine digits or BITS. Three for letters OR plus A to Z, to expand the number of possible combinations, followed by six numbers for premise ID. That gives you 26 million premises IDs. The 9 individual ID digits or BITS gives you 999,999 Individual animal IDs. As you can see we already have examples of data bases that will work and are supposed to be national data bases. They don't have to be just for cattle. What we have learned from application of these data bases is that each state has its own unique character. The bottom line is the data base should be kept at the state level to allow for the unique character, but flexible enough and with enough national standard to serve the broad and diverse needs.

Credibility and accessibility are the next key points to consider. In order to establish credibility with another state, nation, government or enforcement agency you must involve those recognized channels. The bottom line is we must form a partnership, industry and government, using the infrastructure already in place. The connection of local private activity, to county activity, to state activity must be accessible to the national/international community. The place to start I believe is with the State Animal Disease/Industry Division.
Government Agencies currently view animal identification as the cornerstone for many of their regulatory functions. Industry's response to this was a request for a common voice from Agencies such as APHIS, FDA, FSIS, and GIPSA regarding their livestock identification needs. This voice would provide industry guidance in developing new systems which would meet future needs for improved animal identification.

On August 23, 1995, individuals from the four listed agencies met to discuss their livestock identification needs and to agree on the concept of one regulatory voice for animal identification needs. This meeting provided insight on both the unique and common livestock identification needs of the represented Agencies. Some of these identification needs are: accurate identification of livestock for disease control and movement of livestock in international trade, by APHIS; traceability of carcasses for residues and food safety by FSIS and FDA, and personal accountability for livestock by APHIS, FDA, FSIS, and GIPSA. The meeting's goal of developing one governmental voice on livestock identification needs will be met. The following definitions should help in meeting the Agencies' needs:

- **Livestock identification systems**: government or industry-funded systems that provide accessible databases with trace back capabilities either by premises or unique animal identification. These systems will also provide for personal accountability of actions involving livestock movements.
- **Premises of origin**: Any farm or other premises where livestock were born or where they have been kept for 4 months or more before the date of shipping, provided no other livestock as been commingled during the last 4 months period.
- **Records**: Information sufficient to satisfactorily trace back livestock to their herd of origin. The records must be kept for a minimum of 2 years.
- **Personal accountability of actions**: Person responsible for making decisions in the handling of livestock. Example, Person who authorized extra label use of medication in feed.

The government realizes that animal identification has not significantly
changed in last 30 or so years. We still rely on eartags, backtags, tattoos, and brands to provide the means to trace diseased livestock to their premises of origin. As we reach the final stages of brucellosis, pseudorabies, and tuberculosis eradication we cannot afford to become complacent in our efforts to trace the final vestiges of disease. Improved accountability is needed if we are going to indeed find the last pseudorabies, tuberculosis or brucellosis infected herd. We may need to consider identification changes that will enhance the development of national premises identification systems. These systems should provide a means to rapidly trace animals to their premises of origin.

These premises identification systems in the future must meet the needs of animal ID for disease control, quality assurance programs, and food safety. These systems will utilize new technologies such as, electronic implants, bar coded eartags, GIS tracking systems and personalized information on plastic tags identifying the premises of origin.

These premises identification systems would be driven by state assigned premises identification codes conforming to a standard format that would allow the animals to be identified by the producer in such a way as to allow the trace back through marketing channels for ownership or epidemiological purposes.

These systems would allow the producer to be assigned a premises identification number by the State Animal Health Official or the Area Veterinarian in Charge. Premises identification will consist of two parts; (1). a two-letter state abbreviation, followed by (2). a 3-4 digit identification number assigned to the individual premises of the owner. A premises in Iowa could be identified as IA0001. Additional digits could be used to provide for identification of individuals. Thus the next line could be a number assigned to the individual animal, (1234).

The premises identification number and the individual animal number may be utilized with the following methods of animal identification:

1. Plastic ear tags or metal ear tags: The premises identification will be printed on the tags at the time of manufacture. You may also include a number for individual identification.

   first line IA0001 = premises ID
   second line 1234 = individual ID

2. Tattoos. The premises identification number would be placed in the left ear with the individual identification number placed in the right ear.

   Left ear tattoo = IA0001
   Right ear = 1234

The use of individual animal ID numbers could provide the producer with an unique ID number for production records. Also, the use of premises identification tattoos or eartags would provide the producer another method to officially identify livestock back to the premises of origin.

Advantages of premises identification systems:

1. Producer applied.
LIVESTOCK IDENTIFICATION

2. Low cost.
3. The premises ID system is an option that the producer may select over official metal eartags applied by an accredited veterinarian.
4. Provides for rapid trace backs to the premises of origin.
5. Allows for more than one method of identification.
6. The premises identification number could be used by the producer for all livestock located on the premises.
7. Minimum information on the movements of livestock needed for accurate accountability of the animal / carcass in question.
8. Provides for a high percentage of animals correctly identified.
9. At present the databases will be located in the State Animal Health Officials office. The State will maintain these numbers and all related information pertaining to the premises in a database (for trace back purposes) Just, name, premises ID number, Location. Address, and types of species on premises.

Drawbacks of a premises identification system for livestock:
1. Have to restrain the animal to apply and read tattoos or small ear tags.
2. Must contact the State Animal Health Official to get an Approved premises identification number assigned.
3. Still have to record transactions when animals move.

Before we change identification systems we need to be sure that the livestock industry supports the implementation of these changes and that it meets the needs of today as well as the future. Any change will have widespread ramifications to industry such as cost, record keeping and possibly new regulations. At present the Pathogen Reduction Act has been introduced in both the House and Senate. This bill will require the ID of All livestock at slaughter and records kept to identify the animal back to the premises of origin.

Dr. G. A. “Bert” Mitchell
Food and Drug Administration
Director, Office of Surveillance and Compliance

Dr. Mitchell gave an update on the status of electronic identification implant patitions.
REPORT OF THE COMMITTEE ON NOMINATIONS AND RESOLUTIONS

Chairman: Dr. Thomas J. Hagerty, St. Paul, MN

Dr. J. Lee Alley, AL; Mr. J. B. Finley, TX; Dr. R. D. Hull, IL; Dr. J. P. Quigley, GA; Dr. J. C. Shook, PA; Dr. P. L. Smith, CA; Dr. M. A. Van Buskirk, PA; Dr. R. D. Willer, AZ; Dr. E. W. Zirkle, NJ.

PRESIDENT .......................................................... M. R. MARSHALL, UTAH

PRESIDENT-ELECT ....................................... L. L. WILLIAMS, NEBRASKA

FIRST VICE-PRESIDENT ....................... J. W. BRYAN, SOUTH CAROLINA

SECOND VICE-PRESIDENT ....................... R. H. McCAPES, CALIFORNIA

THIRD VICE-PRESIDENT .............................. E. W. ZIRKLE, NEW JERSEY

TREASURER ............................................. J. C. SHOOK, PENNSYLVANIA

Regional Delegates

Northeast.................................................. Robert Eckroade, Pennsylvania
........................................................................ V. P. LaBranche, Massachusetts

North Central ............................................................... D. D. Gingerich, Iowa
................................................................................ L. Lodoen, North Dakota

South ......................................................................... W. C. Baisley, Georgia
........................................................................................ M. C. Turner, Texas

West ........................................................................... O. H. Timm, California
...................................................................................... DeLoyde Satterthwaite, Nevada

RESOLUTION NUMBER: 1

SOURCE: COMMITTEE ON RABIES

SUBJECT MATTER: SUPPORT AND ENCOURAGES ORAL RABIES VACCINATION PROGRAMS IN WILDLIFE

The United States Animal Health Association supports and encourages oral rabies vaccination programs in raccoons in the Eastern States, and in Texas for the control of rabies in coyotes and gray fox.
REPORT OF THE COMMITTEE

RESOLUTION NUMBER: 2
SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF HORSES
SUBJECT MATTER:  U.S. IMPORT QUARANTINE STATIONS FOR HORSES

USAHA urges denial by USDA of the establishment of permanent entry private quarantine stations for horses and other equids entering the U.S.

RESOLUTION NUMBER: 3
SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF HORSES and COMMITTEE ON ANIMAL WELFARE
SUBJECT MATTER:  EQUINE PIROPLASMOSIS - 1996 OLYMPIC GAMES

USAHA continues to support the current prohibition of the entry of "piro"-infected horses, including the granting of waivers for "piro" requirements for imported horses.

RESOLUTION NUMBER: 4
SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF HORSES
SUBJECT MATTER:  EQUINE INFECTIOUS ANEMIA - U.S. CONTROL PROGRAM

USAHA urges the USDA to facilitate the development of a more uniform control program for EIA.

RESOLUTION NUMBER: 5
SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE
SUBJECT MATTER:  DEVELOPMENT OF A TRICHLINA CERTIFICATION AND TESTING PROGRAM

USAHA urges USDA to expand the National Trichinae Research Project to conduct a national trichinae prevalence survey of breeding and market swine, evaluate "at risk" swine populations, develop regional and herd certification pilot projects, and gain international acceptance of U.S. trichinae testing methodology.

RESOLUTION NUMBER: 6
SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE
SUBJECT MATTER:  SWINE HEALTH MONITORING

The USAHA urgesAPHIS to develop, in cooperation with USAHA, an ongoing surveillance program for diseases of high priority to the pork industry,
NOMINATIONS AND RESOLUTIONS

report on their national incidence, prevalence, geographic distribution and trends, and develop economic models based on optimal level of diseases.

RESOLUTION NUMBER: 7
SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE
SUBJECT MATTER: TRADE SURVEILLANCE

USAHA urges APHIS to work with OIE to develop methods to uniformly enforce disease reporting, surveillance and monitoring.

RESOLUTION NUMBER: 8
SOURCE: COMMITTEE ON FOREIGN ANIMAL DISEASES
SUBJECT MATTER: VESICULAR STOMATITIS

USAHA requests that USDA coordinate research efforts by government agencies, universities, and other private sources to study the epidemiology and control of Vesicular Stomatitis.

RESOLUTION NUMBER: 9
SOURCE: COMMITTEE ON FOREIGN ANIMAL DISEASES
SUBJECT MATTER: FOREIGN ANIMAL DISEASE PREPAREDNESS

USAHA requests USDA, APHIS to: 1) conduct a Regional Emergency Animal Disease Eradication Organization test exercise by predetermined teams including participation by Canada and Mexico; 2) to conduct a foreign animal disease laboratory diagnostic meeting between Canada, Mexico, and the USA to address standardization of technologies and related topics; and 3) to pursue establishment of an electronic communication system for foreign animal disease related issues between Canada and the United States.

RESOLUTION NUMBER: 10
SOURCE: COMMITTEE ON EPIZOOTIC ATTACK AND COMMITTEE ON FOREIGN ANIMAL DISEASE COMMITTEE
SUBJECT MATTER: NADC, NVSL, FADDL, and PIADC

USAHA requests that USDA maintain its focus on quality diagnostic capability and that adequate resources be allocated to the nation’s animal disease research and diagnostic infrastructure including the training and retention of quality personnel, facility maintenance and upgrade and adequate operating funds.
REPORT OF THE COMMITTEE

RESOLUTION NUMBER: 11
SOURCE: COMMITTEE ON FOREIGN ANIMAL DISEASES
SUBJECT MATTER: SCREWWORM PRODUCTION FACILITY

USAHA requests that USDA urgently identify the resources necessary to assure the building of a new sterile screwworm production facility in Panama as soon as possible.

RESOLUTION NUMBER: 12
SOURCE: COMMITTEE ON ANIMAL WELFARE
SUBJECT MATTER: HORSE WELFARE RESEARCH FUNDING

USDA make available funds necessary to support and complete an objective study of the welfare of horses being transported to slaughter.

RESOLUTION NUMBER: 13
SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES
SUBJECT MATTER: AVIAN INFLUENZA TESTING REAGENTS

USAHA strongly urges that the NVSL of APHIS continue to provide the high quality reagents at no cost to the testing laboratories.

RESOLUTION NUMBER: 14
SOURCE: COMMITTEE ON BRUCELLOSIS
SUBJECT MATTER: BRUCELLOSIS STATUS WITH FREE ROAMING BISON

The U.S. Animal Health Association requests that USDA, APHIS, VS downgrade a state’s brucellosis Class Free status to Class A if infected or exposed bison are allowed to roam free in the state. In addition, cattle that graze with infected or exposed bison shall be tested and found negative for brucellosis prior to change of ownership. If no change in ownership occurs, cattle shall be tested and found negative within 45 to 120 days after grazing with infected or exposed bison.

RESOLUTION NUMBER: 15
SOURCE: COMMITTEE ON BRUCELLOSIS
SUBJECT MATTER: BISON BRUCELLOSIS IN THE GREATER YELLOWSTONE AREA

The United States Animal Health Association recommends the eradication of brucellosis from the bison and elk populations in the Greater Yellowstone Area, and further supports legislation that accomplishes the following:
NOMINATIONS AND RESOLUTIONS

- Eradication of brucellosis in bison and elk in the Greater Yellowstone Area by December 31, 1998.
- Identifies USDA, APHIS, VS as the lead agency in the eradication effort.
- Provides necessary funding to accomplish the goal of eradication.
- Requires USDA, APHIS, VS to collaborate with state animal health officials in Idaho, Montana, and Wyoming, and other agencies comprising the Greater Yellowstone Interagency Brucellosis Committee in the eradication effort.
- Realizes the objectives contained in the Memorandum of Understanding of the Greater Yellowstone Interagency Brucellosis Committee.

RESOLUTION NUMBER: 16
SOURCE: COMMITTEE ON BRUCELLOSIS
SUBJECT MATTER: COMPREHENSIVE PLAN FOR COMPLETING THE ERADICATION OF SWINE BRUCELLOSIS

USAHA urges that USDA, APHIS, VS develop and implement, in concert with the states, a comprehensive plan for completing the eradication of swine brucellosis from the U.S. These plans should include risk-based surveillance, protocols for vaccine usage and the availability and use of indemnity funds. USAHA further urges that APHIS request adequate swine brucellosis program funding to allow for improved program direction and administration.

RESOLUTION NUMBER: 17
SOURCE: COMMITTEE ON BRUCELLOSIS
SUBJECT MATTER: SWINE MOVEMENT FROM VALIDATED FREE STATES

USAHA urges individual states to accept validated free state status for interstate movement of swine and not to require testing of the herds from which the animals come.

RESOLUTION NUMBER: 18
SOURCE: COMMITTEE ON WILDLIFE and COMMITTEE ON BRUCELLOSIS
SUBJECT MATTER: BRUCELLA NEOTOMAE VACCINATION TRIAL FOR WILDLIFE IN THE GREATER YELLOWSTONE AREA (GYA)

USAHA urges USDA, APHIS to support research utilizing Brucella neotomae as a potential vaccine for the control of brucellosis in the Greater Yellowstone Area (GYA). This research can be concurrent with other vaccine research projects.
REPORT OF THE COMMITTEE

RESOLUTION NUMBER: 19
SOURCE: COMMITTEE ON CAPTIVE WILDLIFE AND ALTERNATIVE LIVE- STOCK
SUBJECT MATTER: USDA IMPORT QUARANTINE CENTERS

USAHA urges that all present quarantine facilities be maintained and that they continue to maintain standards that would meet USDA's commitment to the humane care of animals under their charge. Improved standards should be developed in collaboration with individuals knowledgeable of the species to be quarantined.

RESOLUTION NUMBER: 20 & 23
SOURCE: COMMITTEE ON IDENTIFICATION and COMMITTEE ON PSEUDORABIES
SUBJECT MATTER: NATIONAL PREMISES IDENTIFICATION

USAHA urges USDA, APHIS, and state animal health officials to coordinate the development and implementation of a National Premises Identification system in cooperation with the other stakeholders. USDA, APHIS should work with state animal health officials to develop the guidelines for assigning the premises numbers by January 1, 1996. In addition, USDA, APHIS should coordinate changes in regulations, notices, and memoranda to allow the system to proceed by April 1, 1996.

RESOLUTION NUMBER: 21
SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES
SUBJECT MATTER: POULTRY IMPORT/EXPORT

USAHA recommends that APHIS Import/Export Staff work with the Transmissible Diseases of Poultry subcommittee on Import/Export in continued negotiations regarding poultry and poultry products.

RESOLUTION NUMBER: 22
SOURCE: COMMITTEE ON BLUETONGUE AND BOVINE RETROVIRUS
SUBJECT MATTER: HARMONIZING ANIMAL IDENTIFICATION FOR CATTLE HERDS FOR VARIOUS CONTROL AND ERADICATION PROGRAMS

USAHA should amend Section II B of the "Standards for Certification of Cattle Herds as Bovine Leukosis Virus Free" by adding the following as the second sentence in the paragraph: Official identification as described in Title 9 Code of Federal Regulations is permissible.
RESOLUTION NUMBER: 24
SOURCE: COMMITTEE ON PSEUDORABIES
SUBJECT MATTER: IDENTIFICATION OF FEEDER PIGS IN INTERSTATE COMMERCE

The USAHA requests USDA, APHIS to make the necessary changes in CFR 9 to allow for the interstate shipment of feeder pigs from a Stage III or higher area or state with no change of ownership to move to nurseries and grow-out premises on a health certificate without individual animal identification.

RESOLUTION NUMBER: 25
SOURCE: COMMITTEE ON PRV
SUBJECT MATTER: PRV TEST FOR CULL SOWS AND BOARS

USAHA requests of USDA-APHIS that the Gp1 PRV test be used as the primary test on blood samples collected from cull sows and boars at slaughter in PRV surveillance.

RESOLUTION NUMBER: 26
SOURCE: COMMITTEE ON PROFESSIONAL OVERSIGHT
SUBJECT MATTER:

USAHA supports specific distribution of Federal funds to States for ensuring meat and food safety.

RESOLUTION NUMBER: 27
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: REFERRAL TO SCIENTIFIC ADVISORY COMMITTEE

USAHA recommends that USDA accumulate the results as previously requested relating to SCT, CCT and BTB and culture test results in cervidae and provide that information to the USAHA Tuberculosis Committee Scientific Advisory Subcommittee as soon as possible.

RESOLUTION NUMBER: 28
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: ROLE OF BI-NATINAL COMMITTEE

USAHA requests that USDA/APHIS/VS expand responsibilities of the U.S./Mexico Bi-National Committee to include the disease brucellosis. The revised committee would be known as the U.S./Mexico Bi-National Tuberculosis and Brucellosis Committee, and should include the chairperson of the USAHA Brucellosis Committee.
REPORT OF THE COMMITTEE

RESOLUTION NUMBER: 29
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: VOLUNTARY INSPECTION OF EXOTIC ANIMALS

The United States Animal Health Association recommends that USDA-FSIS treat inspection of all hoofstock in the same manner, rather than charging for Voluntary Inspection Service for exotic animals (Meat and Poultry Regulations Part 352 - EXOTIC ANIMALS; VOLUNTARY INSPECTION) in order to encourage non-traditional hoofstock owners to use this service.

RESOLUTION NUMBER: 30
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: DESIGNATED TUBERCULOSIS EPIDEMIOLOGIST/CHANGE - TUBERCULOSIS ERADICATION, CERVIDAE UNIFORM METHODS AND RULES (UMR CERVIDAE)

USAHA requests USDA to modify the TB Uniform Methods and Rules for Cervidae (UMR Cervidae) to provide the following definitions and prescribe the responsibilities and authority of Designated Tuberculosis Epidemiologists.

Definitions:

Designated Tuberculosis Epidemiologist—an epidemiologist who has demonstrated the knowledge and ability to perform the functions required under the standards of the Tuberculosis Eradication in Cervidae Uniform Methods and Rules. The Designated Tuberculosis Epidemiologist must be selected jointly by the cooperating State animal health official, the Area Veterinarian in Charge (AVIC), and the Regional Tuberculosis Epidemiologist.

Individual Herd Plan—a written disease management plan that is designed by the herd owner, the owner's veterinarian if requested, a Designated Tuberculosis Epidemiologist, and approved by the State Veterinarian and AVIC to eradicate tuberculosis from an affected herd. The herd plan will prescribe appropriate herd test frequencies, tests to be employed and any additional disease or herd management practices deemed necessary to eradicate tuberculosis from the herd in an efficient and effective manner.

Responsibility and Authority of the Designated Tuberculosis Epidemiologist—The Designated Tuberculosis Epidemiologist has responsibility to determine the scope of epidemiological investigations, assist in development of individual herd plans and to coordinate disease surveillance and eradication programs within their geographic responsibility. The Designated Tuberculosis Epidemiologist has authority to make independent decisions concerning the use and interpretation of diagnostic tests and management of affected
NOMINATIONS AND RESOLUTIONS

herds when those actions are supported by sound disease eradication principles.

RESOLUTION NUMBER: 31
SOURCE: COMMITTEE ON THE INFECTIOUS DISEASES OF CATTLE, BISON, AND LLAMA
SUBJECT MATTER: VESICULAR STOMATITIS

USAHA recommends that each State adopt the following recommendations regarding vesicular stomatitis:

1. The State veterinarian in an affected State will immediately quarantine any premises where infected animals are located.
2. The State veterinarian will immediately conduct an epidemiologic investigation to determine if any other premises or area will be included in the quarantine.
3. No livestock under quarantine will be released for a minimum of 30 days after the last lesion has healed in any and all livestock.
4. Other livestock not under quarantine in an affected State should be allowed to move interstate when the State veterinarian in the receiving State determines that circumstances are adequate to protect introduction of vesicular stomatitis.

RESOLUTION NUMBER: 32
SOURCE: COMMITTEE ON THE INFECTIOUS DISEASES OF CATTLE, BISON, AND LLAMA
SUBJECT MATTER: ENDOTOXINS IN VACCINES

USAHA requests USDA, APHIS require that a label of veterinary biologicals provide information regarding endotoxin content and that USDA, APHIS establish a task force of USDA, universities, scientists, and vaccine manufacturer representatives to study the issue of vaccine safety.

RESOLUTION NUMBER: 33
SOURCE: COMMITTEE ON IMPORT/EXPORT
SUBJECT MATTER: THE NORTH WEST PILOT PROJECT

USAHA urges USDA to review import regulations for tuberculosis and brucellosis, and amend the Canadian import requirements based upon current science.

RESOLUTION NUMBER: 34
SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA
SUBJECT MATTER: IMPORTATION OF EMBRYOS

USAHA urges APHIS/USDA to amend the proposed regulation and 9CFR
part 98 to specifically provide that compliance with conditions now specified for importation of embryos from *Bos Indicus* and *Bos Taurus* cattle shall be validated for all other proposed species by USDA veterinarians, through prior on-site inspection, surveillance and certification of all personnel, procedures, processes, methods and facilities utilized by exporters to assemble, process and prepare embryos for export to the United States, so as to minimize the threat of any potential breakdown in compliance by foreign countries or exporters who may willfully or otherwise cause shipment of embryos to create an outbreak of a foreign animal disease in the United States, and

USDA/APHIS should establish a credible system to continuously validate the compliance of exporters of embryos and germ plasm to the United States, so as to significantly minimize the potential threat of terrorism.

**RESOLUTION NUMBER: 35**  
SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON AND LLAMA  
SUBJECT MATTER: BRUCELLOSIS RESEARCH TO EVALUATE THE SENSITIVITY AND SPECIFICITY OF THE DIAGNOSTIC TESTS AND THE PATHOGENICITY OF BRUCELLA FOR LLAMAS AND ALPACAS

USAHA requests that APHIS and ARS approve funding for research studies using statistically significant numbers of animals to evaluate the sensitivity and specificity of the diagnostic tests and the pathogenicity of brucella for llamas and alpacas.

**RESOLUTION NUMBER: 36**  
SOURCE: COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY  
SUBJECT MATTER: VETERINARY BIOLOGICS

USAHA supports the current Veterinary Biologics Regulatory System governed by Title 9 of the Code of Federal Regulations (9 CFR) and to urge APHIS to take immediate action to secure a Mutual Recognition Agreement (MRA) based on equivalence, appropriate risk assessment and final product testing for purity, potency, safety and efficacy.

**RESOLUTION NUMBER: 37**  
SOURCE: COMMITTEE ON SALMONELLA  
SUBJECT MATTER: COMMITTEE ON SALMONELLA SEROTYPING

USAHA requests that NVSL and CDC present a yearly report at the USAHA Salmonella Committee Meeting of serotypes isolated from animals and humans, respectively. NVSL and CDC should each designate a scientist to travel to the USAHA Meeting for such purpose and fund expenses incurred for such travel.
REPORT OF THE COMMITTEE ON
PARASITIC DISEASES AND PARASITICIDES

Chairman: Dr. William E. Pace, Tallahassee, FL
Vice Chairman: Dr. Bob H. Bokma, San Juan, PR

Dr. L. G. Biehl, IL; Dr. Roger O. Drummond, TX; Dr. Thomas J. Galvin, TX; Dr. Thomas J. Holt, NY; Dr. Julie Ann Jarvinen, IA; Mr. Ralph D. Jones, SD; Dr. Sidney E. Kunz, TX; Dr. Larry F. Moore, OK; Dr. J. E. Novy, APO, AA; Dr. Richard E. Omohundro, AZ; Dr. Phillip A. Pickerill, TX; Dr. Robert L. Pyles, NM; Dr. Jack L. Schlater, IA; Dr. M. G. Scroggs, TX; Dr. James E. Strickland, GA.

The committee met at 1:30 PM on Monday, October 30, 1995. Total attendance at the session was 18 with 12 of the 17 committee members present.

Dr. Chester Gipson gave a status report on the Puerto Rico tick eradication program. This program has been a cooperative effort of the U.S. Department of Agriculture and the Commonwealth of Puerto Rico. Objective of the program has been eradication of the southern cattle tick, Boophilus microplus. The program has also successfully eliminated foci of Amblyomma varigatum, the tropical bont tick. The program was initiated in 1979 but efforts have not been successful, primarily due to quality of whole-body-spray treatments, illegal movement of cattle and the lack of united industry commitment. During the past fiscal year, Congress supported conclusion of program management and passing administration to the Commonwealth. Current indications are that the roughly 5,000 infected herds will continue under treatment in order to prevent outbreaks of piroplasmosis. Future of eradication efforts is uncertain.

Dr. John Wyss reported on the status of the screwworm eradication program in Central America. Belize and Guatemala were declared "Free" in May 1995, El Salvador in June 1995 and Honduras in October 1995. Efforts in Nicaragua have reduced the number of cases too less than 25 per week. Activities in Costa Rica and Panama are under development. Dr. Wyss also commented on the large number of human cases which have previously been experienced and that some 40% of those were fatal.

Dr. Jack Schlater reported on tick identification done at the National Veterinary Services Laboratories during the past 12 months (Oct. 1, 1994 to Sept. 30, 1995) from reptiles imported into Florida. In the 150 collections identified, there were 18 species of ticks on 48 species of reptiles from 17 countries. One of these tick species (Amblyomma rotundatum) has been reported as established in Florida. Three of the tick species identified (Amblyomma marmoreum, A. sparsum, and A. dissimile) are capable of trans-
mitting heartwater (Cowdria rumenanti). One of the hosts, the leopard tortoise, has been reported to harbor subclinical heartwater infections.

Dr. Roger Drummond presented highlights from the 39th Annual Livestock Insects Workers Conference held at French Lick, Indiana July 10-13. Preceding the program there was a workshop on livestock IPM (Integrated Pest Management). There were presentations on control of ticks on cattle—the Gulf coast tick is increasing rapidly in Oklahoma. IPM controls filth flies in dairies in New York State. Poultry producers in North Carolina use IPM, but solutions are needed for litter beetles. IPM is used to control filth fly problems in Nebraska feedlots. As usual, all papers presented in the conference were abstracted in a book handed out to attendees. Presentations were informal and there was time for discussion. Sessions included beef and dairy cattle, poultry, swine and miscellaneous pests. Presentations included feeding of stable flies on many hosts in Kansas; the Gulf coast tick is spreading in Kansas (with an increase in gotch ear in calves); livestock pest control practices in Chile and Argentina; the problem with Nosema infections in pupal parasites released at feedlots; use of permethrin-treated meat to control yellow jackets attacking dairy cows in Israel; the importance of ectoparasite control in good, profitable beef cattle production systems in the south; control and reduction of pyrethroid resistance in horn flies with alternative control technologies; management of pH to stabilize pyrethroids in dipping vats for extended use in cattle tick control on the US border; and a variety of other subjects. Of special interest was the active participation by the insecticide industry. Bayer introduced Cylence pouron (cyfluthrin) for cattle. Hoechst-Roussel Agri-Vet introduced Point Guard pouron (amitraz) to control lice and mange mites on swine. Mallencrodt introduced 2 lambda-cyhalothrin products—Saber pouron for cattle and Grenade WP for premises. Y-Tex introduced Brute pouron (permethrin) and a Warrior ear tag that contains 30% diazinon and 10% chlorpyrifos.

Dr. Drummond also presented highlights from the Third International Symposium on Ectoparasites of Pets which was held in College Station, TX, sponsored by the Department of Entomology and School of Veterinary Medicine. Participants presented papers on a variety of subjects. In the Exotic Pets Session, scabies on pot bellied pigs was a problem for pigs and owners. The problem with mites on snakes and other reptiles is increasing as the number of these pets increases yearly (80,000 bald pythons imported last year). In the Flea session, wild reservoirs of fleas in the urban environment makes flea control very difficult. Treatment of lawns with a steinernematid nematode is available even though it kills 11 orders of invertebrates. In the Tick and Biting Fly Session, brown dog ticks were reported to be active at night when humidities are higher. The Protick Remedy was the most effective of several devices evaluated for removing ticks. In the Ectoparasites of Horses Session, the arthropod-born diseases of horses in east Texas were reviewed, but little new information was presented. In the Industry Session, highlights were the new
poueron of Amitraz for mites and lice on pigs and the registration of lufenuron (now described as an insect development inhibitor (IDI)) as an oral treatment for cats. In the Veterinary and Pest Control Session, problems with flea allergy dermatitis and control of fleas were discussed—an estimated $850 million/year is spent on pesticides for pets—85% is over the counter. A computer tutorial for PCOs on flea control was presented. In the Research Methods Session, house dust mite problems and control were reviewed. Various techniques to evaluate testing techniques to control fleas on dogs and to laboratory test flea toxicants were reviewed. The meeting was attended by over a hundred interested persons and a proceeding will be available this fall. The next meeting is scheduled for April, 1997, in Riverside, CA.

Dr. David Wilson provided an update on eradication of the tropical bont tick in the Caribbean. The basic efforts are aimed at control of heartwater disease which is found on several islands and with eradication of *Dermatophilus congoensis* which is widespread throughout the Caribbean. Dr. Wilson showed data which correlates emergence of the tick on new islands with the number of breeding colonies of cattle egrets found on the islands. Significance here is that egrets banded on these islands have later been found in Florida. This program is a cooperative effort of FAO, IICA, and the USDA. Initially, plans were to direct first efforts toward increased surveillance and pilot eradication programs on four islands. Due to the heavy expense of direct surveillance, efforts have been directed more toward eradication. A corollary program on other islands is also underway with major input from the French government.

Dr. Sidney E. Kunz of the Knipling-Bushland U.S. Livestock Insects Research Laboratory reported on research at the Kerrville, Texas, laboratories. This laboratory, which will celebrate its 50th anniversary in 1996, was founded as a compilation of three laboratories in Texas in 1946. He discussed the mission of the laboratory which is to conduct research on the biology and control of insects, ticks, and mites of medical veterinary importance. The laboratory also has the mission of conducting research to support APHIS in its role to control exotic pests.

Dr. Kunz pointed out problems of re-registration which have led to the loss of compounds and the lack of registration of new compounds being developed for ectoparasite use. He indicated the extent of horn fly resistance throughout areas of the United States, Mexico, and Canada. To address the need for alternative controls to replace the classical insecticides that have been used, the laboratory is undertaking studies to develop vaccines. Vaccines have been developed against the cattle grub and are being developed against cattle scabies. Plans are being conducted to develop this technology to control biting flies.

Recently the laboratory was given the added mission to develop control technology for ticks on deer—the vector of Lyme disease. Corn treated with ivermectin has been very effective in controlling lone star ticks on deer being fed medicated corn. This technology was also used to control *Boophilus*
ticks on elk on a ranch in south Texas that eliminated the infestation of *Boophilus* ticks present since the 1950's. After treatment of these alternate hosts, cattle have been free of *Boophilus* ticks since 1992. Dr. Kunz also discussed the development of micro spheres that are being loaded with ivermectin. This technology was used to eradicate *Boophilus* ticks from test plots at Mission, Texas. Additional alternative control technology was discussed using pyrethroids to control ticks. This technology has been patented and looks very promising for the control of ticks in Lyme disease infested areas.

Laboratory personnel, in conjunction with ARS scientists in Beltsville, have found that by maintaining proper levels of pH in dipping vats, the microbial degradation of coumaphos into a more toxic form - potsan - can be eliminated. Additional studies also in conjunction with scientists in Beltsville have developed a microbial degradation system for coumaphos. This is especially important on disposal of dip vat materials which can be reduced to nontoxic materials.

Dr. Kunz also discussed the technology transfer activities amongst United States organizations and also the laboratory's role in technology transfer on the international scene.

Dr. P. A. Pickerill reported on the Cattle Fever Tick Eradication activities along the Mexican border. Highlights this past year included increased surveillance procedures and the successful resolution of an outbreak in the free zone. There is increasing concern regarding the status of one of the designated tick-free areas of Mexico. Nearly 50% of the cattle and horses apprehended in the quarantine zone adjacent to this area were found to be infested with ticks. Dr. Pickerill expressed concerns about bringing ticks into the country with hay originating from the area of questionable status.
I. RACING TO RESPOND TO THE PUBLIC'S VIEW OF GOVERNMENT

In the February issue of "The Atlantic Monthly", Peter. F. Drucker pointed out in his article on "Really Reinventing Government" that less than a fifth of American public trust government to do anything right. He also stated the public would vote against continuing two fifths, if not half, of all civilian agencies and programs and almost none of them would win a vote - that is, be deemed to be properly organized and operating well - by a large margin.

On February 12, 1995, the "Sacramento Bee" newspaper, the most liberal California newspaper with which I am familiar, headlined its editorial "Crossing Delaney." It stated the 1958 law, known as the Delaney clause, which sets a "zero risk" standard and tolerates no traces of a carcinogenic pesticide in processed food is unwarranted today because its assumptions are outdated. It spoke of expert findings that traces of certain pesticides in processed foods present no more than a negligible risk of cancer and recommend revision of the law to accommodate this new information. The editorial suggested that if the Environmental Protection Agency cannot lead on the issue, Congress should and chances are good that it will. Furthermore, it stated that Delaney should reflect what is scientifically known about human tolerance of trace amounts of pesticides, not the fears of the past.

On the very same day, February 12, 1995 and 3,000 miles to the east, the "New York Times" ran a story by Philip Hilts which was titled "F.D.A. Becomes Target of Empowered Groups." It stated the Food and Drug Administration (FDA) has become the first and biggest target in the push for deregulation and that conservatives seek to show that the agency is a prime example of what is wrong with federal regulation. Proposals to overhaul the agency vary, but all make a similar point "Delay in approving drugs is harmful, not only to patients, but to America's competitive edge." Reshaping the way government works, rather than making the agency more efficient is the motivation for change. Interestingly, it observed that traditional opponents of FDA, including representatives of the pharmaceutical industry, are uneasy about their new conservative bedfellows and concerned that their solutions could "create chaos" and end up "throwing the baby out with the bath water."

On March 4, 1995, President Clinton directed a memorandum entitled "Regulatory Reinvention Initiative" to heads of departments and agencies and directed them to focus on four steps: 1) Cut obsolete regulations - He ordered a page-by-page review of all agency regulations now in force and to eliminate or revise those that are outdated; 2) Reward results, not red tape - He directed
heads to change the way they measure performance so as to focus on results, not process and punishment; 3) Get out of Washington and create grass roots partnerships - Heads were directed to immediately convene groups of front line regulators and the people affected by their regulations in locations around the U.S.; 4) Negotiate, don’t dictat - He stated it was time to move to a process where people work in partnership to issue sensible regulations and directed heads to expand efforts to promote consensual rule making.

On April 6, 1995, Drucker’s perception of the public’s generally low esteem for government effectiveness was evident during a C-Span televised hearing of the Senate Labor and Human Resources Committee in which FDA Commissioner Donald Kessler announced additional regulatory changes at the agency to speed up the approval of low-risk human medical devices and to allow the export of unapproved human drugs and devices to foreign countries. In response, observed the April 7 edition of the "Wall Street Journal", several senators scolded FDA and urged even more sweeping changes. Senator Nancy Kassbaum, Chair of the Committee, indicated although the changes were common sense and long overdue, more changes were needed. She also asked whether the agency was looking into change in the animal drug approval process. Senator Judd Gregg (R. NH) said he hears frequent complaints from constituencies about a "culture of confrontation rather than cooperation" at the agency. Senator Barbara Mikulski (D. Md) warned Kessler that the agency needs to adopt a "culture of change" and "if you don't change, Congress will run right over you."

It seemed to me, as I watched C-Span, that Commissioner Kessler had hoped the changes he had proposed would be favorably received as evidence of FDA’s willingness to accommodate new ideas and to go the extra mile. Instead, the senators seemed to brush these aside as needed change, but peripheral to a more basic concern, and demanded sweeping change in the way FDA does business.

There seems to be an air in the country, as reflected by the President’s memorandum, the Senate hearing and the quoted articles that there is at least a four-way race between the Administration, Congress, liberals and conservatives to respond to the public’s disdain for our “old” federal government operations. One also senses that each of the four has differing idea or vision for “new government” and what change is needed (Figure I).

Speaker of the House Newt Gingerich addressed this issue directly in his national television address to the nation on April 8, 1995, by stating that the purpose of government is to improve the life of its citizens. But, he went on to say, something is not quite right today with regard to our federal government, that it is out of touch and in need of deliberate, deep change.

Drucker pointed out that taxpayers, that’s all of us here, are becoming more contemptuous of government and its promises and that neither maintaining nor curtailing it in its current state is acceptable. He further observed
that as the deficit explodes by 1997, the demand for cutting government may become irresistible, overwhelming congress, the bureaucracy and the lobbyists.

He goes on to state that the Vice President's plan to reinvent government is of little interest as these are the types of things we are all expected to do without fanfare or praise and that patching here, there and yonder never accomplishes anything. Instead, Drucker calls for a restructuring and rethinking of government, including the concept of continuous improvement and benchmarking all processes. This, he says, will require a definition of performance objectives, quality objectives and cost objectives and a definition of the results an agency is supposed to attain. A clear mission is required as well as the agreement that it useful and worth carrying our.

II. CLEAR VIEW OF CENTER FOR VETERINARY MEDICINE OBSCURED BY ISSUES, PERCEPTIONS AND EXPERIENCES

The veterinary profession must be actively involved in any process of deliberate and deep change involving the CVM from the onset. And to do so, we must have a clear vision of what the results of such change should be. To start this process, it is perhaps instructive to examine the mission and function of the CVM today.

For many, a clear view of the CVM's mission and operations is obscured by an opaque cloud of immediate issues, conflicting perceptions and experiences and which belies the agency's actual structure, function and interaction with constituencies (Figure 2). It is, for example, likely that our view of the CVM is influenced by the widespread public disdain about federal government effectiveness in general, as well as by personal experience. How can this not be the case?

In 1995, a critical issue clearly visible in the cloud (Figure 2) is the lack of legal therapeutic options for use in animals. For the individual, it is a time consuming and often baffling exercise to grope through this opaque cloud in an attempt to arrive at a complete understanding why this is so. And yet, the understanding of such issues is the prerequisite for effective involvement and leadership in this accelerating era of change, which will inevitably involve the CVM and, ultimately, the practice of veterinary medicine.

Over the years as a poultry clinician, I have attempted to work my way through the cloud and have come to view the CVM as an agency made up of three basic components: 1) the Federal Food Drug & Cosmetic Act (FFDCA); 2) the FFDCA regulations pertaining to animals and; 3) a structured, mission-oriented bureaucracy. These components, in turn, define and shepherd three activities: 1) new animal drug evaluation; 2) surveillance & compliance and; 3) research (Figure 3).

The CVM, in relation to poultry, interacts, to one degree or another, with at least six primary external constituencies (Congress, Administration, veterinary profession, pharmaceutical industries, poultry industries, consumer
groups and public opinion) who, in turn, interact with each other (Figure 3). The din of diverging views emanating from these first and second tier external interactions contributes to the opaqueness of the cloud surrounding the CVM. It is this din of interactions, however, that brings about change to both the components and the activities of the CVM. For this reason, it is important that these interactions be effective as well as appropriate.

III. SOME OF THE REASONS CONTRIBUTING TO A LACK OF LEGAL THERAPEUTIC OPTIONS AND OTHER ISSUES

A. CVM's Mission

The CVM was renamed in 1984, superseding the Bureau of Veterinary Medicine, and is one of six centers within the FDA, which in turn, is a part of the U.S. Public Health Service. It has a staff of approximately 270 and an annual budget in the neighborhood of $40 million.

The FDA is a principal consumer protection and regulatory agency charged with enforcing federal laws involving food, drugs, medical devices and cosmetics as set forth in the FFDCA. Within this framework of consumer protection and regulation, the CVM operates with a new mission statement as follows:

CVM Mission Statement - "The CVM is a public health organization that enables the marketing of effective animal drugs, feed additives, feed ingredients, and animal devices that are safe to animals, humans and the environment. We, in partnership with federal and state agencies and other center customers, ensure animal health and the safety of food derived from animals. We make timely, quality decisions and take regulatory actions to ensure that these products provide for quality health care of animals, minimize the transmission of zoonotic diseases, and increase efficiency of production of animal-derived food and fiber. To support our decisions, we perform research, monitor product safety and efficacy, and continually strive to improve the quality of our processes."

It is important for all of us to recognize that the safety aspects of CVM's mission has three objectives, the protection of human health, the environment and animal health. And the mission clearly states that first and foremost, the CVM is a public health organization. This triple-objective safety mission and legislated tilt towards public health adds complexity to consideration of new animal drug proposals and is a factor in the lack of legal therapeutic options. As we consider ways to address this issue, it is important to recognize that the CVM will always first consider any new animal drug approval in light of its potential impact on public health.

As veterinarians, we understand a mission balanced between animal and public health as it is clearly a part of our veterinary oath (see below). On the other hand, many are probably not as focused or conversant on the environmental safety objective. I'm certainly not. And the environmental safety issues may very well be a growing factor in the lack of therapeutic options.

The Veterinary Oath - "Being admitted to the profession of veterinary
medicine, I solemnly swear to use my scientific knowledge and skills for the benefit of society through the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge. I will practice my profession conscientiously, with dignity, and in keeping with the principles of veterinary medical ethics. I accept as a lifelong obligation the continual improvement of my professional knowledge and competence."

B. Federal Food Drug and Cosmetic Act (FFDCA)

The current FFDCA was enacted in 1938 and, for the first time, manufacturers were required to provide evidence of product safety before distributing new drugs. The Durham-Humphry Amendment of 1951 required the use of physician prescriptions for certain types of drugs and led to the veterinary prescription regulations. The Food Additive Amendments of 1959 expanded authority over animal food additives and drug residues in animal-derived food. The Kefauver-Harris Amendments of 1962 authorized FDA to monitor clinical trials and, for the first time, manufacturers were required to test new drugs for effectiveness as well as safety before they could be cleared for marketing. It also required retroactive efficacy testing for drugs previously tested for safety alone and reporting adverse effects of drugs on the market. In 1968, the FFDCA was amended to include a new "Section 512 - New Animal Drugs" which consolidated and revised the law to ensure that animal drugs were safe and effective for their intended uses and that they do not result in unsafe residues in foods from treated animals. In 1994, the Animal Medicinal Drug Use Clarification Act (PL 103-396) amended the FFDCA to provide veterinarians the ability to utilize, under certain conditions, drug treatment regimes for which no approved drug label exists (extra-label use).

The 1938 FFDCA and the 1951, 1959 and 1962 amendments placed increasing restrictions on the approval of drugs to be marketed. Of particular interest to us today is the 1962 legislation which required prospective and retrospective efficacy testing for new drug approval and provided for monitoring of clinical field trials. The effects of the retroactive efficacy testing requirement of 1962 is being felt in 1995 by the removal from market of drugs, such as penicillin and streptomycin or dihydrostreptomycin combinations in 1993. In the case of these drugs, my understanding is that the manufacturers voluntarily chose to withdraw these drugs from the market and not to submit the necessary retroactive efficacy information.

The 1962 requirement for prospective efficacy testing as part of the New Animal Drug Approval process, and in particular, the requirement for clinical field trials is a major issue of debate in 1995 in relation to lack of legal therapeutic options. Legislation is being proposed to eliminate clinical field trials as a required part of efficacy testing.

The 1968 amendment to the FFDCA ushered in the issue of extra-label use of animal drugs by making it illegal for anyone, including veterinarians, to
THE CENTER FOR VETERINARY MEDICINE

utilize new animal drugs for any use other than explicitly permitted on the label. The 1994 Animal Medicinal Drug Use Clarification Act amendment was passed to repeal the 1968 extra-label use restrictions on veterinarians and to allow such use.

The 1994 Animal Medicinal Drug Use Clarification Act is a landmark amendment of the FFDCA as it is a roll-back of a previous law, not unlike the call for a roll-back of outdated law by the "Sacramento Bee" regarding the Delaney clause. Prior to 1994, amendments to the FFDCA, in relation to animals, had generally been to add additional restriction, requirements and regulations. The 1994 legislation is a shift to repeal prior restriction on the use of animal drugs is quite extraordinary and perhaps the beginning of a trend.

C. Interaction with and among constituencies

As pointed out above, constituencies views and understanding of the CVM can be clouded and incomplete (Figure 2) and the two tiered interaction of constituencies with the CVM and among themselves creates a din of often divergent views difficult for any one person to fully comprehend (Figure 3). Both of these situations can result in ignorance of and slower progress toward solutions of issues of common concern, such as lack of legal therapeutic options for animal treatment. The complexity of the interactive system, which inevitably brings change to CVM, dictates that an enormous effort must be expended by the CVM and all its constituencies to develop and maintain effective, appropriate relationships.

Einstein, as I recall, pointed out something to the effect that the appearance of things is relative to the location of the observer. Stretching this metaphor, it is likely that the CVM itself has a "clouded" view of some of its constituencies similar to that seen in Figure 2. How clear CVM views and understands the poultry industries, for example, is quite important in its assessment of needs, priorities, etc.. Likewise, how Congress views the poultry industries and the veterinary profession is similarly important in regard to issues, such as lack of legal therapeutic options for the treatment of animals.

D. Performance of federal agencies in general

In 1991, Congress held hearings on legislation that would require all federal agencies to develop standards and goals and to measure and report progress towards them. In response, the General Accounting Office issued a 1992 report entitled "Program Performance Measure: Federal Agency Collection and Use of Performance Data, 1992" which was a survey of 103 federal agencies to determine to what extent they had developed performance standards and goals and had created at least some measure of progress towards these goals.

The report stated that traditional management practices involve creation of long term strategic plans and regular assessments of progress towards stated goals. Strategic planning is an effort to establish long term goals and
objectives that will shape and guide activities and programs to fulfill an organization’s mission. Performance measures are a key tool to help managers assess progress towards goals or objectives stated in their plans. They are also an important accountability tool to communicate agency progress to Congress and the public. Performance measures include such things as: inputs, outputs, outcomes, efficiency, workload, customer satisfaction, timeliness and service quality.

GAO concluded that although many agencies had a range of program performance measurements, relatively few reported having the organizational characteristics that would make it more likely for them to use their performance measures to assess progress towards the goals in their strategic plans. GAO stated that not only could such a link provide managers information about accountability, efficiency and effectiveness, but also can provide Congress and the public with information on how public resources are being used.

Of interest to me were the findings that although over 50% of the agencies report some measurement of external customer satisfaction, most retain such information for internal use and only 28% report these findings to Congress and only 20% to the Office of Management and Budget. Also of interest was the finding that only 38% of the agencies reported that they asked customer/clients to assist them in developing the agency’s performance measures.

The overall feeling I had as I read this report is that there are likely areas where the CVM can embrace the traditional management practices, cited by GAO, of strategic planning coupled directly to performance measurement and including significant input from their constituencies in both planning and performance measurement. Performance management of this type could be of critical importance to their constituencies and, at the same time, clarify their mission, strategic plan and progress towards its goals and improve essential interactions (Figure 3).

IV. PATHS OF ACTION ADDRESSING LACK OF LEGAL THERAPEUTIC OPTIONS AND OTHER ISSUES

The real and perceived lack of legal therapeutic options for the treatment of animals has, over the years, triggered into motion a cascade of actions, all aimed at relieving the situation. This paper examines nine specific actions recently completed or under consideration and three proposals for action brought forward by the author. This cascade of 12 specific actions are categorized under five Action Paths as follows (Figure 4):

A. Action Path #1 - Agency performance

1. Government Performance Act and Results Act of 1993

Following the 1992 GAO report on program performance measure, Congress enacted the “Government Performance Act and Results Act of 1993” for the purpose of improving the efficiency and effectiveness of federal programs
by establishing a system to set goals for program performance and to measure results. In writing this legislation, Congress found that "waste and inefficiency in federal programs undermine the confidence of the American people in the government and reduces the government’s ability to address vital public needs." It also stated a purpose of this legislation is to "improve the confidence of the American people in the capability of the government by systematically holding agencies accountable for achieving results; ... ." There is no question that the driving force behind this legislation was anything other than public opinion.

This legislation contains some of the ideas expressed by Drucker and can, I feel, have a significant and positive impact on federal agency job effectiveness by requiring the implementation of performance measurement system. In other words, each agency, and in this context I am thinking of CVM, will identify its mission and specific goals in a strategic plan and then develop a performance plan to measure annual performance in attaining those goals and then will report them ultimately to the Congress. This will be a results oriented management system and will measure outcomes as well as output. At present, congressional policy making, spending decisions, and oversight are all seriously handicapped by lack of both sufficiently precise program goals and of adequate program performance information. It seems incredible that such a plan has not been in effect. It seems so simple an idea.

The law identifies the following elements as parts of the performance measurement system are: 1) strategic plan; 2) performance plan; 3) performance reports; 4) management flexibility waivers and; 5) performance budgeting. These elements will be phased into operation over a period of several years. All agencies are required to submit a five year strategic plan and an annual performance plan to the Office of Management and Budget (OMB) on or before September, 1997. In January, 1998 OMB will submit to Congress performance plans with the FY 99 budget. In March, 2000 each agency will submit a performance report for FY 1999 and annually thereafter. Pilot projects will be completed for performance plans, managerial flexibility and performance budgeting. The implementation of performance budgeting will require additional legislation.

Of interest is the specific statement that while developing a strategic plan, the agency should solicit and consider views of interested members of the public in the process of preparing the plan. The strategic plan will be a public document. The veterinary profession, indeed all CVM constituencies, should take as active a role as possible in this performance measurement system in relationship to the CVM as a part of FDA. This will be an opportunity to improve the effectiveness and clarity of interaction with CVM, to play a useful public service role in assisting improvement of performance of government and, ultimately, improvement in animal and public health and the practice of veterinary medicine.

2. End-user involvement in New Animal Drug Approval Process: A Proposal
The new animal drug approval process involves, as has been pointed out by others, a bipolar working relationship between the drug manufacturer and the CVM in relation to the evaluation of the product. The added participation of the end user of the proposed drug, the turkey industry for example, in the new animal drug approval process from start to finish would, I feel, bring useful insight and additional resources to the drug's evaluation.

Drucker might categorize this proposal as "paste here, there and yonder," but implementation of this proposal could assist, in the short run, the timeliness of the new animal drug approval process and in the awareness of both CVM and the manufacturer to special needs of the drug-users and opportunities to serve those needs. In the case of the turkey, broiler and commercial egg industries, these end-users have the practical and technical capacity to effectively represent and participate in this type of scientific issue.

B. Action Path #2 - Legislation


The Animal Medicinal Drug Use Clarification Act of 1994, became law in October, 1993 and amends the FFDCA by amending several sections of the Act, including the addition of two new paragraphs (4) and (5) to Section 512. The legislation was sponsored by the American Veterinary Medical Association and widely supported by agribusiness and producer organizations.

Paragraph (4) states that, except as limited by the Secretary for public health and other defined considerations, an approved new animal drug shall not be deemed unsafe in terms of misbranding with respect to a different use or intended use in animals, other than use on or in animal feed, if such use: 1) is on or by the lawful order of a licensed veterinarian within a valid veterinary/client/patient relationship as defined by the Secretary; and 2) is in compliance with FDA regulations defining the conditions of such use.

Thus, veterinarians would be permitted extra-label use of approved new animal drugs in food and non-food animals, except in or on animal feeds, in accordance to FDA regulations to be written after passage of the bills and subject to certain findings of the Secretary. Access to veterinarians' medical records is provided to the Secretary under certain conditions where public health is deemed to be at risk.

Paragraph (5) states that an approved human drug shall not be deemed unsafe in terms of misbranding with respect to use or intended use in animals if such use: 1) is on or by the lawful order of a licensed veterinarian within a valid veterinary/client/patient relationship as defined by the Secretary; and 2) is in compliance with FDA regulations defining the conditions of such use.

Strangely, this new paragraph (5) does not contain language prohibiting use of approved human drugs in or on animal feed, nor does it contain language providing the Secretary the ability to limit use of approved human drugs in animals subject to public health and other considerations. In other words, the new law seems to put more restrictions on the extra-label use of approved new animal drugs in animals than it does the use of approved human drugs in...
THE CENTER FOR VETERINARY MEDICINE

animals.

This disparity demonstrates that even with a huge effort to maintain clear and effective interactions between Congress and the various effected constituencies, that glaring discrepancies can make their way into law. This difference in the law between extra-label new animal and human drug use in animals will most likely be addressed by implementing regulations.

The Secretary has two years to promulgate the necessary regulations pertaining to this new law and the conditions of the extra-label use of both approved new animal and human drugs in animals.


The Animal Health Institute (AHI) and the National Turkey Federation are proposing similar, but not identical, legislation named the “Animal Drug Availability Act of 1995” for consideration by Congress. The proponents state this bill would amend the FFDCA to provide for improvements in the process of approving and using animal drugs and for other purposes. The primary purpose of this bill, in my interpretation, is the pharmaceutical industries desire to eliminate the need for field investigation as a required part of the new animal drug approval process as is now the case.

The AHI proposed legislation finds that: the drug approval process is too slow; useful drugs are being kept from the market; the health and well being of animals are at risk; the expense and delay of effectiveness testing outweigh the benefits of such testing; over-reliance on field investigations is the primary problem; that it is a benefit to public health and safety to have as many animal drugs as economically feasible reviewed and approved by the FDA; and economic and regulatory incentives are necessary to convey unlabeled use to approved, labeled uses.

The bill is composed of several sections dealing with change of the Act. The following is a discussion of some of them contained in the AHI version:

a. Evidence of effectiveness - Original applications - This section amends Section 512 (d)(3) and completely redefines the term “substantial evidence” in relation to efficacy testing of proposed new animal drugs. Perhaps most significantly, this redefinition eliminates the current requirement for “well-controlled ... field investigation.” It does provide that the Secretary can require field investigation under certain conditions. The redefinition also provides for recognition of “any studies voluntarily undertaken by or for the applicant,” which would seem to open the door, for example, for other interested parties to participate in the new drug approval process of a particular product.

Supplemental Applications - This would delete the requirement for “new clinical studies or field investigations ...” in relation to supplemental applications for an approved new animal drug and substitute the above new definition of “substantial evidence.”

Minor Species and Uses - The current Act does not address minor species or minor use. The proposed change states that lack of “substantial evi-
“Evidence” would not be a reason to disapprove a previously approved product for a subsequent proposed claim for use in a minor species or for a minor use.

Combination Drugs - The current Act does not address combination drugs. This section addresses situations where a drug contains more than one active ingredient or its labeling prescribes, recommends or suggests its use in combination. In such cases, the Secretary would consider when evaluating safety and efficacy the following:

- Whether the combination alters the safety of any of the active ingredients or drugs or interferes with methods of their analysis.
- Whether each of the active ingredients or drugs in the combination claiming the same effect actually contribute to that effect or whether a particular drug in the combination, not claiming the same effect, represents appropriate concurrent therapy for a targeted population (microorganisms, etc.).

Implementation - This legislation directs the Secretary to take into account several items during deliberation in the implementation of the Act within 24 months. These include the encouragement of submission of applications, flexible labeling and consensus with industry on appropriate evidence for efficacy of combination drugs.

b. Dispute Resolution - This legislation adds a new process of dispute resolution between an applicant and FDA in addition to the hearing process in the current law. Under the proposed legislation, the applicant can declare that an “impasse” exists in the review of the application for a specific issue. Whereas the current hearing process comes at the very end of the review process, the impasse declaration can come anytime before that. The impasse declaration sets into motion a third party review involving either an existing advisory committee, a special advisory committee or an individual acceptable to the Secretary and the applicant. A report is submitted to the Secretary within 60-90 days and the Secretary, in turn, responds within 30 days.

My first reaction to the impasse declaration is that it will likely slow down the process of approval, rather than speed it up. On the other hand, others have pointed out that the inclusion of outside experts into dispute resolution will provide much needed intellectual competition within CVM.

c. Limitations on Residues - This legislation changes the wording of the Act in regards to residues, by stating that approval will be denied if the recommended or suggested labeling use of a drug will result in residues in excess of the tolerance found by the Secretary to be safe.

The current law can result in denial if tolerance limitation proposed exceeds that reasonably required to accomplish the effect for which the drug is intended, meaning one should not use more of a drug than is necessary to accomplish the intended purpose.

d. Export of New Animal Drugs - Would allow a new animal drug not approved in the U.S. to be manufactured in the U.S. for export to a country where the drug is lawful. The current law generally prohibits this, but FDA has
a case by case discretion under certain investigational conditions.

3. Eliminate CVM efficacy testing for new poultry drugs: A Proposal

There is something that bothers me, a poultry clinician, and others about the proposed Animal Drug Availability Act of 1995 sponsored by AHI. On the one hand, the pharmaceutical industry wants to do away with field investigation as a required part of the efficacy testing in the new animal drug process. On the other hand, as a poultry clinician, I'm not going to recommend the use of a new therapy without the knowledge and confidence regarding efficacy that can only be gained through well controlled clinical investigations under field conditions of the proposed use the treatment in question.

Regardless, then, of whether or not the FFDCA requires it, clinical field investigations will be carried out, one way on another, in relation to new drugs proposed for the broiler, turkey and commercial egg industries. If the law is changed as proposed by AHI, these poultry industries are still going to demand clinical field investigations as part of their assessment of a proposed new drug's efficacy.

The elimination of field investigation from the FFDCA as proposed by the AHI initiative, seems to me to fit squarely into Drucker's "patch here, there and yonder" category, with the result enabling the pharmaceutical industries to eliminate clinical field investigations, yet retain the same FDA sanctioned credibility for efficacy as they now enjoy. In other words, get the cake and eat it too.

As an alternative to this "patch here, there and yonder scheme", we should be "rethinking" (as Drucker recommends) the entire issue of government efficacy testing in relation to new poultry drugs and to ask question "Is it necessary for FDA to include efficacy testing for approval of new animal drugs for use in poultry?" In my and others' opinion, the answer is "No." CVM need only to evaluate new poultry drugs for safety to the target animal, the environment and humans, from the point of view of residues in foods of poultry origin. Such a change would, in my and others' opinion, significantly speed up the CVM new drug approval process for poultry drugs. The elimination the efficacy testing requirement for new poultry drugs would require an amendment to the FFDCA.

The pharmaceutical industries in collaboration with the broiler, turkey and commercial egg industries have the management and science-based resources to determine, by themselves, the efficacy of new animal drugs utilized in poultry. Perhaps a third party efficacy testing process, such as the Underwriters Laboratory (UL) for electrical appliances, could be an effective way to go. Restriction of the use of such products to the order of a licensed veterinarian operating within a valid veterinarian/client/patient relationship might also be considered for professional oversight for the first year of sales.

CVM expressed, in a September 1994 letter to National Turkey Federation, that lack of drug effectiveness represents both a human food and target animal safety issue and, therefore, efficacy testing is required for for human
health as well as animal health reasons. Failure of an anti-infective drug, for example, might result in prolonged suffering in the animal and the spread of pathogens to both animals and humans. If a sponsor of a new animal drug cannot establish effectiveness for an intended use, in CVM's view, there is no rationale for exposing animals or the consuming public to the drug.

My response to this CVM position is that they are operating on too general a level and are viewing all of their animal owning constituencies as a homogeneous lot. This is a very clouded view of their constituencies (Figure 2) and, as a result, I feel the Center is overlooking important differences among the animal owning publics and their capabilities to assess and control drug use in animals. In my and other's opinion, the poultry industries represent an opportunity for CVM to break out of the mold of status quo or traditional mindset and to lead the FDA in rethinking its mission and how to reach its objectives.

The economics of the poultry industries' market place demands the industries avoid use of ineffective drugs because they will not alleviate real problems. If a drug is ineffective, illness is not alleviated, productivity decreases and production costs increase. The poultry industries, and especially the meat industries, are highly vertically integrated and have the management controls and the science-based capability to determine whether or not a drug is working. The competition between companies and with other competing livestock industries for market share is intense and fractions of cents per pound in production costs influence drug use decisions. There is no economic incentive to incur increased costs in order to utilize ineffective drugs and nor is there an incentive to purposely expose its customers to unsafe drug residues both of which can result in loss of market share. The incentives are all in the opposite direction. The poultry industry is now and will be looking after the best interests of itself and its customers.

For the above reason, in my opinion, eliminating efficacy testing by CVM for poultry industry drugs would not lead to increased illness in animals nor associated increased risk to human health from residues or spread of pathogens. Quite the contrary, the resulting speed up of new poultry drug approvals would decrease illness and reduce the risk to human health.

It should also be pointed out that extra-label use of human drugs in animals by definition is the use of drugs in which no efficacy testing has been accomplished and, which according to the Animal Medicinal Drug Use Clarification Act of 1994, is now permitted by law.

C. Action Path #3 - Rethink existing FFDCA law
1. Professional/Flexible labeling

CVM is considering guidelines on flexible, prescription labeling of antimicrobials which would enable veterinarians, operating within a veterinary/client/patient relationship, to select appropriate therapy from an approved dose range within given restrictions. A 1991 AVMA/AHI citizens petition proposed professional/flexible drug labeling for use by veterinarians. In 1993, CVM published the document "Points to Consider: Preliminary considerations for
development of a guideline enabling flexible labeling of antimicrobials for therapeutic use" and is now considering responses to that document in relation to developing the above guidelines.

In its Points to Consider document, CVM perceives flexible labeling to be prescription labeling which bears: suggested doses for each claim within an acceptable dose range and; in vitro microbial sensitivity information and pharmacokinetic information about the drug (including information correlating dose and residue depletion) useful to the attending veterinarian.

The proposed "Animal Drug Availability Act of 1995" requests the Secretary to consider the AVMA/AHI petition pertaining to flexible labeling in the implementation of the proposed legislation.

2. Veterinary Feed Order

A March 17, 1995 draft of a concept paper "Coalition to Develop a Veterinary Feed Order" (VFO) Drug Alternative" states that FDA has expressed the need for greater control over certain new therapeutic antimicrobial drugs in the pipeline, such as the fluoroquinolones, when administered in the feed. The development of a VFO would provide a mechanism that can be used by new animal drug sponsors when faced by this need for greater control over a drug. It further states that the VFO is an alternative to prescription status for these medicated feeds and thus avoids triggering state pharmacy laws and regulations which would be disruptive to the marketplace.

The basic idea of the VFO is to provide control over these drugs in a manner compatible with current feed manufacturing and use practices by enlisting the oversight and professional judgment of licensed veterinarian operating under a valid veterinarian/client/patient relationship.

Scenario for use of VFO Drugs - This concept paper calls for the licensed veterinarian, working within a valid veterinary/client/patient relationship to initiate the control procedures required by FDA for use of certain new therapeutic antimicrobial drugs in medicated feed.

After being called in by the producer, the veterinarian determines use of the VFO drug is necessary and issues a preprinted VFO form provided by the drug manufacturer for Type B or C medicated feed. This form includes instructions for the producer and the producer's feed manufacturer in regard to use and manufacture of the medicated feed, specifics about the location of the farm and animals it is to be used in, the name and addresses of all concerned, the veterinarian's signature and its expiration date. Copies maintained by all concerned.

All drugs used with a VFO are considered Category II drugs. Feed manufacturers have to meet certain requirements depending on their role in the manufacture of the VFO drug and whether Type A, B or C medicated feeds are involved. Inventory stocking of Type A, B or C VFO drugs is allowed under certain restrictions by feed manufacturers. Type B and C VFO medicated feeds can be inventoried by producers under certain restrictions. Type B and C VFO medicated feeds cannot be fed to animals without a VFO.
D. Action Path #4 - Regulatory discretion
1. Compliance policy guides

The Compliance Policy Guide is CVM's primary action path to identify and verbalize its policies and priorities for enforcement of the various sections of the FFDCA. That is, the identification of those infractions of the law that are considered most serious and should result in enforcement action and those infractions which, under normal circumstances, will not be subject to regulatory enforcement. This is accomplished by issuing Compliance Policy Guides (CPGs) which, in turn, guide the field enforcement arm of FDA on where to focus its attention and resources for attaining compliance with the most important aspects of the law. The CPG also serves to instruct the public, such as users of new animal drugs, for example, on CVM's enforcement priorities.

In terms of enforcement priorities pertaining to Section 512's current prohibition of extra-label use of new animal and human drugs and related issues (until implementation of the Animal Medicinal Drug Use Clarification Act of 1994), CVM has issued CPG #7125.06 - Extra-label use of new animal drugs in food-producing animals (7/20/92); CPG #7125.35 - Human-labeled drugs distributed and used in animal medicine (7/20/92); CPG #7125.37 - Proper drug use and residue avoidance by non-veterinarians (7/9/93). It is also developing a compliance policy guide for veterinary pharmaceutical compounding.

During the two year period, beginning in October 1993, CVM will develop regulations for implementation of the Animal Medicinal Drug Use Clarification Act of 1994. As part of this regulation development, CVM will consider the above compliance policy guides and will likely, I would think, include much of their content in the new regulations and/or refer to them in the new regulations. This is particularly true of CPGs #7125.06 and #7125.37 and the CPG being developed for veterinary pharmaceutical compounding.

Special mention should be made of "CPG 7125.37 - Proper drug use and residue avoidance by non-veterinarians" as, among other things, it sets down CVM's findings that live food animals are considered to be unprocessed food, just as unroasted coffee beans are and, for that reason, the live food animal is subject to all the provisions of the FFDCA pertaining to unprocessed food. This has far-reaching ramifications as the presence of certain residues and microorganisms in unprocessed food (live food animals) can result in that food (live food animal) being considered adulterated. Also, CVM considers the lack of drug-use controls and records on the farm to fit within the meaning of "unsanitary conditions", and thus a potential reason for declaring the food (live food animals) to be adulterated under Section 402 (a) (4) of the Act.

E. Action Path #5 - Professionalism
1. Professional Standards for Proper Drug Use by Veterinarians: A Proposal

Background - The Animal Medicinal Drug Use Clarification Act of 1994, the professional/flexible labeling proposal, the Veterinary Feed Order proposal, and the five compliance policy guides, including the proposed compliance guide on veterinary pharmaceutical compounding have three themes in com-
mon as follows:

a) Food safety - All place their highest priority on preventing illegal drug residues in raw foods of animal origin.

b) Professional judgment and responsibility - All delegate to the licensed veterinarian, through enforcement discretion or legislation, the ability and responsibility for the use of certain new animal or human drugs in an extra-label or controlled manner in specified circumstances and ways in animals.

c) Societal controls for safe drug use - All identify and require a valid veterinarian/client/patient relationship between producer and veterinary practitioner and specified drug use record systems as the primary societal control measures to ensure safe drug use in animals.

These common themes and cascading actions are placing more and more responsibility on the veterinary profession to assure society that not only is animal well being be cared for by sound drug use in animals, but that human health and the environment are also being safeguarded at the same time. It occurs to me that, as a profession, we are not fully prepared to accept this responsibility or to demonstrate to society, over time, that we are up to human health and environmental responsibilities as well as the animal health responsibility. Others have expressed similar views.

Professional Standards for Proper Drug Use by Veterinarians: A Proposal - I believe the veterinary medical profession must demonstrate to itself, FDA, Congress and the public that it can effectively carry out the societal responsibilities delegated to it by law and regulation for control of the use of drugs in animals. The profession must clearly assure society that effective prevention of illegal drug residues in foods of animal origin and the controlled use of drug therapy in food and non-food animals are compatible goals and that oversight by the veterinary profession can assure this compatibility.

Providing assurance to society can be best accomplished by initiating a fifth action path to establish and recognize professional standards for proper drug use by veterinarians. Such a program would be a profession-wide quality assurance or accreditation program spelling out standards of practice pertaining to use of drugs in food and non-food animals by veterinarians. I feel the veterinary profession itself should implement and administer such a program, perhaps through the American Veterinary Medical Association, the United States Animal Health Association, and/or state veterinary associations in cooperation with animal owners and regulatory agencies. Others have suggested the state licensing boards as possible vehicles for such a program.
Response To Public Disdain for Old Government:
At least four differing ideas for new government
Figure 2
Center for Veterinary Medicine: Some Issues and Views of the Center by Constituents

Lack of legal therapeutic options

Competent Individuals

Confrontational

Conscientious Individuals

Intimidating

Bureaucratic

Responsive Individuals

Impenetrable

Respected Individuals

Unresponsive

???
Figure 3
Center for Veterinary Medicine: Components, Activities and Interactions With and Among Constituencies
Figure 4
Action Paths to Improve Availability of Legal Therapeutic Option

FFDCA - Federal Food Drug & Cosmetic Act
1 - Action completed and in place
2 - Action being developed
3 - New actions submitted by author
Chairman: Dr. R. Flint Taylor, Edgewood, NM
Vice Chairman: Dr. Roy A. Schultz, Avoca, IA

D. A. Armstrong, CO; A. J. Beaulieu, MD; L. G. Biehl, IL; R. E. Bohlender, NE; M. Brown, KS; S. A. Brown, MI; J. Caspers, IA; N. J. Corlett, OH; G. L. Cowman, CO; J. E. Fox, GA; D. L. Froe, MO; R. A. Gessert, MI; D. D. Gingerich, IA; J. S. Gloyd, DE; C. H. Graham, KS; G. W. Hausman, FL; J. P. Honstead, MD; L. Leach, VA; G. D. Lindsey, IN; K. B. Meyer, IN; G. A. Mitchell, MD; J. F. Mock, NJ; T. A. Neuzil, IA; J. J. Rash, MO; M. G. Scroggs, TX; M. Sharar, MD; T. K. Shotwell, TX; J. Webb, FL

The Committee met at 1:30 p.m. on Tuesday, October 31, 1995, in the Washoe Room of John Ascuaga’s Nugget Hotel in Reno, NV; 13 committee members and 10 guests were in attendance.

The Committee has maintained a continuing emphasis on providing a forum to identify and address issues concerning the availability and safe use of pharmaceutical products in animals. Continuing education at all levels regarding proper and effective use of pharmaceuticals has been encouraged as a means of achieving these goals. Invited speakers included Dr. Michael Blackwell, Deputy Director, Center for Veterinary Medicine; Dr. Robert Collier, Senior Fellow and Dairy Research Director, Monsanto Corp; Dr. Robert Jorgenson, Director, Division of Governmental Affairs, AVMA; Dr. Joe Gloyd, Associate Director for Scientific Activities, AVMA; and Dr. G. A. Mitchell, Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

Dr. Collier provided an update on bovine somatotropin, citing a variety of issues and concerns; the detailed text of his presentation is provided in Appendix A.

Dr. Jorgenson’s presentation included an overview of current AVMA legislative activities including a review of the legislative process in how an idea becomes law. This concept was further exemplified with a detailed description of the Extra-Label Drug Use Bill’s progress, beginning with the idea and a historical description of it’s progress thru staffers, committees, FDA, Houses of Congress, and final sign-off by the President. Dr. Jorgenson then presented a summary of legislative issues in which the AVMA is currently interested and involved. These include:

4. 1995 Farm Bill

Dr. Gloyd presented a series of AVMA issues and concerns. These included:
1. The professional/flexible labeling (PFL) concept initiated by Animal Health Institute and AVMA is supported by the Center for Veterinary Medicine (CVM), FDA. The proceedings of the PFL Workshop were published in JAVMA 10/1/95. Establishment of a data base for extra-label use information relating to products carrying flexible labeling is under scrutiny by AVMA Network on Animal Health (NOAH); the Veterinary Information Network, FARAD, USDA, Virginia/Maryland College of Veterinary Medicine and others. Questions as to where and how the data-base will be kept or how it will be handled have not been resolved. A 2nd Flexible Labeling Workshop will be held on December 11-13 in Gaithersburg, MD. The workshop’s emphasis will be to develop a “model” for flexible labeling of bovine antimicrobials.

2. With respect to drug availability and lack of availability issues, Dr. Gloyd cited that some niche-type products that are presently unavailable due to failure to meet current GMP’s which are based on human product GMP’s. These include atropine, thiamylal, epinephrine, and phenylbutazone).

3. The Center for Veterinary Medicine has announced the pending removal of dipyrone via a ban of manufacture and sale of the product. The removal of this product, plus the unavailability of phenylbutazone will decrease the veterinary practitioner’s capability for pain management in client animals.

4. The Veterinary Feed Order, a concept to allow for prescription feed additives, was developed and supported by a coalition of veterinary practice speciality, animal production, and feed industry groups as well as the AVMA. This issue is being addressed by Sen. Nancy Kassebaum’s FDA Reform Bill, which is currently in draft form. Legislation is being proposed by the Animal Drug Alliance that will require the CVM to set up standards to differentiate manufacturing GMP’s of veterinary drugs from human drugs. Language to this effect is being included in the Senator Kessebaum’s FDA Reform package; AVMA supports the concept of separate GMP’s.

5. The CVM has proposed a ban on extra-label use of fluoroquinolones in major food producing species; this presents a problem for the veterinary profession that the Animal Medicinal Drug Use Clarification Act of 1994 was intended to resolve. An AVMA position on this ban will be forthcoming.

6. The Pharmacy Protection Act, which pertains to drug compounding, has been introduced by the American Pharmaceutical Association; this legislation, if enacted, may have implications for drug compounding by the veterinarian.

7. The U.S. Pharmacopeia Practitioner’s Reporting Network provides veterinarians a means of reporting, through a single entity, problems with drugs, biologics, pesticides, and devices.

Dr. Michael Blackwell presented an update of the Center for Veterinary Medicine’s goals and timelines for their “customer-oriented philosophy” resulting from Dr. Sundloff’s emphasis and approach. His presentation is included in its entirety as Appendix B.

Dr. Mitchell presented a historical review of the illegal use of clenbuterol.
during the past few years. It had been reported to have been used in both the
U. S. and Canada in 1988 and 1989. Human illness resultant from consump-
tion of meat from cattle treated with this product had been reported in Spain
and France. These incidents were characterized by a transient illness includ-
ing heart palpitations, shortness of breath, and dizziness. There were no long
lasting effects nor any deaths reported in humans from the consumption of
clenbuterol residues. Allegations of use were reported in U. S. show animals
beginning in the early 1990’s; on 4/3/91 a letter from FDA/USDA sent to
NASDA and all state veterinarians citing that the agencies were aware of the
reports of illegal usage, and that it should be stopped. The FDA was ham-
pered at that time by lack of an adequate analytic method. A detection
method has since been developed; this is an electrospray LC/MS/MS method
reported by Tomlinson, et. al. from the National Forensic Chemistry Center,
FDA, Cincinnati, OH. Positive show animals were detected at the National
Western Stock Show in Denver, CO, in January, 1994 as well as at Tulsa, OK
in October, 1994. A veterinarian involved has since been indicted. The FDA
enforcement strategy is to survey show animals and food producing animals,
transfer and improve analytical technology. Samples from Texas and Okla-
homa state fairs have been negative in 1995.

Dr. Mitchell then presented a review of new drug approvals. These in-
cluded a total of 50 new approvals; the breakdown was as follows:

New chemical entities:  4 (1 in food animals)
Expanded claims (new species or expanded usage) : 24
Generic: 22

A specific breakdown of these new approvals is included as Appendix C.
Dr. Mitchell then gave a detailed presentation regarding the Government
Performance and Results Act, National Performance Review, and CVM’s
Strategic Plan. The detailed text of his presentation is provided in Appendix
D.

A good discussion session followed the presentations by each of the
speakers. No resolutions were drafted or forwarded. The Committee ad-
journed at 5:40 p.m.
Posilac, 18 Months Later
Robert J. Collier
Senior Fellow and Dairy Research Director
Protiva, A Business Unit of
Monsanto Company

Commercial sales of Posilac (bovine somatotropin) for use in lactating dairy cows began in February, 1994. For a variety of reasons this technology had produced significant opposition to its approval. These included concerns about the impact of commercial use in the dairy industry on consumer consumption of milk, impacts on cow health, effects on small farms, potential labeling of milk and economics of use. Now that 18 months have passed we have answers to many of these questions.

I. CONSUMER CONSUMPTION OF MILK
Consumer consumption of fluid milk and dairy products increased substantially during the first 12 months of Posilac sales and for the entire 18 month period. For examples, commercial disappearance of fluid milk increased 8.3% in 1995, butter consumption increased 32.3% and total cheese consumption increased 7.2% (Table 1). Clearly, consumers had accepted the safety of the American Milk Supply and had not decreased their consumption of milk due to Posilac use.

II. LABELING OF MILK AND DAIRY PRODUCTS
Voluntary labeling is permitted under Federal Guidelines in all 50 States. There is some indication that labeling has resulted in development of some additional niche markets for milk rather than reducing milk consumption. At equivalent price labeled milk appears to hold about 5% of market share and at higher prices this share declines. There has been no labeling of dairy products other than fluid milk.

III. ADOPTION RATE OF POSILAC USE BY DAIRY PRODUCERS
At the end of 12 months of sales it was estimated that some 13,000 dairy producers representing 30% of the U.S. dairy herd had used 14.5 million units of Posilac with their dairy cows. Results for the second 12 month period are not in but substantial growth of Posilac use from the first 12 months is expected. Results also indicate that Posilac was adopted by small, midsize and large producers and that the majority of adopted Posilac users were small farms which mirrored the demographics of farm size distribution.

IV. ADVERSE EXPERIENCE REPORTS
The Center for Veterinary Medicine of the Food and Drug Administration has issued reports at six month intervals on numbers of Adverse Drug Reports (ADR’s) coming in through the monitoring system established by Protiva with FDA concurrence. This system is unprecedented in scope and activity due to the direct marketing approach adopted by Protiva. Information on
ADR's can come in through: The Protiva Technical Hotline 800 number, the 800 sales number, (in fact, each producer is asked if he or she has any concerns when placing an order), field sales and technical service contact with producers who indicate concerns, direct calls to the CVM 800 numbers. To date, the CVM has determined that the number and severity of the reported conditions are not greater than expected, based on the data from the clinical trials of the drug, and as set out in the product's approved labeling. All of the reported clinical manifestations are known to occur in cattle not supplemented with Posilac (Table 2).

V. POST-APPROVAL MONITORING PROGRAM

In addition to the monitoring of ADR's, Protiva offered to establish a field trial in at least 24 herds around the country for a full lactation to demonstrate the animal safety of Posilac use. Objective of the program was to monitor the general health of cows given Posilac under field conditions in commercial herds for one lactation. The program was expanded to include 28 herds across the 4 major regions of the United States. The demographics of herd locations for this study is presented in Figure 1. Of these, 23 herds had 110 to 1740 milking cows and five herds had 40 to 60 milking cows. A total of 1213 cows were started on study and to date 16 of these herds have completed the study with 12 herds in the final stages of the in life phase. After completion of the study the data will be analyzed and presented to the Center for Veterinary Medicine as a written report and in oral form to the Veterinary Medicine Advisory Committee (VMAC) in late 1996. None of the 28 herds reported any catastrophic effects of Posilac use. Determination of any subtle health effects will require completion of the statistical analysis.

VI. ECONOMICS OF POSILAC USE IN DAIRY HERDS

The first estimates of economics of Posilac use in dairy herds are becoming available. The first in depth study was reported by Knoblauch, Smith and Putnam of Cornell University utilizing data from the Cornell University Dairy Farm Business Summary. Approximately 400 New York dairy farms participate in the DFBS project and were utilized as a random sampling of various adoption rate of Posilac use including no adoption. Their results (attached) indicate that veterinary costs increased for both adopters and nonadopters of Posilac but the largest percentage increase in veterinary costs occurred in the nonadopter group. In addition, feed costs per hundredweight of milk sold was reduced in herds adopting Posilac versus those that did not. In general, the data supported the safety of Posilac use in dairy herds and did not indicate that veterinary costs were being increased in cows using Posilac.

VI. SUMMARY

In summary, the overall information from a variety of independent sources indicate that Posilac is being successfully adopted by the U.S. Dairy Industry with no adverse effects on farm income and profitability, cow health or consumer acceptance of milk.
TABLE I

U. S. Dairy Product Highlights

(Compared to Same Months, 1993: Year End 1993 and January, 1994)

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<thead>
<tr>
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<tbody>
<tr>
<td>Total Milk</td>
<td>-2.2%</td>
<td>-0.2%</td>
<td>-2.4%</td>
<td>-1.3%</td>
<td>-3.3%</td>
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<tr>
<td>Butter</td>
<td>-3.3%</td>
<td>-1.6%</td>
<td>-6.3%</td>
<td>-5.3%</td>
<td>-32.2%</td>
</tr>
<tr>
<td>Total Cheese</td>
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<td>-2.0%</td>
<td>-3.4%</td>
<td>-7.2%</td>
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<tr>
<td>Nonfat Dry Milk</td>
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<td>-13.5%</td>
<td>-6.3%</td>
<td>-15.3%</td>
<td>-12.2%</td>
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Sales of Fluid Milk¹

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<tbody>
<tr>
<td>Total Fluid Milk Sales</td>
<td>-0.3%</td>
<td>-0.3%</td>
<td>-0.1%</td>
<td>-0.7%</td>
<td>-0.7%</td>
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<tr>
<td>Whole Milk Products</td>
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<td>-0.4%</td>
<td>-0.7%</td>
<td>-0.3%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>Lowfat Milk Products</td>
<td>-1.3%</td>
<td>-1.1%</td>
<td>-0.2%</td>
<td>-1.5%</td>
<td>-1.7%</td>
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Production of Dairy Products

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</tr>
</thead>
<tbody>
<tr>
<td>Cottage Cheese</td>
<td>-2.4%</td>
<td>-5.3%</td>
<td>-5.3%</td>
<td>-3.3%</td>
<td>-2.0%</td>
</tr>
<tr>
<td>Yogurt</td>
<td>-5.5%</td>
<td>-4.6%</td>
<td>-11.4%</td>
<td>-7.0%</td>
<td>-3.2%</td>
</tr>
<tr>
<td>Hard Ice Cream</td>
<td>-2.7%</td>
<td>-3.9%</td>
<td>-3.3%</td>
<td>-1.4%</td>
<td>-8.3%</td>
</tr>
<tr>
<td>Lowfat Ice Cream</td>
<td>-2.7%</td>
<td>-5.3%</td>
<td>10.5%</td>
<td>-4.5%</td>
<td>-2.4%</td>
</tr>
<tr>
<td>Frozen Yogurt</td>
<td>-1.2%</td>
<td>-9.2%</td>
<td>-5.3%</td>
<td>-0.1%</td>
<td>-25.4%</td>
</tr>
</tbody>
</table>

¹ Data represents packaged sales of fluid milk products in Federal Milk Marketing Orders and California and includes over 95% of U. S. fluid milk sales.

Source: USDA

392
The following table summarizes the important clinical manifestations (CM) from the 392 adverse experience reports possibly related to the use of Posilac® from the February 1 through August 25, 1995.

This summary is intended only as a general reference to the type of reactions that veterinarians and dairy farmers have voluntarily reported to the manufacturer or FDA. Therefore, the summary is not by itself a basis for determining the frequency or incidence rate of a clinical manifestation. Each of the reports may contain one or more CMs, and as a result the number of CMs exceeds the number of reports. It is important to recognize that all of the reported clinical manifestations are known to occur in dairy cattle not supplemented with Posilac®.

<table>
<thead>
<tr>
<th>Clinical Manifestation (CM)</th>
<th>Number of Reports with the CM</th>
<th>Estimated Number of Cows Reported with the CM</th>
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<tr>
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<td>Counts in Milk</td>
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<td>Other Udder Abnormalities*</td>
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<td>Reproductive Disorders**</td>
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<td>Injection Site Reactions</td>
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<td>Cattle Deaths****</td>
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* Includes udder swelling, udder edema, or abnormal milk.
** Includes decreased fertility, abortions, premature births, and retained placentas.
*** Includes anorexia, weight loss, and other digestive tract signs.
**** The most commonly reported CM for all dairy cattle drug products is death. This includes cows that were euthanized or slaughtered due to an illness, such as chronic mastitis.
REPORT OF THE COMMITTEE

PAMP REGIONS AND SITE LOCATIONS
I am pleased to be here this afternoon on behalf of Dr. Stephen Sundlof, the Director of the FDA's Center for Veterinary Medicine. He sends you greetings and best wishes for a very successful meeting.

Dr. Sundlof asked that I share with you some of the many exciting happenings in CVM over the past year. When he talked with you last year he was able to describe some of the plans we were making and some of our hopes for improving the ways we do business. Since that time we have made definite progress towards implementing significant and fundamental change within the organization. Upon his arrival as Center Director in June 1994, Dr. Sundlof committed to a thorough and exhaustive review of our entire organization. This process was expedited by the development of a CVM Strategic Plan. The process of developing our plan involved everyone in CVM and we had significant input from outside CVM and outside the agency. The process may have seemed slow at times but we were addressing the need for fundamental change in our organization and in the way we accomplish our mission.

In fact, one of our first tasks was to address the need to rethink and perhaps restate our mission. This mission statement tells you (and reminds us) that we have a three pronged mission. We must balance the needs for us to act responsibly in protecting human and animal health, in assuring the consumer against fraud, and in assuring the most available supply of safe and effective animal drugs. This is our “new paradigm”. The subtitle of the CVM Strategic Plan, which was issued in June 1995, is “Shifting the Paradigm”. The new paradigm does not negate the old paradigm, rather it properly extends it to encompass the broader societal needs that must be balanced. It is no longer enough just to assure that no “bad products” enter the market. We must continue to guard against unsafe products and fraud while actively assuring that needed safe and effective products gain access to the market in a timely manner.

Previously, it was like trying to balance a stool with only two strong legs. We know we can balance the stool better if we have an equally strong third leg. Likewise, we can balance our efforts at accomplishing our mission better if we emphasize equally the importance of approving needed animal drugs.

During my time here with you today, I hope to expand the dialogue with you on how we can improve the drug approval process. Dr. Sundlof has stated, on numerous occasions, that his primary emphasis as Director of CVM is to increase the number of approved new animal drug applications (NADAs). The number one goal in the CVM Strategic Plan is stated as; “We will reengineer product evaluation, surveillance and compliance, research, and administrative processes to increase the availability and diversity of safe and effective
REPORT OF THE COMMITTEE

products”. This is no longer just a personal goal of Dr. Sundlof, we now have a CVM-wide commitment to achieve this goal. We have defined specific tasks designed to accomplish this goal. We currently have groups hard at work on many key aspects of improving our processes. The Center is literally buzzing with activity. We are well aware that a “plan” can be nothing more than an attractive shelf item, useful for waving at people when we want to make a point. We are also aware that it will take hard work and dedicated pursuit to achieve our goals. Our commitment to you and to ourselves is that we will accomplish our goals and we expect to be judged by what we actually do rather than by what we say we will do.

But I want you to know that we do recognize that CVM cannot unilaterally accomplish all the actions that will be necessary to increase animal drug availability. To be successful in this effort we must include everyone associated with or affected by the use of animal drugs.

When I use the phrase “increasing animal drug availability”, I am referring to several interrelated actions such as increasing the number of compounds approved for animal use, increasing the number of permitted uses via approved labeling for these products, and increasing the number of species in which these products may be used. We will not be able to achieve this goal until we accomplish a number of other things first. These include, but are not necessarily limited to:

- Reducing the length of time it takes to obtain an approval.
- Making more efficient use of data submitted in support of an approval.
- Improving the relevance of data supporting approvals.

In order for the animal drug approval process to be effective, a balance must be maintained between public health, animal health, and industry incentive to develop new drugs. If there is too great an emphasis on any one of these areas, then the system begins to lose efficiency. For example, the greater the cost of developing data to support new approvals, the fewer drugs that will be approved. Fewer approvals mean that producers and veterinarians will have fewer options for treating certain animal diseases thus weakening animal health protection. Fewer approvals also can lead to greater extra-label drug use which can increase public health risk. And fewer approvals mean fewer products to generate revenues for drug manufacturers, reducing financial resources available for research to support new approvals.

Industry health is best served when the requirements for obtaining drug approvals are clearly defined and universally accepted by all segments of the food animal production chain and the public.

Animal health is best served when veterinarians and animal owners have access to an adequate number of safe and effective approved new animal drugs to treat the myriad of diseases affecting animals. Having approved drugs available reduces the need to use unapproved compounds or to use approved compounds in unapproved ways.

As we consider actions that will increase the availability of approved new animal drugs, we have to expand the dialogue beyond the Center for Veteri-
nary Medicine and animal drug manufacturers. We need to include all parties who will be affected by those changes.

This includes, but may not be limited to:

- Animal Feed Manufacturers
- Animal Drug Distributors
- Veterinarians
- Other Animal Health Professionals
- Food Animal Producers
- Other parts of the Food and Drug Administration
- Other Federal and State Regulatory Agencies
- Universities
- Consumers

In addition to animal drug manufacturers, the needs of each of these groups must be addressed if the animal drug approval system is to work efficiently and effectively. If any of these groups feels their respective needs are not being met, then their effort will not support the drug approval process and may actually oppose or impede it. Our challenge is to implement needed changes in the approval process while maintaining the support of all these parties. We need to keep in mind the fact that maintaining the status quo may be the easiest thing to do for the majority of the parties. For them to support change they must receive some benefit or, at the very least, experience no negative effect from the change.

So how do we improve the drug approval process? I'll offer some of my thoughts on some things that can be done. Then, if you have suggestions or comments, I would like to hear them. Your suggestions and comments are always welcomed by us.

First, I believe a key to resolving the animal drug availability problem is increasing communication between ALL parties involved with animal drug issues. Although there have been extensive interactions on animal drug issues in the past, in many cases those meetings have not been as productive as they could have been because there was not a balanced representation of all parties that needed to be involved. Vital perspectives were not addressed because the parties present were not fully aware of the impact of their decisions on other groups. In some cases, the missing groups did not recognize they had a role to play in the process until after a decision had been reached. Then, they (or we) realized the decision-making process had an undesirable effect which caused an equally undesirable response.

Considerable resources have been expended in this manner with unsatisfactory progress to show for our efforts.

We need to make all parties aware that they share the responsibility to improve drug availability and we need to provide them with the opportunity to participate in the effort to improve it. CVM accepts the responsibility for leading this effort and being the catalyst to bring all parties together. Everyone must realize that substantial improvement will only come when everyone is involved.
Second, we need to recognize that we already have considerable ability to improve the process. Although there may be situations where legislative changes are appropriate, there is a lot we can do under the existing requirements. There are reasonable and practical changes that can be, and are being, made to improve the animal drug approval process. But, just as CVM is reviewing its current operating procedures, other organizations need to carefully re-evaluate the respective policies and procedures they are using to conduct daily business.

Third, we also have to recognize that this is a continuing process. There is not one thing alone that will improve the drug availability situation. It is a complex situation that took a long time to evolve to the current state and it cannot be corrected with a single action. However, that does not mean the task is impossible to accomplish, it only means that we must be resolved to having a continuing goal of improving the process.

Whatever changes we make must be scientifically relevant and legally sound if we are to maintain confidence in the drug approval process and, ultimately, confidence in the safety of meat, milk, and eggs. CVM is 100% committed to improving the availability of approved new animal drugs, but we all must recognize that it will take effort by everyone associated with the use of animal drugs to bring about beneficial changes. However, CVM can be the catalyst to bring all the appropriate parties together and to coordinate their actions. I can relate to you today Dr. Sundlof's commitment to applying the level of effort necessary so that we will reap substantial benefits not only for the primary client groups but also for society at large and the animals for which we provide care.

Before I conclude today, I would like to bring you up to date on some recent drug approvals for which some fundamental policy discussions were necessary prior to approval. The Food and Drug Administration has recently approved two fluoroquinolone antibacterial products for use in chickens and turkeys. In August we approved SARAFLOX WSP, to be administered in drinking water for use in broiler chickens and growing turkeys for the control of mortality associated with Escherichia coli organisms susceptible to sarafloxacin. Sarafloxacin is the first fluoroquinolone approved for use in food-producing animals. Another fluoroquinolone drug, enrofloxacin, was approved in 1989 to treat certain infections in non-food animals. In October, we have just announced the approval of SARAFLOX Injection, which is indicated for the control of early chick mortality associated with bacterial infection by the E. coli organism.

On May 11-12, 1994, CVM's Veterinary Medicine Advisory Committee and the Center for Drug Evaluation and Research's (CDER) Division of Anti-Infective Drugs Advisory Committee heard presentations from human and animal health researchers and food-animal producers relative to concerns raised about the development of bacterial resistance to fluoroquinolones. The concerns which have been raised about the use of this new class of antimicrobials come about from the national and global increase in antibiotic resis-
tance and the complex issues surrounding this increase, both in community and institutional settings. Human infections caused by resistant pathogens result in increased morbidity and mortality from treatment failures and increased health care costs as newer, more expensive antibiotics are needed to treat common infections. The causes of this antibiotic resistance are multifactorial and complex. The issue of drug resistance among veterinary pathogens is a small part of this larger health issue and its role needs further delineation. We also recognize that the concern of increasing antimicrobial resistance needs to be reviewed with the knowledge that, as in the case of diseases in humans, the number of therapeutic options for treatment of infectious diseases in animals is diminishing. The members of both committees meeting in May 1994 concluded that FDA could approve fluoroquinolones found to be safe and effective for animal use.

CVM is interested, as is the rest of the animal health care community, in preserving the usefulness of these valuable new drugs and other fluoroquinolones by minimizing the potential for development of resistant pathogens. To achieve this objective, CVM believes it will be necessary to control unnecessary treatment of animals with fluoroquinolones. CVM is initiating an educational program to inform veterinarians and producers about the appropriate use of fluoroquinolones and is revising the Compliance Policy Guide 7125.06, Extra-Label Use of Animal Drugs in Food-Producing Animals, to include regulatory guidance for these drugs. To control the extra-label use of this class of drugs, FDA will assign a regulatory priority based on their actual use. The highest priority for regulatory action will be for extra-label use of fluoroquinolones in major food-producing animal species and classes of species that are not the subject of approved labeling. A lesser regulatory priority will apply to extra-label use of fluoroquinolones in minor food-producing species or within a major food-producing species or class for which the drug is approved but for which the actual use is not included in the approved labeling of the drug. As defined in 21 CFR 514.1(d)(1)(ii) major species include cattle, horses, swine, chickens, turkeys, dogs, and cats. All other species are considered minor species.

FDA is collaborating with the USDA and CDC to develop a surveillance system to monitor antimicrobial resistance in enteric pathogens. Under the program, USDA periodically will test Salmonella samples from animals for continued susceptibility to antimicrobial drug products. The CDC will conduct similar testing on samples of human Salmonella and E.coli. The manufacturer, Abbott Laboratories, will test samples of animal E.coli to measure the emergence of any resistance in the drug's target organism. The manufacturer will also provide geographically based drug distribution information to CVM as part of their annual Drug Experience Reports. The information from the monitoring programs will be used to assess the development of antibiotic resistant organisms and make any adjustments in the regulatory program.
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<tr>
<th>Date of Pub.</th>
<th>Date of Approval Letter</th>
<th>NADA #</th>
<th>Sponsor</th>
<th>Drug</th>
<th>Species</th>
<th>Type of Action</th>
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<td>47</td>
<td>6/18/95</td>
<td>200-288</td>
<td>Veterinary Laboratories</td>
<td>Flunixin Meglumine</td>
<td>Horses</td>
<td>New Indication (Species)</td>
</tr>
<tr>
<td>48</td>
<td>6/28/95</td>
<td>200-124</td>
<td>Fort Dodge</td>
<td>Flunixin Meglumine</td>
<td>Horses</td>
<td>Genotoxic</td>
</tr>
<tr>
<td>49</td>
<td>6/28/95</td>
<td>200-015</td>
<td>Abbott Labs</td>
<td>Euthanasia Hydrochloride</td>
<td>Chickens</td>
<td>New Chemical Entity</td>
</tr>
<tr>
<td>50</td>
<td>6/26/95</td>
<td>200-020</td>
<td>Fermenta Animal Health</td>
<td>Ketamine Hydrochloride</td>
<td>Cats</td>
<td>Non-human primates</td>
</tr>
</tbody>
</table>

Appendix C (continued)
We who work in government are experiencing substantial change. The GPRA, National Performance Review, and CVM’s Strategic Plan are major change-oriented initiatives that will mean real change in what we do and how we do it. Timely responsiveness and customer service are key motivations driving much of the change. We are being called on to answer to the questions of how best for us to prepare so that we can achieve the goals of the government in a work environment of accelerating change.

In August 1993, Congress enacted the “Government Performance and Results Act” (GPRA) to provide for the establishment of strategic planning and performance measurement in the Federal Government. The key purposes are to hold Federal agencies accountable for achieving results; set program goals, measure program performance against the goals, and publicly report progress; promote a focus on results, service quality, and customer satisfaction; help Federal managers improve delivery of service; provide Congress with objective information on achieving statutory objectives, relative effectiveness and efficiency of Federal programs and spending; and improve internal management of the Federal Government.

In September 1993, Executive Order 12862 set Customer Service Standards to carry out the principles of the National Performance Review. In it, the President declared that the Federal Government must be customer-driven and that customer service shall be equal to the in business. For the purposes of the Executive Order “customers” means an individual or entity who is directly served by a department of agency. “Best in business” shall mean the highest quality of service delivered to customers by private organizations providing a comparable or analogous service. Agencies are directed to identify the customers served; determine the kind and quality of service they want and their level of satisfaction with existing services; post our service standards and measure results against them; benchmark customer service performance against the best in business; survey front-line Federal employees on barriers to, and ideas for, matching the best in business; provide customers with choices in both the sources of services and the means of delivery; make information, services, and complaint systems easily accessible; and provide means to address customer complaints.

In May 1995, Alice Rivlin, Director, Office of Management and Budget speaking at a Symposium on the GPRA noted that Act responds to, and seeks to overcome, two deficits that shackle our nation and the federal gov-
ernment: the trust deficit and the more discussed, closely-related budget deficit. Over the period of the last 30 years, many Americans have changed from an expectation that government will do the right thing most of the time. Lack of trust and respect for government is a serious problem for those of us who believe that we play an important and constructive role in society. Now more than ever to be credible, we must have evidence that our programs produce measurable results and accomplish goals. GPRA is an important piece in a puzzle that we must solve. It will help us present a clear picture of our goals and links between these goals and how we spend our portion of the tax dollar. GPRA gives a set of tools to do what we should be doing anyway.

In June 1995, the Center Director issued the Strategic Plan for CVM. It is a plan for the future that emphasizes "Shifting the Paradigm." It guides us to be proactive in assuring the needed, safe, and effective products gain access to the market, and that we protect public and animal health, and maintain vigilance against economic fraud from products regulated under the Food, Drug and Cosmetic Act.

Over the past 2 years, the Office of Surveillance and Compliance has taken the first steps in orienting the CVM post approval programs toward compliance with GPRA. For example, last year, we shared the Annual Report with the regulated drug and feed industries, and with the leadership of the food-producing animal organizations. This year we plan to share the Strategic Goals and the Annual Report. From this sharing, we expect to hear increasing feedback about the effectiveness and quality of the CVM programs and services. We expect that we will be responsive to that feedback with revisions to this plan or in the next planning cycle.

The Strategic Goals are organized according to major outcomes. As we work with these during the year, we should anticipate refinements and simplifications from both internal and external feedback. GPRA requires implementation by September 30, 1997. However, several agencies have already implemented GPRA and I am sure that we can effectively do so too.

One of the sources of greatest job satisfaction is the achievement of specific results. Most of us derive pleasure from completing work that makes a difference. These Strategic Operational Goals, emphasizing outcomes as they do, can serve as a means of gaining greater job satisfaction from having better served all our stakeholders.
TABLE OF CONTENTS

Outcome A: p. 405
Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary devices.

Outcome B: p. 410
Ensure the safety of food derived from animals which were treated with drugs, and a safe animal feed supply.

Outcome C: p. 412
Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA offices, Federal and State agencies, industry, and consumers.

Outcome D: p. 423
Maximize FDA/CVM resource utilization by establishing cooperative compliance and educational efforts with industry, veterinarians, producers, Federal, State and Foreign governments, academia, and consumers.

Outcome E: p. 425
Accomplish the work outlines in the Strategic Plan and achieve the vision of CVM.
## S&C Operational Strategic Goals

### Outcome A: Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary medical devices.

<table>
<thead>
<tr>
<th>Goal</th>
<th>Activity</th>
<th>Description</th>
<th>Target Date</th>
<th>Status</th>
</tr>
</thead>
</table>
| A-1  | 1, 3     | Review veterinarian requests to purchase antidiote | Sept 96 | Ready to receive

- Review antidiote depot proposals
- Review proposed product labels
- Meetings and teleconferences with industry, veterinarians, and antidiote deposits
- Coordinate with NAD

<table>
<thead>
<tr>
<th>Goal</th>
<th>Activity</th>
<th>Description</th>
<th>Target Date</th>
<th>Status</th>
</tr>
</thead>
</table>
| A-2  | 3, 4     | Finalize and implement policy regarding the compounding of veterinary drugs | Jun 96 | Cleared guidance to field offices and other internal customers and stakeholders

### Notes:

- 0 - UNY 300
- 1 - UNY 210
- 2 - Office of Animal Drug Evaluation
- 3 - UNY 220
- 4 - Office of Science
- 5 - UNY 230

**This text is an endnote/footnote that does not affect the activity except for Sept 96.**

This date can also mean that the activity will carry over into the next fiscal year in which case the progress of the activity will be evaluated at the end of the fiscal year.
<table>
<thead>
<tr>
<th>Outcome A</th>
<th>Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>Review Investigational Food Additive (IFA) application for decisions on marketing treated food producing animals and to assist petitioners in preparing Food Additive Petitions (FAPs)</td>
</tr>
<tr>
<td>A-2</td>
<td>Letters issued advising petitioner of petition status</td>
</tr>
<tr>
<td>A-3</td>
<td>Letters issued permitting/not permitting marketing of food-producing animals fed experimental food additives</td>
</tr>
<tr>
<td>A-4</td>
<td>Review Medicated Feed Applications (MFAs) for compliance with regulations</td>
</tr>
<tr>
<td>A-5</td>
<td>Lettter issued advising applicant of application status</td>
</tr>
<tr>
<td>A-6</td>
<td>Obtain concurrence to develop third party certification</td>
</tr>
<tr>
<td>A-7</td>
<td>Sept 96</td>
</tr>
<tr>
<td>A-8</td>
<td>Reduced economic burden on FDA. Greater requirement to provide training</td>
</tr>
<tr>
<td>A-9</td>
<td>Improved response for inspections</td>
</tr>
<tr>
<td>A-10</td>
<td>More drugs permitted in animal feeds</td>
</tr>
<tr>
<td>A-11</td>
<td>Increased animal drug availability</td>
</tr>
<tr>
<td>A-12</td>
<td>Regulations amended allowing additives to be marketed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process</th>
<th>Action</th>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>Review Investigational Food Additive (IFA) application for decisions on marketing treated food producing animals and to assist petitioners in preparing Food Additive Petitions (FAPs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-2</td>
<td>Letters issued advising petitioner of petition status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-3</td>
<td>Letters issued permitting/not permitting marketing of food-producing animals fed experimental food additives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-4</td>
<td>Review Medicated Feed Applications (MFAs) for compliance with regulations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-5</td>
<td>Lettter issued advising applicant of application status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-6</td>
<td>Obtain concurrence to develop third party certification</td>
<td>Sept 96</td>
<td></td>
</tr>
<tr>
<td>A-7</td>
<td>Policy paper</td>
<td>Sept 96</td>
<td></td>
</tr>
<tr>
<td>A-8</td>
<td>Monograph process</td>
<td>Sept 97</td>
<td></td>
</tr>
<tr>
<td>A-9</td>
<td>Establish monograph functions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-10</td>
<td>More drugs permitted in animal feeds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-11</td>
<td>Improved response for inspections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-12</td>
<td>Increased animal drug availability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-13</td>
<td>Regulations amended allowing additives to be marketed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Date</td>
<td>Activity Description</td>
<td></td>
</tr>
<tr>
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<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>A-9</td>
<td>Jan 96</td>
<td>Develop and maintain accurate inventory of products.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oct 95</td>
<td>Provide critical information to support Medically Necessary Veterinary Products (MNVP) determinations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mar 96</td>
<td>Provide marketed products that requested by customers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refer evaluative products for review</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provide information for regulatory enforcement actions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Field inspections.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Known product inventory for industry and customers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Label revisions yielding acceptable food or drug product.</td>
<td></td>
</tr>
</tbody>
</table>

**Outcome A:** Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary medical devices
### Outcome A

Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary medical devices

<table>
<thead>
<tr>
<th>No.</th>
<th>Dir.</th>
<th>Activity</th>
<th>Outcomes</th>
<th>Actions</th>
<th>Outcomes</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-10</td>
<td>1, 3</td>
<td>Monitor all compliance and non-compliance related situations involving product shortages</td>
<td>Document noting the cause of reported shortages</td>
<td>Sept 96</td>
<td>Alter specific enforcement action</td>
<td>Needed drugs are available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Coordinate with Division of Compliance/Surveillance</td>
<td>Report on confirmed drug shortage situation (sent to CVM Drug Shortage Coordinator to determine MNVP status)</td>
<td></td>
<td>Alter NADA review priorities</td>
<td>Potential and actual drug shortage situation prevented</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Receive reports from FDA, industry, veterinarians and others</td>
<td>Maintain product data base</td>
<td></td>
<td>Alter enforcement strategy</td>
<td>Revise/Revise marketing decisions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Consult with field</td>
<td></td>
<td></td>
<td>Regulatory discretion</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Consult with NADA review Divisions</td>
<td></td>
<td></td>
<td>Expedite NADA review</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Dist.</td>
<td>Activity</td>
<td>Status</td>
<td>Date</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>-----</td>
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<td>----------</td>
<td>--------</td>
<td>------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>A-12</td>
<td></td>
<td>Promote science-based harmonization of international standards, by initiating and participating in discussions, and the sharing of information, with foreign regulators of animal drugs, veterinary medical devices, food additives, and feed ingredients.</td>
<td>Objectives are approved for the Strategic Plan. SIGs are formed.</td>
<td>Mar 96</td>
<td>Harmonization of foreign and domestic standards. Participate in discussions/sharing.</td>
<td></td>
</tr>
</tbody>
</table>

Outcome A: Provide for needed, safe, and effective animal drugs, medicated feeds, food additives, and veterinary medical devices.
### Outcome B: Ensure the safety of food derived from animals which were treated with drugs, and a safe annual feed supply

<table>
<thead>
<tr>
<th>No</th>
<th>Description</th>
<th>Completion Dates</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Develop Basic Dairy Farm Inspection &amp; Special Problems in Milk Protection training courses 306 &amp; 510 Conduct training of State sanitarians and FDA Milk Specialists on the aspects of the Grade A Pasteurized Milk Ordinance: drug labeling and storage requirements, proper drug use, and residue avoidance Coordinate training with CPSAN and ORA/DAHED 1,3</td>
<td>Scheduled courses</td>
<td>Communication is improved inside FDA Uniform training results in uniform interpretation of rules and regulations Improved Federal and State relations Resource efforts are focused on issues of importance Inquiries are handled in an expeditious fashion Improved effectiveness of milk monitoring program and tissue residue program Efficient utilization of FDA resources</td>
</tr>
<tr>
<td>2</td>
<td>Serve as a resource person(except) for questions from within FDA and states on dairy drug compliance issues 3,1 Coordinate with CVM Compliance on issues related to drug use in dairy cattle 1,3 Participate in Milk Safety Working Group 1,3</td>
<td>Work with field personnel (State &amp; FDA) in resolving issues related to milk safety Resolve problems Prioritization of pressing issues relating to drug use in the dairy industry Provide Residue Violation Information System (RVIS) information and information regarding residue program to participating states officials</td>
<td>Sept 96</td>
</tr>
<tr>
<td>3</td>
<td>Monitor National Conference on Interstate National Conference on Interstate Milk Shipments (NCMIS) activity 3,1 Participate coordination of meetwith illegal residue reports between states and FDA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Outcome B: Ensure the safety of food derived from animals which were treated with drugs, and a safe animal feed supply.

<table>
<thead>
<tr>
<th>No</th>
<th>Desc</th>
<th>Status</th>
<th>Date</th>
<th>Project</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-2</td>
<td>Prepare Compliance Policy Guide (CPG) and FR Notice of Availability allowing ammoniation of aflatoxin contaminated ingredients</td>
<td>Documents completed</td>
<td>May 96</td>
<td>Project completed</td>
<td>Standards established for ammoniation</td>
</tr>
<tr>
<td>B-3</td>
<td>Prepare article on 4 D meat publication in veterinary journal</td>
<td>Article published</td>
<td>Sept 96</td>
<td>Provide support for enforcement</td>
<td>Improved labeling</td>
</tr>
<tr>
<td>B-4</td>
<td>Review data from FY 95 Salmonella survey</td>
<td>Report prepared and additional action items identified</td>
<td>Jan 96</td>
<td>Establishes benchmark and provides scientific data for regulatory policy</td>
<td>Provides data to use for improving product quality and safety</td>
</tr>
<tr>
<td>B-5</td>
<td>Add Salmonella survey data from FY 96 research contract to existing database</td>
<td>Amended benchmark data published</td>
<td>Sept 96</td>
<td>Review of regulatory policy in light of new data</td>
<td>Provides data to use for improving product quality and safety</td>
</tr>
<tr>
<td>B-6</td>
<td>Initiate two HACCP pilot programs with feed industry (renderer and feed mill)</td>
<td>Report identifying strengths and weaknesses</td>
<td>Sept 96</td>
<td>Provides guidance on applicability of HACCP to feed industry</td>
<td>Positive aspects of HACCP utilized by the feed industry</td>
</tr>
<tr>
<td>B-7</td>
<td>Review scientific articles on important health issues, such as BSE, mycotoxins and heavy metals</td>
<td>Emerging issues are identified and recommendations offered</td>
<td>Sept 96</td>
<td>Establishes scientific bases for decision making</td>
<td>Increase industry confidence in FBA</td>
</tr>
<tr>
<td>B-8</td>
<td>Review report from Monsanto and keep apprised of National Toxicology Program (NTP) studies on ethoxyquin</td>
<td>Position document prepared</td>
<td>Sept 96</td>
<td>Decision whether to revise its food additive status in pet food</td>
<td>Clarification of safety of ethoxyquin</td>
</tr>
<tr>
<td>B-9</td>
<td>Review comments on Propylene Glycol (PG) proposed regulation and prepare final rule</td>
<td>Final rule published</td>
<td>Sept 96</td>
<td>Final rule published</td>
<td>All pet food manufacturers remove PG from their products</td>
</tr>
</tbody>
</table>
Outcome C  Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.

<table>
<thead>
<tr>
<th>No.</th>
<th>Action</th>
<th>Outcome</th>
<th>Date</th>
<th>Option (Goal, Method)</th>
<th>Comment (Product, FDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-1</td>
<td>1,3</td>
<td>Update CFR 510 300 (Records &amp; Reports)</td>
<td>Final Regulation publication</td>
<td>Sept 96</td>
<td>Final Regulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Complete internal review</td>
<td></td>
<td></td>
<td>• Publish Final Regulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Send Final Rule to OGC</td>
<td></td>
<td></td>
<td>• Better guidance for drug sponsors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Send Final Rule out of CVM</td>
<td></td>
<td></td>
<td>• Reduce the reporting burden for industry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Send for External Clearance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-2</td>
<td>3</td>
<td>Evaluate regulatory action recommendations from the Field and make articulate sound decisions on behalf of the Center</td>
<td>Memoranda relaying CVM’s evaluation and approval or disapproval, alternate strategies, and guidance as appropriate</td>
<td>Sept 96</td>
<td>Efficient use of resources by ensuring that actions forwarded are properly developed, clearly justified, and well supported</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Ensuring compliance with FFDCA</td>
</tr>
<tr>
<td>C-3</td>
<td>3,2,1</td>
<td>Review and coordination of Center evaluation of recommendations for product recalls</td>
<td>Memos classifying the recalls based on hazard involved and scope of recall</td>
<td>Sept 96</td>
<td>Conserve FDA resources by achieving compliance through voluntary recalls</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poster compliance and remove violative products from distribution efficiently</td>
</tr>
<tr>
<td>C-4</td>
<td>3</td>
<td>Review, evaluate, coordinate input, and respond to requests for information, regulatory and policy decisions, and litigation support</td>
<td>Timely, accurate, and articulate written and verbal communication</td>
<td>Sept 96</td>
<td>Effective and reliable information and guidance response to informal requests, training events, conferences, etc</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Effective and reliable transfer of information and guidance in response to informal requests, to meetings, complaints, etc</td>
</tr>
<tr>
<td>C-5</td>
<td>3,2,N</td>
<td>Monitor Bio Research program on Clinical Investigations (CT)</td>
<td>Recommend appropriate administrative action on CI</td>
<td>Sept 96</td>
<td>Accomplish bio research monitoring mission</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Issue letters</td>
<td></td>
<td></td>
<td>Increase the accuracy of data in submissions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Negotiate consent agreements</td>
<td></td>
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</tr>
</tbody>
</table>
**Outcome C: Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.**

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>C-6</td>
<td>1</td>
<td>Process DERs</td>
<td>90% of regulatory NADA supplements are completed within division and statutory time frames</td>
<td>Sept 96</td>
<td>Monthly Management Information update</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Process NADA Regulatory Supplements</td>
<td>90% of periodic DERs processed within 150 days of receipt</td>
<td></td>
<td>Identify delinquent or deficient product DER's and sponsors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enhance Stars 2 database</td>
<td>90% of spontaneous ADEs processed within 30 days of receipt</td>
<td></td>
<td>Receive DERs in a timely manner</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Prepare and submit Stars 2 enhancements to CVM Information Resources Management (IRM)</td>
<td></td>
<td>Increase adequacy of Stars 2 database</td>
</tr>
<tr>
<td>C-7</td>
<td>1, 3</td>
<td>Monitor Promotion and Advertising in the DE Rs for prescription drugs</td>
<td>Letters for Violative activity</td>
<td>Sept 96</td>
<td>Stop initial violative promotional activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Review DER-Submitted Labeling</td>
<td>Meetings and teleconferences with industry sponsors</td>
<td></td>
<td>Educate Industry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Review Consumer and Competitor Complaints</td>
<td>Revised advertisements</td>
<td></td>
<td>Revised advertisement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Conduct other Surveillance Activities</td>
<td>Guidance documents</td>
<td></td>
<td>Withdraw promotional piece/print retraction</td>
</tr>
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<td>1,3,N</td>
<td>Monitor labels submitted to the DERs</td>
<td>Recall warning statement</td>
<td>Sept 96</td>
<td>Process and approve Supplements</td>
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<td>Review Drug Listing (DL) information</td>
<td>Compliance Policy for Sterile Injectable containers</td>
<td>Sept 96</td>
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<td>Process competitor complaints</td>
<td>Implement metric conversion legislation</td>
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<td>Prepare reminder letters</td>
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<td><strong>C-9</strong></td>
<td>1,3</td>
<td>Monitor the non NADA drug and device product advertisements</td>
<td>Product status determined: NAD-adulterated/misbranded</td>
<td>Sept 96</td>
<td>Establish product/sponsor data base for unapproved products</td>
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<td>Regulatory reviews and recommendations</td>
<td>Identify and assist expert winceses</td>
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<td>Encourage and increase approval activity</td>
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<td>Prepare consultant memos to HFY-236</td>
<td>Seizures/Injunctions recommendations</td>
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<td>Recommend policy decisions on products (class actions)</td>
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<td>Obtain expert winceses</td>
<td>Letters to industry establishing product status</td>
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<td>Participate with Compliance, GC, DOI in case preparation</td>
<td>Proper conditions for use and regulatory discretion</td>
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<td>Review Animal medical devices</td>
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<td>Review interpretation of Food GMP regulations with emphasis on assays</td>
<td>Compliance program changes made</td>
<td>May 96</td>
<td>Improved guidance to Field</td>
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<td><strong>C-11</strong></td>
<td>2</td>
<td><strong>2. Improve compliance with FDA regulations</strong></td>
<td>Guide published for cattle feedlot feedmills</td>
<td>Jan 96</td>
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<td>Training held for agency and State inspectors</td>
<td>Aug 96</td>
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<td>Participate in industry workshops</td>
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<td><strong>C-12</strong></td>
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<td><strong>3. Articulate S&amp;C enforcement priorities</strong></td>
<td>Enforcement strategy document finalized</td>
<td>Jan 96</td>
<td>Clearer guidance to FDA headquarters and field; enforcement strategies that foster buy-in and support</td>
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<td>Disseminate documents within FDA</td>
<td>June 96</td>
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<td>3</td>
<td><strong>3. Clarify inapplicability of Dietary Supplement Health Effects Act (DSHEA) to animal products</strong></td>
<td>Notice of policy published information disseminated within FDA</td>
<td>Mar 96</td>
<td>Clearer guidance to field offices</td>
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<td><strong>C-14</strong></td>
<td>3</td>
<td><strong>3. Draft - &quot;Publish Approvals&quot; of NADA/ANADA, and PAP's and Notice of availabilities of Center guidelines &amp; policies on the Federal Register</strong></td>
<td>Draft documents</td>
<td>Sept 96</td>
<td>To provide timely and accurate regulations that describe NADA, ANADA, and PAP approvals</td>
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<td>Finalize FR document</td>
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<td><strong>3. Administer CVM's responsibilities under FDA's Application Integrity Policy (AIP), oversee Ad Hoc committees and formulate recommendations</strong></td>
<td>Decision memoranda prepared for Center concurrence</td>
<td>Sept 96</td>
<td>All affected units are informed of AIP status of applicants and their submissions</td>
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<td>Ensure affected firms compliance with AIP requirements</td>
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<td>C-16</td>
<td>Incorporation of CI and Establishment Inspection Report (EIR) databases into Center-wide database</td>
<td>Center-wide Notice of Drug Shipment (NODS) and EIR database</td>
<td>Sept 96</td>
<td>Improved utilization of field investigational resources</td>
<td>Increase accuracy of data in submissions</td>
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<tr>
<td>C-17</td>
<td>Compliance/scientific review of EIRs</td>
<td>Reviews and post-inspection correspondence</td>
<td>Sept 96</td>
<td>To improve guidance</td>
<td>Education of customers</td>
</tr>
<tr>
<td>C-18</td>
<td>Implement the Animal Medicinal Drug Use Clarification Act (MDUCA) * Draft concept paper * Draft Proposed Rule * Publish Proposed Rule * Evaluate public comments</td>
<td>Concept Paper Proposed Rule draft Proposed rule Public comments evaluation Final rule</td>
<td>June 95 Sept 95 Nov 95 May 95 Oct 96</td>
<td>Regulations will permit the extra-label use of drugs in the practice of veterinary medicine, under certain conditions.</td>
<td>Veterinarians will be able to legally use drugs in an extra-label manner in their practice of veterinary medicine.</td>
</tr>
<tr>
<td>C-19</td>
<td>Provide guidance to CVH staff on the proper procedures for dissemination and clearance of Guidelines * Provide advice * CVH Policy and Procedures (P&amp;P) on proper dissemination and clearance procedures for guidelines * Clear document and incorporate into CVH P&amp;P Manual</td>
<td>Draft a CVH P&amp;P on proper dissemination and clearance procedures for guidelines</td>
<td>Sept 96</td>
<td>CVH staff is provided information on the proper handling of Guidelines.</td>
<td>The public will receive guidance documents in a uniform manner.</td>
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<tr>
<td>No.</td>
<td>Act</td>
<td>Activity</td>
<td>Initials</td>
<td>Date</td>
<td>Outcome (in FDA)</td>
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</table>
| C-20 | 3   | Revise the stated policy of CVM on the testing requirements for demonstration of chemical and positional stability of liquid medicated feeds  
- Draft a proposed rule to modify 558.5  
- Publish the proposed rule  
- Provide a final answer to the AFIA Citizen Petition  
- Evaluate public comment submitted on the Proposed Rule  
- Draft Final Rule  
- Publish Final Rule | Proposed rule drafted to modify 558.5  
Proposed Rule published  
Final answer to the AFIA Citizen Petition  
Public comment evaluation on Proposed Rule  
Final Rule drafted  
Final Rule published | June 95 | We will have completed the Citizen Petition requesting the changes in Information required to demonstrate chemical and positional stability to be in accord with current scientific standards | Data requirements to demonstrate Chemical and Positional stability of liquid medicated feeds will be at the level of current scientific expertise |
| C-21 | 3, ON | Reconsider the interim marketing of certain medicated feeds containing chlorovesicline or oxytetracycline which are labeled with unproven claims, which will be done in tandem with the DESI finalization of CTC and OTC  
- Draft a proposed rule to modify 558.5  
- Publish the proposed rule  
- Provide a final answer to the AFIA Citizen Petition  
- Evaluate public comment submitted on the Proposed Rule  
- Draft Final Rule  
- Publish Final Rule | Proposed rule drafted to modify 558.5  
Proposed Rule published  
Final answer to the AFIA Citizen Petition  
Public comment evaluation on Proposed Rule  
Final Rule drafted  
Final Rule published | June 95 | Stop the marketing of some of the sanctioned interim  
marketing products listed in 558.15 and provide a real answer to congressional concerns regarding the lack of basis to generically copy some currently marketed CTC and OTC medicated feed products | We will provide a basis to generically copy effective CTC and OTC medicated feed products  
Products will carry only claims that have been shown to be effective |
### Outcome C Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Action</th>
<th>Output</th>
<th>Date</th>
<th>Status</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>C-22</td>
<td>Revise the current regulations to delineate the responsibilities of clinical investigators</td>
<td>Propose Rule to amend 311 10(7) drafted</td>
<td>July 95</td>
<td>Provide regulations that clearly identify the responsibilities of clinical investigators, take regulatory action against those who do not comply by these regulations</td>
<td>The animal drug industry can rely on clinical investigations. Enforceable regulations describe responsibilities.</td>
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<tr>
<td></td>
<td></td>
<td>Proposed Rule published</td>
<td>Jan 96</td>
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<td>Evaluation of comments submitted regarding the Proposed Rule</td>
<td>Sept 96</td>
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<td></td>
<td>Final Rule drafted</td>
<td>Dec 96</td>
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<td></td>
<td></td>
<td>Final Rule published</td>
<td>Mar 97</td>
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<td>Draft a Proposed Rule to amend 311 10(7)</td>
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<td></td>
<td>Clear and publish the Proposed Rule</td>
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<td>Evaluate comments submitted regarding the Proposed Rule</td>
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<td></td>
<td>Draft a Final Rule</td>
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<td></td>
<td>Clear and publish the Final Rule</td>
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<td>Support the drafting of the HADA/AHADA proposal to modify existing drug application requirements</td>
<td>Resubmit to amend Part 514 drafted</td>
<td>Sept 96</td>
<td>Modify the existing regulations to include current application requirements and abbreviated application process so that it will be uniformly applied</td>
<td>Provide regulations that reflect current application requirements intended to allow for more efficient application procedures (e.g., phasing) as well as covering the abbreviated application process, that should result in increased approved animal drug availability.</td>
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<td>Rejected</td>
<td>Mar 97</td>
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<td></td>
<td>Evaluation of submitted public comments</td>
<td>FY 97</td>
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<td>Final Rule drafted</td>
<td>FY97</td>
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<td>Final Rule published</td>
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<td>Draft a Final Rule</td>
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<td>Clear and publish Final Rule</td>
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<td>No.</td>
<td>Div.</td>
<td>Action</td>
<td>Activity Description</td>
<td>Date Arrest</td>
<td>Date Proposed Rule (Approximate)</td>
<td>Outcome (Note)</td>
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<tr>
<td>C-24</td>
<td>3,1,N</td>
<td>Support the revision and clearance of the regulations covering Investigational New Animal Drugs</td>
<td>Supporting revision and clearance of the regulations</td>
<td>Sept 96</td>
<td>Sept 96</td>
<td>CVM has enforceable regulations regarding the investigative phase of drug product development. Public health is better protected by enforceable regulations. The animal drug industry has a clear understanding of CVM's policies covering INADs.</td>
</tr>
<tr>
<td>C-25</td>
<td>4</td>
<td>Determine tissue residue violations by slaughter class, drug class, reasons for residue occurrence, and trends in occurrence</td>
<td>Generate reports and publish results</td>
<td>July 96</td>
<td>July 96</td>
<td>Identify violations of public health concern and potential areas in need of compliance activity. Set program priorities for follow-up activities. Comment on and provide input to FSIS's surveillance activities to concentrate on particular types of violations.</td>
</tr>
<tr>
<td>C-26</td>
<td>4,1</td>
<td>Determine tissue residue violations due to extra-label drug use</td>
<td>Generate reports and publish results</td>
<td>August 96</td>
<td>August 96</td>
<td>Identify producer practices of PHI concern. Set program priorities for follow-up activities. Develop educational initiatives directed at producers and veterinarians on proper animal drug use.</td>
</tr>
<tr>
<td>C-27</td>
<td>4,M</td>
<td>Disseminate reports on tissue residue violations</td>
<td>Identify areas in need of compliance activity</td>
<td>July 96</td>
<td>July 96</td>
<td>Alert USDA, other agencies, and state officials of potential food safety problems.</td>
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</tbody>
</table>

Outcome C: Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.
### Outcome C: Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.

<table>
<thead>
<tr>
<th>No.</th>
<th>Rep</th>
<th>Activity</th>
<th>Goal</th>
<th>Date</th>
<th>Evaluation (FDA)</th>
<th>Outcome (FDA)</th>
</tr>
</thead>
</table>
| C-28 | 4   | Expand quality control procedures for TRMS  
Check incoming Attachment C for completeness and accuracy | Report on completeness and accuracy | Sept 96 | Alert tissue residue monitors and other field personnel of problems | Alert state contract investigators of problems |
| C-29 | 0.1.2.3.4.5 | Verify and adjust as necessary the guidance contained in CVM Compliance Programs  
- Finalize Draft Tissue Residue Compliance Program (CP 71 006)  
- Publish and distribute CP 71 006 to Field  
- Form team and review the Imported Bulk New Animal Drugs Compliance Program (CP 71 007)  
- Rewrite or relaise Program per review.  
- Form team and review Drug Process/NADA Inspections Compliance Program (CP 71 001) objectives  
- Define Program Evaluation Scope  
- Complete database input (FY - 93 / FY - 95)  
- Analyze data  
- Prepare report | FY - 96 version of Tissue Residue Compliance Program  
FY - 96 version of Imported Bulk New Animal Drugs Compliance Program  
Drug Process/NADA Inspections Compliance Program Evaluation  
- baseline data  
- recommendations | Sept 96 | Maintain/improve investigational guidance:  
- Compliance Program guidance is current thus investigational focus is current  
- Compliance Program guidance for screening imports and inspecting importers is current.  
Identification of type of post-approval GMP violations  
Increases ability to correct and prevent problems:  
- education  
- partnership | Educational guidance to manufacturers of animal drugs  
Decrease availability of drugs of unknown quality, safety, and effectiveness from foreign sources.  
Increased compliance through improved guidance/education to manufacturers of animal drugs |
**Outcome C: Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.**

<table>
<thead>
<tr>
<th>No.</th>
<th>RS-1</th>
<th>AREA</th>
<th>#</th>
<th>ACTIVITY</th>
<th>COMPLIANCE</th>
<th>DATE</th>
<th>COMMENTARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-30</td>
<td>4,0,N</td>
<td>Verify</td>
<td>Workplan Forecasts:</td>
<td>Sept 96</td>
<td>Center planned and Field conducted activities are justified</td>
<td>Equitable coverage of the Official Establishment inventory.</td>
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<td></td>
<td></td>
<td>and</td>
<td>• Preliminary</td>
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<td>Field activities are converted into analytical and investigational FTB's</td>
<td>Ensure Industry compliance with safety and efficacy requirements</td>
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<td></td>
<td></td>
<td>valid</td>
<td>• Final</td>
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<td>Inspectional and investigational planning across Centers conserves resources</td>
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<td>of CVM</td>
<td>Resource Utilization</td>
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<td></td>
<td></td>
<td>resource budget</td>
<td>Documents:</td>
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<td></td>
<td></td>
<td></td>
<td>• Monthly report</td>
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<td>• Mid-year Report</td>
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<td>• End of Year Report</td>
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<tr>
<td>C-31</td>
<td>4,2,3</td>
<td>Monitor</td>
<td>Type A Medicated Articles FY-95 Directed Assignment Evaluation</td>
<td>Sept 96</td>
<td>Identification of level and type of GMP compliance and non-compliance improves Field ability to direct attention to areas of greatest public health risk.</td>
<td>Increased compliance by Industry through identification of potential problem areas</td>
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<td>Compliance Program Activities:</td>
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<td>Determine the incidence of compliance with GMP regulations by Type A Medicated Feed manufacturers:</td>
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<td>• Analyze data from the FY-95 directed assignment</td>
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<td></td>
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<td>• Prepare and issue assignment evaluation</td>
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<td></td>
<td></td>
<td>• Inform field about sources of GMP problems</td>
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<td>Determine the incidence of compliance with GMP regulations by Non-registered Feed Mills:</td>
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<td>• Analyze data from the FY-95 directed assignment</td>
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<td></td>
<td>• Prepare and issue assignment evaluation</td>
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</table>
### Outcome C: Foster compliance by providing timely, articulate communication of regulations, policy, and other information to the Field, other FDA Offices, Federal and State agencies, industry, and consumers.

| No. | Emr. | Action | Supply | Date | Outcome & Action Plan | Results & Outcomes
<table>
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<tbody>
<tr>
<td>C-32</td>
<td>4.3</td>
<td>Identify the repeat violators for FY93</td>
<td>Annual repeat violator list produced</td>
<td>April 96</td>
<td>Prioritize field resources for follow-up activities; concentrate compliance activity on producers who repeatedly introduce adulterated animals into the food supply. Estimate field resources needed for coming years.</td>
<td>Identify areas for educational efforts. Identify individuals or geographic regions for concentrated FSIS sampling. Enforcement actions. Increased protection of public health.</td>
</tr>
</tbody>
</table>
**Outcome D: Maximize FDA/CVM resource utilization by establishing cooperative compliance and educational efforts with industry veterinarians, producers, Federal, State, and Foreign governments, academia, and consumers.**

| D-1 | 1,3 | Process estimated 2400 Adverse Drug Experience (ADE) Reports | Monitor Adverse Reaction Committee (MARC) Evaluations and Recommendations | Aug 95 | Enhanced ADE database leading to better decision-making | ADE Awareness increased leading to reduced and better managed risk |
|     |     | Educate Industry | Annual ADE Summary | Jan 96 | Warning Letters | Label changes |
|     |     | Educate Veterinarians | Participate in Workshops | | Increased cooperation with customers | Voluntary Product Recall |
|     |     | Conduct investigations | Upgrade Database | | Regulation changes | Change industry practices |
|     |     | Meet with Industry | FR Announcements | | Process and Approve Supplements to change product/label | Improved customer service |
|     |     | Educate veterinary students | Letters to Industry | | Establishes product safety profile | Improved industry competitiveness |
|     |     | | Guidance Documents | | Identifies trends and determines drug causality | Increased ADE Reporting |
|     |     | | Provide educational information to veterinary colleges | | | Prepare and submit supplements to change product/label |
| D-2 | 1,4 | Coordinate ADE Database upgrade with IRM | Develop criteria and specification for Oracle system | Oct 93 | Improved ADE information availability | Safer products and more informative product labels |
|     |     | IRM develop database program | Test new system | Dec 93 | Better decision-making | Level playing field |
|     |     | Review and revise database program updates | Accept new system | Jan 96 | | |
|     |     | | Enter new data into system | Jan 96 | | |
|     |     | | Down load old data from FoxBASE to new system | Sept 96 | | |
### Outcome D: Maximize FDA/CVM resource utilization by establishing cooperative compliance and educational efforts with industry, veterinarians, producers, Federal, State, and Foreign governments, academia, and consumers.

<table>
<thead>
<tr>
<th>No.</th>
<th>Date</th>
<th>Activity</th>
<th>Description</th>
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<tbody>
<tr>
<td>D12</td>
<td>4.1.1</td>
<td>Antibacterial resistance testing of veterinary origin Salmonella isolates by USDA/ARS and National Veterinary Services Laboratory (NVSL)</td>
<td>Test results of Salmonella isolates originating from cattle, swine and poultry for resistance to 17 antimicrobials reported to CVM. (Isolates will originate from slaughter plants via FSL, from healthy animals via National Animal Health Monitoring System (NAHMS) studies and from sick animals via NVSL.) Sept 96 Determine the prevalence of antibacterial resistance among the Salmonella isolates collected from cattle, poultry and swine (both healthy and sick). Identify emerging resistance to specific antimicrobials in particular species or geographic locations. Assess relationship to drug distribution data. Continue data with data on resistance to human origin isolates to construct a complete surveillance system for antibacterial resistance in zoonotic enteric organisms. Initiate educational programs to producers and veterinarians on emerging resistance and proper drug usage.</td>
</tr>
<tr>
<td>D13</td>
<td>4.1.1</td>
<td>Antibacterial resistance testing of human origin Salmonella and E. coli O157:H7 isolates by CHINCIDA</td>
<td>Test results of Salmonella and E. coli O157:H7 isolates collected from humans within selected surveillance sites for resistance to 17 antimicrobials reported to CVM. Analysis and maintenance of the data in collaboration with FDA, USDA and the emergency expert working group. Sept 96 Determine the prevalence of antibacterial resistance among the human Salmonella and E. coli O157:H7 isolates collected from the surveillance sites. Identify emerging resistance to specific antimicrobials among humans in particular geographic locations. Determine the association between antibacterial resistance among human and animal enteric pathogen isolates, especially among types of animals and geographic regions. If increasing resistance to antibiotics of importance is identified in bacteria that pose a public health threat, FDA will take timely and decisive action to contain the resistance and minimize the health hazard to humans.</td>
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**Outcome E. Accomplish the work outlined in the Strategic Plan and achieve the vision for CVM.**

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<th>No.</th>
<th>Dir.</th>
<th>Description</th>
<th>Date</th>
<th>Result</th>
<th>Outcome (outside FDA)</th>
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<tr>
<td>E1</td>
<td>0.1,2,3,4</td>
<td>Support implementation of the CVM Strategic Plan. Actively participate and make meaningful contribution to the efforts of goal groups Strategic Implementation Group (SIGs), and other teams.</td>
<td>Sept 96</td>
<td>Improved work quality and improved work life quality</td>
<td>Increased customer service and customer satisfaction</td>
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</tbody>
</table>
The Committee on Professional Oversight convened at 1:35 p.m. on Thursday, November 2, 1995 with six members present.

A review of last year's committee report determined that satisfactory progress had been made in each area discussed.

A resolution from the Southern Animal Health Association was considered. It would recommend that states rescind rules or statutes which require Certificates of Veterinary Inspection for interstate movement of dogs and cats, and only require evidence of current rabies vaccination. We recommend that USAHA ask state animal health authorities to review the costs and benefits of cat and dog certificates of inspection and consider supporting the SAHA resolution and taking such action.

The committee considered a recommendation that all tests and Certificates of Veterinary Inspection for cattle be recognized for 45 days instead of 30 days. It declined to support the resolution.

It was agreed that a review would be made to determine what action AVMA had taken with regard to the 1993 proposals on improving standards, educational support, and professional standing of state animal health officials.

One resolution regarding federal funding of state meat inspection activity was forwarded to the Resolutions Committee.
The 2nd International Symposium on the eradication of Aujeszky's Disease (pseudorabies) virus was held in Copenhagen, Denmark from August 6-8, 1995. There were 170 registrants from 26 nations.

Having attended the 1st International Symposium on the eradication of Aujeszky's Disease virus in St. Paul, Minnesota in 1991, it is only natural to make comparisons. In 1991 there did not appear to be a consensus as to how the task could be accomplished. The 2nd symposium clearly showed that many nations have a plan and are pursuing eradication. A total vaccination plan of both breeders and finishers administered by the practicing veterinarians is being used. After 5 years of vaccination a test and removal of all positive breeders will begin.

Denmark and the United Kingdom have been free of pseudorabies since 1992. Finland was declared free in 1995. Large areas of Germany (south and east) and France (southwest) are free. Sweden apparently has very little if any infection and will soon be declared free.

Both Denmark and the United Kingdom completed the eradication without using vaccine. Positives were removed with indemnity. Producers created their own funds for much of the program through a check off on slaughter pigs.

Danish producers became reinfected from nearby producers in Germany. To stop this threat the Danish producers have furnished vaccine for use in a zone of northern Germany that joins Denmark. This has apparently stopped the virus spread.

The gE(gl) vaccine is the only vaccine used in Europe. Vaccine usage was universally credited for reducing the percentage of positives in both the breeders and in the finishers, yet vaccine did not totally prevent infection. One of the scientists from the Netherlands reported on increased performance from finishers that did not sero-convert.

After the symposium, I spent a few days visiting farms, veterinarians, laboratories, and government officials in Germany, the Netherlands, and in France.

In Germany, I visited the Borden area. This is a swine dense area with approximately 2500 producers in that county. Herds seemed to range from...
100 to 300 breeders, totally confined, and on small farms that had other livestock and a diversity of vegetables and small grain production. Wheat seemed to be the primary diet for swine in the areas that I visited. All farms have a premise identification and every pig is identified with a plastic tag. All breeding swine are vaccinated 3 times a year by a local veterinarian. All pigs are vaccinated at 10-12 weeks of age. Every herd is blood-tested twice a year.

All tags, vaccine, blood testing, and veterinary service for testing and vaccination are furnished by the government. The government generates approximately 1/2 of this cost by an assessment levied once a year based on inventory of animals.

All herds found to be positive must then enter into a test and removal program for the breeders. If producers cannot feed out the piglets, a sale can be arranged to restricted premises for feeding at a 30-35 percent discount. Regulatory veterinarians and compliance personnel maintain an office in a beautiful county building. This office is very well staffed and computerized. I have no doubt about this program advancing rapidly.

In the Netherlands I found the same type of farms. All brick buildings, driveways, barnlots, very clean and well maintained. All herds have an identification number assigned. All vaccination and testing must be done by a veterinarian. All costs are paid for by the government. The government collects about 1/2 of all program costs from the producer through a slaughter check-off. The program calls for the collection of 12 random blood samples 3 times a year from each herd. Test and removal will commence on all positive herds. Indemnity is paid. Excellent laboratory and research facilities were available to assist animal health programs. I was very impressed with a bar coding system developed to track all tests charts, blood vials, animal movement permits, and premise identification.

In France the program is somewhat similar. Herds all have an identification number. Herds must test once a year in low incidence areas and as much as four times a year in areas heavily infected. Practicing veterinarians do the testing but not all of the vaccination. All herds are supposed to be vaccinating at their own expense but not all do it. Vaccination is not enforced very well, however, I visited one herd owner who organized a community program to see that everyone complied. This happened after his herd became reinfected. I was very impressed with the cleanliness of the European farms that I visited. These farms were beautifully landscaped and had very little swine farm odor. Laboratory and research facilities in France were excellent. A major portion of research and health programs are funded by slaughter check funds.

I am indebted to Dr. Hans-Joachim Batza, Germany, Dr. Jan A.Smuk, the Netherlands, and Dr. Phillippe Vannier, France, for arranging visitation programs for me in their countries.
Chairman: Mr. Don D. Gingerich, Parnell, IA
Vice Chairman: Dr. George W. Beran, Ames, IA

Ms. JoAnn Alumbaugh, IA; Dr. Paul L. Anderson, MN; Dr. Joseph Annelli, MD; Mr. Don Benson, SD; Dr. C. Carter Black, GA; Mr. Neal Black, MN; Dr. Decatur Blanchard, NC; Mr. Philip E. Bradshaw, IL; Dr. Donald Bridgewater, CO; Mr. Eric Dee, IA; Mr. Robert Dykhuis, MI; Dr. George C. Edwards, NC; Dr. Walter D. Felker, IA; Dr. Thomas W. Freas, IN; Dr. Merwin L. Frey, IA; Dr. Anthony M. Gallina, PA; Dr. Larry M. Granger, MI; Dr. Thomas J. Hagerty, MN; Dr. Edwin Hahn, IL; Dr. Mark Hammer, VA; Ms. Jody Hauge, ND; Dr. Howard Hill, IA; Dr. Sam D. Holland, SD; Mr. Donald Hoogestraat, SD; Dr. Irwin H. Huff, ND; Dr. Richard D. Hull, IL; Dr. John W. Hunt, MO; Dr. John P. Huntley, NY; Dr. Owen James, MT; Dr. John A. Johnston, IN; Dr. Charles L. Kanitz, IN; Dr. John P. Kluge, IA; Mr. Willard Korsmeyer, IL; Mr. John H. Lang, WI; Mr. James W. Leafstedt, SD; Dr. James L. Lindstrom, TX; Dr. Herbert E. Little, CA; Dr. Bret D. Marsh, IN; Dr. Charles E. Massengill, MO; Dr. Thomas J. McGinn, III, NC; Mr. John McNutt, IA; Dr. I. Lee McPhail, OH; Dr. William L. Mengeling, IA; Dr. Rita D. Michaels, MO; Dr. Harry F. Moberly, Jr., IL; Mr. Armand D. Moles, MO; Dr. F. J. Mulhern, MD; Dr. Donald H. Person, MN; Dr. Nancy Pfeiffer, NE; Dr. John R. Ragan, TN; Ms. Nancy Robinson, MO; Mr. Jeff Schnell, IA; Dr. George P. Shibley, KS; Mr. Gary Simpson, CO; Mr. Michael L. Snyder, ME; Dr. Charles E. Starkey, AR; Mr. James W. Stocker, NC; Dr. Paul Sundberg, IA; Dr. Arnold C. Taft, MD; Dr. David G. Thawley, MN; Dr. Dennis L. Thompson, CA; Dr. E. Thomas Thurber, NE; Dr. Paul O. Ugstad, NE; Dr. James W. Van Buren, MI; Mr. Joseph A. Vansickle, MN; Mr. Willard H. Waldo, NE; Dr. Douglas L. Weiss, MN; Dr. Larry L. Williams, NE; Mr. Fred Wise, IN

DRAFT

Chairman Don Gingerich called the meeting to order with over 50 participants. He began the meeting with a report from the National Pork Producers Council (NPPC). While significant progress has been made with the national eradication program, he cautioned program officials about becoming apathetic. Surveillance and identification will become critical as the program moves forward. The Congressional level of funding will be the same as last year's appropriation.

Dr. Arnold Taft gave the USDA report. For the first time in this program's history, there are more states free of the disease than any other status or stage in the program. The number of infected herds decreased from 6,205 to 4,541 in one year, a reduction of 27%. Only approximately 2% of the nation's herds remain infected. Dr. Taft also reported on the International PRV Symposium and the current PRV status in several European countries.

Dr. Erickson reviewed the Biologics and Diagnostics Subcommittee report. The statistical review of a 2-year study of 45 problem cleanups and 28
successful cleanups were presented by Dr. John Deen. Dr. Osorio presented new data on the ability of vaccine strains of PRV to prevent infection by wild type, field strains of PRV. Dr. Richard Hull presented diagnostic testing information to the subcommittee to evaluate the most effective testing method for cull boars and sows.

Dr. Teclaw and Dr. Schoenbaum reported on changing testing requirements for Qualified Negative and Qualified Negative Vaccinated herds. They stressed the importance of representative and random sampling. Dr. Schoenbaum reported on a proposed slaughter surveillance project.

Glen Slack reported on the Great Lakes Area Workshop and National PRV Work Conference sponsored by the Livestock Conservation Institute (LCI). These meetings were viewed as very successful and have been encouraged in other areas of the country.

Phil Bradshaw reported on the National PRV control board. Fourteen states were approved for advancing in status and 20 states were approved for renewal of stage III status.

Dr. Nolan reported on the industry's use of premise identification. His premise identification uses a company logo and a premise number on plastic eartags. This identification is used on the farm for management purposes and will identify the sows when they are culled and go to slaughter.

Dr. Annelli and Gary Simpson reported on the swine identification stakeholder meeting. The meeting prompted action which calls on USDA/APHIS to coordinate the development and implementation of a national premises identification system for use in the identification of cull sows and boars by the end of this year.

Dr. Hahn reviewed the NC-197 research project and the feral swine research report. The NC-197 regional project focuses on genetic diversity in virus strains. The feral swine activity is focusing on work to provide oral vaccine for pseudorabies and brucellosis.

Several states reported on progress being made towards eradication.

Dr. Hagerty reported on the Program Standards Subcommittee. The following recommendations were approved as amendments to the Program Standards:

Revision of section B on page 23 would be amended to read as follows:

B. QN breeding herd status may be maintained by pseudorabies testing as follows:

1. Monthly testing
   a. Conduct an official pseudorabies serologic test of 7% of all swine 6 months of age or older every 30 days, and
   b. Every 30 days test offspring 4 to 6 months of age located on the same premises as the breeding herd. The number to be tested shall be equal to 2% of the breeding animals in the herd, or
   c. On approval of the state veterinarian, herds in Stage III, IV or V states or areas may maintain status on the basis of a
PSEUDORABIES

monthly negative official random sample test (95/5) in each separate population of sows on a premises. Sampling in the population must be random and the testing protocol in the herd must be a part of the approval, and
d. Every 30 days test 50 offspring 4-6 months of age located on the same premises as the breeding herd. Progeny must be selected at random from all groups on the premises.
e. Progeny testing on multi-site herds is covered in item D on page 25 regarding establishment and maintenance of QN growout premises on which no adult breeding swine are maintained.

2. Quarterly testing
   a. Conduct an official pseudorabies serologic test of 20% of all swine 6 months of age or older every 80 to 105 days, and
   b. Test offspring 4 to 6 months of age located on the same premises as the breeding herd. The number to be tested every 80 to 105 days shall be equal to 6% of the breeding animals in the herd.
   c. Progeny testing on multi-site herds is covered in item D on page 25 regarding establishment and maintenance of QN growout premises on which no adult breeding swine are maintained.

3. All swine tested shall be randomly selected and, in the case of adult swine, representative of all age groups on the premises.

4. All swine intended to be added to a QN herd shall be isolated, etc. (continue as presently at the bottom of page 23).

D. QNV breeding herds status may be maintained by pseudorabies testing as follows:
   Repeat items 1, 2, and 3 above.

Revise Subpart III--The Pseudorabies-Monitored Feeder-Pig Herd Section C. (Page 27) by striking the word “a” and adding an “s” to the word “herd” in the second line to make the sentence read as follows:

E. A remote growout nursery to which pits have been moved within 1 week of weaning from pseudorabies-monitored feeder-pig herds may qualify as a pseudorabies-monitored feeder-pig herd on the basis of a negative official random sample test (95/10) as determined by an official pseudorabies epidemiologist. Each segregated group of swine on an individual premises must be considered a separate herd for testing purposes.

Addition to the same section the following new section:

F. Off-site nurseries in Stage III may be recognized as Pseudorabies-Monitored Feeder-Pig Herds if all pigs in the herd come from sow herds in Stage III or higher.
Significant progress has been made in the past year in the elimination of pseudorabies. Sixteen States have advanced their status. Today, seventeen States are in stage V (free) status. For the first time ever, there are more States in stage V (free) status than in any other stage.

Stage II  Stage II/III  Stage III  Stage II/IV  Stage IV  Stage V
Florida    Indiana    Alabama    Wisconsin    Colorado    Alaska
Iowa       Minnesota  Arkansas    Boston    Puerto Rico    Delaware
Kansas     Nebraska   California  Philadelphia    Idaho
Pennsylvania  North Carolina  Georgia    Texas    Virginia    Maine
US Virgin Islands     Georgia    Hawaii    Texas    Rhode Island    Mississippi

(6) (5) (15) (1) (8) (17)

Figure 1 shows the status of all States and the approximate number of infected herds. On July 1, 1994, there were 6205 pseudorabies infected herds in the United States. By July 1, 1995, the number had been reduced to 4541 or a total reduction of 1664 herds (27%). This number has continued to decline with only 4062 infected herds being reported in late September. Infected herds would have declined even more had not newly infected herds been discovered.

Figure 2 shows States with infected herds with or without cleanup plans. The percentage of herds that have cleanup plans has continued to improve.
Today approximately 98% of all known infected herds have a cleanup plan. Figure 3 shows the source of new herd infections. The percentage of unknowns has decreased in the past year. Figure 4 shows the prevalence trends. The Iowa progress is well demonstrated. Figure 5 shows the apparent incidence rate per quarter. Reducing the number of newly infected herds is one of our major challenges. Figure 6 shows quarterly (March-June 95) change in infected herds. Again, emphasizing the importance of preventing between herd spread and reducing the number of newly infected herds.

Infected herds have been identified by the following methods during the past year July 1, 1994 to July 1, 1995.

<table>
<thead>
<tr>
<th>On Farm Testing</th>
<th>Herds tested</th>
<th>Percentage Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slaughter traceback</td>
<td>584</td>
<td>2.4%</td>
</tr>
<tr>
<td>First Point traceback</td>
<td>1030</td>
<td>3.5%</td>
</tr>
<tr>
<td>Tracing from infected herd</td>
<td>226</td>
<td>15.5%</td>
</tr>
<tr>
<td>Tracing into infected herd</td>
<td>175</td>
<td>25.9%</td>
</tr>
<tr>
<td>Circle testing infected herd</td>
<td>602</td>
<td>17.9%</td>
</tr>
<tr>
<td>Other epidemiology</td>
<td>2020</td>
<td>24.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Area Testing</th>
<th>Herds tested</th>
<th>Percentage Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breeding herds</td>
<td>9008</td>
<td>9.0%</td>
</tr>
<tr>
<td>Grower/Finisher</td>
<td>6476</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Herd Status Testing</th>
<th>Herds tested</th>
<th>Percentage Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeder pig monitoring</td>
<td>11,774</td>
<td>2.9%</td>
</tr>
<tr>
<td>Qualified Negative Herd</td>
<td>12,308</td>
<td>0.6%</td>
</tr>
<tr>
<td>Q-N Vaccinated Herd</td>
<td>9,060</td>
<td>0.6%</td>
</tr>
<tr>
<td>Sale/Exhibition</td>
<td>20,120</td>
<td>4.9%</td>
</tr>
<tr>
<td>Retest of Imported Swine</td>
<td>15,769</td>
<td>0.4%</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>8,666</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

In June of 1995 a pseudorabies work conference was held to develop strategic plans and goals for the elimination of pseudorabies within the next 5 years. Program managers and industry leaders from the 12 States that have approximately 63 percent of the swine and 99 percent of the pseudorabies infection were at this conference. The goals have been established. It is now our challenge to see that these goals are accomplished.

Two major impediments to achieving our goals need to be addressed in the very near future:

1) The producer who owns a pseudorabies infected herd and is making no effort to cleanup, and
2) The community that is continually circulating pseudorabies virus, thus creating a hazard to those producers that do not have infected swine. Solutions to these problems are not easy. The silent majority (98.1%) of...
pork producers who do not have pseudorabies must be politically active so as to overcome these impediments.

In conclusion, here are some strategies that could be useful:

A. Have a strong, progressive State enforcement program.
B. Develop a community plan that will;
   1. Stop seroconversion in the grow/finishers
      - make up 87% of our swine
      - create enormous amount of virus when positive
      - accomplished by
        a. segregation (all in/all out)
        b. vaccination
        c. reduced stress (proper stocking density, feeders, etc.)
   2. Improve biosecurity during the marketing process
   3. Isolate and retest new additions to the herd
   4. Rotate infected breeding herds rapidly
      - reduce virus shedding by
        a. vaccination
        b. grouping according to age
        c. reducing other stress
Pseudorabies Program Stages and No. Infected Herds - Oct. 1, 1995

- Stage I (11 States)
- Stage II (11 States)
- Stage III (15 States)
- Stage IV (8 States)
- Stage V (17 States)
Pseudorabies

States with Infected Herds

Iowa reported 2,623 infected herds (2,580 with cleanup plans) June 30, 1995
Pseudorabies

Source of New Herd Infections - June 1995

- Area Spread: 143 (50.7%)
- Feral Swine: 4 (1.4%)
- Purchased Breeders: 27 (9.6%)
- Purchased Feeders: 14 (5.0%)
- Unknown: 94 (33.3%)
Pseudorabies
Prevalence Trends

Thousands

- with Iowa
- without Iowa

1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
Pseudorabies

Apparent Incidence Rate per Quarter

Rate = # newly discovered infected herds per quarter
Pseudorabies
Quarterly Change in Infected Herds

FL | GA | HI | IL | IN | IA | LA | MI | MN | MO | NE | NC | OH | OK | PA | SD | SL* | 100

| Herds Found Infected | Herds Cleaned Up |

- FL: 3
- GA: 5
- HI: 0
- IL: 0
- IN: 0
- IA: 0
- LA: 7
- MI: 18
- MN: 19
- MO: 59
- NE: 66
- NC: 170
- OH: 0
- OK: 0
- PA: 0
- SD: 1
- SL*: 100
PSEUDORABIES PROGRAM
WORK CONFERENCE SUMMARY

Glenn N. Slack
Executive Director
Livestock Conservation Institute

A national Pseudorabies Program Work Conference was held June 6-8, 1995 at the National Animal Disease Center in Ames, Iowa. The purpose of the conference was to develop and present strategies and goals for the completion of pseudorabies eradication from the United States by the year 2000.

Participants in the conference mostly consisted of state and federal program managers and epidemiologists from the twelve states with the most concentration of pseudorabies virus, as well as selected producer leaders and members of the research community. Approximately 35 people participated in the three day conference.

It was noted that tremendous progress has been made in the pseudorabies eradication effort and the industry is well positioned to meet the year 2000 goal. However, obstacles will present themselves throughout the five year period.

Each of the twelve states participating developed a plan to complete the eradication effort in their state within the next five years. These plans and goals were presented at the conference and discussed in separate work groups. Neal Black, Secretary of the National Pseudorabies Control Board, prepared and presented a summary of issues common to all states from his review of the states’ plans.

The need was widely expressed for an enhanced effort in the area of education. LCI-facilitated workshops involving producers and practitioners, and separate workshops targeting state and federal fieldforce from several states were deemed important during the next two years. It was felt that more emphasis should be placed on PRV prevention and biosecurity.

One particular observation that should be noted was that the contingency from Michigan resembled a true team approach. Their contingency consisted of the state program coordinator, a key federal counterpart, and the chief staff executive of that states’ pork producers association. This type of interaction is critical. A recommendation for future gatherings similar to this conference would be to include more producer leaders and practitioners. They will be key in realizing complete eradication by the established deadline.

Outcomes: 1) The conference re-established a vision. States completed the exercise of developing a five-year plan, identifying potential obstacles, needed resources, and establishing goals; 2) The conference facilitated the exchange of information, strategies and ideas; and 3) The conference motivated participants. Substantial progress has been made to date.
PSEUDORABIES PROGRAM
WORK CONFERENCE SUMMARY

What did we learn?: 1) *Waitin' for Iowa* - no longer an excuse; 2) Most believe 2000 is an achievable goal; 3) Focus on high-prevalent areas; 4) Enhanced educational initiatives are needed; and 5) Greater emphasis on biosecurity.

Dr. Arnold Taft, National Pseudorabies Program Coordinator, and Dr. Joe Annelli, Chief, National Animal Health Programs, should be commended for conducting this work conference at a very strategic point in time in the eradication effort.

A proceedings of the work conference, including the five year plans from the 12 participating states, has been published and is available through APHIS.
The goal of the Minnesota pseudorabies eradication program is to reach free status by December 31, 1998. In order to reach this goal, we must decrease the cumulative number of infected herds in the state at a rate of 12 per month. During the last year, the rate of herd cleanup surpassed expectations and the number of herds under quarantine dropped from 611 to 394. This was 39 herds ahead of schedule (figure 1).

Cleanup progress has been so encouraging that we submitted an application to expand the Stage III area of Minnesota by nine counties. The National Pseudorabies Control Board approved our application on November 1, 1995. Seventy-five (75) counties are now in Stage III and twelve (12) counties remain in Stage II (figure 2).

The Minnesota rules for pseudorabies control and eradication were updated this year to reflect changes in the swine industry and in Program Standards. In general, more pressure will be placed on quarantined herd owners to complete cleanup plans, and movement of quarantined swine will be more strictly controlled. Import rules were modified in order to recognize the pseudorabies status of other states and to accept the Gpi differential test as an official test for interstate movement of swine. Breeding swine may now be imported into Minnesota from qualified negative gene-altered vaccinated herds or on the basis of an individual negative Gpi differential pseudorabies test. Import permits and post-entry retests are no longer required on swine imported from areas in Stage III, IV, V. In addition, pre-entry pseudorabies tests are no longer required on swine from Stage IV, V areas.

The goal for 1996 is to reduce the number of quarantined herds to 250 and prepare to add another six counties to Stage III. To accomplish these goals, we must continue to help producers with their herd cleanup plans. We also must become more creative in developing plans to clean up chronically infected herds. If unresolved, these residual quarantines will delay completion of the program and erode producer enthusiasm.
PSEUDORABIES ERADICATION IN MINNESOTA
Projected Completion Date

Minnesota Board of Animal Health - October 2, 1995
MINNESOTA
PRV QUARANTINED HERDS
OCTOBER 2, 1996
394 Herds

Stage III
- 75 Counties
Stage II
12 Counties
Through the efforts of many dedicated people, Illinois has always taken the initiative and remained steadfast in the belief that pseudorabies is a disease that can and will be eradicated. The state has demonstrated substantial accomplishment in its eradication program since 1990.

Illinois organized the first Pseudorabies Advisory Committee in the nation and has implemented the practices recommended by this group. These adopted practices have been extremely beneficial to the eradication of this disease.

The Illinois pork producers have given strong support to the eradication program and has been essential in its maintenance. All law and regulation changes are reviewed by the Illinois Pork Producers Association (IPPA) and the Pseudorabies Advisory Committee before they are implemented. A member of the IPPA serves on the Pseudorabies Technical Committee, which is composed of three members from the Advisory Committee. The Technical Committee meets with producers (on an individual basis) who are not progressing satisfactorily toward cleaning up their herds. After examining the herd operation and management, this committee makes recommendations for improving their cleanup efforts. A new penalty section has been propagated in the law that creates stringent penalties on non-compliant producers.

In 1989, there were 486 herds under quarantine, which was the height of PRV infection. As of October 25, 1995, there were 100 quarantined herds located in eleven of the state's 102 counties. Approximately 70 percent of the state's infected herds are concentrated in one county (Henry). To focus more emphasis on the PRV cleanup issues, the Pseudorabies Advisory Committee agreed to convene their summer meeting in Henry County. It was the intent of this meeting to present current status and goals for the Illinois cleanup. Producers and area veterinarians were invited to attend and participate in the discussion.

The Henry County Pork Producers association met this fall and invited Department personnel to present similar information to their members. Through these efforts, we have been able to provide educational information and increased perception of their county's PRV status. We have also initiated neighborhood cleanups, in which new methods and vaccination procedures are being used. Providing no unforeseen break-backs occur, there should be a uniform progress in the cleanup program. It is anticipated Illinois will apply for Stage III status in the spring of 1996.

Illinois' goal is to become a PRV Stage Free state by the year 1999. To attain this goal, it will be imperative to emphasize vaccination of the breeding herd and finishers in the infected herds and to develop strict guidelines for vaccination of nursery pigs at appropriate ages. It will be essential to con-
ILLINOIS PSEUDORABIES UPDATE

Continue vaccinating the breeding animals four times a year in the endemic areas.

The focus in 1998 will be on continued vaccination of breeding and finishing hogs in endemic areas and to maintain appropriate surveillance activities. It may be necessary to initiate some first-point testing if additional slaughter plants are not added to the surveillance program.

Illinois producers, along with the Illinois Department of Agriculture, are committed to be one of the leaders in the effort to eliminate this disease by the year 2000.
IOWA PSEUDORABIES ADVISORY COMMITTEE
COMMENTS

Dr. Paul Armbrecht, Committee Co-Chair

1. Represent Iowa's PRV Advisory Committee
   A. 5 Producers
   B. 1 Veterinarian
   C. 1 Auction Market Owner

2. All 99 counties involved
   A. Approximately 25,215 herds
   B. 25,196 herds tested (98.8% tested)
   C. 94 counties have completed 100% testing

3. Infection status
   A. 2,356 herds infected (9.3%)
   B. Of those 2,316 on a herd clean-up plans (98.3%)
   C. During previous 12 months - 1070 fewer herds are infected.
      (The infection rate has dropped from 22.8% in Dec. '93 to 11.4% in
      Dec. '94 to 9.3% in Oct. '95)
   D. Also 11 counties have no infected herds and 47 have fewer than 10
      infected herds.

4. Veterinarian/Producer relationship continues to improve; This is a critical
   part of Iowa's program; Vet's oversee clean-up plans.
   A. Veterinarians are supportive
   B. Producers are supportive
   C. The Industry is supportive
   D. The Iowa Legislature continues to be supportive;
      Approximately $900,000 annually

   However, more Federal and State manpower may be needed to clean-up
   remaining difficult herds.

5. Changes in herd clean-up plans (April 1, 1995)
   A. Quarterly Veterinarian visits
   B. Required vaccination for finishers at producer expense
   C. Infected or exposed cannot move into "clean" counties
   D. Conducting Official Herd plan reviews every 6 months

*****Overhead of colored triggered counties*****
IOWA PSEUDORABIES ADVISORY COMMITTEE COMMENTS

6. Break backs/Area spread still a problem
   A. Attitude problems when this occurs
   B. Non-infected herds putting pressure on infected herds
      "Why should I clean-up again, when my neighbor keeps re-infecting
      our herd". (This is producer to producer peer pressure instead of
      regulatory pressure.)
   C. The state committee sponsored 13 meetings across the state for
      producers and veterinarians, educating them on area spread and pro-
      gram regulatory changes. Over 825 attended.
   D. We feel producers threaten their own herds bio-security themselves,
      but they naturally blame new outbreaks on other factors.

******Overhead of Dr. Armbrecht's 4 questions******

7. Needs
   A. Other states should use G1 differential diagnostic test for slaughter
      screening test; this would save us from testing SN positives that turn
      out to be differential negatives. We are finding 55% positives with SN
      testing, and only 10% if the G1 Differential test is used!! This would
      save a lot of re-testing slaughter samples.
CURRENT DISTRIBUTION OF WORKLOAD BY SECTION

PSEUDORABIES INFECTED HERDS (total 2366)

Source: Iowa Monthly Summary, September, 1995
The Pseudorabies Eradication program in Michigan is in high gear. Adequate resources, workforce, administrative support, good producer participation and cooperation of producers with infected herds all help to make a successful program. The result is a continuing decrease in the number of quarantined herds.

Michigan has two endemic areas, both located in the southwest region of the lower peninsula. The Ottawa/Allegan county area is home to 48 herds still under quarantine. These are primarily modern confinement operations while 100 miles to the south the industry is characterized by large outdoor production units with 84 of these herds under quarantine. The number of quarantined herds is 3.6% of the total number of herds in the entire state of Michigan or 13.1% of those in the stage II area. The animals resident in these herds is 5% of the total for the entire state and 18% of those in the six county stage II area. This is less than half the numbers in 1991.

Michigan boasts a well trained staff of dedicated professionals as members of a cooperative state and federal eradication team. The State of Michigan is responsible for clerical support, recordkeeping, and program administration. There are three state employed veterinarians in the field in full time equivalent positions and one licensed veterinary technician on a two year limited term appointment. The USDA supports the program with three full time veterinarians in the field and by maintaining the market surveillance (MSI) program. Identities are blurred except as the goal of pseudorabies eradication brings roles into focus. The working relationship between the two agencies is excellent. As a result, Michigan swine producers enjoy tremendous support. Owners of infected herds under quarantine and those with herds in the Stage II area are tested frequently.

Michigan's short term objective is to do this testing and encourage routine vaccination of all swine in the Stage II area. Especially those in quarantined and high risk negative herds during the fall and winter of 1995. This will be followed by a public relations campaign encouraging rollover of infected breeding swine in 1996. During this time, area testing of herds for case finding and surveillance in the Stage II area will continue. Testing of swine detects spread of PRV early and arms producers with knowledge that is useful when making management decisions that might otherwise encourage virus transmission. High risk herds are tested every six months and others in the
Stage II area once yearly. This testing is done by the cooperative field force or by private practitioners on a fee-basis assignment. We have learned that virus spread between herds is minimal. Thirty herds have been placed under quarantine in the past year. Of these, only one experienced a clinical outbreak of pseudorabies disease. Herds infected as a result of area spread are generally well vaccinated because herd owner's are aware of the risk implicit with their location in the endemic area. Spread of virus in seven herds exposed to PRV as a result of movement of positive swine into these herds was prevented when the eradication team acted quickly to complete the epidemiology and respond appropriately.

All infected herds are tested for prevalence at least 3-4 times a year as part of the herd cleanup plan. From this we have learned that virus circulation has stopped in all except a handful (4) of herds in the Ottawa/Allegan county endemic area. This is encouraging news. It means that Michigan should be able to meet the goal of moving Allegan and Ottawa Counties to Stage III by fall of 1996. If prevalence testing currently underway in the Cass county area provides similar results, we expect that the remaining four counties may be eligible to move to Stage III by spring of 1998 with the goal of Pseudorabies free status achievable by 1999.

Surveillance of herds in the Stage III area continues to be a problem for Michigan. The number of samples collected at slaughter and reported back to Michigan are not enough to satisfy surveillance index requirements. Michigan must maintain a first point testing program as a supplement to MSI to reach adequate levels as defined by the Program Standards. A project that may make it possible to replace both programs will begin on a trial basis in a limited marketing area next year. Producers in this area will be supplied with special backtags such that cull breeding swine and market pigs may be identified on farm, then marketed on a designated day when state, federal or fee basis veterinarians can be available to test these specially identified animals.

In addition, these backtags are designed in a manner that also allows other states to recognize them and return them to Michigan so that the negative test results can be credited to the farm of origin. The producer will be responsible for providing enough animals to the market on these designated days or to slaughter subject to MSI collection, to produce an official random sample total over a year's period. It is hoped that these herds can then be removed from the total number of herds in the sample pool necessary to test for calculating the surveillance index. In the future, first point testing may not be necessary if surveillance at slaughter can supply adequate numbers of animals tested. Removing herds from the sample pool when their status is established as a result of testing adequate numbers for an official random sample is a cost containment advantage preventing oversampling of large herds and unnecessary testing of herds under quarantine. It offers the advantage also, of identifying samples to be tested by differential test. Government and industry demonstrate fiscal responsibility with this approach. Spot checks using the present MSI system in its present form can be arranged to monitor program integrity.
I would like to express my appreciation to this Committee for giving me the opportunity to review the progress that North Carolina pork producers have made toward the eradication of pseudorabies in North Carolina.

NORTH CAROLINA'S SWINE PRODUCTION

According to North Carolina Agricultural Statistics, as of September 1, 1995, the total number of hogs and pigs on North Carolina farms totaled 8.1 million which was up by 23 percent from 1994. Breeding swine numbered 920,283 and market hogs were 7.22 million. During the next 6 months, it is anticipated that the number of sows to farrow will increase over 14 percent. North Carolina ranks second nationally in the number of hogs and pigs.

CURRENT STATUS

As of October 25, 1995, there were 107 quarantined sow herds consisting of 99,985 sows, 385 quarantined nursery\finisher premises representing 1,093,501 finishers and 41,240 nursery pigs. All have herd plans. Any newly infected herds in Stage III counties have a herd plan in place in 30 days, and all herd plans in Stage II counties are in place within 30-90 days. Herd plans are reviewed at least yearly and sow herd plans are reviewed and/or tested at least twice each year.

Last year at this time, there were 138 quarantined sow farms representing 109,500 sows and 366 quarantined nursery\finisher premises with 1,062,735 finishers and 51,840 nursery pigs. Even though the number of nurseries\finishers under quarantine statewide during the past year increased by 5.19 percent, there has been a 23 percent increase in the total number of hogs and pigs on North Carolina farms.

Most of the increases in quarantined herds have been in Sampson and Duplin Counties, the State's and Nation's two counties that contain the highest swine populations. At the end of September of 1994, there were 43 sow herds consisting of 41,277 sows and 280 nurseries\finishers consisting of 895,890 swine under quarantine, compared with 74 sow herds consisting of 68,650 sows and 315 nurseries\finishers comprised of 1,056,115 swine under quarantine in these two counties as of October 1, 1995.

Based on the above data, there has been a 22.4 percent state wide reduction in the number of sow herds under quarantine and an overall reduction
NORTH CAROLINA PSEUDORABIES UPDATE

of 2.38 percent of all herds under quarantine in North Carolina during the past year.

RECOMMENDATION FOR CHANGE IN STATUS

On October 23, 1995, an application was submitted to expand the Stage III area in North Carolina to include 97 counties. This application proposes to add Greene, Pitt, and Wayne Counties to the Stage III area. If this application is approved, only Duplin, Lenoir, and Sampson will remain in Stage II.

PROPOSED CHANGES IN SENTINEL VACCINATED HERDS

Last year, I discussed North Carolina's policy on vaccination and "sentinel" herds which are non-infected vaccinated herds. Any herd which is considered at high risk is allowed to vaccinate; however, a request must be submitted to the State Veterinarian's Office requesting a specific vaccine. Changing vaccine is not allowed without prior approval. Previously, sentinel herds required a test twice each year. The following changes are being considered that will affect vaccinated herds in North Carolina:

1. The PRV GI deleted diagnostic test will be approved as an official test in North Carolina.
2. Swine from a negative herd that have been vaccinated with a GI deleted vaccine can be moved interstate provided the receiving state will receive them.
3. Non-vaccinated pigs from negative GI vaccinated sow herds could be sold through North Carolina feeder pig markets provided they otherwise meet requirements.
4. Negative, non-exposed, GI deleted vaccinated herds would no longer be placed under a sentinel quarantine, and such herds in a Stage III county would now require an annual test rather than the semi-annual test that is currently required. All vaccinated herds in a Stage II county would still require semi-annual tests.

LOCATION OF FINISHING FLOORS

Last year it was reported to you that certain areas in Sampson and Duplin Counties were designated as high risk areas for the relocation or concentration of positive finishing spaces. During the past year the industry agreed to no longer place infected-exposed pigs in non-vaccinated blocks or areas in these two counties, and to release nurseries and finishing floors in the non-vaccinated areas. Producers also agreed to vaccinate all finishing swine in the designated vaccination blocks, and to vaccinate all finishing swine within 1 mile surrounding a new outbreak for two finishing cycles.
McGinn

PROGRAM FOCUS

In order to more effectively focus on the eradication of pseudorabies, several actions are being emphasized and taken.

As indicated previously, finishing floors which will receive finishers in a positive flow are being located in designated areas in Sampson and Duplin Counties. (b) Vaccination and frequency is being increased, (c) Biosecurity is being emphasized and evaluated with biosecurity indexes being established, (d) Epidemiological activities are being increased and strengthened, both by the veterinary medical officer and the State Epidemiologist, (e) Surveillance methods are reviewed on an ongoing basis and will be expanded as necessary to more rapidly find new outbreaks, and (f) A Veterinary medical officer and an inspector have been assigned to intensify efforts in Sampson and Duplin counties.

GOALS

The eradication of pseudorabies in North Carolina will continue to be a major challenge due to the size and rapid expansion of the swine industry. NCDA is convinced that we can meet the National objectives without additional funding. We are presently writing all herd clean up plans with a goal date of December of 1997. To accomplish this, however, everyone must be committed to that objective and the resources and support for the program must be provided.
Chairman Bradshaw called the meeting to order with all members present except Schroeder, plus one guest, Paul Anderson of Minnesota.

State applications were acted on as follows:

- Minnesota, renewal of Stage III status and addition of 9 counties to the Stage III area—Approved.
- Georgia, renewal of Stage III Status—Approved.
- Maine, renewal of Stage V—Approved.
- Connecticut, renewal of Stage V—Approved.
- Missouri, renewal of Stage III—Approved with a comment encouraging acceleration of the program to clean up the few infected herds.
- New Mexico, renewal of Stage V—Approved.
- Massachusetts, renewal of Stage III—Approved with a comment calling attention to Stage III requirement that progress must be shown from year to year and the Board will expect the next application to detail progress including efforts to clean up the one infected herd.
- Utah, renewal of Stage V—the Board approved a motion asking that the application be resubmitted with additional information.
- North Carolina, renewal of Stage III status with addition of three counties to the Stage III area—Recommend approval.

Note: The Board recommends that all letters advising states of continuation or new status in the future call attention to the feral pig requirements for Stage II and Stage III on pages 16 and 18 of the Program Standards (Jan. 1995)

The Board asked Dr. Taft to ask states to submit with applications for Stage III or higher, an annual summary of quarterly reports rather than copies of the four quarterly reports, if possible.

Black announced that he has indicated to USAHA that he would like to give up his press relations assignment with USAHA following the 1996 annual meeting, which would mean he would not be attending the meeting and would not be available to continue as secretary of the Board, especially in view of the difficulty he has had in obtaining promised reimbursement of his expenses by APHIS.
The Livestock Conservation Institute (LCI) convened a meeting of major stakeholders of swine identification on October 19, 1995, in St. Louis, MO. Present were representatives of LCI, American Association of Swine Practitioners, American Veterinary Medical Association, National Pork Producers Association, Livestock Marketing Association, USAHA, and USDA, APHIS.

The purpose of the meeting was to focus on the problem of the identification of cull breeding swine in slaughter channels and develop a consensus on the appropriate course of action. To establish this focus, the group set forth the following mission statement:

To make improvements in swine identification systems for the long-term benefit of the consumer. Premises identification of cull breeding swine is essential for the following reasons: 1. To improve consumer confidence, 2. To promote domestic and foreign markets, and 3. To protect the domestic supply of pork.

THE PROBLEM:

Market swine slap tattoos are working well for slaughter identification. This is especially true when payment for the animals is based on carcass characteristics. Livestock markets and buying stations are careful to identify these animals correctly.

Some identification compliance problems are still noted in markets that buy animals based on live weight. We hope this can be corrected with improved communication and compliance efforts.

Most of the problems in traceback have been in slaughter breeding swine and cull animals. As the animals are skinned during the slaughter process, slap tattoos are lost. Methods as easy and effective as slap tattoos have not been developed. Market operators do not perceive any direct benefit to themselves.

Approximately 25% of breeding age animals arrive at slaughter with back tags. This is not sufficient for industry needs. Slaughter surveillance for the PRV Eradication Program requires that more animals be identified. As the number of infected herds decreases, the reliance on inexpensive surveillance methods will increase.

The lack of identification reduces the quality of trace-back of carcass residues and biological contaminants. Lack of identification is primarily due to the inadequacy of the official back tag for swine. Efforts at improving reten-
NATIONAL PREMISES IDENTIFICATION
FOR CULL BREEDING SWINE

tion through the development of better glue, different methods of application, and enforced compliance at the markets have had little permanent impact on the overall level of identification. Producers and regulatory officials have a low level of confidence in the present system.

THE SOLUTION:

Dr. Wiemers outlined a program in which States would assign a National Premises Identification Number (NPIN) to swine herd.

In order for the program to be practical and achievable, it must have low impact on State systems already in place. Most States involved in the Pseudorabies Eradication Program have already identified swine premises with a "herd number" or premises location number. For instance, Iowa uses County, township, section and herd; North Carolina uses a QBSP number.

It is proposed that the numbers already issued to herds in the State databases be used. If no numbers are currently assigned, the State can issue any number it deems appropriate as long as premises numbers are not repeated.

The number must have a National identity. In this regard, it is proposed that all numbers be preceded with the postal code abbreviation for that State. The State designator will allow us to quickly establish the State database to access to determine the location of the premises of origin.

In order to gain producer acceptance, the program must initially be a voluntary one. Producers would apply for their NPIN through the State Animal Health Official in charge of animal identification. An application form for doing this will be distributed to the states. The data obtained will be maintained on a State database.

The numbering system would initially be a simple alpha-numeric identifier. Bar codes or other electronic identification could be added at a later time as the industry needs dictate.

Upon receiving the NPIN, the producer will also receive a National Premises Identification Card. This can be used to order producer tags or to verify the origin of hogs at the time of marketing.

NPIN will be incorporated into the ear tags used by producers for production record-keeping purposes. Ear tags have greater retention rate than back tags, and they are already commonly applied at the farm level.

At the time of marketing of cull breeding swine, producers will show their NPIN cards when animals enter slaughter channels. Livestock markets and buying stations will apply ear tags to animals arriving without identification.

NPIN ear tags will be collected at slaughter with blood samples. Samples and tags will be sent to official testing laboratories.

The benefits of NPIN are many. First is the ability to rapidly trace animals to the premises of origin. This is vital in our efforts in foreign animal disease investigations, eradication program surveillance, animal movement risk assessments, food residue trace back, and quality assurance verification. Sec-
ondly, the system is low cost, it easily fits into modern swine production practices, and it will have good retention.

Furthermore, it will be adaptable to electronic identification (EID) systems. This will allow rapid and accurate data entry at testing laboratories. Collection and utilization of negative tests will be possible. Producers can then receive credit toward herd status qualification for negative tests. Accurate assessment of the geographical distribution of slaughter surveillance samples will be possible.

DESIRED OUTCOMES:

Members of the group discussed their respective roles. Each stakeholder agreed to take the information presented back to those they represented along with a list of desired outcomes.

It is suggested that:

USDA, APHIS, VS, will agree to coordinate the development and implementation of a National Premises Identification system with stakeholders. The agency will agree to coordinate changes in regulations, notices, and memoranda to allow the system to proceed. The agency will coordinate the identification needs of other federal agencies and develop a method of measuring progress.

States will accept the responsibility of assigning premises numbers to producers. This is already taking place in many States. In addition, States will agree to maintain the premises identification databases within the State.

Producers and Practitioners (NPPC, MSP) will agree to demonstrate to APHIS that there is broad producer support for this initiative. They will accept the challenge to ambitiously promote widespread use of producer-applied premises identification of breeding swine. Upon demonstration that the majority of sows and boars are marketed with a producer applied premises identification device, consideration will be given to mandating premises identification nationally.

Livestock Markets will agree to consider the application of ear tags to unidentified breeding swine entering slaughter channels. This is contingent upon demonstration that sufficient numbers of sows and boars are marketed with a producer applied premises identification device to warrant the effort by livestock market operators.

Pork Packers and Processors will accept the responsibility to assess slaughter plant animal identification needs. Slaughter plants will help facilitate the collection of samples and identification devices.

THE NEXT STEP:

Members of the group agreed to report to their respective stakeholder groups and receive feedback. The next meeting is scheduled for Friday, December 8, 1995.
Pennsylvania, pending current legislative efforts to acquire authority to mandate elimination of pseudorabies virus (PRV), has met criteria for classification as a Class 3 State. Statewide prevalence of PRV infected herds was reduced to less than one percent (57) by September, 1995. Intensive surveillance of high risk areas and routine case reporting resulted in the discovery of six new cases during the past year. Review of infected herd histories indicates that fewer than one-half are circulating virus. Projection of eradication effort at the current pace indicates that prevalence will be below one-half percent (25) by the end of 1996.

Concern remains for PRV spread in areas surrounding infected herds because depressed hog prices have discouraged vaccination of exposed or at risk swine. Concern also exists for provision in the pending rule changes that will allow owners of infected herds a period of three (3) years to eliminate the virus. There remain approximately eight infected herds of long standing whose owners refuse to cooperate. Reaching our goal of Free State Status by year 2000 depends on resolution of the uncooperative attitudes and general improvement of biosecurity of high PRV risk areas.
PA HERDS QUARANTINED FOR PRV

Number of Herds

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
</table>

QTR/YR

INFECTED HERDS

Inf herd prevalence <1% in 3rd Qtr 1995
PSEUDORABIES QUARANTINED HERDS
PROJECTED 1994-1999

ASSUMES NO NEW QUARANTINED HERDS
PA HERDS CIRCULATING PRV VIRUS
September 1995

- Circulating: 14
- Not circulating: 33
- Unknown: 10
PA CLEAN-UP STATUS
September 1995

- DEPOPULATING < 6 MO: 7
- TESTING OFF < 6 MO: 10
- TESTING OFF 6-12 MO: 17
- NOT TRYING: 8
- NOT READY: 15
UPDATE ON THE MAJOR ISSUES THAT ARE CENTRAL TO THE SUCCESSFUL IMPLEMENTATION OF PRV DIFFERENTIAL VACCINES

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Presented at the 98th Annual Meeting in Grand Rapids, Michigan

One of the main reasons for the progress of the ongoing Pseudorabies eradication campaign is the use of Modified Live Virus (MLV) vaccines that permit a serological differentiation of vaccinated from infected animals. Since the initial development and release of these gene-deleted vaccines, several points have been considered to be of critical importance for their successful implementation in the field.

Initially, emphasis centered on the selection of a consistent, efficacious marker protein which would allow an adequate serological differentiation of infected animals. This goal has been fairly well accomplished worldwide with the uniform adoption of the gl-based tests. The gl marker system has now been adopted in the US for state and inter-state testing.

Later on, concerns focused on the possible recombination of these MLV gene-deleted vaccines with field strains that could produce virulent strains capable of escaping serological detection (i.e., marker-negative field strains). Although such a contention is viable from a theoretical standpoint, all the evidences argue against the likelihood of this event and would indicate that it can be considered virtually negligible.

Currently a key issue in relation to PRV MLVs is their immunogenic properties. Based only on the determination of the eradication commitment, it might be argued that no further research on vaccines against Pseudorabies is necessary. However, it is becoming evident that a more efficient and rational use of vaccines is essential to face the challenges of cleaning up large herds at this stage of eradication. If not new vaccines, at least more rational strategies for their use is now very important. In this respect, there is an increased perception that not all of the differential vaccines in use perform with the same ability when it comes to eliminating PRV from endemically-infected large herds.

For a vaccine to be able to prevent the circulation and perpetuation of PRV in a herd it is essential that the vaccine prevent the establishment of latent PRV in animals surviving an acute PRV infection. Figure 1.A summarizes the biology of establishment of latent infections by herpesviruses. Latency is essentially the property which allows herpesviruses to survive in certain sites of the body of convalescent animals in a quiescent status. Those animals that survive an acute infection with virulent (wild-type or “field”) PRV, will, in all likelihood, become carriers of the disease by establishment of latency in specific neural tissues, especially sensory ganglia (trigeminal and spinal ganglia)(Fig. 1.A). The PRV carriers are very important for the dis-
UPDATE ON THE PRV DIFFERENTIAL VACCINES

Semination and perpetuation of PRV in swine populations because, after certain specific stimuli such as stress, these latently infected animals can reactivate and re-excrete infectious PRV, thus transmitting the infection to contact (naive) animals.

Although it had been commonly assumed that no vaccine would be capable of preventing the establishment of latency by wildtype PRV, no clear substantiation of this matter had ever been provided. Now our laboratory has solid evidence that prevention of wild-type PRV latency is possible using commercial PRV MLV vaccines. First, by means of quantitative PCR, we proved that the MLV vaccines can colonize (establish latency) by themselves when given through an appropriate route such as the nasal path (Fig. 1B)(1, 2). This colonization of latency target tissues by the vaccine strain is a direct consequence of the replication of the MLV at the mucosae (portal of entry). The level of colonization attained by different MLVs varies significantly with the type of strain, dose, and route of immunization. More importantly, we demonstrated that pre-colonization by MLVs of the latency target tissues (trigeminal ganglia) of vaccinated animals directly correlates with protection against WT PRV latency. To do that, we compared the level of latency established by WT PRV after challenge of groups of animals that had been pre-colonized by MLVs at three distinct levels (low, medium and high) by use of different MLV strain/dose combinations (table 1, and ref. 3).

The highly colonizing strain tested by us significantly blocked the establishment of latency by a superinfecting challenge with WT PRV (6 out of 10 challenged animals exhibited no detectable WT PRV in their trigeminal ganglia 45 days after challenge, ref.3). The different genetic deletions of the strains we used have certainly influenced the different colonization abilities observed in our experiments. It has been reported that PRV gl is an important factor in targeting the virus into the central nervous system (4) and also that thymidine kinase TK is important for herpesvirus replication in quiescent cells (i.e.: neurons)(5). The simultaneous deletion of both of these genes in the strain that exhibited the less colonizing ability (SG, table 1) should then have impaired both targeting of the virus to, as well as its replication in, neurons; therefore explaining the poor colonization of TGs observed with this strain. It is interesting to remark that colonization studies conducted in our laboratory with a gl+ strain isogeneic to SG (which means identical to SG to but in one gene) showed that this strain (strain SMB: gX-,TK-, gl+) has significantly higher colonization ability than any of the strain/doses combinations used in our challenge experiment. This would confirm not only the important role of PRV gl in targeting neural tissue but also suggest that gl+ attenuated PRV strains may have optimal ability to precolonize TGs and therefore to interfere with superinfecting WT latency.

We believe that the ability of a highly colonizing vaccine to prevent establishment of WT PRV latency is not merely based on classical immunological protection against replication at the primary site of infection (mucosal surfaces). No significant difference in the level of protection against acute
wildtype PRV challenge (i.e., shedding upon challenge) could be noticed among the three groups tested in our experiments (3). We postulate instead that the blocking of WT PRV establishment takes place at the translocation (axonal path) or neuronal level instead. The protection against WT PRV latency observed in our experiments could be an example of resistance at the level of the tissues that are the target for latency, for which pre-infection of the neurons of that tissue with another (preceding) strain of PRV is required (Fig. 1C). Our case of ganglionar resistance would then be a special example of intracellular interference active against homologous or homotypic viruses (6). It is possible that the interference is based on some of the viral functions expressed by the interfering strain during latency/reactivation or on some competition for certain important cellular factors that would be essential to the establishment and maintenance of latent infection in neurons.

Therefore, a thorough understanding of the mechanism by which vaccines prevent latency should certainly have high impact on the efficiency of infection clean-up efforts in large herds. Current research efforts in our laboratory are addressed to ascertain the relative efficiency of different strains to interfere with latency. Although our research focuses on only one spacial aspect of efficacy of the vaccines (i.e., the ability to prevent latency), we think that our data indicatives that a wide spectrum of responses exists among the vaccines currently in the market, and therefore a more concentrated research on comparative efficacy of these vaccines is warranted. We also seek to picture the interference phenomenon at a single neuron level. In this case we want to ascertain if the two different PRV strains (preceding and superinfecting) can indeed co-localize in the same cell.

Acknowledgements:
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References
UPDATE ON THE PRV DIFFERENTIAL VACCINES


**TABLE 1.** Mean TG pre-colonization level attained by three PRV strain/dose inoculations and mean level of WT PRV colonization established upon challenge of the three pre-colonized groups

<table>
<thead>
<tr>
<th>Strain/Dose(a)</th>
<th>Mean Pre-Colonization by Preceding Strain</th>
<th>Std. Error</th>
<th>Mean WT PRV Colonization After Challenge</th>
<th>Std. Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>WT PRV</td>
<td>N/A</td>
<td></td>
<td>&gt;-1.80 (*)</td>
<td></td>
</tr>
<tr>
<td>SG 10^5</td>
<td>-5.21</td>
<td>0.190</td>
<td>-1.777</td>
<td>0.286</td>
</tr>
<tr>
<td>BA 10^5</td>
<td>-4.236</td>
<td>0.257</td>
<td>-2.799</td>
<td>0.471</td>
</tr>
<tr>
<td>BA 10^7</td>
<td>-2.88</td>
<td>0.464</td>
<td>-4.281</td>
<td>0.633</td>
</tr>
</tbody>
</table>

(*) Results of quantitative PCR are expressed in negative log(viral copies/cell equivalent). Higher exponents mean lower amount of the PRV strain in the cells of the trigeminal ganglia analyzed.

(a) Doses of MLVs express plaque-forming-units(P.F.U.) per intranasal inoculum.

Deletion Phenotypes were as follows:

**SG** (low colonizing strain): gX-, gl-, TK-

**BA** (medium -10^5- or high -10^7-colonizing strain): gl-

**Figure 1**
Biology of latent infections established by PRV in sensory ganglia.

A. After acute infection caused by wildtype PRV, convalescent animals become permanently infected by establishment of latency in certain areas of the CNS and in, more importantly, sensory ganglia of the PNS, mainly trigeminal ganglia.

B. Modified Live Virus strains of PRV used commonly as vaccines can establish latency when delivered through administration routes that facilitate "colonization" of the latency target tissues.

C. Pre-colonization of latency target tissues by a preceding MLV strain of PRV may interfere with establishment of latency by ensuing wildtype PRV infection.
UPDATE ON THE PRV DIFFERENTIAL VACCINES

A.

Mucosal infection with Virulent Wildtype (WT) PRV

nerve endings

WT PRV

Establishment of Latent WT PRV in sensory neurons

CNS

sensory ganglion

(trigeminal ganglion)

B.

Mucosal Delivery of PRV MLV Vaccine

nerve endings

MLV virus

"pre-colonized" neuron (latent MLV virus)

CNS

sensory ganglion

(trigeminal ganglion)
Infection with Wild-Type PRV

nerv endings

Interference with establishment of WT PRV latency

"pre-colonized" neuron (latent MLV virus)

sensory ganglion (trigeminal ganglion)
REPORT OF THE COMMITTEE ON PUBLIC HEALTH AND ENVIRONMENTAL QUALITY

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Vice Chairman: Mr. Larry D. Woodson, Topeka, KS

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The Committee met at 1:30 pm, Wednesday, November 1, 1995, in the Nugget Hotel, Reno, NV. Forty two people attended the meeting including 14 members.

Dr. Stephanie Ostrowski, National Center for Prevention Services, Centers for Disease Control and Prevention, gave a presentation titled “Issues in the Importation and Translocation of Wildlife.” Dr. Ostrowski was assisted in the preparation of her presentation by Drs. Peter Schantz, Tom Gomez, Tom Ksiazek, James Childs, and C.J. Peters.

Complacency resulting from our success in reducing deaths caused by many infectious diseases has fostered a false sense of security that these reductions can be easily maintained and that any new infections can be easily conquered. It is time to mount an organized, collaborative national and global counteroffensive against these potentially deadly microorganisms. “Pathogenic microbes can be resilient dangerous foes. Although it is impossible to predict their individual emergence in time and place, we can be confident that new microbial diseases will emerge.” This quote from the 1992 Institute of Medicine report describes the urgency of addressing the problem of emerging infectious pathogens.

Emerging infectious diseases, including re-emergent and drug-resistant infections, pose an increasing threat to the health of the American public. In response to this threat, the Centers for Disease Control and Prevention has developed a plan, “Addressing Emerging Infectious Disease Threats,” which is a prevention strategy for the United States.

Since 1991 alone, many new and re-emerging infectious disease outbreaks have occurred worldwide. Emerging infections, such as those caused
by HIV and hantavirus, illustrate that no nation can be complacent regarding its vulnerability to the new or evolving microorganisms with which we share our planet. In addition, the incidence of many diseases widely presumed to be under control, such as cholera, dengue, and yellow fever, has increased in many areas or spread to new regions or populations throughout the world.

The Division of Quarantine, part of the National Center for Infectious Diseases, CDC, has been given a pivotal role by Congress in the task of preventing the importation of exotic zoonotic pathogens into the United States. This authority is in addition to the role of USDA in preventing the introduction of foreign livestock diseases. Whereas USDA, Veterinary Services, regulates the importation of pet birds, poultry, ruminants, swine, working dogs, and certain animal and poultry products under 9 CFR Part 92, the Division of Quarantine has authority over all etiologic agents and vector species, including potential vector species under 42 CFR Part 71.54.

The Division of Quarantine derives its authority from the Foreign Quarantine Regulations which implement the Public Health Service Act. The origins of this authority date from the days when immigration to the New World was by ship, and the primary duties of the Quarantine officers were to conduct a medical examination on arriving immigrants and refugees at Ellis Island, New York, and other ports of entry. In addition to the health status of arriving passengers, Quarantine officials were responsible for animals and things arriving which might be biologic or mechanical vectors of disease, such as rats, monkeys, human remains, etc.

Imported non-human primates (NHP) are quarantined upon arrival in one of 30 quarantine facilities. These facilities must be inspected by and registered with CDC. Diagnostic necropsies are performed on all animals that die within the first 31 days. In contrast, to the extreme degree of care and regulatory oversight that currently accompanies NHP importations, animals imported for the exotic pet trade have no current program of inspection and quarantine. Neither USDA, US Fish and Wildlife, nor CDC currently inspects for evidence of disease or requires health certification for these animals. Who has the regulatory authority to do so?

The Code of Federal Regulations (42 CFR 71.54a) states “A person may not import into the United States, nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director [of CDC].”

Viral hemorrhagic fevers, many of which have rodent reservoirs, have become epidemic several times in the last two years. The Norwegian rat has spread virtually worldwide. Mastomys rodents, the reservoir of Lassa Fever, have the same capabilities. Most of the American arenaviruses, which cause hemorrhagic fevers in South America, are associated with rodents. A map of the distribution of North American hantavirus is only limited by time to inves-
tigate it. Red foxes are spreading Echinococcus multilocularis, a serious human health threat, through central North America. One survey in South Dakota revealed that 64% of foxes were positive and the infection is spreading to Kansas, Missouri and Ohio. Coyotes, gray foxes, dogs and cats can also serve as definitive hosts for this parasite in domestic and sylvatic cycles. Foxes and coyotes are being translocated to hunting pens in the Southeast. Egyptian fruit bats were imported briefly to the U.S. as pets and *Aedes aegypti*, the mosquito vector of urban yellow fever and dengue, is returning to areas where it had been eradicated.

USDA, APHIS, Veterinary Services (VS) regulates the importation of pet birds, poultry, horses, ruminants, swine, dogs for handling livestock, and certain animal and poultry products (9 CFR part 92). VS establishes importation requirements which include general prohibitions/exceptions, import permits, diagnostic tests, inspection at the port of entry, quarantine requirements, and inspection and other requirements for certain means of conveyance and shipping containers. Some recent situations illustrate the risks associated or potentially associated with the importation of exotic species into the U.S.

New Zealand has reported that tuberculosis is endemic in the brushtail possum and they are a source of disease for domestic livestock. An APHIS risk assessment indicated that 45.8% of consignments of imported brushtail possums would contain one or more possums infected with *M. bovis*. Because hedgehogs from New Zealand occupy the same habitat and geographic areas as the brushtail possum, there is some risk that hedgehogs could contract TB from TB-infected possums. There is no recognized test for detecting TB in either animal. In addition, both these animals could likely survive and thrive in the wild in much of the U.S. and could disseminate the TB organism over range and pasture land, thereby posing a disease risk to livestock and resulting in severe economic impact on the domestic cattle industry. The annual costs in New Zealand for possum damage, e.g., environmental damage, bovine TB attributable to the brushtail possum, disease surveillance, control and research, probably exceed $20 million. On January 23, 1995, USDA, APHIS, adopted as a final rule (60 FR 4372, Docket No. 94-032-2) an interim rule that amended the animal importation regulations to prohibit the importation of brushtail possums and hedgehogs from New Zealand. The action is necessary to prevent the introduction of tuberculosis animals into the U.S. The intended effect is to protect domestic livestock from tuberculosis.

Published research indicates that hedgehogs may harbor foot-and-mouth disease virus (FMDV). Tenrecs are often referred to as the Madagascar hedgehog and are similar to hedgehogs in appearance and behavior, thus may be capable of harboring and transmitting FMDV. Currently, there are no tests or treatments for FMDV in hedgehogs or tenrecs. Further, research and APHIS' experience with hedgehogs and tenrecs indicates that these animals present a significant risk of carrying ectoparasites including ticks capable of spread-
ing diseases of livestock, e.g., East coast fever, heartwater, and African swine fever, which do not exist in the U.S. Therefore, certain restrictions would be imposed on the importation of hedgehogs and tenrecs from countries declared free of FMDV, including requirements for inspection and treatment for ectoparasites. On May 9, 1995, USDA, APHIS published a proposed rule (60 FR 24580, Vol. 60, No. 89) that would amend the animal importation regulations to 1) prohibit the importation of hedgehogs and tenrecs from countries affected by foot-and-mouth (FMD) disease; and 2) impose certain restrictions on the importation of hedgehogs and tenrecs from countries declared free of FMD. This action is necessary to prevent the introduction of FMD and other communicable animal diseases into the U.S. The final rule is drafted and is in clearance for publication in the Federal Register.

Ticks submitted by USDA, APHIS to the National Veterinary Services laboratory (NVSL) from Florida indicated that ticks which are competent vectors of livestock disease, e.g., Amblyomma species as a vector for heartwater disease, were being introduced into the U.S. through importation of tick-infested exotic reptiles. U.S. Fish and Wildlife Service import permits are required for all imported reptiles. Currently, there is no routine standardized ectoparasitic treatment for reptiles at U.S. ports of entry. In addition, reptile imports are not subject to a quarantine period at the port of entry and in some cases, reptiles are not inspected prior to their release into trade channels [Clark, L.G. and Doten, E.H. Ticks on imported reptiles into Miami International Airport: November 1994 through January 1995. Proceedings from the Veterinary Epidemiology and Economics Symposium. 1995]. During the course of this study, APHIS personnel inspected 349 reptile import shipments with a total of 117,690 animals, comprising 142 reptile species in 82 genera, and 2 amphibian species in 1 genus. Inspected specimens came from 22 countries of origin. Ticks were removed from one or more animals in each of 97 shipments. Infested shipments included 54,376 animals. Ticks identified consisted of 13 species in 3 genera (some identifications are pending). Amblyomma species were recovered in 40 (41%) of the 97 shipments, due in part to the large number of iguanas imported from Central and South America.

During 1994-1995, health departments in 13 states reported to CDC persons infected with unusual Salmonella serotypes in which the patients had direct or indirect contact with reptiles (i.e., lizards, snakes, or turtles). In many of those cases, the same serotype of salmonella was isolated from pet reptiles associated with these patients. For some cases, infection resulted in invasive illness, such as sepsis and meningitis [CDC. Reptile-associated Salmonellosis-Selected States, 1994-1995. MMWR 1995;44:347-350].

A high proportion of reptiles are asymptomatic carriers of Salmonella; fecal carriage rates may be over 90% [Chiodini, R.J., Sundberg, J.P. Salmonellosis in reptiles: a review. Am J Epidemiol 1981;113:494-9]. Since the most popular reptiles species will not breed if closely confined, most newly acquired reptiles are wild-caught and imported. The number of reptile
imported into the U.S. has increased dramatically since 1986 and primarily reflects importation of iguanas (27,806 in 1986 to 798,405 in 1994).

In 1979-1980, a Fennec fox-initiated outbreak of *Mycobacterium bovis* occurred at the zoo in Duluth, Minnesota. Apparently, three Fennec foxes (source unspecified) were added to the zoo collection and housed in the primate building. Within 30 days, two foxes became ill and died. *M. bovis* was isolated from lung, liver, spleen, kidney, and thoracic lymph nodes. TB skin-testing in association with this episode found that four of 36 animal handlers, 23 of 674 general public and zoo visitors, and three of 13 non-human primates tested were TST-positive.

Dr. Tim Cordes, USDA, APHIS, National Animal Health Programs, gave a presentation titled "Morbilivirus of horses and humans in Australia: An overview and update." Dr. Cordes presentation was co-authored by Dr. Tom Gomez. An outbreak of what is now known as Acute Equine Respiratory Syndrome or AERS occurred in thoroughbred horses on two premises in the Brisbane area of Queensland, Australia, during the period September 7-26, 1994. Fourteen horses died or were euthanized in extremis with high temperatures, ataxia and bloody nasal discharge. In addition, the trainer of the diseased horses, died of an identical respiratory condition.

On September 7, two horses had been moved to the Hendra (suburb of Brisbane) stable from a paddock. One of these, a pregnant mare, was noted to be ill and died two days later, no necropsy was performed. A companion horse in the paddock had also died several days earlier but was not examined. The other horse was subsequently moved and never became sick. By September 26, 14 horses had died of an acute respiratory syndrome—one in the paddock, 11 at the Hendra stables, one in the adjoining stable and one on a property north of Brisbane after relocation from the Hendra stable. Seven other horses were later considered to have been exposed (seropositive for the agent) and recovered from the illness—3 of these were asymptomatic.

The clinical features of the affected horses included inappetence, pyrexia, and dyspnea in most cases with a frothy nasal discharge varying from clear to blood-tinged. Mucous membranes were usually dark to cyanotic. Several horses developed marked dependent edema, ataxia, and head-pressing. Terminal patients usually died in extremis with a copious frothy, bloody nasal discharge. Pathological findings were consistent grossly with severe pulmonary edema and blood-stained froth in the major airways; and consistent microscopically with acute interstitial pneumonia including damage to the endothelial lining of small blood vessels, hemorrhage and foci of early necrosis. Additional pathology was not consistent.

Five days after the death of the index mare, a 40-year-old male stable hand from the Hendra stable who had close contact with the mare developed an influenza-like illness. His symptoms were myalgia, headaches, lethargy, and vertigo. He did not develop respiratory symptoms or require hospitalization and his physical examination was unremarkable. His illness persisted
for six weeks and he gradually recovered. Six days after the death of the index mare, a 49-year-old male horse trainer from the Hendra stable became ill with symptoms similar to those of the stable hand. He had considerable exposure to fluids from the dying mare in attempting to hand-feed her while he had abrasions on his hands and arms—no cellulitis was noted. Four days after the onset of symptoms he developed nausea and vomiting, was hospitalized on day five and transferred to the Intensive Care Unit on day six for ventilation. The trainer died after seven days in ICU and found at postmortem to have had severe interstitial pneumonia.

Australian animal and public health officials are to be commended for their extensive investigations of this outbreak. The Commonwealth Scientific and Industry Research Organization's (CSIRO) Australian Animal Health Laboratory (AAHL) isolated a previously undescribed morbillivirus from the lungs of five of the six horses tested and from the kidney of the trainer. Evidence that a new morbillivirus was responsible for the outbreak included the following: 1. No bacterial pathogen or toxin could be demonstrated. 2. In horses, African horse sickness, equine influenza, equine rhinopneumonitis, equine viral arteritis, hantavirus, Legionnaire's disease, and the equine viral encephalites were ruled out. 3. The virus was isolated from the lungs of 5 horses tested and from the kidney of one human. 4. In horses, antibody to the virus was present in 4 recovered cases and in 3 contact cases which suffered mild and transient illness, but not in other horses. 5. Serologic tests (serum neutralization and immunofluorescence) were positive in both human patients. 6. Positive transmission studies were completed in 4 horses, with recovery of the virus at necropsy.

Five premises were placed under quarantine in the Brisbane area due to movement of horses from the 2 affected premises. Restrictions were also instituted prohibiting the movement of horses, donkeys, and mules in a 5-km zone around the quarantined premises. Horse movement, race meets, and other equestrian competitions continued outside the restricted area. The Australian Government provided certification stating that exported horses had not been in the quarantined zone for 30 days prior to export. In September, 1994, the USDA implemented a temporary requirement for statement of certification that imported horses had not resided in the State of Queensland for a 60-day period immediately prior to export. It was lifted in January, 1995.

The incubation period in natural horse cases was 8 to 11 days. The AAHL transmission studies incubation period ranged from 3 to 12 days. The 2 human cases had an assumed incubation period of 5 to 8 days. All of the equine cases and the human cases can be linked to the original index case; it was first determined to be ill on September 7, and died on September 9, 1994. Epidemiology suggests that, although highly virulent, the virus does not spread easily among horses as evidenced by its limited spread to only two premises; natural transmission is most likely by direct contact with nasal discharges. Aerosol transmission seems less likely as the upper respiratory tract of af-
Public Health and Environmental Quality

Infected horses did not demonstrate pathology and coughing was not a part of the clinical picture. By September 29, 1994, all additional sick horses had recovered, and to date, no new cases have been reported. One thousand nine hundred and sixty-four horses from over 630 premises throughout Queensland tested negative to the virus on the serum neutralization test. It is not considered highly infectious to humans. There was no serologic evidence of infection in 157 humans who had some association with the sick horses or humans.

Virologic, serologic and transmission studies definitively showed that a new morbillivirus was responsible for this limited respiratory outbreak in horses and humans. No other infected humans or horses were found, despite widespread publicity, active case-finding in humans, and a wide serologic survey of human and horse contacts. The source of the virus at this time is still unknown. Studies are underway to identify the original host species.

The genus Morbillivirus includes canine distemper, seal plague, rinderpest, peste des petits ruminants, and measles, the only one previously known to infect humans. The specific factors precipitating the emergence of the equine Morbillivirus in this outbreak and the circumstances under which the virus changed hosts are yet to be identified. However, the zoonotic pool is an important and potentially rich source of emerging diseases; periodic discoveries of new zoonoses suggest (such as equine morbillivirus) that the zoonotic pool appears by no means exhausted.

References:

Dr. Karen Wernette, AVMA, reported on activities of the AVMA Committee on Environmental Affairs. The purpose of the Committee is to assist AVMA in the development of appropriate environmental policy and implementation of the policy at the national and local levels. Veterinarians have an opportunity to make a major contribution to the development of environmental public policy. Recent Committee activities include tracking of regulation of medical waste incinerators, the Clean Water Act, the Farm Bill, the National Institute of the Environment, the National Association of Physicians for the Environment, the Endangered Species Act, and global warming.

During the past year, the U.S. Environmental Protection Agency (EPA) has been re-evaluating various aspects of the medical waste incinerator regulations purposed on February 1, 1995. Under court order, the final regulations
must be signed by the Administrator on or before April 15, 1996. To meet the schedule of promulgation, EPA must come to closure on various issues raised during the public comment period. EPA stated in a letter of August 8, 1995, that they had not progressed in their re-analysis as rapidly as they had planned. Consequently, rather than hold one meeting in October to review all of their re-analysis, they are planning to hold a series of meetings (late September, Late October, and mid-December) to review various parts of their analysis.

According to a study by the Army Corps of Engineers and EPA, 60 to 75% of all the nation’s existing wetlands would lose federal protection under the Clean Water Act if the full Congress passes a bill similar to one already approved by the House.

Reauthorizing of the Farm Bill should begin this fall. The House and Senate committees are preparing for a seven-year reauthorization to coincide with the seven-year period covered by the budget reconciliation. The House has yet to mark up any of the Farm Bill’s agriculture titles.

The AVMA Committee is considering recommending that AVMA support the National Institute of the Environment (NIE) proposal. The NIE is meant to supplement existing environmental scientific programs by addressing the issues that are too long range and too crosscutting to fall within the purview of any existing agency. Scientists have proposed the creation of the NIE, whose mission would be to improve the scientific basis for making decision on environmental issues by coordinating environmental information to bridge the gaps that currently exist in the area. The agency would work to complement current efforts rather than replace them. The NIE would work toward its mission by carrying out four key functions: research, assessment, dissemination of information, and education and training. Modeled after the National Institutes of Health, the NIE would focus on long-term, peer-reviewed extramural research relevant to policy issues.

The National Association of Physicians for the Environment (NAPE) organizes physicians by medical specialty to deal with impacts of environmental pollution on body organs and systems about which they are expert.

A bill reauthorizing the Endangered Species Act has been introduced in the Senate. The bill would rewrite the act to subscribe to economic and social considerations in listing endangered species and habitats.

The Committee feels that global warming will increase disease, especially those that are vector-borne. Increased temperatures are likely to increase vector habitat. Examples are zoonotic encephalitis and heartworm disease.

Dr. Don Franco, National Renders Association, Inc., gave a presentation titled “Pesticides and Chemicals that Impact Agriculture: Implications for the Food Chain.” Pesticides and chemicals that impact agriculture with emphasis on the food chain were reviewed, including the history of pesticide use and the bioaccumulation of these compounds in the fatty tissues of humans and animals. His presentation covered the classification of pesticides, the clinical manifestations, and a general overview of the pesticides banned, suspended, or severely restricted in the United States. The FSIS testing results
for chemicals in meat and poultry products provide a comprehensive overview of domestic and imported samples analyzed including the level of violations for 1992. There has been a relatively low number of total violations. An educated inference could be made that chemical residues do not play a significant role in impacting food safety according to existing data. Nonetheless, accidental poisoning could be a problem in livestock (e.g. PBB in Michigan and PCB in Montana).

Mr. Charles Moses, Nevada Division of Agriculture, gave presentation titled “Pesticides and Ground Water.” Reports of ground water contamination by agrichemicals have increased over the last 20 years. Nationwide, approximately 46 different pesticides have been found in ground water in 26 states. In most cases, the concentrations found are a very small fraction of the levels believed to be harmful to humans. Although pesticides have been detected in a small percentage (4%) of the total ground water wells sampled, in some instances, the pesticide concentrations exceed human health based drinking water standards.

Sources of contamination can be traced to legal, prescribed use or a direct source such as a spill or accidental injection into a well. The combinations of weather, site, management practices, and pesticide characteristics normally determine the likelihood of pesticides reaching ground water aquifers.

Agrichemicals are permitted to be deliberately introduced into the environment only if, for every use of every chemical, estimated risks are not unreasonable and are balanced by the societal benefits of the pesticide. Because risks are never zero, the risk assessment process is used to balance risk and benefit.

Although acute health effects can result from short-term exposure to elevated levels of pesticide in ground water, acute effects are not likely. Chronic effects are more likely based on the fact that in most cases, only low levels of pesticides are found in ground water. Chronic effect include birth defects, cancer, and nerve damage. Of all chronic health effects, cancer is the major focus of concern. Atrazine is classified as a possible human carcinogen and was detected in ground water in 13 states. Alachlor, which is categorized as a probable human carcinigen, has been found in ground water in 12 states.

It is difficult to prove long term health impacts. Therefore, health risks can only be estimated or projected. However, projected health risks due to pesticide exposure may be regarded by the public and some interest groups with a great deal of suspicion. The uncertainty associated with projecting risks due to chemical exposure has also played a role. Experts can interpret the data in different way which result in controversy and confusion.

Detections of pesticides in ground water serve as an early warning of potential problems. Mitigation should be undertaken to minimize or eliminate exposure. Our challenge is to develop an orderly process to maximize the protection of humans and the environment and to minimize the disruption of food and fiber production.

Dr. John Gillies, Nevada Energy & Environmental Engineering Center, gave
a presentation titled "Fugitive Dust Emissions and Health." Fugitive dust is defined as fine particles of primarily geologic origin. These particles are injected into the atmosphere by the wind or by anthropogenic activities which loft dust into the air where it may be carried by the wind. Sources of fugitive dust include soil erosion by wind, resuspension from roads, construction/demolition, tillage operations, crop harvesting and storage piles of wind erosion susceptible material. Fine particulate matter with aerodynamic diameters less than 10 \( \mu \text{m} \) may be taken deep into the respiratory tract and studies suggest statistical associations between airborne particulate matter and mortality and sickness, even at levels well within current national air quality standards.

Dr. Robert Loux, Executive Director, Nevada Agency for Nuclear Projects, gave a presentation on "High-level Radioactive Waste Disposal: Policy Considerations." Nevada's Yucca Mountain has been designated as the only site for a depository of high-level radioactive waste (HLRW). Currently, such waste would come from commercial spent fuel from nuclear power plants. Later, HLRW will also be coming from defense activities. The construction of nuclear power plants was encouraged in the 1950's, 60's and 70's without plans for disposal of wastes. Deep burial repositories are considered the best way to store such wastes which may take from 10,000 to 1 million years to decay. In the late 1970's and early 80's, a national policy was developed culminating in the passage of the National Radioactive Policy Act in 1982. A number of sites were identified for the two deep burial repositories planned. One repository was to be located in the East and one in the West. However, no state wanted a site. In 1985, the Department of Energy encountered political resistance and in 1987, Nevada was chosen, against the wishes of its citizens, as the only site to be developed. Approximately $2 billion have been spent so far studying the Yucca Mountain site and it is estimated that another $4-6 billion will be needed. It is estimated that it will take $35-40 billion to build, stock and close the site, and it will not even hold all of the HLRW that currently needs to be stored. Consequently, the plan has changed from a permanent, deep repository to an interim surface storage site at Yucca Mountain.

During the business meeting, the Committee reviewed the AVMA statement on the translocation of wildlife. It was decided that the statement contained too many vague elements for the Committee to support it at this time. The Chairperson will discuss this statement with AVMA staff and the Chairperson of the USAHA Committee on Wildlife Diseases.

The Committee Chairperson will also explore options of forming an ad hoc USAHA committee or working group to do a risk assessment of a scenario whereby a foreign pathogen might be introduced to the U.S. through the unregulated entry of animals in the pet trade. This risk assessment could serve as an example of how to deal with the many potential risks to human and animal health from this source.

Suggestions for the meeting next year in Little Rock were made and the Committee adjourned at 6:05 pm.
REPORT OF THE COMMITTEE ON PUBLIC RELATIONS

Chairman: Dr. H. Wesley Towers, Dover, DE  
Vice Chairman: Dr. John K. Atwell, Apex, NC

Mr. Neal Black, MN; Mr. Joe B. Finley, TX; Mr. Don D. Gingerich, IA; Dr. Thomas J. Hagerty, MN; Dr. Richard H. McCapes, CA; Dr. Roger E. Olson, MD; Dr. J. C. Shook, PA; Mr. Alan J. Stern, FL; Mrs. Michele C. Turner, TX; Dr. Gary M. Weber, DC.

The USAHA Public Relations Committee met at 3 p.m. on Sunday, October 29, 1995, in the Southern Pacific D room of John Ascauga’s Nugget Hotel. There were seven committee members and one guest present.

Chairman Towers opened the meeting by telling the committee of some of the relevant activities that have taken place during the year. A copy of the 1994 Proceedings was sent to each college of veterinary medicine for inclusion in their library. As time for this meeting approached, letters of invitation for the meeting were sent to each veterinary school. There were several favorable responses received. Supplies of the USAHA general information brochure were sent to each AVIC so that they could include one in each new veterinary accreditation applicant’s information package. Second requests for more brochures have already been received from some offices.

Next, Mr. Neal Black, USAHA public information officer, told us that he had received responses asking for one hundred eight speech texts and three hundred forty committee reports from the information request forms that he had sent out. Mr. Black maintains a list of over three hundred press contacts. It was suggested that Mr. Black write a one-half to one page summary of our meeting, including a picture of President Towers and AVMA President-Elect Leininger for inclusion in the AVMA Journal.

The next item discussed was the USAHA newsletter. Each committee member congratulated Dr. Dick McCapes, USAHA Third Vice President and editor of the newsletter, for the fine job he was doing. It was everyone’s opinion that the newsletter was the very best public relations vehicle that the organization has at the present time. A very complimentary letter from Dr. Clarence Campbell, past USAHA President, concerning the style, format, and content of the newsletter was read into the record. Dr. McCapes presented an accounting of the costs for producing the newsletter during the past year. It is expected that a budget for the newsletter will be proposed at the Board of Director’s meeting in February. As a possible way of cutting mailing costs, a discussion was held on bulk rate mailing. Mr. Neal Black suggested the possible addition of his three hundred plus press contacts to the newsletter mailing list.

The next agenda item was a report from the promotional vehicle subcom-
REPORT OF THE COMMITTEE

mittee. Drs. Haggerty and Atwell reported that, while a video is modern technology and can be made easily available, it would be very costly to produce in relation to its usefulness. They pointed out that a video would also run the risk of becoming dated very quickly. The subcommittee felt that professionally developed printed material would be the better choice. This material could then be made available to veterinary students, licensed veterinarians, and industry groups. Printed material can be updated as needed relatively inexpensively. It was also suggested that the mention of continuing education credits for attending the meeting be included in it. The redesigning of the USAHA brochure will be an item to be brought before the Board of Directors.

The last item to be brought before the committee was the suggestion that USAHA have a page on Internet. There was indecision as to how much information would be included. After some discussion, it was determined that the amount to be included would probably be determined by cost. It was agreed, however, that the page should include a brief description of the organization, its purposes, and functions.

There being no further business to bring before the committee, adjournment took place at 4:30 p.m.
REPORT OF THE COMMITTEE ON RABIES

Chairman: Dr. Deborah J. Briggs, Manhattan, KS
Vice Chairman: Dr. Robert E. Miller, Gaithersburg, MD

Dr. H. Michael Chadock, MI; Dr. Donald S. Davis, TX; Dr. Nancy A. Frank, MI; Dr. E. P. J. Gibbs, FL; Dr. Keith N. Haffer, SD; Dr. Cathleen Hanlon, NY; Dr. Richard E. Hill, IA; Dr. Owen J. James, MT; Dr. Calvin W. S. Lum, HI; Dr. John C. New, TN; Dr. Charles E. Rupprecht, GA; Dr. Leon H. Russell, TX; Dr. Lyle P. Vogel, IL; Dr. James C. Wright, AL.

The Committee on Rabies met at 1:30 P.M. on Monday, October 30, 1995, in the Carson Room of the John Ascuaga's Nugget Hotel in Reno, Nevada. Ten committee members and 15 guests were present.

Dr. Charles E. Rupprecht, Centers for Disease Control and Prevention, gave a presentation entitled, "Update on Recent Human Rabies Cases". Since the 1950's, human deaths attributed to canine rabies have significantly decreased in association with canine rabies vaccination programs. However, with the development of molecular techniques, it has become apparent that more humans in the United States have succumbed to the bat strain of rabies associated with *Lasionycteris noctivagans*, the silver-haired bat. Current recommendations involving human exposures to bats have been re-evaluated due to the fact that many of the individuals that have died of bat rabies have no documented exposure.

Dr. Cathleen Hanlon, New York State Department of Health, updated the committee on "New York State Wildlife Rabies Vaccination: First Evaluation in an Enzootic Area". The oral rabies vaccination program in the New York enzootic area has significantly decreased the number of confirmed rabid raccoons in the study area. This study indicates that there is value in initiating an oral raccoons vaccination program in areas in which raccoon rabies has been established.

Dr. Diane Cahill, DyNAgenics Laboratory, discussed "PCR-A Proposed Method for the Ante and Postmortem Diagnoses of Rabies. Dr. Cahill stated that PCR is a molecular technique that can be used for diagnosing a variety of viral diseases including rabies. With PCR, a specific segment of a viral genome is amplified, electrophoresed and visualized on an agarose gel. In some instances this method may have value as a method to differentiate various rabies strains. Currently the Centers for Disease Control, the World Health Organization and the Pasteur Institute do not recommend usage of PCR as the sole diagnostic tool in rabies diagnoses.

Dr. David W. Dreesen, University of Georgia, presented data on "The Lyssavac Berna Human Diploid Cell (HDC) for Human Pre- and Post-exposure Immunizations". The vaccine trial for Lyssavac HDC was conducted at
the University of Georgia, Kansas State University, and Oklahoma State University. Lyssavac HDC differs from the currently licensed HDCV in that it contains no antibiotics, and is administered as a 0.5 ml dose. The adverse reactions experienced by subjects involved in the trial were mild, and contrary to the currently licensed HDC rabies vaccine, no type III hypersensitivity reactions were noted.

Dr. Keith A. Clark, Texas Department of Health, presented a review entitled, "An Update on Coyote & Fox Rabies Epizootics in Texas: Epidemiology & Control. In 1994, two ongoing rabies epizootics were declared a state health emergency: canine rabies in South Texas and gray fox (Urocyon cinereoargenteus) rabies in West-Central Texas. Subsequently, in 1995, a statewide rabies quarantine was enacted. Prior to 1988, rabid coyotes were infrequently reported in Texas. In 1988, Starr and Hidalgo Counties, located in extreme South Texas, experienced an epizootic of canine rabies resulted in 11 laboratory-confirmed cases of canine rabies in domestic dogs (Canis familiaris) and 6 cases in coyotes (Canis latrans). By 1991, the epizootic had expanded approximately 160 km north of the US-Mexico border and included 10 counties. During the next 3 ½ years, 10 additional counties became involved in the epizootic as it continued to move northward. During the 7 ½-year-period, there were 644 cases of canine rabies in a 20-county area. Gray fox rabies, which was endemic in West-Central Texas, also became epizootic in 1988. It began in Sutton County and rapidly expanded to include 6 additional counties by the end of the year with 23 laboratory-confirmed cases of gray fox rabies. The epizootic continued through 1993, with 260 gray fox rabies cases in 22 counties during a 6-year-period. In 1994, there was an upsurge in the epizootic as it expanded in a northeasterly direction; 13 additional counties became involved and there were 264 recorded cases of gray fox rabies. The expansion of the epizootic continued in 1995 with the inclusion of 200 cases and 10 new counties during the first 6 months. From 1988 through June 1995, the epizootic included 724 cases of gray fox rabies in a 45 county area. Antigenic and genetic analysis revealed the ecotype primarily affecting domestic dogs and coyotes in South Texas to be urban Mexican dog (UMD) and the rabies ecotype primarily affecting gray foxes in West-Central Texas to be Texas fox (TF). The epizootics are approaching large metropolitan area; an increase in vaccination levels of domestic animals would help provide a barrier between rabid wild animals and humans.

Mr. Michael Neizgoda, Centers for Disease Control and the University of Georgia, discussed the "Pathogenesis of Skunk Variant Rabies Virus in the Domestic Ferret (Mustela putorium furo). Little is known about the clinical course and periods of rabies viral transmission in ferrets. To this end, groups of ferrets were inoculated with rabies virus of skunk origin at 5 different concentrations and were held for an observation period of 6 months. Ferrets were observed daily, and weekly samples included oral swabs, body weights, rectal temperatures and blood specimens. Susceptibility and incubation periods
RABIES

were directly and indirectly dependent, respectively, upon inoculation dose. Incubation periods ranged from 2 weeks to > 3 months. Typical clinical presentation included ascending paralysis, fever, ataxia, hyperactivity, weight loss and paresthesia. Morbidity periods were similar in each group at approximately 4 days. Rabies antigen was detected upon examination of brain tissue of 33 clinically rabid ferrets by immunofluorescent microscopy. Rabies virus was not isolated from oral swabs, but was recovered from one salivary gland collected at necropsy. The proportion of ferrets that developed rabies virus neutralizing antibodies was directly related to inoculum dose and usually appeared concomitant with clinical signs. One ferret that presented with clinical signs of rabies seroconverted and eventually recovered but with severe paralytic sequelae. Given that rabies pathogenesis (including viral excretion) may vary, depending upon viral dose, route and strain, and that rabies virus has been isolated from the salivary glands of naturally and experimentally infected ferrets, and that these data are preliminary based upon a single rabies variant of mustelid origin, caution is urged in evaluation of the rabies risk when a ferret bites a person. To adequately ensure the public's health, studies in progress must be completed before any changes inferret rabies control recommendations can be considered by the Compendium of Animal Rabies Control Committee.

Following the presentations, a business meeting was held. One resolution to support and encourage oral rabies vaccination programs in wildlife was passed. The committee declined to act on a resolution proposing an elimination of Certificates of Veterinary Inspection in dogs and cats.

The meeting ended at approximately 4:45 P.M.
PCR - A PROPOSED METHOD FOR THE ANTE- AND POSTMORTEM DIAGNOSIS OF RABIES

Allen R. Cahill, K. Diane Swabby & Eddie J. Sullivan
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Polymerase Chain Reaction (PCR) is a technique used to study the molecular pathogenesis and diagnosis of a variety of viral diseases, including rabies. Unlike conventional methods however, this new technology makes antemortem testing both practical and feasible. Testing is relatively inexpensive and does not require a complex facility.

With PCR, a specific segment of a viral genome is amplified. Then, the size of the amplified segment is determined by electrophoresis before being visualized on an agarose gel. This method can even differentiate between mutants of a virus.

PCR is generally more sensitive and more accurate than conventional methods, especially on degraded samples. Therefore, it will soon become the preferred technology for medical and veterinary diagnosticians and public health officials.

Introduction

We have investigated the commercial practicality and feasibility of the diagnosis and detection of a number of infectious diseases, including rabies, by polymerase chain reaction methodology (PCR). Immunofluorescent Antibody test on brain tissue has historically been the basic method for routine rabies diagnosis. However, this protocol requires relatively fresh postmortem samples. There are instances when an antemortem test would be preferable. Examples include exposure to possible rabid animals by veterinary neurologists. Rabies would often be a consideration, since these professionals see patients exhibiting neurological signs. A reliable ante-mortem test is needed to protect these and other veterinarians and their staffs from possible rabies exposure. As a group, the veterinarians' risk for exposure to rabid animals is over 300 times greater than that of the general population. [1]

PCR Applied Research

The most common specimen for laboratory diagnosis of rabies is the brain of the biting animal to which the DFA (Direct Fluorescent Antibody) test is applied. The DFA technique is dependent upon the virus being present and is reliable if using relatively fresh postmortem samples. However, it is not sensitive during the early stages of the disease and decreases in reliability when the specimen has autolyzed or decomposed. The DFA yields a false negative rate of four out of every 1,000 cases. French investigators at the Pasteur Institute performed analysis on over 100 field samples by three diagnostic methods; 1) DFA on brain tissue, 2) RTCIT (Rabies Tissue Culture
PCR - METHOD FOR THE ANTE- AND POSTMORTEM DIAGNOSIS OF RABIES

Infection Test), and 3) an ELISA technique - the Rabies Enzyme Immunodiagnosis (RFEID). The same 22 and 78 samples were respectively found to be positive or negative by each of the three methods. [2]

PCR can detect rabies virus in cerebral spinal fluid (CSF) and serum. Antibodies to the virus, however, occur in only approximately 20% of the clinical cases and are rarely found in the CSF. Virus spreads from the site of inoculation and generally ascends in the spinal cord or brain stem by CSF pathways. Diagnosis by PCR in CSF could be demonstrated by Thai investigators in proven rabies patients, both human and canines. [3]

The advent of PCR methodology provides information about the pathogenesis of the virus which could not be obtained by the DFA method. PCR has been used to study the disease progression in a murine model. Mice were infected intramuscularly in the masseter muscle. PCR analysis demonstrated that virus replication had occurred in the trigeminal ganglia during the early stages. It was found that at later stages (96 hours postinfection) intense replication had occurred because positive sense RNA was detected. The PCR method demonstrated in this case that the average speed for axonal transport of virus is 1 mm/hr and that the replication cycle for the virus is approximately 12 hours. [4]

Discussion

The advent of the PCR technique has increased our knowledge and understanding for the pathogenesis and diagnostics of viral as well as other pathogenic organisms. Experimentally, PCR has been shown to be highly sensitive and accurate. The studies cited above, with reference to rabies, provide information which can be applicable for routine diagnostics. Since PCR can detect virus in CSF and saliva, this offers an ante-mortem alternative. Also, PCR can detect virus at the inoculation site as soon as one hour post-injection and may provide a means to readily detect virus at a bite site without depending upon the availability of the head of the biting animal. [4]

The main requirement for a laboratory to practically apply PCR as a diagnostic method is that good laboratory practices be established. It is imperative that Pre- and Post-PCR areas be maintained. The sample preparation area must be kept clean and dedicated as the Pre-PCR or Post-PCR Zone. Care must also be given to the movement of personnel. Technicians should not move from the preparation area to the PCR section. The PCR reaction is generally performed in a "clean room" in a laminar flow hood. Standard sterile techniques which are applied to cell culture or microbiological manipulation will greatly reduce the risk of PCR contamination.

The equipment required is relatively inexpensive. There are a variety of thermocyclers or "PCR machines" available. Small units are less than $3,000. Complete setup for PCR can be as little as $11,000 for an existing laboratory.

Sample collection will require more skill though, especially for ante-mortem samples. The sedation of animals to obtain saliva samples requires the use of prescription drugs (e.g. Rompun) which produce salivation and a coopera-
tive patient. These drugs necessitate a veterinarian’s administration or supervision. In a highly suspicious case the use of a dart gun greatly reduces the chances of being bitten. Of course, CSF samples could be routinely supplied for testing by specialists such as neurologists. This would permit them to "rule in" or "rule out" rabies as a definitive diagnosis.

Conclusion

Our laboratory has been performing PCR for over a year and has succeeded in providing diagnostic services for the veterinary community and in monitoring pathogenic protozoans in water supplies. In our experience, PCR has provided more accurate results than conventional test methods which depend upon the ability of the host to produce antibodies. As far as rabies is concerned, an ante-mortem test would fulfill a dire need. We in no way suggest or imply that PCR should replace the current regulated rabies requirement, only that it be an adjunct to it. More research and development needs to be done. Unfortunately, the public's health officials have been reluctant to permit any research and development for a reliable ante-mortem test to be implemented. The PCR test for rabies has been reported to work quite well on saliva samples among the few universities performing the test.

As we move to the 21st century, and technology becomes more advanced, there is a challenge ahead. Is public health going to become more sophisticated in molecular biology and utilize DNA technology to fulfill their duty to protect the public (including veterinarians) with an ante-mortem test, or is it going to continue to only utilize testing which requires the death of the animal being tested?

Acknowledgments

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REPORT OF THE COMMITTEE ON CANINE AND GRAY FOX RABIES EPIZOOTICS IN TEXAS

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Abstract: In 1994, two ongoing rabies epizootics were declared a state health emergency: canine rabies in South Texas and gray fox (Urocyon cinereoargenteus) rabies in West-Central Texas. Subsequently, in 1995, a statewide rabies quarantine was enacted. Prior to 1988, rabid coyotes were infrequently reported in Texas. In 1988, Starr and Hidalgo Counties, located in extreme South Texas, experienced an epizootic of canine rabies resulting in 11 laboratory-confirmed cases of canine rabies in domestic dogs (Canis familiaris) and 6 cases in coyotes (Canis latrans). By 1991, the epizootic had expanded approximately 160 km north of the US-Mexico border and included 10 counties. During the next 3 ½ years, 10 additional counties became involved in the epizootic as it continued to move northward. During the 7 ½-year-period, there were 644 cases of canine rabies in a 20-county area. Gray fox rabies, which was endemic in West-Central Texas, also became epizootic in 1988. It began in Sutton County and rapidly expanded to include 6 additional counties by the end of the year with 23 laboratory-confirmed cases of gray fox rabies. The epizootic continued through 1993, with 260 gray fox rabies cases in 22 counties during a 6-year-period. In 1994, there was an upsurge in the epizootic as it expanded in a northeasterly direction; 13 additional counties became involved and there were 264 recorded cases of gray fox rabies. The expansion of the epizootic continued in 1995 with the inclusion of 200 cases and 10 new counties during the first 6 months. From 1988 through June 1995, the epizootic included 724 cases of gray fox rabies in a 45-county area. Antigenic and genetic analysis revealed the ecotype primarily affecting domestic dogs and coyotes in South Texas to be urban Mexican dog (UMD) and the rabies ecotype primarily affecting gray foxes in West-Central Texas to be Texas fox (TF). The epizootics are approaching large metropolitan areas; an increase in vaccination levels of domestic animals would help provide a barrier between rabid wild animals and humans.

Key words: canine, coyote, Canis familiaris, Canis latrans, dog, epizootic, gray fox, rabies, Urocyon cinereoargenteus

Rabies, a fatal viral disease that is transmitted from animals to humans, has become a serious problem in Texas. There are two rabies epizootics (epidemics in animals) that started in 1988 and have continued through mid-1995: canine rabies in South Texas and gray fox (Urocyon cinereoargenteus) rabies in West-Central Texas. In July 1994, the ongoing rabies epizootics
were declared a state health emergency; subsequently, in January 1995, a statewide rabies quarantine was enacted.

Between 1961 and 1988, only 25 rabid coyotes (Canis latrans) were reported in Texas. In 1988, however, a viral ecotype that had been confined to urban dogs became established in the coyote population along the US-Mexico border. This canine strain of rabies is readily transmitted from coyotes to domestic dogs (Canis familiaris) and, subsequently, between domestic dogs (Clark et al. 1994). The transmission capability of the virus is pertinent from a public health standpoint because a rabies outbreak involving domestic animals greatly increases the chances for human exposure, as opposed to an outbreak that is maintained strictly in a wild animal population. The first case was recorded in Starr County, located in extreme South Texas. Adjacent Hidalgo County became involved by the end of 1988, and these were the only 2 active counties through 1990. In 1991, the epizootic expanded to include 8 additional counties, followed by 4 more counties between 1992 and 1993 and an increase of 4 new counties in 1994; it was now approximately 255 km north of the US-Mexico border. During the first 6 months of 1995, 2 other counties were included in the epizootic. By mid-1995, the northeasterly movement of the epizootic had expanded to include 644 laboratory-confirmed cases of canine rabies in 20 contiguous counties.

Gray fox rabies is defined as that strain of rabies virus that is adapted to gray foxes and is transmitted from fox to fox; it does not include spillover to foxes from other species, such as when a rabid skunk (Mephitis mephitis) infects a fox, but does include any animal that is infected by the strain of rabies peculiar to gray foxes. In 1946, an epizootic of fox rabies began in Sabine County, located in East Texas, and moved in a southwesterly direction through 1955, with 1,095 recorded cases. During the 1960's, fox rabies disappeared from the eastern portion of the state and localized in West Texas where, in the 1970's and 1980's, it became enzootic (present at low levels in animals in an area or population at all times) (G.M. Moore, TDH, unpubl. data). In 1988, an epizootic of gray fox rabies began in Sutton County, located in the mid-western portion of the state; within the year, 6 additional counties became involved. From 1989 to 1994, a range of 1 to 13 new counties per year had recorded confirmed gray fox rabies cases; the epizootic had spread approximately 130 km northward and 225 km eastward from the index case. During the first 6 months of 1995, 10 other counties were included in the epizootic. By mid-1995, the epizootic included 45 counties in West-Central Texas with 724 laboratory-confirmed cases of gray fox rabies.

CANINE AND GRAY FOX RABIES EPIZOOTICS IN TEXAS

STUDY AREA and METHODS

Case Report Form
Each case of animal rabies was investigated by Texas Department of Health (TDH) Zoonosis Control Division (ZCD) personnel. A standardized form, the Zoonotic Incident Case Report (ZIR), was used statewide. The form included date, location, and description of the incident that caused rabies to be suspected and the animal's medical history (if known), vaccination status, and any human or domestic animal contacts. The policy of the TDH is to test only animals that have potentially exposed a human or a domestic animal; active surveillance is not routinely conducted because an adequate sampling is provided under this policy.

Laboratory Procedures
Brain tissue specimens were tested for rabies antigen by immunofluorescence microscopy at the TDH Laboratory in Austin. Positive specimens were further tested with a panel of monoclonal antibody (MAB), each directed against a specific antigenic site on the rabies virus nucleocapsid and were evaluated by immunofluorescence microscopy (Smith et al. 1986). Differences in nucleotide sequences were examined by polymerase chain reaction (PCR) techniques (Smith et al. 1984, Smith et al. 1991).

Monoclonal antibody and PCR procedures identified 3 ecotypes common in terrestrial animals in Texas, which were designated as Texas skunk, Texas fox (TF), and urban Mexican dog (UMD). Although the Texas skunk ecotype was distinguished using only MAB techniques, the TF and UMD ecotypes could not be differentiated by MAB. Polymerase chain reaction techniques were required on specimens that were classified, according to MAB results, as Texas fox/Mexican dog (TFMD) to determine if they were the TF or UMD ecotype. The TF ecotype was found in southwest Texas in gray foxes and animals infected by contact with gray foxes, and the UMD ecotype was found along the US-Mexico border in dogs, coyotes, and animals infected by dogs and coyotes (Clark et al. 1994).

RESULTS and DISCUSSION

Canine Rabies Epizootic
The index case for the canine rabies epizootic in South Texas occurred on 3 September 1988 in Starr County, which is located on the US-Mexico border. A coyote that had fought with 2 vaccinated dogs was submitted for rabies testing and determined rabid by immunofluorescence microscopy. This was the first rabid terrestrial animal reported in the area in 18 years. Four weeks later, another rabid coyote was detected approximately 16 km north of the index case; it was tested after it attacked 3 unvaccinated dogs. Two months after the index case, a rabid coyote was reported near Rio Grande
City, which is located on the US-Mexico border in south-central Starr County; this coyote also fought with 3 unvaccinated dogs prior to being tested. Three weeks later, the first rabid dogs in Starr County were recorded, both from the Rio Grande City area. By the end of 1988, there were 6 rabid coyotes and 2 rabid dogs reported from Starr County. Hidalgo County, adjacent to Starr County, became involved in the epizootic on 15 November 1988 when a 9-week-old dog was confirmed positive for rabies. This incident occurred 55 km southeast of the index case and involved a dog that had been mauled 12 days earlier by a wild animal that was suspected to be a coyote. From mid-November through December 1988, there were 9 rabid dogs recorded in Hidalgo County.

During the first 6 months of 1989, only 1 rabid coyote was reported from Starr County. However, from July through December, 15 rabid dogs (all from the Rio Grande City area), 4 rabid coyotes, and 1 rabid raccoon (Procyon lotor) were detected in this county. Hidalgo County continued to have recorded cases of rabid dogs; 19 dogs, 1 coyote, 1 cat (Felis catus), and 1 raccoon were confirmed rabid during 1989. In 1990, the localized Rio Grande City epizootic continued and involved 15 dogs, 3 cats, and 3 coyotes. Two of the dogs had a known attack by a coyote within a month prior to developing clinical signs. In Roma, 20 km upriver from Rio Grande City, 16 rabid dogs were reported. After state health department officials and local health professionals initiated aggressive rabies control measures, Hidalgo County had no reported rabies cases during 1990.

In 1991, the canine rabies epizootic expanded approximately 160 km north of the US-Mexico border to include the following 10 counties: Brooks, Duval, Hidalgo, Jim Hogg, Jim Wells, Kenedy, Kleberg, Nueces, Starr, and Zapata. By the end of 1991, there were 25 dogs, 42 coyotes, and a raccoon, cat, skunk, and cow (Bos taurus) confirmed rabid. A human death attributable to canine rabies also occurred in 1991. The patient, a 55-year-old Starr County woman, had no history of exposure, but laboratory tests determined that she was infected with the canine strain of rabies virus.

Webb and Willacy counties became active in 1992; there were 41 rabid dogs, 70 rabid coyotes, and a rabid bobcat (Felis rufus), cat, cow, goat (Capra hircus), horse (Equus caballus), and raccoon reported from the 12-county area. Cameron County, located in the southernmost tip of Texas, was included in the epizootic in May 1993 when a raccoon with the canine strain of rabies was reported. La Salle County became the northernmost extension of the epizootic in November 1993. During 1993, positive rabies cases in the 14 South Texas counties included 42 dogs, 69 coyotes, 7 cats, 4 raccoons, 1 cow and 1 bobcat.

The northward movement continued in 1994 with the addition of Live Oak and McMullen Counties in March and Frio and Dimmit Counties in September, extending the epizootic approximately 255 km north of the US-Mexico border. Confirmed rabies cases for 1994 included 32 dogs, 74 coyotes, 7
raccoons, 4 cows, 2 horses, 2 cats, and 1 bobcat. Another human death attributable to canine rabies occurred in South Texas in 1994. The 14-year-old Hidalgo County boy had no history of exposure, but the rabies virus was confirmed to be the UMD strain (Kelley et al. 1995). This second case of human rabies with the Texas canine strain of rabies virus emphasizes the fact that, because it involves the domestic dog population, the canine rabies epizootic is particularly dangerous to humans due to increased exposure rates.

During the first 6 months of 1995, Zavala and Atascosa Counties were included in the leading northern front of the epizootic. Canine rabies cases from January through June 1995 included 29 dogs, 57 coyotes, 10 raccoons, 8 cows, 6 cats, 2 bobcats, and 1 horse. From 1988 through June 1995, the epizootic encompassed 20 South Texas counties and 644 laboratory-confirmed cases of canine rabies consisting of 245 dogs, 327 coyotes, 25 raccoons, 21 cats, 15 cows, 5 bobcats, 4 horses, 1 goat, and 1 skunk (Figure 1).

From 1989 through 1990, the number of rabid dogs reported in South Texas was greater than the number of rabid coyotes. In 1991, more rabid coyotes than rabid dogs were recorded per year; this trend has remained consistent through mid-1995. The shift in predominant rabid species may be attributed to increased vaccination levels in dogs initiated by increased public awareness and low-cost vaccination clinics. In Starr County, clinics have been sponsored by the Texas Department of Health, the U.S. Army, Rhone Merieux, Inc., the Texas National Guard, and a local veterinary practitioner. Consequently, vaccination levels in Starr County dogs that were exposed to a known rabid animal increased from 18.2% in 1988 to 50% in 1994.

Gray Fox Rabies Epizootic

Prior to 1988, gray fox rabies was enzootic in West Texas with case levels ranging from 3 to 16 per year from 1982 through 1987. The highest number of cases during this 6-year-period occurred in Kimble (7 cases) and Kerr (6 cases) Counties. In 1988, the number of animals confirmed infected with gray fox rabies escalated to 23 and involved 12 gray foxes, 6 cats, 1 goat, 1 sheep (*Ovis aries*), 1 bobcat, 1 cow, and 1 raccoon. The first case occurred on 1 January 1988 near the city of Sonora in Sutton County, which is adjacent to the west side of Kimble County. Surrounding counties that subsequently became involved in the outbreak included, in chronological order, Val Verde, Menard, Crockett, Tom Green, Uvalde, and Kinney. Rabies positive cases were reduced in number in 1989 with 11 foxes and 1 cat; 2 new counties, Pecos and Terrell, were included in the epizootic.

During 1990, the epizootic was centralized in Val Verde County, which is adjacent to the south side of Sutton County, with 19 cases of gray fox rabies. At this time, Edwards was added to the list of involved counties. Animals confirmed infected with gray fox rabies during 1990 included 23 foxes, 3 goats, 3 bobcats, 3 cows, 2 horses, 2 dogs, and 2 raccoons. In 1991, the epizootic expanded in a southeast direction to include Bandera, Kerr, Kimble, Medina,
REPORT OF THE COMMITTEE

Real, and Schleicher Counties. There were 68 recorded gray fox rabies cases in 12 counties; Uvalde County was the most active with 21 cases. A wide variety of species were laboratory-confirmed positive for rabies, including 34 foxes, 10 raccoons, 7 cats, 5 cows, 4 goats, 4 coyotes, 2 dogs, 1 bobcat, and 1 porcupine (*Erethizon dorsatum*).

In 1992, Irion and McCulloch Counties were added to the list of counties afflicted with gray fox rabies. Kimble County was the most active with 14 of the 60 reported cases. Gray fox rabies cases during this time included 28 foxes, 8 bobcats, 6 cats, 5 dogs, 4 goats, 4 raccoons, 2 sheep, 1 cow, 1 llama (*Lama glama*), and 1 ringtail (*Bassariscus astutus*). Concho, Kendall, Presidio and Upton Counties became involved in 1993; rabid species in the epizootic consisted of 35 foxes, 10 raccoons, 5 dogs, 3 cats, 2 bobcats, 2 coyotes, 1 cow, and 1 goat.

During 1994, 13 new counties recorded gray fox rabies cases, including Bexar, Brewster, Brown, Coke, Coleman, Crane, Lampasas, Mason, Mitchell, Reagan, Runnels, San Saba, and Sterling. Concho, Edwards, Irion, Kerr, Kimble, McCulloch, Medina, Menard, Sutton, Tom Green, Upton, Uvalde, and Val Verde Counties continued to be involved. The epizootic had rapidly expanded from the index case in Sutton County northward approximately 130 km to Runnels, Coleman, and Brown Counties, and eastward approximately 225 km to Lampasas County. McCulloch County, which had 8 cases of gray fox rabies during the last two months of 1993, had an impressive upsurge in 1994 with 67 cases. Of these cases, 55 were during the first 3 months of the year. By March, the cases of gray fox rabies in Tom Green County, which is adjacent to the west side of Concho County, began to greatly escalate resulting in 80 cases for the year. There were 264 cases of gray fox rabies in 26 counties during 1994, including 140 foxes, 52 raccoons, 20 cats, 16 dogs, 12 cows, 9 goats, 5 bobcats, 3 coyotes, 2 horses, 2 ringtails, 2 sheep, and 1 rabbit (*Oryctolagus cuniculus*).

In the first 6 months of 1995, Callahan, Comanche, Erath, Glasscock, Howard, Nolan, and Taylor Counties formed the epizootic’s northern front and Gillespie, Llano, and Mills Counties were added to the eastern edge. During January through June, gray fox rabies cases included 110 foxes, 25 raccoons, 15 dogs, 14 bobcats, 13 cows, 11 cats, 6 goats, 2 horses, 2 sheep, 1 ringtail, and 1 coyote.

During 7 ½ years, there were 393 foxes, 104 raccoons, 54 cats, 45 dogs, 36 cows, 34 bobcats, 28 goats, 10 coyotes, 7 sheep, 6 horses, 4 ringtails, 1 porcupine, 1 llama, and 1 rabbit confirmed positive for gray fox rabies in a 45-county area (Figure 2). A characteristic of gray fox rabies that became evident during the epizootic was that it readily transmitted to raccoons and to livestock, especially cows and goats. This may be attributable to greater inherent susceptibility, habitat relationships with other species, and behavioral traits that increase exposure.
Management Implications

The northernmost identified case of canine rabies was within 25 miles south of San Antonio. Based on the average spread rate of the epizootic since 1988, it will reach this large metropolitan area by the end of 1995 if it is not controlled. As in many major cities in the United States, San Antonio has an urban coyote population; this, combined with the estimated 75% unvaccinated dog population in the area, forms an explosive combination for the canine rabies epizootic.

The reestablishment of gray fox rabies as an epizootic can be explained by the fact that rabies is a disease of overpopulation. An increase in the number of gray foxes has resulted from the loss of the market for pelts. Gray foxes inhabit approximately 230 of the 254 counties in Texas (they are not commonly found in the northernmost 24 counties) and give birth to 3 to 6 pups per litter each year. Therefore, it is expected that the gray fox epizootic will continue to move north and east toward metropolitan areas, such as San Antonio, Austin, Abilene, and Dallas.

To prevent the translocation of animals that play a critical role in the epidemiology of the rabies epizootics to unaffected portions of Texas or to other states/countries, a statewide rabies quarantine was enacted in January 1995 (Rules of the Board of Health, Rabies Control Act). The quarantine prevents movement within or out of Texas of any dogs, cats, and wolf-dog hybrids 3 months of age or older for which an official, current rabies vaccination certificate cannot be produced, plus any coyotes, indigenous foxes, and raccoons. In addition, the Rabies Control Act (Chapter 826, Texas Health and Safety Code) was amended in May 1995 to prohibit the transportation or sale (or possession for purposes of transportation or sale) of any dogs or cats 3 months of age or older for which an official, current rabies vaccination certificate or tag cannot be produced, plus any animals that are defined in the Rules of the Board of Health as high risk for transmitting rabies (coyotes, foxes, raccoons, skunks, and bats).

An increased vaccination level in pets and livestock is very important for rabies prevention. Historically, human rabies cases declined when canine rabies cases decreased because of increased vaccination rates, even though rabies cases in wild animals were elevated during the same time period. In the early 1950's, the number of U.S. rabies cases in dogs and humans peaked. In the mid-1950's, dog and human rabies cases declined with the advent of highly effective rabies vaccine for dogs and maintained this lower level through the early 1980's. However, U.S. rabies cases in wild animals peaked in the early 1960's, the late 1970's and early 1980's, and again in the early 1990's. People do not commonly encounter rabid wild animals, but rabid pets and livestock can bring the disease into the home or ranch area. Rabid domestic animals are 5 (Clark 1988) to 10 (J.C. Mahlow, TDH, pers. commun.) times more likely to come into contact with a human than are rabid wildlife. Vaccinated domestic animals can break the rabies transmission cycle by creating
REPORT OF THE COMMITTEE

a buffer zone between rabid wild animals and humans. It is also beneficial to decrease the number of stray animals and increase knowledge of bite avoidance techniques. To ensure these actions, rabies education for government employees, animal control officers, and the general public is essential.

Literature Cited

CANINE AND GRAY FOX RABIES EPIZOOTICS IN TEXAS

Figure 1. Canine rabies cases in South Texas, 1988 - June 1995
Expert scientific groups such as the Institute of Medicine and the American Society for Microbiology have expressed concern about the national and global increase in antibiotic resistance and the complex issues surrounding this increase both in community and institutional settings. Human infections caused by resistant pathogens result in increased morbidity and mortality from treatment failures and increased health care costs as newer, more expensive antibiotics are needed to treat common infections. The causes of this increase in antibiotic resistance are multifactorial and complex.

The issue of drug resistance among veterinary pathogens is a small part of this larger health issue and its role needs further delineation. We also recognize that the concern of increasing antimicrobial resistance needs to be reviewed with the knowledge that, as in the case of diseases in humans, the number of therapeutic options for treatment of infectious diseases in animals is diminishing. The Food and Drug Administration’s (FDA’s) Center for Veterinary Medicine (CVM) is concerned about maintaining antibiotic effectiveness, ensuring safety, and increasing the availability of new products to veterinary practitioners and the food animal industry.

Many studies and several monitoring systems have been initiated to study various aspects of antimicrobial resistance in humans. Both the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have several surveillance systems in place for nosocomial infections, respiratory pathogens, and others. However, currently there is no comprehensive national or global surveillance system for monitoring antimicrobial susceptibility of enteric pathogens in human or animal populations. The lack of systematic information on zoonotic enteric pathogen susceptibility makes public health decision making difficult and the ability to be proactive in assisting practitioners in the appropriate use of antimicrobials impossible. Several groups, including a joint Veterinary Medicine and Anti-Infective Drug Products Advisory Committee to the FDA and a recent task force of the American Society for Microbiology, have urged the federal government to establish a monitoring system. The CDC Foundation, a separate and independent group from the Centers for Disease Control and Prevention, has designated monitoring for antimicrobial susceptibility as one of the top four national health priorities. Also, the WHO has identified antimicrobial susceptibility monitoring as a priority in the international arena.

CVM has recently established a program to monitor antimicrobial sus-
ANTIMICROBIAL SUSCEPTIBILITY MONITORING OF SALMONELLA ORGANISMS

cceptibility among Salmonella bacteria, selected as a sentinel organism. As a first step, CVM is collaborating with USDA’s Agricultural Research Service’s National Animal Disease Center and the Animal and Plant Health Inspection Service’s National Veterinary Services Laboratories to conduct susceptibility testing of Salmonella isolates to establish baseline antibiogram profiles. Baseline testing will be conducted for approximately 1,000 Salmonella isolates. Isolates will originate from cattle, swine, and poultry (chickens and turkeys). The isolates selected for the baseline testing will be obtained from the National Animal Health Monitoring System’s (NAHMS) Dairy Heifer Survey 1991-92 (n=150), the 1994 Cattle on Feed Survey (COFE) (n=280), FSIS isolates from slaughter plants from 1994-95 (n=400), an on-farm swine survey (n=100), and a group of randomly selected isolates from the National Veterinary Services Laboratories (NVSL) reference data base. The antibiograms to 17 antimicrobics will be determined. The antimicrobics have been configured on a custom made antimicrobial plate for use in the Sensititre System. The fluoroquinolones included on the plate are nalidixic acid and ciprofloxacin.

Future monitoring of the 1,500 isolates per year originating from animals will be conducted at NVSL and NADC. Approximately 500 isolates will be obtained from slaughter plants via FSIS - 100 cattle, 200 poultry, and 200 swine. The isolates will be identified by a confidential slaughter plant identification number, date of collection, animal source of specimen, and geographic location of plant. An additional 500 isolates each year will be obtained from NAHMS studies and from NVSL. NVSL will select a sample of approximately 100-125 Salmonella isolates from sick cattle, poultry, and swine each quarter. By the end of each year, approximately 100 cattle, 200 poultry, and 200 swine isolates should be selected.

The National Center for Infectious Diseases (NCID) of the Centers for Disease Control and Prevention (CDC) will test selected Salmonella and Escherichia coli 0157:H7 isolates collected from humans within surveillance sites. Approximately seven to ten state health departments will participate in the collection. After serotyping the Salmonella isolates and typing the Escherichia coli isolates, participating state public health laboratories will send all nontyphoidal Salmonella isolates and E. coli 0157:H7 isolates submitted to their laboratory to CDC.

The monitoring system will provide descriptive data on the extent and temporal trends of antimicrobial susceptibility in Salmonella from the human and animal populations. The goals of the monitoring program are to use the information in a timely way to guide practitioners in each arena, to prolong the lifespan of drugs that are approved, to facilitate the identification of resistance in either population as they arise, and to identify areas for more detailed investigation by the appropriate group. By providing ongoing and systematic collection, analysis, and interpretation of antimicrobial susceptibility data, agencies can ensure accurate and valid information that will be interpreted in an appropriate, consistent, and balanced fashion. The early identification of
new resistance patterns will allow agencies to focus educational efforts in the human and veterinary medical communities on the appropriate use of antimicrobial agents. Monitoring will also allow assessment of the impact of these efforts. Moreover, the identification and attempts to contain resistance will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs.

CVM has accepted the responsibility for coordinating an Interagency Working Group on Antimicrobial Susceptibility Monitoring to provide guidance and technical expertise on the broad array of activities that comprise the monitoring effort, to periodically review the results of the monitoring system, and to discuss the need for more detailed information from additional studies. The Working Group has allowed us to solicit comprehensive expertise to address these issues. The initial meeting of the Working Group took place in Bethesda, Maryland, on September 11 and 12. Summary minutes will be produced for this and all future meetings of the Working Group and will be made available to interested parties.
SELECTED RISK REDUCTION FACTORS FROM THE SALMONELLA ENTERITIDIS PILOT PROJECT FOR CONSIDERATION IN FOOD SAFETY PROGRAMS IN THE EGG INDUSTRY

David J. Henzler, William M. Sischo, Dave C. Kradel and Wayne Schlosser

Introduction
The *Salmonella enteritidis* Pilot Project was a cooperative program among the Pennsylvania poultry industry, the Pennsylvania Department of Agriculture, Penn State University, the University and the USDA. The project consisted of a series of field studies to identify risk factors and gather prevalence data for *Salmonella enteritidis* in commercial chicken layer flocks. These studies were conducted from April of 1992 through September of 1994. Some results suggest on-farm flock interventions for reducing *Salmonella enteritidis* contamination in flocks are presented. A Progress Report on the *S. enteritidis* Pilot Project, May 22, 1995, is available from USDA-FSIS-Animal Production Food Safety.

Relationship Between *S. enteritidis* Positive Environments and Eggs
In one study, environmental risk factors for the production of *S. enteritidis* contaminated eggs was investigated. Sixty flocks which had a minimum of one environmental sample of either the egg-handling equipment or manure which was culture positive for *S. enteritidis* were studied. Each farm had 4000 eggs collected over an 8 week period following culture of the environment. A total of 238,900 nest run eggs were cultured. Eggs were cultured in either pools of 10 or 20 eggs. Eighteen of the flocks produced at least 1 egg pool from which *S. enteritidis* was isolated. The estimated overall occurrence of *S. enteritidis* positive eggs was 2.64 per 10,000 eggs. Farms tended to have either a high (greater than or equal to 50%) or low number (less than 50%) of total manure or egg-handling equipment samples positive for *S. enteritidis*. Farms which had 50% and greater of the manure and egg belts *S. enteritidis* positive were more likely to produce contaminated eggs. These results suggest that sampling of the environment, especially the manure, may be used as a screening tool for identifying flocks of commercial hens likely to pose a greater risk to public health through the production of *S. enteritidis* contaminated eggs. A previous study noted the association of a high level of environmental contamination of *S. enteritidis* and the likelihood for producing contaminated eggs.¹

Rodents and *S. enteritidis* Risk
Rodents, specifically the house mouse (*Mus musculus*) have previously been established as possible amplifiers of *S. enteritidis* contamination on
SELECTED RISK REDUCTION FACTORS FROM THE SALMONELLA ENTERITIDIS PILOT PROJECT

Chicken farms. A method was developed in Pennsylvania termed Rodent Indexing (RI) to measure rodent densities in chicken houses. Rodent Indexing was determined on each farm by placement of 12 Tin Cat\textsuperscript{R} multiple-catch traps (Woodstream Corp., Lititz, PA) for a one week period. Traps were placed in areas where mouse activity was noted following a detailed visual evaluation form (Salmonella enteritidis Pilot Project: Rodent Evaluation and Inspection Form). Traps were baited with an ounce of chicken feed. Total numbers of mice captured in traps, checked twice during the week, were recorded. Traps were checked 2 to 5 days after placement and mice collected, and any trap not containing a mouse was moved to a new location a minimum of 15 feet away and again checked at the seven day mark. An equation was developed to adjust for numbers of mice caught if traps were left on the farm for periods lessor or greater than 7 days. The equation takes the total number of mice caught and multiplies by the number of days the traps were placed and divides by 7. The Rodent Indexes were grouped as follows: 10 or less mice = RI of 1 (low), 11-25 mice = RI of 2 (moderate), and 26 or more mice = RI of 3 (high).

Chicken farms in Pennsylvania had mice populations evaluated and placed in one of the 3 Rodent Indexes. Farms with a RI of 3 as compared to 1 were 4 times more likely to have S. enteritidis contaminated environments (culture from the manure and egg-handling equipment). This study suggests that high numbers of mice in chicken houses in a region where S. enteritidis has been found, are likely to be associated with isolation of this organism from the house environment. In Maine studies, the relationship between rodents and S. enteritidis positive environments was also demonstrated.

Rodent control procedures were evaluated on more than 100 poultry farms in Pennsylvania. The evaluations were conducted independently of the farms’ RI. Evaluators were instructed to disregard any knowledge of RI when assigning categories. Rodenticide-based programs were categorized as: closed bait stations, open bait stations, inconsistent, poor and nonexistent. Maintaining closed bait station rodenticide-based programs were significantly associated with maintaining low numbers of mice on poultry farms. Using 12 multiple-catch Tin Cat\textsuperscript{R} traps checked twice weekly, yielded an average 1.8 mice captured, where closed bait stations were used. Mean numbers of mice trapped on farms in these other categories were 15 times higher.

Other Risk Reduction Procedures

Other S. enteritidis risk reduction procedures that have been evaluated in Pilot Project and or by other researchers include the following: production of S. enteritidis clean chicks, placement of chicks and pullets into cleaned and disinfected poultry houses, proper egg washing techniques (proper temperature and pH), and refrigeration.

Vertical transmission has been demonstrated to be a potential risk factor, and purchasing chicks from NPIP U.S. Salmonella enteritidis Monitored or an
HENZLER, SISCHO, KRADEL, SCHLOSSER

Equivalent Program, and checking of meconium (chick papers) at time chicks are delivered is recommended. These chicks should then be raised in S. enteritidis clean pullet houses which have an effective rodent control.

Proper washing techniques and pH of wash water are essential in killing S. enteritidis and other Salmonellae. A pH of > 10.5 and higher is important to kill Salmonellae. The USDA requires wash water to be a minimum of 20 F warmer than eggs being processed and at least 90 F or higher. The importance of wash water temperature and pH is further discussed in several publications.  

Refrigeration of eggs must be continuous on farm, in egg processing, in storage, transportation and distribution, and at institutional, restaurant and retail markets. Further information discussing the benefits of egg refrigeration are available. Future applications of new cooling methods may lend themselves to reduced potential for growth of S. enteritidis and other microorganisms in shell eggs.

Third Party Monitoring

A credible and acceptable risk reduction program at the production level should include appropriate environmental monitoring. It should also include third party, random monitoring from an individual or agency that ideally is an independent or neutral party. In the Pennsylvania Egg Quality Assurance Program (PEQAP) which grew out of the S. enteritidis Pilot Project, and which today has 230 flocks enrolled, this third party monitoring has been by USDA personnel. In many cases third party monitoring might come from the State or Federal governments.

Food Handling Errors Responsible for Many Foodborne Outbreaks

Food Science experts agree that the majority of all foodborne outbreaks occur from improper food handling or preparation. It is essential that all segments of the food chain from on-farm production to consumption follow established risk reduction procedures if illnesses from foodborne S. enteritidis infections are to be significantly reduced.

Summary

1) A positive relationship exists between the level of environmental contamination and the risk of producing S. enteritidis positive eggs.
2) Effective rodent control which includes the use of closed bait station rodenticide-based programs and Rodent Indexing (RI) is associated with significantly reduced S. enteritidis environmental positivity.
3) S. enteritidis clean chicks and pullets, and appropriate environmental monitoring are important parts of an S. enteritidis risk reduction program.
4) Other risk reduction considerations include: proper egg washing and

504
SELECTED RISK REDUCTION FACTORS FROM THE SALMONELLA ENTERITIDIS PILOT PROJECT

egg refrigeration at all segments of the food chain.

5) Third party monitoring is necessary for a credible and acceptable risk reduction program.

6) Food handling errors are directly responsible for most foodborne illness.

References:
3. Henzler, D. J. Determining the number of mice on farms is difficult task. Poultry Times Vol. XL No. 6, March 1993.
REPORT OF THE COMMITTEE ON SALMONELLA

Chairman: Dr. Bradford P. Smith, Davis, CA
Vice Chairman: Dr. K. V. Nagaraja, St. Paul, MN

Dr. Colin Baxter-Jones, WV; Dr. Charles W. Beard, GA; Dr. Fred D. Bisplinghoff, FL; Dr. Hector Cervantes, AR; Dr. Jhung Won Colby, MD; Dr. Donald Corrier, TX; Dr. Morris S. Cover, MD; Mr. Kevin Custer, MN; Dr. Mark A Dekich, MD; Dr. Thomas G. Dickson, GA; Dr. Nicholas M. Dorka, Jr., CT; Dr. Robert J. Eckroade, PA; Dr. Paula J. Fedorka-Cray, IA; Ms. Kathleen Ferris, IA; Ms. Rose Foster, MO; Dr. Don A. Franco, VA; Dr. Leonard W. Fusell, AR; Dr. G. Yan Ghazikhanian, CA; Dr. Hashim M. Ghori, AR; Dr. Robert D. Glock, CO; Dr. Eric Gonder, NC; Dr. Dale M. Grotelueschen, NE; Dr. Thomas J. Hagerty, MN; Dr. A. H. Halvorson, MN; Dr. Mike Hellwig, AR; Dr. G. Tom Holder, MD; Dr. John House, CA; Dr. William James, DC; Dr. Daryl C. Johnson, GA; Dr. Glenn E. Kolb, WI; Dr. David C. Kradel, PA; Dr. Ted T. Kramer, IA; Dr. Mahesh C. Kumar, MN; Dr. Beth Lautner, IA; Dr. Joan Leonard, KS; Dr. Edward T. Mallinson, MD; Ms. Michelle Marcotte, CAN; Dr. John Mason, MD; Dr. Richard H. McCapes, CA; Dr. Patrick L. McDonough, NY; Dr. Kenneth McEnroe, AR; Dr. Edward L. Menning, DC; Dr. Rita D. Michaels, MO; Dr. Gordon P. Miller, Sr., NC; Dr. G. A. Mitchell, MD; Dr. Ahmed Matalib, MS; Dr. B. S. Pomeroy, MN; Dr. Morris E Potter, GA; Dr. Robert D. Ragland, VA; Dr. G. Donald Ritter, MD; Dr. Robert A Robinson, MN; Dr. Mahdi Saeed, IN; Dr. John P. Sanders, Jr., Fl; Dr. H. L. Shivaprased, CA; Dr. Richard D. Slemons, OH; Dr. Ken Takeshita, CT; Dr. Lee Ann Thomas, IA; Dr. Susan C. Trock, NY; Dr. Stanley A. Vezey, GA; Dr. Mahlon W. Vorhies, KS; Dr. Amy L Waldroup, AR; Dr. Douglas Waltman, GA; Dr. Gary L Waters, IL; Dr. Ronald D. Welsh, OK; Dr. David H. Willoughby, CA; Dr. Saul T. Wilson, Jr., AL; Dr. Stan Bailey, GA; Dr. Greg Bevier, MO; Dr. Hailu Kinde, CA; Dr. Nelson Cox, GA; Dr. Helen Wojcinski, CAN.

The Salmonella Committee met at 1:30 pm, Monday, October 30, 1995. X members and X guests were present. There were ten papers and two videos shown.

Dr. Lee Ann Thomas from NVSL presented Serotyping results for Salmonella isolates from animals and related sources for July 1, 1994 through June 30, 1995. There were 21,552 Salmonella isolates and the most frequently identified serotypes were Salmonella typhimurium, S. enteritidis, S. heidelberg, S. kentucky, and S. hadar. Salmonella typhimurium was the most frequently identified serotype for the first time since 1989. Salmonella derby and S. muenster were among the 10 most frequently identified serotypes for the first time. Forty percent of the total number of isolates were from chickens, 13 percent from cattle, and 10 percent from swine.

506
REPORT OF THE COMMITTEE

Dr. Diane Holder and coworkers presented a 24 hour filter monitor procedure for isolation of Salmonella from poultry products and environmental samples. The method is less time consuming and uses less media than the traditional MPN procedure.

The system uses self-contained, sterile, plastic, filtration recovery components to capture bacteria and allows each cell, or CFU, to grow into a single, identifiable and countable colony. After the filtration step, this system requires the addition of liquid agarless XLT4, which preferentially allows Salmonella to grow while inhibiting background bacteria.

Dr. Lamichhane and his colleagues, reported a rapid colony lift immunoassay for detection of Salmonella. In the test enriched cultures of suspect samples were plated on selective or non-selective agar and incubated overnight (18 to 24 hours) at 35-37 C. On the following day imprints of the pattern of bacterial colonies present on the master plates were made by lifting the colonies onto protein-binding membranes. The membranes were blocked and then soaked with horse radish peroxidase (HRP) labeled affinity purified Salmonella antibody. After incubation with chromogenic substrate for HRP, blue chromogenic spots were formed on the membrane at locations corresponding to Salmonella colonies on the master plate.

Drs. Richard Gast and Steven Berson of USDA-ARS in Georgia reported on virulence, intestinal colonization and organ invasion in chicks experimentally infected with Salmonella enteritidis phage Type 4 and other phage Types found in poultry and humans in the United States. Significant differences in virulence were evident within the set of phage type 4 isolates examined. Severe morbidity or mortality following SE infection occurred more often in chicks of an egg-type line than in meat-type chicks. When 5-day-old-type chicks were infected orally with SE isolates if various phage types, differences in the frequency of both cecal colonization and invasion to spleens were observed between isolates, but no consistent pattern emerged to differentiate phage type 4 from the other phage types. These data suggest that, although some phage type 4 isolates apparently possess heightened virulence and colonizing abilities, the differences between phage types do not appear to be of sufficient magnitude or consistency.

Dr. Saeed and his colleagues from Indiana reported that strains of Salmonella enteritidis phage type 8 that expressed different fimbrial classes; 14 kD, 21 Kd, and no fimbrial protein demonstrated mannose resistant local attachment, mannose resistant local attachment, and mannose resistant diffuse attachment to chicken ovarian granulosa cells respectively. Results of their study suggest that cecal colonization in laying hens by S. enteritidis may involve surface expression of fimbrial proteins. This protein may mediate local attachment to chicken granulosa cells and may be also involved in elicitation of humoral immune response against S. enteritidis.

Dr. Kinde and coworkers reported on result of an epidemiological investigation of SE phage type 4 in egg laying hens in Southern California. Their
SALMONELLA

study indicated the source of infection to be a nearby creek which passes beside the ranch. The creek was entirely supplied by a “treated” effluent from municipal sewage treatment plant.

Dr. Fedorka-cray and colleagues presented results of a survey on Salmonella in feedlot cattle. A national study of health and management of cattle in feedlots were conducted. Within this study, the prevalence of Salmonella species (spp.) in fecal samples was determined. The total number of samples collected was 4,977; 2,484 and 2,495 from the shortest and longest on feed, respectively. Salmonella spp. were recovered from 38% (38/100) of the feedlots. Salmonella spp. were recovered from 5.5% (273/4,977) of all samples and from 3.5% (88/2,484) and 7.4% (185/2,495) of samples from cattle shortest and longest on feed, respectively. The most common serotype recovered was S. anatum (27.9%), followed by S. montevideo (12.9%), S. muenster (11.8%), S. kentucky (8.2%) and S. newington (4.3%). The most common serogroups associated with human illness occurs infrequently (13/273; 4.8%). This study provides information on the status of Salmonella spp. from cattle in feedlots and may severe as baseline information for future studies.

Dr. B. Smith and coworkers at Davis, California reported on how Salmonella serology can aid in controlling endemic Salmonellosis in cattle. In this test LPS antigen was used in an ELISA. The procedure includes testing cattle first with a composite screening antigen composed of serogroups B, C1 C3 and E1. A positive or suspicious ELISA test indicates prior exposure to Salmonella. The serum is then tested against specific serogroup LPS to determine which serogroup the antibody is directed against. The authors reported that testing and elimination of carriers has proven successful on several dairies in controlling endemic Salmonellosis.

Report by A.R. Rhorer from NATIONAL POULTRY IMPROVEMENT PLAN Pullorum-typhoid Status:

In Calendar Year 1994, there were 40 isolations/outbreaks of Salmonella pullorum reported to the Poultry Improvement Staff. These isolations were reported from 7 states. All of 40 isolates were standard pullorum. During calendar year 1995 from January to October 16, there were 8 isolations of Salmonella pullorum. These isolations were reported by 3 states. Of the 8 isolates, 2 were intermediate, 1 was variant and 5 were standard pullorum. Of the 5 standard pullorum isolates, 1 was atypical (ornithine negative). This atypical isolate was identified as Salmonella gallinarum on the Analytical Profile Index (API). There have been no official isolations of Salmonella gallinarum since 1988 in any poultry and no isolations in commercial poultry since 1980. This atypical pullorum was isolated from a flock of non-release quail.

One hatchery and its supply flocks were responsible for 35 isolations of Salmonella pullorum in 1994. Investigations were completed on approximately 250 shipments from the suspect hatchery. All suspect flocks that were capable of being traced from the source hatchery were serologically tested. All reactors to the serological tests were submitted for further testing to Autho-
rized Laboratories or destroyed.

In 1994-95 there were 31 isolates of Salmonella pullorum in bantman chickens, 10 in standard chickens, 3 in game chickens, 1 in game bird, and 3 in mixed breeds.

Dr. House and his colleagues at Davis, California presented Age and antigen related differences in the bovine humoral immune response to Salmonella dublin infection and vaccination. A tendency for vaccination with salmonella killed bacterin to favor an IgG1 response and chronic infection to favor and IgG2 response was observed in both calves and adults. Similarly a stronger correlation between porin and LPS titers following chronic salmonella infection compared to vaccination and acute salmonella infection in calves is consistent with the humoral response of adult cattle to salmonella vaccination and infection. Assessing IgG2 production to both antigens provides a more specific prediction of carriers status than assessment of IgG2 titers to each antigen individually, however, in calves less than 12 months of serologic detection of chronic salmonella infection is limited by a transient anergy to salmonella antigens in some salmonella infected calves.

Acute infection and vaccination with salmonella bacterin produced a humoral immune response to salmonella LPS consistent with the O antigen specificity of the infecting or vaccination strain. In contrast the humoral immune response of carrier cows is not a serogroup specific suggesting that with chronic infection cattle produce a humoral immune response to conserved regions of the LPS that are common to multiple serogroups.

Dr. Don Franco from APPI showed a video. The video highlights specific recommendations that were observed that resulted in a marked decrease in the incidence of contamination and ultimately served as an educational tool for members of the association.

Respectfully submitted,

Bradford P. Smith
SALMONELLA SEROTYPES FROM ANIMALS AND RELATED SOURCES REPORTED DURING JULY 1994 - JUNE 1995

K. E. Ferris, B.S., M.S.
L. A. Thomas, D.V.M., M.S.

Summary
Serotyping results for 21,552 Salmonella isolates from animals and epidemiologically related sources are reported for July 1, 1994, through June 30, 1995. The most frequently identified serotypes were Salmonella typhimurium, S. enteritidis, S. heidelberg, S. kentucky, and S. hadar.

Introduction
Data was accumulated by the National Veterinary Services Laboratories and, with the exception of serotyping results, were provided by laboratories that requested serotyping services. The data were screened for errors, and their accuracy reflects the commitment of referring laboratories to generating a quality report. This report also contains information from several laboratories that serotype Salmonella. We are grateful to them for these results. The purpose of this report is to make available serotype distribution and frequency data. Isolates formerly identified as "Arizona" which are now reported on the basis of their corresponding Salmonella antigens, are reported separately in Tables 4, 5, and 6.

Discussion
Serotyping data is presented for a total of 21,552 isolates, which is a slight decrease from the 22,029 isolates reported last year. A total of 246 serotypes were identified from isolates submitted by laboratories in 47 states, the District of Columbia, and Puerto Rico. One hundred and seventy-two of the 246 serotypes identified were isolated fewer than 10 times. The 10 most common serotypes (Table 12) accounted for 58% of the total isolates serotyped. Salmonella typhimurium was the most commonly identified serotype (Table 12) for the first time since 1989. This was due to a 30% decrease in the number of S. enteritidis isolates rather than an increase in S. typhimurium. The number of isolates identified as S. typhimurium var copenhagen did increase significantly from 578 last year to 1129 this year (Table 3).

The percent of isolates from chickens continued to increase from 37% last year to 40% this year. The percentage of isolates from cattle increased slightly from 12% to 13%. Swine isolates decreased from 13% to 10%. Salmonella derby and S. muenster were among the 10 most frequently identified serotypes for the first time (Table 12). The number of isolates of S. derby increased 200% from 206 last year to 620 this year. Most of these
isolation (550) were from swine and 52% were from Iowa and Pennsylvania. *Salmonella muenster* isolates increased from 240 last year to 537 this year. Most of the isolates (69%) were from turkeys, and 57% were from North Carolina and West Virginia. Isolates of *S. brandenburg* continued to increase from 423 last year to 747 this year. Again, the majority (92%) of isolates were from turkeys, and 77% were from West Virginia. *Salmonella dublin* decreased from 415 isolates identified last year to 264 isolates received this year. *Salmonella dublin* isolates were received from 26 states, and 48 of the 264 isolates received were from sources other than cattle.

**References**

| SEROTYPE        | AL | AR | AT | CA | CT | DE | DC | FL | GA | IL | IN | IA | OR | OH | MA | MI | MS | NJ | NY | NC | NH | SC | TN | VA | WV | WY | ME |
|----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
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| 2 J. HERMANNIE  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  |
| 2.2 J. HERMANNIC | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  |
| 4 J. HERMANNIE  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  |
| 4.1 J. HERMANNIC | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  |

**TABLE 1: DISTRIBUTION OF SALMONELLA SEROTYPES BY STATE FROM 1954 THROUGH 1965 - EASTERN STATES**
TABLE 1 CONTINUED

| SEROTYPE  | AL | AR | CA | CO | CT | DC | DC | FL | GA | IL | IN | KY | IE | MA | ME | MD | MA | MI | NJ | NY | NC | OH | PA | SC | TN | VA | WV | WI | WY |
|-----------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| SALMONELLA SEROTYPES FROM ANIMALS |

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<td>FROM IT: 1 HABKIN, 1 TYPHIMURAIN, 1 VIRGINIA</td>
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<td>FROM PR: 1 ADOBAG</td>
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<td>(B) VAR. ALBICOLOR</td>
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**FERRIS, THOMAS**
SALMONELLA SEROTYPES FROM ANIMALS

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# Table 5: Distribution of Arizona Serotypes by State from 07/78 Through 05/79 - Western States

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|----------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| !5 L-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| !4 L-7-Z | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| !8 L-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| !6 Z-V-291 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 Z-V-294 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 Z-16-E,H,X,Z15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 33 N-C,H,X,Z15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 38 Y-V-Z28 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 58 H-Z | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 38 H-Z | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 40 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 41 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 41 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 42 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 43 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 44 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 45 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 46 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 47 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 48 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 49 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 50 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 51 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 52 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 53 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 54 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 55 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 56 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 57 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 58 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 59 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 60 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 61 Z-V-292 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 61 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 62 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 63 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 64 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 65 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 66 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 67 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 68 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 69 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 70 Z-V-293 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Totals**

|   | 3 | 23 | 54 | 1 | 3 | 45 | 6 | 7 | 4 | 3 | 3 | 1 | 2 | 15 | 6 | 520 |
### TABLE 5: DISTRIBUTION OF ARIZONA SEROTYPES BY SOURCE FROM 1974 THROUGH 1978

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>TURKEY</th>
<th>CHICKEN</th>
<th>4-WAY</th>
<th>CATTLE</th>
<th>SWINE</th>
<th>HORSE</th>
<th>SHEEP</th>
<th>REPTILE</th>
<th>ANIMALS</th>
<th>OTHER</th>
<th>UNSPEC.</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:1;2,7:1</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>1</td>
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<td>1</td>
<td>16</td>
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<td>4,5,12:1</td>
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<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>12</td>
</tr>
<tr>
<td>4,5,12:1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
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<td>4,5,12:1</td>
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<td>4</td>
<td>2</td>
<td>4</td>
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<td>3</td>
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<td>1</td>
<td>1</td>
<td>55</td>
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<td>1</td>
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<td>1</td>
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<td>1</td>
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<td>10</td>
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<td>1</td>
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<td>1</td>
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<td>1</td>
<td>1</td>
<td>10</td>
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<td>4,5,12:1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
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<tr>
<td>4,5,12:1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>4,5,12:1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>4,5,12:1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>4,5,12:1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>4,5,12:1</td>
<td>1</td>
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<td>1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
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</table>

**TOTALS:** 167 10 6 7 6 33 64 17 22 377
**Table 7.** Turkey—Most Frequently Identified Serotypes from 07/94 through 06/05

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>CLINICAL</th>
<th>SURVIVE/RESEARCH ENVIRONMENT</th>
<th>UNKNOWN</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRANDENBURG</td>
<td>20</td>
<td>902</td>
<td>51</td>
<td>2</td>
</tr>
<tr>
<td>WIENSTER</td>
<td>18</td>
<td>357</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>HEIDELBERG</td>
<td>72</td>
<td>156</td>
<td>49</td>
<td>3</td>
</tr>
<tr>
<td>MONTEVIDEO</td>
<td>51</td>
<td>200</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>SENFTENBERG</td>
<td>73</td>
<td>107</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td>SAINT-PAUL</td>
<td>5</td>
<td>180</td>
<td>22</td>
<td>9</td>
</tr>
<tr>
<td>BREDENFELD</td>
<td>136</td>
<td>58</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>19 24 23M(ARIZONA)</td>
<td>48</td>
<td>131</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>AGONA</td>
<td>40</td>
<td>42</td>
<td>22</td>
<td>3</td>
</tr>
<tr>
<td>HADAR</td>
<td>23</td>
<td>88</td>
<td>23</td>
<td>1</td>
</tr>
<tr>
<td>ALL OTHERS</td>
<td>203</td>
<td>534</td>
<td>188</td>
<td>190</td>
</tr>
<tr>
<td>TOTAL</td>
<td>701</td>
<td>2468</td>
<td>443</td>
<td>261</td>
</tr>
</tbody>
</table>

**Table 8.** Chicken—Most Frequently Identified Serotypes from 07/94 through 06/05

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>CLINICAL</th>
<th>SURVIVE/RESEARCH ENVIRONMENT</th>
<th>UNKNOWN</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTERITIS</td>
<td>38</td>
<td>1728</td>
<td>451</td>
<td>66</td>
</tr>
<tr>
<td>MONT S. ENTERITIS</td>
<td>0</td>
<td>1683</td>
<td>171</td>
<td>32</td>
</tr>
<tr>
<td>HEIDELBERG</td>
<td>51</td>
<td>709</td>
<td>643</td>
<td>3</td>
</tr>
<tr>
<td>MADAR</td>
<td>9</td>
<td>108</td>
<td>266</td>
<td>3</td>
</tr>
<tr>
<td>KENTUCKY</td>
<td>24</td>
<td>207</td>
<td>138</td>
<td>0</td>
</tr>
<tr>
<td>TYPHIMURUM</td>
<td>20</td>
<td>174</td>
<td>97</td>
<td>1</td>
</tr>
<tr>
<td>BRAENDERUP</td>
<td>2</td>
<td>121</td>
<td>50</td>
<td>3</td>
</tr>
<tr>
<td>ISTANBUL</td>
<td>1</td>
<td>10</td>
<td>170</td>
<td>0</td>
</tr>
<tr>
<td>SCHWARZENGRUND</td>
<td>2</td>
<td>70</td>
<td>67</td>
<td>3</td>
</tr>
<tr>
<td>MONTEVIDEO</td>
<td>1</td>
<td>57</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>ALL OTHERS</td>
<td>87</td>
<td>706</td>
<td>310</td>
<td>19</td>
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<tr>
<td>TOTAL</td>
<td>253</td>
<td>5661</td>
<td>2644</td>
<td>131</td>
</tr>
</tbody>
</table>

**Table 9.** Cattle—Most Frequently Identified Serotypes from 07/94 through 06/05

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>CLINICAL</th>
<th>SURVIVE/RESEARCH ENVIRONMENT</th>
<th>UNKNOWN</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYPHIMURUM</td>
<td>540</td>
<td>43</td>
<td>14</td>
<td>50</td>
</tr>
<tr>
<td>TYPHIMURUM (COPENHAGEN)</td>
<td>417</td>
<td>10</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>KENTUCKY</td>
<td>127</td>
<td>154</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>DUBLIN</td>
<td>190</td>
<td>7</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>ANATUM</td>
<td>48</td>
<td>117</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>WIENSTER</td>
<td>61</td>
<td>67</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>MONTEVIDEO</td>
<td>63</td>
<td>46</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>CERRO</td>
<td>48</td>
<td>44</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SAL 9.1:NONMOTILE</td>
<td>71</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>NEWPORT</td>
<td>37</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>ALL OTHERS</td>
<td>400</td>
<td>166</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2050</td>
<td>654</td>
<td>36</td>
<td>123</td>
</tr>
</tbody>
</table>
### Table 10: Swine—Most Frequently Identified Serotypes from 07/84 through 06/85

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>TIMES IDENTIFIED BY CASE TYPE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CLINICAL</td>
<td>SURV/RESEARCH</td>
</tr>
<tr>
<td>Derby</td>
<td>251</td>
<td>222</td>
</tr>
<tr>
<td>Cholerasus (Kunendoor)</td>
<td>369</td>
<td>2</td>
</tr>
<tr>
<td>Typhimurium (Copenhagen)</td>
<td>67</td>
<td>91</td>
</tr>
<tr>
<td>Agona</td>
<td>92</td>
<td>40</td>
</tr>
<tr>
<td>Typhimurium</td>
<td>64</td>
<td>44</td>
</tr>
<tr>
<td>Heidelberg</td>
<td>70</td>
<td>73</td>
</tr>
<tr>
<td>Cholerasus</td>
<td>44</td>
<td>15</td>
</tr>
<tr>
<td>Anatum</td>
<td>94</td>
<td>1</td>
</tr>
<tr>
<td>Wibangaka</td>
<td>5</td>
<td>31</td>
</tr>
<tr>
<td>Schwarzengrund</td>
<td>4</td>
<td>38</td>
</tr>
<tr>
<td>All Others</td>
<td>161</td>
<td>83</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>1234</td>
<td>640</td>
</tr>
</tbody>
</table>

### Table 11: Horse—Most Frequently Identified Serotypes from 07/84 through 06/85

<table>
<thead>
<tr>
<th>SEROTYPE</th>
<th>TIMES IDENTIFIED BY CASE TYPE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CLINICAL</td>
<td>SURV/RESEARCH</td>
</tr>
<tr>
<td>Typhimurium</td>
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<td>1</td>
</tr>
<tr>
<td>Newport</td>
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<td>0</td>
</tr>
<tr>
<td>Anatum</td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Typhimurium (Copenhagen)</td>
<td>21</td>
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</tr>
<tr>
<td>Krefeld</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Dublin</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Thompson</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Agona</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Oranienburg</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Braenderup</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>All Others</td>
<td>113</td>
<td>10</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>413</td>
<td>13</td>
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523
TABLE 12. SALMONELLA SEROTYPES IDENTIFIED MOST FREQUENTLY FROM JULY 1, 1994, THROUGH JUNE 30, 1995, WITH COMPARISON DATA FOR 5 YEARS (ALL SOURCES)

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<tbody>
<tr>
<td>TYPHIMURIUM***</td>
<td>2926 (1)**</td>
<td>2685 (2)</td>
<td>3696 (2)</td>
<td>3321 (2)</td>
<td>3137 (2)</td>
<td>2550 (2)</td>
</tr>
<tr>
<td>ENTERITIDIS</td>
<td>2626 (2)</td>
<td>3780 (1)</td>
<td>7148 (1)</td>
<td>3675 (1)</td>
<td>4824 (1)</td>
<td>1499 (1)</td>
</tr>
<tr>
<td>HEIDELBERG</td>
<td>2222 (3)</td>
<td>1748 (3)</td>
<td>2314 (3)</td>
<td>2181 (3)</td>
<td>2507 (3)</td>
<td>1038 (1)</td>
</tr>
<tr>
<td>KENTUCKY</td>
<td>800 (6)</td>
<td>1183 (6)</td>
<td>789 (8)</td>
<td>312 (8)</td>
<td>534 (11)</td>
<td>908 (5)</td>
</tr>
<tr>
<td>HADAR</td>
<td>755 (5)</td>
<td>963 (5)</td>
<td>1375 (4)</td>
<td>1308 (4)</td>
<td>1376 (4)</td>
<td>973 (6)</td>
</tr>
<tr>
<td>BRANDENBURG</td>
<td>747 (6)</td>
<td>423 (8)</td>
<td>184 (25)</td>
<td>107 (37)</td>
<td>82 (41)</td>
<td>163 (27)</td>
</tr>
<tr>
<td>DERBY</td>
<td>620 (7)</td>
<td>206 (18)</td>
<td>259 (19)</td>
<td>273 (22)</td>
<td>260 (21)</td>
<td>171 (25)</td>
</tr>
<tr>
<td>MONTEVIVO</td>
<td>609 (8)</td>
<td>423 (8)</td>
<td>305 (7)</td>
<td>939 (6)</td>
<td>954 (6)</td>
<td>730 (9)</td>
</tr>
<tr>
<td>HUNSTONER</td>
<td>587 (9)</td>
<td>240 (16)</td>
<td>306 (15)</td>
<td>202 (27)</td>
<td>185 (26)</td>
<td>110 (32)</td>
</tr>
<tr>
<td>AGONA</td>
<td>538 (10)</td>
<td>692 (6)</td>
<td>856 (6)</td>
<td>326 (7)</td>
<td>714 (9)</td>
<td>547 (10)</td>
</tr>
</tbody>
</table>

* NUMBER OF TIMES SEROTYPE WAS IDENTIFIED
** RANK BEGINNING WITH THE MOST COMMON
*** INCLUDES S. TYPHIMURIUM AND S. TYPHIMURIUM VAR. COPENHAGEN
EPIDEMIOLOGIC STUDY OF AN OCCURRENCE OF SALMONELLA ENTERIDITIS, PHAGE TYPE 4 IN A COMMERCIAL LAYER FLOCK IN SOUTHERN CALIFORNIA

D. Willoughby,' H. Kinde,' D. Kerr,2 H. Little,2 R. Tarbell,2 A.A. Bickford,' D.H. Read 1

On May 10, 1994, the California Veterinary Diagnostic Laboratory System in San Bernardino confirmed the isolation of Salmonella enteriditis from 27-week-old layers in a commercial egg production ranch in Riverside County. On May 19, 1994, this isolate was confirmed as S. enteriditis phage type 4 (SE PT4) by the National Veterinary Services Laboratory. This event was the first known occurrence of SE PT4 in commercial poultry in the United States.

The involved ranch holds 178,000 chickens producing commercial shell eggs as well as several categories of specialty eggs. The housing includes:

- 3 units of 45,000 birds in conventional 4-deck cage systems.
- 2 units of 12,000 birds in "cage free" housing on wooden slats over a deep pit. One unit produces fertile eggs. The other produces nonfertile eggs.
- One unit of 12,000 "cage free" birds on low plastic slats with a central litter area. Part of this unit produces fertile eggs.
- 2 units of 4,000 "free range" birds on dirt and litter flooring with access to a screened outdoor area.

The ranch is watered with well water run through a chlorination system of questionable reliability. Manure is spread over an area of approximately five acres for drying and/or composting. Feral cats, skunks, and other wildlife are abundant in the scrub vegetation surrounding the ranch. At the time of investigation, these animals had frequent and easy access to the perimeter egg production units. Approximately 50 feral cats were observed around the ranch. Trappers estimated the rodent population to be quite low. The northern border of the ranch is formed by a creek containing the effluent from a WWII vintage sewage treatment plant with a reputation for occasional overflow problems.

By May 25, 1994, personnel from the Animal Health Branch, California Department of Food and Agriculture had collected the following samples for culture:

- Approximately 60 birds from each housing unit (469 total).
- Two samples of 1000 eggs from each housing unit (16,000 total).
- 81 drag swabs from nests, egg belts, litter, manure belts, etc.
- 5 water samples from ranch sources.
- 7 feed samples from ranch bins.
- Wildlife including 7 feral cats, 2 skunks, 1 opossum, 12 mice, 1 sparrow, 1 pigeon.
S. enteriditis PT4 was isolated from eggs from two houses, chickens from four houses, four cats, two skunks, and one mouse. Similar collections made at the associated pullet ranch and two other company layer ranches were negative for S. enteriditis. Ranch personnel were cultured by county health services and were negative at the time of testing.

Following the initial investigations on the ranch, water from the border creek and sewage treatment plant was extensively cultured. SE PT4 was recovered from sewage flowing into the treatment plant, effluent at the plant outlet, and creek water upstream from the ranch.

Plasmid profiles were determined for Salmonella enteriditis isolates from eggs, chickens, wildlife, and sewage treatment plant sources. All isolates have shown an identical plasmid profile and restriction digestion pattern. California Department of Food and Agriculture epidemiologists suspect that SE PT4 was introduced to the ranch from a human source, either via contaminated water from the sewage treatment plant drainage or by ranch personnel. Further testing and analysis are in progress.

1 California Veterinary Diagnostic Laboratory System, University of California, Davis
2 California Department of Food and Agriculture, Animal Health Branch
The Committee on Sheep and Goats met in the Genoa Room, John Ascuaga’s Nugget Hotel, in Sparks, Nevada from 1:30 p.m. to 6:30 p.m. on Monday, October 30, 1995. There were 40 persons in attendance.

Dr. Cleon V. Kimberling, chair of the committee, welcomed members and guests and introduced the speakers:

- National Animal Health Monitoring System
  - N. Wineland
  - USDA/APHIS/CEAH

- Death Loss in Sheep and Lambs
  - K. Bretzlaff
  - TX A&M

- Health Status of the Boer Goat Industry
  - D. Harpster
  - USDA/APHIS

- Status Update of the Voluntary Scrapie Flock Certification Program
  - K. O'Rourke
  - USDA/ARS/ADRU

- Prion Genes and Scrapie Susceptibility in Suffolk Sheep
  - N. East
  - UC, Davis

- Vaccine Progress Report
  - G. Ross
  - US MARC

- Sheep Industry Development Flock Health Program and Educational Material
REPORT OF THE COMMITTEE

Comparative Evaluation of the Agar Gel Immunodiffusion Test and ELISA for the Diagnosis of Ovine Progressive Pneumonia

A. de la Concha-Bermejillo
TX A&M

BUSINESS MEETING:

Three Resolutions were introduced:

1. To recommend that USDA/APHIS work toward a plan to certify laboratories for conducting serological tests for OPP and CAE.
2. That the Western States reach an agreement allowing the interstate movement of rams from B. ovis certified flocks without the currently required negative 30 day test.
3. To encourage USDA to fund research on embryos as it pertains to scrapie transmission.


The National Agriculture Statistics Service (NASS), in cooperation with USDA:APHIS, conducted a sheep and lamb death loss survey in January 1995. Randomly selected producers were asked about death loss as a part of the quarterly agricultural survey. Most of the reported losses occurred in lambs and the majority of reported losses for both sheep and lambs were attributed to predators. Lambing problems were the most common cause of health related death losses. Regional comparisons of death losses as a percent of regional inventory were presented. USDA:APHIS plans to prepare this information in FACT SHEET format for distribution in early 1996. USDA:APHIS and the American Sheep Industry Association are in final planning stages for a sheep health and productivity survey which will be mailed to randomly selected producers in early 1996. Results from this survey will be available in the summer of 1996.

HEALTH STATUS OF THE BOER GOAT INDUSTRY: Dr. Katherine Bretzlaff, Dept. of Large Animal Medicine & Surgery, Texas A&M University

The Boer goat is a superior meat goat breed developed in South Africa. A limited number of embryos were smuggled into a 5-year quarantine in New Zealand and were released in April 1993. By March 1994, Boer goats in the United States were selling for $20-40,000 or more. Prices stayed high for approximately six months, but by September 1995 had trended downward to averages generally less than $5,000, and in many cases less than $2,000.

The American Boer Goat Association (ABGA) opened its office in Whitewright, TX on January 1, 1994. On January 1, 1995, there were 3896 animals registered by the ABGA, including approximately 850 fullbloods. By October 24, 1995, there were 17,139 registered animals, including 7627 fullbloods. Numbers of ABGA members with registered animals had risen during the same time period from 75 to 1410.
Controversy had erupted during 1994 about whether the USDA should relax its importation protocol for genetics from South Africa. The New Zealand genetics had been rather narrow resulting in some inbreeding. Additional Boer goat genetics that had entered quarantine in Australia were not due to be available until September 1, 1995. Several producers felt that genetics remaining in South Africa offered the best hope to revitalize the Boer goat industry in the U.S. In November 1994, South African Boer goat embryos were entering Canada under a new protocol established by Agriculture Canada. Embryos collected under strict guidelines could be put in tested recipients that were retested in 90 days and, if negative, released from quarantine. Canadian goats would be free to come into the U.S. with a health certificate only. (See Buckrell, B. et al; Embryo Transfer with South African Boer Goat Embryos: The Canadian Experience. Proc. Society for Theriogenology Annual Meeting, 1995, San Antonio, pp. 292-5.) This was generally recognized to be a plan by U.S. producers to circumvent the USDA’s 5-year protocol. To address this concern USDA published an interim import regulation on March 15, 1995 for embryos and goats coming in from Canada. Recipient does and recently born kids may be imported into the U.S. from Canada as long as the importer has a USDA-issued import permit for those particular animals and the animals are placed in a flock enrolled in USDA’s Voluntary Scrapie Flock Certification Program. All sheep and goats from Canada are subject to these rules except slaughter animals and wethers.

Health problems in Boer goats include obesity, parasites, and urinary calculi. Floppy kid syndrome, a metabolic acidosis without dehydration, was common in neonates in Texas in the spring of 1995. Scours, respiratory problems, caseous lymphadenitis, caprine-arthritis-encephalitis, Johne’s, abortions due to Chlamydia and other causes, and congenital problems are all conditions that impact the Boer goat industry.

UPDATE OF THE VOLUNTARY SCRAPIE FLOCK CERTIFICATION PROGRAM: Daniel E. Harpster, Senior Staff Veterinarian, Veterinary Services, Animal and Plant Health Inspection Services.

The Voluntary Scrapie Flock Certification Program (VSFCP) has recently received attention in the following areas:

1-International Trade;
2-Electronic Identification Pilot Project; and
3-Enrollment Status.

The disease of scrapie has recently gained prominence in the international trade arena. Scrapie import regulations for sheep and goats have been proposed and the US scrapie status has often been reviewed by other countries when considering the purchase of US sheep.

A proposed regulation to import sheep and goats, semen and embryos, from other countries was published in May with the comment period ending July 10, 1995. Under this proposal, sheep and goats would be allowed
to be imported to the US using the VSFCP in lieu of a five-year quarantine. The final rule is currently being developed following consideration of the written comments.

Scrapie is regarded by some countries, such as Australia and New Zealand, as a foreign animal disease since it is not found there. The importation of US sheep into Australia and New Zealand is an expensive and long procedure, lasting at least five years and importing offspring of the US-origin animals. While some countries such as China, South Africa and Argentina desire to import US sheep, such action has been banned due to the presence of scrapie in the United States.

US regulations prohibit exportation from a scrapie infected flock or flock in which an infected animal was born. Offspring, parents and siblings of a scrapie-positive animal are also excluded from export.

Plans are being made for an electronic identification (El) pilot project with enrolled flocks in the VSFCP. The project's goal is to demonstrate El's costs and benefits in VSFCP enrolled flocks. El implants will be made available to all enrolled flocks either at reduced or no cost to the producer. Readers will also be supplied to producers at no cost. Bids from El companies are currently being sought.

A survey citing estimated or actual costs involved with official identification in the VSFCP and some associated management practices will be conducted before enrolled flocks use the El. A second survey of the same items as the first will be conducted after El has been in use for some time. Details on the timing, distribution and eligibility will be announced.

Producer interest in the VSFCP has recently grown. There are approximately 160 flocks enrolled in the program and the first flocks to reach "A" status will be this fall. Potentially, we are two years from the first Scrapie Certified flocks. Some possible reasons for this increase in interest are:

1-Use in international trade;
2-The VSFCP is not as difficult as initially perceived; and
3-More enrollment attracts more interest.

Information regarding the Voluntary Scrapie Flock Certification Program is available through each State Veterinarian, Federal Area Veterinarian in Charge, or the National Animal Health Programs Staff at (301) 734-6954.

There are currently 68 infected flocks and 6 source flocks in the United States. From October 1, 1994 to September 30, 1995, there were 44 confirmed scrapie cases at the National Veterinary Services Laboratories from 103 submissions. Seven of the 44 confirmed cases were from previously infected premises.

**PRION GENETICS AND SUSCEPTIBILITY TO SCRAPIE IN SUFFOLK SHEEP IN THE UNITED STATES:** Katherine O'Rourke, Ph. D., USDA,ARS,ADRU, Pullman, WA.

Control of scrapie by sire selection was proposed more than 30 years
SHEEP AND GOATS

ago, based on the observation that sheep in some bloodlines remain free of natural and experimental disease for extended periods of time. The prolonged incubation period in these sheep was linked to the gene for the prion protein, the major component of infectious material. There are at least 2 sites in the sheep prion gene associated with incubation time. The site encoding amino acid 136 varies in the Cheviot breed and several other breeds common in Europe. This site does not show variability in U.S. Suffolks tested to date. The site encoding amino acid 171 varies considerably in U.S. Suffolks. The gene is found in 6 forms. An individual sheep can carry the genes for amino acids QQ, RR, QR, QH, RH or HH. Approximately 50 sheep with natural scrapie have been analyzed for position 171 forms: all 50 carry the genotype QQ. A small sample of unaffected Suffolks by Westaway et al in 1994 demonstrated that 51% of sheep were QQ, 43% were QR, and 6% were RR. In collaboration with Dr. James Mickelson at the University of Minnesota, a sample of 500 Suffolk sheep was genotyped. Fifty-four percent carry the QQ genotype, 39% are QR, 4% are RR, 2% are QH, and 1% is RH. This study supports the observation that the QQ genotype is associated with natural scrapie but fails to determine whether QR or RR animals are resistant to the disease.

In an allied study, genotype analysis was performed on 112 experimentally inoculated animals with known clinical outcomes. These animals were used in studies by Drs. Warren Foote and Wilbur Clark, and DNA was provided by Drs. Reed Holyoak and S. Wang at Utah State University. Clinical scrapie was observed in 79% of the QQ sheep and only 7% of the QR sheep. There were only 5 RR sheep in the study and none developed scrapie during the course of the study. Data on incubation times and losses due to factors other than scrapie must be analyzed before these results can be interpreted fully.

These studies have been performed with a single scrapie strain in Suffolk sheep. Different isolates of the scrapie agent may result in different clinical outcomes in QR and RR Suffolk sheep and in sheep of other breeds. Although these preliminary results are encouraging, genetic control of scrapie by sire selection cannot replace selection of sheep from scrapie-free flocks as the producers' most effective control measure.

Two additional studies are in progress. The susceptibility of sheep with the H allele will be determined. Most importantly, QR and RR sheep which resist clinical infection or develop disease only after prolonged incubation times will be studied to determine whether they are silent carriers of the disease and represent a risk to susceptible flockmates.

PROGRESS ON VACCINES: Nancy East, DVM, Dept. of Medicine and Epidemiology, School of Veterinary Medicine, University of California, Davis.

Work done at the Moredun Research Institute (UK) by Herring et al identi-
REPORT OF THE COMMITTEE

tified the major outer membrane protein (MOMP) of *Chlamydia psittaci* to be of importance in immunity against ovine abortion. MOMP is a large surface antigen which apparently must retain native configuration for biological activity. Attempts at Moredun and UC Davis have not yielded usable recombinant MOMP. However, work is continuing and Moredun workers feel that they are close to vaccine production which we are prepared to participate in for U.S. licensing. Moredun workers (Jones et al) have developed a tissue culture origin vaccine with ISCOM matrix (adjuvant) which is enriched semipurified chlamydial protein. Initial challenge trials are promising and we have approached Mallinckrodt about pursuing licensing of this product. It is hoped that this vaccine would have a greater efficacy and fewer undesirable reactions (fever, lameness, stiffness, anorexia, depression, abortion (following booster dose), etc.) than current vaccines. Work on MOMP and vaccine trials is supported by the California Wool Growers Association, California Dairy Goat Milk Marketing Association, and USDA/LDRL.

Development of a vaccine using field isolates of *Campylobacter fetus* var. *fetus* and *Campylobacter fetus* var. *jejuni*. The isolates came from 2 commercial herds that had experienced abortion outbreaks following vaccination with commercially available products. The vaccine has been developed with Hygiera Biological Labs and is inactivated culture in aluminum hydroxide adjuvant. Safety studies have been completed and the vaccine has a provisional California license. We are using the vaccine in flocks with laboratory confirmed vibrio abortion documented or in the face of a new outbreak with good results. Forty-five thousand doses have been used in California. A challenge trial will be completed in 1995-96 to complete licensing requirements. Work on this vaccine has been supported in full by the California Wool Growers Association.

Vaccination protocol:

- yearlings - prebreeding and booster (60-90 days)
- adults - booster every year

(Most important is to have the booster near the beginning of the last trimester to maximize immunity near lambing.)

Footrot Control Using Vaccination:

1. **Footvax** - specifically to help control contagious footrot of sheep due to *Bacteroides nodosus* infection. Used in conjunction with trimming, footbath, and segregation. Should aid in eradication of the organism from the flock.
   - used as a preventative
   - used as part of treatment.

2. **Volar** useful in treatment and prevention of hoof scald due to *Fusiform necrophorum* infection. Environmental contaminant (feces) usually occurs in sheep that are in muddy conditions. Antibiotics may speed recovery. May occur in flocks that are “footrot free” due to environmental conditions. Make management changes to get sheep
SHEEP AND GOATS

out of mud if possible.

Control of *C. pseudotuberculosis* using vaccination:
1. Caseous D-T<sup>R</sup> and Case-Bac<sup>R</sup> are currently available bacterin/toxoid.
2. Cell wall component vaccine: USDA promising clinical trials in sheep and goats over 2 year period.
   - decreases prevalence
   - decrease severity od disease.
3. Glanvac<sup>R</sup> Toxoid currently working towards U.S. license with UC, Davis. A 40-month study showed:
   - decreased infection rate by 74% in vaccinated sheep compared to unvaccinated sheep
   - decreased infection rate by 97% in vaccinated sheep exposed only to vaccinated sheep
   - infection rate in unvaccinated sheep was 76%.

Vaccination programs are a long term plan concentrating on replacement stock. It may not be advisable to vaccinate adults due to a possible increase in the number of adverse reactions. In addition, vaccination probably does not alter the course of the disease. Adverse reactions have been reported, especially in infected adult goats, and include abortion, death, stiffness/lameness, anorexia, fever, depression, vaccination site swelling and granuloma.

AMERICAN SHEEP INDUSTRY DEVELOPMENT OF FLOCK HEALTH CERTIFICATION PROGRAM AND EDUCATIONAL MATERIAL: Mr. Paul Rodgers, ASI, Englewood, CO; Dr. Cindy Wolf, University of Minnesota Veterinary Hospital, St. Paul, MN; and Dr. Gary Ross, U.S. MARC, Clay Center, NE.

The American Sheep Industry Association (ASI) is producing the following producer education material concerning sheep health during 1995-96:
- A revised Sheep Production Handbook
- Sheep Care Guide
- Flock Health Guidelines
- Quality Assurance Training Manual
- National Sheep Database on CD ROM
- Fact Sheets on Dentition; Club Lamb Fungus; Caseous Lymphadenitis

In addition, ASI in cooperation with USDA/APHIS/CEAH is conducting a National Sheep Health Producer Needs Assessment Survey. ASI, in cooperation with AASRP, has also developed a computerized Veterinarian and Sheep Producer Proximity Map to assist practitioners and producers in developing working relationships.

Dr. Gary Ross, a member of the ASI Animal Health and Welfare Committee, has developed a Veterinarian - Sheep Producer database. This database can provide state and county maps which show the location of sheep producers relative to veterinarians who have an interest in serving sheep producers. The potential uses of this database-mapping project include an improved pair-
ing of sheep producers and veterinarians interested in this industry to enable
improved care of flocks through educational meetings and exchange of infor-
mation which can be used as a regular part of flock management and veteri-
nary practice.

COMPARATIVE EVALUATION OF THE AGAR GEL IMMUNODIFFUSION
TEST AND RECOMBINANT ELISA TESTS FOR THE DIAGNOSIS OF OVINE
PROGRESSIVE PNEUMONIA: Dr. Andres de la Concha-Bermejillo, Texas
Agricultural Experiment Station and Dept. of Veterinary Pathobiology,
San Angelo, TX

Dr. de la Concha-Bermejillo presented work by R.A. Juste, J. Kwang, and
A. de la Concha-Bermejillo.

The accurate identification of ovine progressive pneumonia virus (OPPV)-
infected animals is a critical issue for the sheep industry. Serological tests,
including agar gel immunodiffusion (AGID) and ELISA tests, are the most
frequently used methods to identify OPPV-infected animals. Although the
sensitivity of the AGID test has been questioned, in many cases the sensitiv-
ity and specificity of serological tests has been determined by using serum
samples collected from the general population in which the precise state of
infection of the animals cannot be confirmed by other means. In order to
compare the sensitivity and specificity of the AGID test with that of recombi-
nant ELISA, serum samples from OPPV or placebo experimentally inocu-
lated lambs were collected before inoculation and weekly for 26 weeks there-
after. Serum samples were tested for the presence of OPP antibodies by the
AGID, a recombinant p24-OPPV protein ELISA (rp24-ELISA) or a recombi-
nant trans membrane-OPPV protein ELISA (rTM-ELISA). Paired serum
samples were also submitted to a private diagnostic laboratory that uses a
caprine arthritis encephalitis virus (CAEV) envelope recombinant protein ELISA
(rCAEV-ELISA) for the identification of OPPV-infected sheep.

OPPV was reisolated from all virus inoculated lambs but never from the
placebo controls, thus confirming the infectious- or free-OPPV status of the
experimental animals. The specificity of the AGID test was always 100%,
and the sensitivity ranged from 11% on post-inoculation week 2 to 100% from
post-inoculation week 5 until the end of the experiment (average 91.5). The
specificity of the recombinant ELISA test varied depending on the recombi-
nant OPPV protein used. While the sensitivity and specificity of the rp24-
ELISA varied from 22.2 to 100 (average 87.7) and 50 to 100 (average 94.6),
respectively, the sensitivity and specificity of rTM-ELISA test ranged from 5.5
to 100 (average 86) and from 62.5 to 100 (average 94.9). Surprisingly, the
CAEV-ELISA missed all OPPV-infected cases.

Our results indicate that the OPPV AGID has a high sensitivity and speci-
licity for the diagnosis of OPP in this experimental setting. Recombinant
ELISA tests based on OvLV recombinant proteins had good sensitivity and
specificity but the ELISA test based on CAEV recombinant antigens per-
SHEEP AND GOATS

formed poorly. Therefore, each test must be carefully standardized before they can be recommended for diagnostic purposes.

To determine the effect of OPPV inoculum size on the time of seroconversion by the AGID test, pairs of lambs were inoculated with 10-fold dilutions of OPPV from $10^5$ to $101 \text{ TCID}_{50}$. The 2 lambs inoculated with $10^1 \text{ TCID}_{50}$ of OPPV seroconverted by 8 weeks after inoculation. Lambs inoculated with $10^{2.5} \text{ TCID}_{50}$ seroconverted between 4 and 6 weeks post-inoculation. Therefore, the amount of virus inoculum seems to have only a minor effect on the time of seroconversion. However, the sensitivity and specificity of serological tests using different strains of OPPV needs to be further investigated.
COMPARATIVE EVALUATION OF THE AGAR GEL IMMUNODIFFUSION TEST AND RECOMBINANT ELISA TESTS FOR THE DIAGNOSIS OF OVINE PROGRESSIVE PNEUMONIA

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Abstract

The accurate identification of ovine progressive pneumonia virus (OPPV)-infected animals is a critical issue for the sheep industry. Serological tests, including the agar gel immunodiffusion (AGID) and ELISA tests, are the most frequently used methods to identify OPPV-infected animals. Although the sensitivity of the AGID test has been questioned, in many cases the sensitivity and specificity of serological tests have been determined by using serum samples collected from the general population in which the precise state of infection of the animals cannot be confirmed by other means. In order to compare the sensitivity and specificity of the AGID test with that of recombinant ELISA, serum samples from OPPV or placebo experimentally inoculated lambs were collected before inoculation and weekly for 26 weeks thereafter. Serum samples were tested for the presence of OPPV antibodies by the AGID test, a recombinant p24-OPPV protein ELISA (rp24-ELISA) or a recombinant transmembrane-OPPV protein ELISA (rTM-ELISA). Paired serum samples were also submitted to a private diagnostic laboratory that uses a caprine arthritis encephalitis virus (CAEV) envelope recombinant protein ELISA (rCAEV-ELISA) for the identification of OPPV-infected sheep. To confirm the OPPV-infected or -free status of the experimental animals, virus isolation was attempted every other week from blood mononuclear cells.

OPPV was reisolated from all virus inoculated lambs but never from the placebo controls, thus confirming the infectious- or free-OPPV status of the experimental animals. The specificity of the AGID test was always 100%, and the sensitivity ranged from 11% on post-inoculation week 2 to 100% from post-inoculation week 5 until the end of the experiment (average 91.5). The specificity of the recombinant ELISA test varied depending on the recombinant OPPV protein used. While the sensitivity and specificity of the rp24-ELISA varied from 22.2 to 100 (average 87.7) and 50 to 100 (average 94.6), respectively, the sensitivity and specificity of rTM-ELISA test ranged from 5.5 to 100 (average 86) and from 62.5 to 100 (average 94.9). Surprisingly, the CAEV-ELISA missed all OPPV-infected cases.

Our results indicate that the OPPV AGID has high sensitivity and speci-
COMPARATIVE EVALUATION OF THE AGAR GEL IMMUNODIFFUSION TEST AND RECOMBINANT ELISA TESTS

Specificity for the diagnosis of OPP in this experimental setting. Recombinant ELISA tests based on OPPV recombinant proteins had good sensitivity and specificity. The lower sensitivity of the rTM-ELISA compared to the AGID test was partially due to the lower percent of infected cases detected by the rTM-ELISA in the early stages of infection; however, the sensitivity of this test after week 8 post-inoculation was always 100%. The ELISA test based on CAEV recombinant antigens performed very poorly. Therefore, each test must be carefully standardized before they can be recommended for diagnostic purposes.

To determine the effect of OPPV inoculum size on the time of seroconversion by the AGID test, pairs of lambs were inoculated with 10-fold dilutions of OPPV from $10^5$ to $10^7$ TCID$_{50}$. The 2 lambs inoculated with $10^7$ TCID$_{50}$ of OPPV seroconverted by 8 weeks after inoculation. Lambs inoculated with $10^2$ to $10^5$ TCID$_{50}$ seroconverted between 4 and 6 weeks post-inoculation. Therefore, the amount of virus inoculum seem to have only a minor effect on the time of seroconversion. However, the sensitivity and specificity of serological tests using different strains of OPPV needs to be further investigated.

Introduction

Ovine lentivirus (OvLV) comprises a subgenus of the lentivirus genus of exogenous, non-oncogenic retroviruses. Maedi-visna, the prototype species of OvLV, was first isolated by Sigurdsson et al., in Iceland in 1960. The North American strains of OvLV are usually referred as ovine progressive pneumonia virus (OPPV).\(^1\) Ovine lentiviruses are widespread throughout most of the sheep producing areas of the world. In the United States, the reported seroprevalence is 26% but a wide variation exists between states and between farms.\(^2\)

Lentiviral infection of sheep may lead to a disease complex characterized by cachexia and chronic active inflammation of the lungs, lymph nodes, joints, mammary gland and the central nervous system.\(^3\)\(^-\)\(^5\) In the United States, pulmonary disease is the most important cause of morbidity and mortality in lentivirus infected sheep.\(^6\) The financial loss attributed to OPP may be due to animal deaths, depressed lamb growth due to agalactia of ewes with mastitis, losses from secondary infections and loss of trade due to restrictions in the international export market. Ovine lentiviruses have been eradicated from Iceland and several countries of the European community have eradication campaigns underway. Sheep infected with OPPV remain infected for life; therefore, early detection of infected animals is critical for the control of this infection.\(^1\)

Agar gel immunodiffusion (AGID) test is the most commonly used serological technique to identify infected animals because of its low cost, simplicity and high specificity. However, generally the sensitivity of the AGID test is considered low. More recently, indirect ELISA tests using either whole virus
or recombinant OPPV proteins have come to the scene claiming a high degree of sensitivity. In many cases the sensitivity and specificity of serological tests are based on the used of serum samples collected from the general population in which the precise state of infection cannot be confirmed by other means. In this paper, we compare the sensitivity and specificity of an AGID test with those of two recombinant ELISA tests using serum samples collected chronologically after experimental OPPV or placebo inoculation. In addition, paired serum samples were submitted to a private veterinary diagnostic laboratory that runs an ELISA test for the identification of OPPV infected animals using a caprine arthritis encephalitis virus recombinant protein (rCAEV-ELISA).

Materials and Methods

Animals and animal inoculation. Twenty-six Rambouillet or Rambouillet x Suffolk newborn lambs from seronegative ewes were allowed to ingest colostrum and then separated from their mothers and raised on an artificial diet. Newborn lambs were randomly allocated into two groups. The first group consisting of 18 lambs was inoculated intratracheally with 1 x 10⁶ TCID₅₀ of OPPV strain 85/34 (8 of these 18 lambs received daily treatment with recombinant ovine interferon- [rIFN ] for 30 days as part of another experiment). The second group consisted of 8 lambs inoculated with a non-infected cell culture supernatant. Serum samples collected before inoculation and weekly for 26 weeks after inoculation were assigned a code and tested blindly for the presence of OPPV antibodies by the AGID test, by two different recombinant ELISA tests, or were submitted to a private diagnostic laboratory. Blood samples collected every other week starting before experimental inoculation until the end of the experiment were tested for the presence of infectious virus by standard virus isolation in tissue culture.

Ten additional one month-old Rambouillet lambs were inoculated in the same way as above with OPPV dilutions (2 lambs/dilution) ranging from 1 x 10⁵ to 1 x 10⁶ TCID₅₀, and serum samples collected weekly were tested by the AGID test.

Agar Gel Immunodiffusion Test. Serum samples were tested for the presence of OPPV antibodies by the AGID test using a commercially available kit and following recommendations by the manufacturer (Veterinary Diagnostic Technology, InC. 4890 Wheat Ridge, CO 80033).

ELISA. An ELISA test was used to determine the antibody responses to the transmembrane (TM) and p24 OPPV-structural proteins, as previously described. Briefly, microtiter plates were coated with 120 g/well recombinant TM or p24 proteins in 0.1 sodium bicarbonate buffer (pH 9.6) and kept refrigerated until further use. The plates were then washed 3 times in ELISA washing solution (0.15 M NaCl, 0.05% Tween 20), and excess binding sites were saturated with 100 l of 1% bovine serum albumin (BSA) in phosphate-buffered saline (pH 7.2, 0.15 M) for 1 hr at 37 C. After 3 washes, 100 l diluted
sheep serum (1:50) in 1% BSA buffer was added to each well, and plates were incubated at 37°C for 1 hr. Following a subsequent washing of the wells, 100 μl of anti-sheep immunoglobulins conjugated with horse radish peroxidase was added to each well, and plates were incubated at 37°C for 1 hr. Wells were washed again, and 100 μl of substrate solution (citric acid, 2,2'-azinobis, 3-ethyl benzthiazoline sulfonic acid, H₂O₂) was added. The color reaction was allowed to proceed at room temperature for 30 min, and the absorbance of each well at 405 nm was recorded in an automatic ELISA plate reader.

**Virus Isolation.** Blood samples were collected in EDTA-containing vacuum tubes and blood mononuclear cells (BMNC) were separated by centrifugation on a Ficoll-Hypaque gradient as previously described. Subsequently, a total of 4 x 10⁶ separated BMNC were cocultivated with semi-confluent monolayers of goat synovial membrane (GSM) cells in 25 cc tissue culture flasks for 12 days. At the end of this period, cell cultures were rinsed in Hank's balanced salt solution (HBSS), fixed in methanol, stained with Giemsa and evaluated for the presence of syncytia. A positive score was given when at least one cell containing at least five nuclei was found.

**Data Analysis.** Due to their quantitative character, the results obtained from the rTM-ELISA and the rp24-ELISA were corrected for between-plate variability by dividing the OD reading of the test samples by the OD reading of the positive control in their respective plate. Initially, cut-off points that had been determined previously were used as the positive-negative threshold for the rp24- and rTM-ELISAs. However, after realizing that under this criteria too many infected animals were scored as negative during the initial weeks after infection, new cut-off values that results in a better trade-off between sensitivity and specificity were established. (Figures 1 and 2).

**Results**

Ovine lentivirus was re-isolated at least in two occasions from all OPPV-inoculated lambs. Virus isolation in individual lambs ranged from 2 to 12 times during the course of the experiment and the frequency of isolation in the OPPV-inoculated experimental group was higher between post-inoculation weeks 2 and 8. Ovine lentivirus was never isolated from any of the placebo-inoculated controls.

The results of the sensitivities and specificities of the AGID, the rp24-ELISA and the rTM-ELISA are presented in table 1. Positive reactions to the core protein in the AGID test were first seen in two OPPV-inoculated lambs by 2 weeks post inoculation. On week 3 after inoculation, 8 OPPV-inoculated lambs showed a weak positive reaction against the envelope (env) protein, while in 8 OPPV-inoculated lambs the predominant reaction was against the core protein. By 4 weeks post-inoculation, only one OPPV-inoculated animal was still negative, 10 lambs showed clear anti-p24 bands and the remaining 7 reacted with different levels of intensity to the env protein. All
JUSTE, KWANG, de la CONCHA-BERMEJILLO

Lambs infected with $1 \times 10^6$ TCID$_{50}$ were positive by the AGID test by 5 weeks post-inoculation and remained positive for the rest of the experiment. None of the placebo-inoculated controls showed any positive reactions by the AGID test during the experiment. Based on these results the specificity of the AGID test was always 100%, on the other hand the sensitivity ranged from 11% on post-inoculation week 2 to 100% from post-inoculation 5 week until the end of the experiment (average 91.5%).

The initial cutoff points between positive and negative rp24- and rTM-ELISA OD readings were taken from the experience of a previous report; however, because under this criteria many infected animals were scored as negative during the initial phases of infection, new cutoff values, to obtain the optimal trade-off between sensitivity and specificity, were established for each ELISA format by plotting the percent accuracy in the detection of infected and non-infected animals in each of the OD values (Figure 1 and 2). Based on this system a cutoff value of 0.4 for the rp24-ELISA and of 0.08 for the rTM-ELISA were selected, respectively.

The specificity of the rp24-ELISA ranged from 50 to 100 (average 94.6%) and the sensitivity from 22.2 to 100 (87.7%). The average specificity of the rTM-ELISA was 94.9 (range 62.5 to 100) and the average sensitivity was 86% (range 5.5 to 100). In this experiment, preinoculation serum samples had a particularly high OD reading in both ELISA formats, regardless of the experimental group, resulting in specificities of 50.0 for the rp24-ELISA and of 62.5 for the rTM-ELISA during the experimental week 0.

The time of seroconversion in lambs inoculated with $10^5$ or $10^4$ TCID$_{50}$ of OPPV occurred by week 4 post-inoculation. One of each lamb inoculated with $10^3$ and $10^2$ TCID$_{50}$ seroconverted at weeks 5 and 4, respectively, and the other 2 lambs in these groups seroconverted by week 6 post-inoculation. The two lambs inoculated with $10^1$ TCID$_{50}$ seroconverted by 8 weeks post-inoculation.

Discussion

For the most part the specificity of the AGID test for the detection of lentivirus infected sheep has been found to be 100%; however, its sensitivity has been reported to be lower than that of ELISA tests. Using experimentally lentivirus-inoculated sheep, Simard and Briscoe, found that by 2 weeks post-infection, 70% of the experimental animals could be detected by an indirect whole virus ELISA while none could be detected by AGID. The average sensitivities of these tests from week 3 to 14 were 96% for the ELISA test and 70% for the AGID test. Similarly, increased sensitivities of an indirect whole virus ELISA and a recombinant ELISA tests over the AGID test have been found by Houwers et al., and by Kwang et al., respectively. However, false positives reactions, that affect the sensitivity of some recombinant ELISA tests, have been reported and ascribed to reactions to E. coli antigens that contaminate the recombinant viral proteins during purification.
COMPARATIVE EVALUATION OF THE AGAR GEL IMMUNODIFFUSION TEST AND RECOMBINANT ELISA TESTS

In our study, we compared the sensitivity and specificity of a commercially available AGID test with 2 recombinant ELISA tests using sheep serum samples collected sequentially after OPPV or placebo inoculation. OPPV was reisolated from all virus-inoculated sheep but never from the placebo inoculated animals, thus confirming the infectious- or free-OPPV status of the animals in each of the 2 experimental groups. The average sensitivity (91.5) and specificity (100) of the AGID test was slightly superior to the rELISAs. The average sensitivities and specificities of the rp24ELISA (87.4 and 94.6, respectively) and the rTM-ELISA (86 and 94.9, respectively) were not significantly different between each other. In our experiment, we used the OPPV strain 85/34 for animal inoculation. This strain of OPPV is a biological clone and therefore is constituted by a genetically diverse pool of OPPVs or quasispecies. Both antigens used for the rELISAs were originally cloned from an OPPV infectious molecular clone. Although the OPPV p24 and TM proteins carry conserved epitopes, it is possible that some immunogenic differences in the critical epitopes between strain 85/34 and the recombinant OPPV proteins existed, thus resulting in lower cross reactivity between these 2 OPPV strains and decreased sensitivity of the rELISA tests. This observation is supported by the fact that the relative sensitivity and specificity of the rTM-ELISA using serum samples of OPPV naturally infected sheep (where a wide range of strains may exist) were 97.6 and 100% respectively. Furthermore, this theory also could explain the reasons why the rCAEV-ELISA failed to detect all infected animals, since differences in epitope immunological cross reactivity between small ruminant lentiviruses exists. In a recent publication, the sensitivity of the CAEV AGID was higher (91.0) than that of the OPPV AGID test (56.0) for the detection of caprine antibody to CAEV. Similarly, some CAEV recombinant antigens might fail to detect ovine antibody to OPPV. Variability in the sheep immune response to different regions of OPPV env protein has been found. The private veterinary diagnostic laboratory that runs the rCAEV-ELISA indicated that the antigen used for their test was a recombinant CAEV envelope protein but did not specified the characteristics. It is known that many of the epitopes in the env protein of lentiviruses are poorly conserved. Therefore, if the immunological epitopes present in the recombinant env protein of the CAEV-ELISA are different from those in the OPPV strain 85/34, the test would fail to detect infected animals. Further evidence that different proteins from small ruminant lentiviruses have different immunological cross reactivity comes from the fact that the OPPV rTM-ELISA test was more effective than the OPPV rp24-ELISA and the OPPV AGID test in identifying CAEV antibodies in the goat population.

Our results indicate that the OPPV AGID has a high sensitivity and specificity for the diagnosis of OPP. Other advantages of the AGID test include its low cost and simplicity. Recombinant ELISAs varied greatly in their effectiveness to detect infected animals. Recombinant ELISA tests based on OPPV recombinant proteins had good sensitivity and specificity. The slight lower
sensitivity of the rTM-ELISA compared to the AGID test was partially due to the lower percent of infected cases detected by the rTM-ELISA in the early stages of infection; however, the sensitivity of this test after week 8 post-inoculation was always 100%. This delayed detection by the rTM-ELISA may be explained by the fact that ELISA tests detect only the IgG antiviral response, while the AGID test detects both IgM and IgG antibodies. It is well known that the initial antibody response is by IgM, subsequently switching to IgG.

Because ELISA tests may be easier to perform when a large number of animals are screened, this test may be the one of choice for eradication campaigns; however, when individual infected animals need to be identified, the AGID test could be chosen. In addition, the sensitivity and specificity of ELISA tests can be manipulated by moving up or down the cutoff value depending on particular needs in each diagnostic situation. Because ELISA tests can quantify the amount of antibody, these tests are ideal in research situations in which the kinetics of the host immune response to particular lentivirus proteins needs to be studied. It is not clear why the OD readings in all serum samples collected at week 0 (before inoculation) were higher than the readings at week 1, but this suggests that serum samples from newborn lambs have a higher affinity for non-specific binding and therefore result in false positive reactions. The ELISA test based on CAEV recombinant antigens performed very poorly, indicating that each test must be carefully standardize before they can be recommended for diagnostic purposes.

In one study, in which 10% of the animals in a group of 20 sheep were found seropositive by ELISA, 70% were found positive by in situ hybridization, PCR and cocultivation, suggesting that latent OPPV infections may occur.17 In our study, all experimental lambs infected with 1 x 10^6 TCID_{50} became seropositive by the AGID test by 5 weeks post-inoculation, indicating that delayed seroconversion or latency did not occur. Furthermore, the amount of virus inoculum seemed to have only a minor effect on the time of seroconversion. Lambs inoculated with 10^6, 10^5 or 10^4 TCID_{50} of OPPV seroconverted between 2 and 5 weeks post inoculation. One of each lamb inoculated with 10^3 and 10^2 seroconverted at weeks 5 and 4, respectively, and the other 2 lambs in these groups seroconverted by week 6 post-inoculation. The two lambs inoculated with 10^1 seroconverted by 8 weeks post-inoculation. Nevertheless, the role of genotypically and phenotypically diverse OPPV strains in latency and time of seroconversion needs to be further investigated.

References


COMPARATIVE EVALUATION OF THE AGAR GEL IMMUNODIFFUSSION TEST AND RECOMBINANT ELISA TESTS

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545
THE DEVELOPMENT OF A RECOMBINANT AVIAN INFLUENZA-FOWL POX VACCINE

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An outbreak of highly pathogenic avian influenza (H5N2) was reported in Mexico during January 1995. A genetically engineered fowl pox virus containing the hemagglutinin gene from a subtype H5 virus was previously reported to be efficacious against a virulent AI virus from the Pennsylvania outbreak in 1983. Several experiments were conducted to see whether the recombinant FP-AI virus would provide protection against the Mexican AI virus. The recombinant virus has been shown to be safe in chickens, turkeys, quail, pigeons and ducks. Transmission of the vaccine virus from vaccinated birds to unvaccinated hatchmates has not been demonstrated. Chickens inoculated by subcutaneous injection in the neck or by wing web stab were protected from morbidity and mortality after challenge with a highly pathogenic influenza virus isolated from Mexican chickens. The vaccine also immunized the chickens against fowl pox.

Introduction
Avian influenza virus is a member of the Orthomyxoviridae family and the type A virus causes an infectious disease of economic importance to poultry. Outbreaks of influenza in Pennsylvania during 1983 and now in Mexico have increased the interest in developing more effective vaccination strategies.
THE DEVELOPMENT OF A RECOMBINANT AVIAN INFLUENZA-FOWL POX VACCINE

to control or prevent this disease.

The use of fowl pox vectored vaccines has been previously reported in the literature. However, all of the studies were conducted under laboratory conditions. A true field trial in thousands of birds has not been done with a recombinant AI-fowl pox vaccine.

Experiments have been conducted to evaluate the safety and efficacy of a recombinant fowl pox virus that contains a gene that codes for the hemagglutinin surface protein of the H5 subtype of avian influenza. An application has been made to the United States Department of Agriculture to license this vaccine in the United States and to export the virus to Mexican Animal Health authorities for experiments in animal biocontainment facilities.

Materials and Methods

Viruses: The recombinant avian influenza-fowl pox vectored vaccine was constructed by Virogenetics Corporation by inserting the cloned hemagglutinin gene from a pathogenic AI virus, A/Turkey/Ireland/1378/83 (H5N2), into a non-essential region of a commercially available fowl pox vaccine. The highly pathogenic avian influenza virus identified as A/Chicken/Quaretaro/14588-19/95 (H5N2) was supplied by Dr. David Swayne, USDA-ARS, Southeastern Regional Poultry Laboratory (SERPL), Athens, Georgia. The virulent fowl pox challenge virus was obtained from the National Veterinary Services Laboratory, Ames, Iowa.

Monoclonal antibodies: A pool of monoclonal antibodies specific for H5 influenza was received from Robert G. Webster, St. Jude Children’s Research Hospital, Memphis, Tennessee.

Animals: Specific pathogen-free embryonated eggs were purchased from either SPAFAS, Inc., Storrs, Connecticut, or Sunrise Farms, Catskill, New York. SPF leghorns from SERPL were also used. Additional SPF leghorn chickens were supplied by the Southeastern Regional Poultry Laboratory (SERPL), Athens, Georgia.

Bird experiments: One-day-old chicks were inoculated with either a 10X or 100X dose of vaccine to evaluate the safety of the recombinant virus. The birds were observed for 21 days and necropsied at the conclusion of the experiment. Safety was also evaluated in non-target avian species including turkey pouls, pigeons, quail and ducks by inoculation with 10 times the recommended field dose. Unvaccinated contact controls were included to determine if the vaccine virus would spread. Laboratory mice were inoculated to determine whether the host range and safety of the recombinant virus was altered by the insertion of the foreign gene material.

The ability of the experimental vaccine virus to be transmitted horizontally from vaccinated to unvaccinated chickens was evaluated. Tissue samples from the injection sites and swabs from the cloacae and tracheas were obtained on days 5, 11, 14, 21 and 28 post-inoculation. Unvaccinated contact control chicks were included to determine if virus could be isolated from them.
after exposure to vaccinated birds.

Non-reversion to virulence studies are required of all live virus vaccines by Title 9 Code of Federal Regulations. Master Seed virus was inoculated into one-day-old SPF chicks. A separate group of chicks were vaccinated with the parent pox virus for comparison. Fowl pox scabs were removed from the wings of the vaccinated chickens seven days post-inoculation. The material was homogenized and inoculated into a new group of one-day-old SPF chicks. The backpassage was done five times. At the completion of the fifth backpassage the pox virus was reisolated and characterized on the same molecular level as the original X Master Seed virus.

A vaccination and challenge experiment was conducted with the experimental vaccine called TROVAC-AIV H5. The vaccine was diluted to contain either $10^{1.5}$, $10^{2.0}$ or $10^{3.0}$ TCID$_{50}$ per dose. Groups of one-day-old chickens were inoculated by either subcutaneous injection or wing web stab. Hatchmates were also inoculated with the parent fowl pox virus or sterile diluent. Three weeks later, all of the chickens in every group were bled and challenged with a highly pathogenic avian influenza virus, A/Chicken/Queretaro/14585-19/95 (H5N2). Oropharyngeal and cloacal swabs were obtained on 0, 3, 7, 10 and 14 days post-challenge. The birds were observed for signs of morbidity or mortality for two weeks post-challenge. Serum antibody titers were monitored with the agar gel precipitin test and the hemagglutinin inhibition test.

In a separate study the efficacy of the vaccine against virulent fowl pox was examined. One-day-old chicks were inoculated with similar concentrations of vaccine by subcutaneous injection or wing web stab. Two weeks later, each chicken was challenged with a virulent fowl pox virus from the National Veterinary Services Laboratories, USDA, Ames, Iowa. Chickens were examined for fowl pox lesions two weeks after challenge.

**Results**

**Safety studies:** All of the vaccinated chickens remained healthy after the 21 day observation period. Even the injection with 100 times the recommended dosage failed to cause any adverse reactions.

The recombinant was capable of limited replication in turkeys and quail, but it did not establish a systemic infection in pigeons or ducks. Laboratory mice were not infected by the fowl pox vectored vaccine. The host range of avipox viruses is restricted to birds, and the insertion of the HA5 gene did not alter this biological property.

Horizontal transmission was not detected in any experiment that included unvaccinated contact controls. Pox virus was routinely isolated from either the inoculation site in the nape of the neck or the wing web, but only for a few days following injection. No adverse reactions or signs of either AI or fowl pox were observed.

**Backpassage:** The backpassage study confirmed the stable expression of the H5 protein through five tissue culture passages. There was no alterna-
The development of a recombinant avian influenza-fowl pox vaccine

tion in the appearance or size of the pox "takes" when compared to the parent fowl pox virus.

Vaccination-Challenge

The experimental TROVAC-AIV H5 vaccine was highly effective in preventing morbidity or mortality in the chickens vaccinated subcutaneously or by wing web stab. None of the unvaccinated chickens remained healthy after challenge with the virulent Mexican AI virus. Only a small number did not die within one week post-challenge. None of the vaccinated chicks developed antibodies that could be measured in the agar gel precipitin test. The hemagglutinin inhibition titers were also low. The number of chickens that had measurable HI titers increased as the concentration of virus increased.

Ninety-five (95) percent of all chickens that were vaccinated were protected from developing fowl pox lesions after challenge. The immunity was just as effective using either route of inoculation. All of the unvaccinated chickens were infected with fowl pox.

Summary

The efficacy and safety of the recombinant avian influenza-fowl pox virus TROVAC-AIV H5 has been confirmed. As little as 10^{1.5} TCID_{50} per dose protected vaccinated chicks from morbidity and mortality from infection with avian influenza and fowl pox. No transmission or shedding of the vaccine virus was detected based on the ability to reisolate fowl pox virus.

References

REPORT OF THE COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES

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Vice Chairman: Dr. Robert J. Eckroade, Kennett Square, PA

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The committee met on October 31 and November 1, 1995, with a total of 82 members and guests attending.

I. USDA/FDA updates

Dr. Bonnie Buntain, Director of the Animal Production Food Safety (APFS) Program for FSIS provided an update on animal production food safety activities. She emphasized that the APFS Program will be an integral part of the farm to table FSIS strategy to improve food safety. To accomplish this, APFS will help to establish research priorities, assist in developing model intervention projects, and assist in developing voluntary commodity food safety/quality assurance programs. FSIS regulatory authority will be limited to processing plant sites and will not extend to on-farm production, where industry will be expected to take the lead in developing production animal programs. She also announced that FSIS will no longer be allowed to participate in the Salmonella enteritidis task force.
Dr. Lonnie King, Administrator of APHIS, provided his view of future problems and opportunities in APHIS and his view of the interaction of APHIS with poultry producers. He emphasized the changes in regulatory activities associated with the globalization of agriculture and discussed implications in arriving at import/export agreements with other countries.

Dr. King complimented the National Poultry Improvement Plan as a program which exemplifies the best example of government-industry cooperation. He also emphasized the importance of APHIS officials becoming intimately familiar with the poultry industry and proposed the initiation of APHIS poultry industry liaison officers who are intimately familiar with poultry industry dynamics and economics.

An update on the activities of the APHIS Veterinary Biologics Program was provided by Dr. David A. Espeseth, Deputy Director, Veterinary Biologics. One hundred eighty two product licenses were issued in FY95 to give a total of 2,309 active product licenses, and five new production establishments were licensed to give a total of 120 licensees and permittees. Several reinvention initiatives have been initiated within the program to improve the uniformity, consistency, and efficiency of licensing, inspection, and testing activities. The future direction of these process improvement efforts will be influenced by the results of a program-wide review that will be initiated in mid November '95. Licensed manufacturers are being asked to assist in improving licensing efficiency by providing more complete submissions including risk assessments for new live vaccines and more complete biometric analysis. APHIS actions taken to permit the production of vaccines for highly pathogenic avian influenza, the development of a PCR test procedure for reticuloendotheliosis virus that may be applied to avian Master Seed virus and final products, new guidelines for production of live chicken anemia vaccine, procedures for demonstrating bursal origin bursal disease vaccines are free of chicken anemia agent, and an amended standard requirement for Marek's disease vaccine were discussed.

Dr. Bob Khars of the Import/Export staff of APHIS, discussed the complexities of negotiating disease-related export/import requirements with various countries. He outlined the various factors and motivations involved in establishing requirements and described the negotiation procedures involved in arriving at such agreements. He indicated the willingness of the import/export staff to work with USAHA and poultry industry representatives in improving the language of poultry export certificates.

A report of the activities of the FDA Center for Veterinary Medicine (CVM) was provided by Dr. Michael J. Blackwell, Acting Deputy Director.

The Food and Drug Administration (FDA) has recently approved two fluoroquinolone antibacterial drug products for use in chickens and turkeys. In August FDA approved Saraflox WSP, sponsored by Abbott Laboratories, to be administered in drinking water for use in broiler chickens and growing turkeys for the control of mortality associated with Escherichia coli organ-
isms susceptible to sarafloxacin. Sarafloxacin is the first fluoroquinolone approved for use in food-producing animals. Another fluoroquinolone drug, enrofloxacin, was approved in 1989 to treat certain infections in non-food animals. In October, we have just announced the approval of Saraflox Injection, which is indicated for the control of early chick mortality associated with bacterial infection by the *E. coli* organism.

On May 11-12, 1994, CVM's Veterinary Medicine Advisory Committee and the Center for Drug Evaluation and Research's (CDER) Division of Anti-Infective Drug Advisory Committee heard presentations from human and animal health researchers and food-animal producers relative to concerns raised about the development of bacterial resistance to fluoroquinolones. Members of both committees concluded that FDA could approve fluoroquinolones found to safe and effective for animal use.

The concerns which have been raised about the use of this new class of antimicrobials come about from the national and global increase in antibiotic resistance and the complex issues surrounding this increase, both in community and institutional settings. Human infections caused by resistant pathogens result in increased morbidity and mortality from treatment failures and increased health care costs as newer, more expensive antibiotics are needed to treat common infections. The causes of this antibiotic resistance are multifactorial and complex. The issue of drug resistance among veterinary pathogens is a small part of this larger health issue and its role needs further delineation. We also recognize that the concern of increasing antimicrobial resistance needs to be reviewed with the knowledge that, as in the case of diseases in humans, the number of therapeutic options for treatment of infectious diseases in animals is diminishing. FDA/CVM is concerned about maintaining antibiotic effectiveness, ensuring safety, and increasing the availability of new products to veterinary practitioners and the food animal industry.

The joint CVM/CDER advisory committees, in concluding that fluoroquinolones found to be safe and effective could be approved for animal use, also recommended that FDA establish appropriate conditions of approval to minimize any potential for development of resistant bacteria. Although there are some national and global surveillance systems in place to study various aspects of antimicrobial resistance in humans, there currently is no comprehensive national or global surveillance system for monitoring antimicrobial resistance of enteric pathogens in human or animal populations. The lack of systematic information on zoonotic enteric pathogen resistance makes public health decision making difficult and the ability to be proactive in assisting practitioners in the appropriate use of antimicrobials impossible. Several groups have urged the federal government to establish a monitoring system. The CDC Foundation, a separate and independent group from the Centers for Disease Control and Prevention, has designated monitoring for antimicrobial resistance as one of the top four national health priorities. Also, the World Health Organization has identified antimicrobial susceptibility monitoring as a
REPORT OF THE COMMITTEE

priority in the international arena.

In recognition of this real need, FDA is cooperating with USDA and CDC in a monitoring program to detect and prevent disease resistant microbes. As a first step, CVM is collaborating with USDA’s Agricultural Research Service’s National Animal Disease Center and the Animal Plant Health Inspection Service’s National Veterinary Services Laboratories to conduct susceptibility testing of Salmonella isolates to establish baseline antibiogram profiles. Baseline antimicrobial resistance testing will be conducted for approximately 1,000 Salmonella isolates. Isolates will originate from cattle, swine, and poultry (chickens and turkeys). The isolates selected for the baseline testing will be obtained from the National Animal Health Monitoring Systems (NAHMS) Dairy Heifer Survey 1991-92 (n=150), the 1994 Cattle on Feed Survey (COFE) (n=280), FSIS isolates from slaughter plants from 1994-95 (n=400), an on-farm swine survey (n=100), and a group of randomly selected isolates from the NVSL reference data base. The antimicrobial resistance patterns to 17 antimicrobics will be determined. The antimicrobics have been configured on a custom made antimicrobial plate for use in the Sensititre System. The fluoroquinolones included on the plate are nalidixic acid and ciprofloxin.

Future monitoring of the 1,500 isolates per year originating from animals will be conducted at NVSL and NADC. Approximately 500 isolates will be obtained from slaughter plants via FSIS (100 cattle, 200 poultry, and 200 swine). The isolates will be identified by a confidential slaughter plant identification number, date of collection, animal source of specimen, and geographic location of plant. An additional 500 isolates each year will be obtained from NAHMS studies and from NVSL. NVSL will select a sample of approximately 100-125 salmonella isolates from sick cattle, poultry, and swine each quarter. By the end of each year, approximately 100 cattle, 200 poultry, and 200 swine isolates should be selected.

The CDC’s National Center for Infectious Diseases (NCID) will test selected Salmonella and Escherichia coli 0157:H7 isolates collected from humans within surveillance sites. Approximately 7-10 state health departments will participate in the collection. After serotyping the Salmonella isolates and typing the E. coli isolates, participating state public health laboratories will send all nontyphoidal salmonella isolates and E. coli 0157:H7 isolates submitted to their laboratory to CDC.

We expect this monitoring system will provide descriptive data on the extent and temporal trends of antimicrobial susceptibility in Salmonella from the human and animal populations. The goals of the monitoring program are to use the information in a timely way to guide practitioners in each arena, to prolong the life span of drugs that are approved, to facilitate the identification of resistance in either population as they arise, and to identify areas for more detailed investigation by the appropriate group. The availability of ongoing and systematically collected, analyzed, and interpreted antimicrobial susceptibility data will be useful to agencies in ensuring that they have accurate and
valid information that has been interpreted in an appropriate, consistent, and balanced fashion. The early identification of emerging resistance will allow agencies to focus educational efforts in the human and veterinary medical communities on the appropriate use of antimicrobial agents. Monitoring will also allow assessment of the impact of these efforts. Moreover, the identification and containment of resistance will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs.

CVM has accepted the responsibility for coordinating an Interagency Working Group on Antimicrobial Susceptibility Monitoring to provide guidance and technical expertise on the broad array of activities that comprise the monitoring effort, to periodically review the results of the monitoring system, and to discuss the need for more detailed information from additional studies. The Working Group has allowed us to solicit comprehensive expertise to address these issues. We have had the initial meeting of the Working Group. We met in Bethesda, Maryland on September 11-12, 1995. We will produce summary minutes from this initial meeting and all future meetings. These minutes will be made available to all interested parties.

We believe that these steps will go a long way toward preserving the usefulness of these valuable new drugs and other fluoroquinolones by minimizing the potential for development of resistant pathogens, while increasing the therapeutic options available to poultry veterinarians to use in managing disease problems in the U.S. chicken and turkey industry.

II. Diseases of importance and related issues

Dr. C.W. Beard, V.P. for Research and Technology, Southeastern Poultry and Egg Association, presented the following report:

Since the beginning of the Southeastern research grants program in 1968 when $16,000 was distributed, the total has risen to $8,945,630 with $1.1 to 1.2 million now being allocated for research each year. The research proposals are evaluated by a diverse group of professionals who are principally employed by industry. These sixteen individuals who represent many scientific disciplines score and rank the proposals at two sessions each year in March and August.

Poultry disease proposals have fared well with 34 of the 80 currently active projects relating to diseases of poultry. The deadline for proposals which have been prepared according to the guidelines to be received at Southeastern in December 31 and June 30 for each of the competitions. Problem-oriented research proposals have historically received the highest scores from the panel.

A proposal may be submitted on any subject but a list of priorities generated from industry surveys may be used to determine what they view as problem areas in need of research. Submission materials are available from Southeastern, (770)493-9401.
REPORT OF THE COMMITTEE

A report on current broiler industry health and health related issues was presented by Dr. Tom Holder, Allen's Hatchery, Seaford, DE. Members of the Association Veterinarians in Broiler Production were polled for this report.

1. **Marek's Disease** was the major concern of this group. The virus seems to be changing, getting more virulent and possibly some breed interaction. Ongoing research in this area is needed.

2. **Avian Influenza** was a close second to Marek's disease. With the concentration of poultry in most areas, biosecurity is virtually impossible. **Prevention is a must.** Why can't the genetically engineered vaccines be field tested in Mexico?

3. **Infectious Bronchitis.** This is the fourth year that the subject of an IB typing lab has been discussed. A resolution was passed in 1992 recommending the establishment of a typing lab. Budgets are being cut but couldn't monies be shifted to take care of this ongoing problem.

4. **Infectious Laryngotracheitis.** This disease has reappeared and seems to be more virulent than the last time an outbreak happened.

5. **Science based inspection/HACCP/Food Safety.** This is an all encompassing situation that needs very little explanation to this group.

Dr. Gary Waters, DeKalb Agresecrch, DeKalb, IL presented the following report on concerns of the egg production industry.

The egg production industry has evolved into an automated environment that places large flocks in multiple age non-depopulated facilities. Regulatory concern involving EPA, OSHA, USDA/APHIS, FDA, and Animal Welfare receive a much greater amount of management attention than disease control and biosecurity.

Diseases are generally viewed as those that cause catastrophic results or those that variably erode efficiency and profitability.

There is a feeling of being repetitious in presenting this report since many of the disease concerns are longstanding issues, the concern for which only varies by the intensity of the moment.

The concern for Avian Influenza outbreaks is viewed as a serious potential threat that would have catastrophic industry results. Without any prospect of government indemnity for producers, their only prospect for economic survival is authorization of vaccine use. We have a newly authorized killed bacterin that can be used to control an initial outbreak area.

As in previous reports, Marek's disease remains a serious threat due to the pathogen evolving faster than effective vaccines can be developed for these new virulent pathotypes. We are using the last weapon in our current arsenal - the original Rispsins vaccine. Unfortunately there appears to be as much research emphasis on delivery systems as there is on pathotype control.

*Salmonella enteritidis* concerns are centered upon biosecurity to prevent flock exposure and contingent legal liability. The pathological effect on chickens of the phage types normally present in the United States doesn't create
concern. Various developments in cross-immunity that can be conferred from mass administration of non-human effect *Salmonella* spp. and effective probiotic competitive exclusion products are encouraging. The cumulative effect of all the control efforts utilized to date has greatly improved the incidence of S.e. problems, but we have probably reached a plateau below which we will not go without a scientific breakthrough.

The egg production industry has accepted the insidious losses of production and efficacy associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae* infection when it committed to the “complex” environments described in my opening comment. There remains the “conflict of interests” between this industry and the turkey and broiler industry. Recently some participants in the broiler industry appear to have accepted the inevitability of MS in their production systems. New “non-turkey affecting” vaccines are being offered for MG.

Layer hepatitis syndrome and variant Fowl Pox and variant Infectious Bronchitis are diseases of less widespread incidence but bear watching.

“Research is Crisis Driven” per Charlie Beard, and the egg industry concentrates upon the last major disaster - this summer’s heat loss of 5,000,000 layers will probably stimulate desire for weather control.

The report of the USAHA Turkey Industry Subcommittee was prepared by Dr. G. Yan Ghazikhanian.

Once again several members of the United States Turkey Breeders & Integrators were contacted to inquire their concerns and experiences regarding turkey health matters from mid 1994 to mid 1995. We are grateful to them for their cooperation.

We are pleased to report that there was neither an epidemic of infectious disease nor a statewide industry disruptive disease which occurred for this period. However, the major concern of the turkey industry in the Eastern region, namely in North Carolina, remains to be the early (7-28 days) poult enteritis, feed refusal and mortality leading to stunting and condemnation, the so-called Spiking Mortality Syndrome (SMS). Extreme poor flock performance and high mortality have brought about flock depopulations prior to market age. Etiology remains to be a mystery yet. The industry needs help in this respect.

An unusual sudden increase in heat and humidity in the summer of 1995, caused significant turkey mortality (1,000,000) due to heat prostration.

The commercial meat industry would like to see that reliable and controlled studies are conducted to evaluate the efficacy of live MG vaccines in commercial turkey flocks to assist the growers in managing outbreak flocks, not necessarily to use such products as a means to live with MG infections.

The industry would like to see NVSL assist local laboratories in pathotyping filed Newcastle viruses in the regions with high incidences and prevalence.

The turkey industry is very pleased to see that a new antibiotic (Saraflox®) was finally approved for use in turkeys to control colibacillosis, a major cause
REPORT OF THE COMMITTEE

of turkey mortality. We are also pleased to see that the use of Monensin® and Bacitracin combination in turkeys was approved. Preliminary results indicate that both of these actions will have a positive effect on the nation’s turkey health.

In general, the overall prevalence of various health disorders and diseases were minor. As before in this presentation, some of the diseases and health disorders in turkeys reported by our industry colleagues are presented under three major regions in the U.S.A.; East, Midwest and West/Southwest.

Eastern Region (NC,SC,VA,PA,MI,OH).

- Infection with B. avian and subsequent complications with E. coli in young pouls.
- Colibacillosis as a secondary infection which also is a primary cause of mortality in growing turkeys. Field Newcastle disease, bordetellosis, sudden heat and humidity, and stress of moving out of brooder houses to growout units often pave the road for colibacillosis outbreaks.
- Early enteritis/feed refusal resulting in mortality (Spiking Mortality Syndrome), stunting, size variations and increased condemnation.
- M. gallisepticum outbreak in breeders causing progeny outbreaks. Disease was missed in diagnosis due to faulty HI tests.
- P. multocida P1059 outbreaks in breeders and commercial turkeys.
- Minor incidences of leg problems, mainly in summer. Turkey “leg problems” is not what it used to be. It does not presently constitute a major industry problem.
- A few cases of Ornithobacterium rhinotracheale (OR) infection reported in breeder and commercial turkeys.

Midwest Region (MN,IA,WI,MO,AR,IN)

- Early poult enteritis followed by colibacillosis.
- Bordetellosis/Newcastle complications followed by colibacillosis in young pouls.
- Colibacillosis caused by strain 078 in adult turkey breeder hens caused egg yolk peritonitis with considerable mortality.
- Mortality due to avian influenza, serotype H9N2, in commercial turkeys exacerbated by unusual high heat and humidity.
- Minor incidences of fowl cholera in meat turkeys.
- A swollen head syndrome in 2-3-week old turkeys caused variable mortality. An adenovirus group 1 is suspected to be the etiological cause! It is still under the investigation.
- Hatchery associated/recycled aspergillosis in very young pouls resulted in early high sporadic mortality with no excessive condemnation at the processing plant.
- Egg production drops in a few breeder flocks due to outbreaks of field Newcastle and one case of WEE.

557
TRANSMISSIBLE DISEASES OF POULTRY
AND OTHER AVIAN SPECIES

West/Southwest (CA, CO, TX, WA)

- Bordetellosis, temperature fluctuation and moving stress followed by colibacillosis. Sporadic complications with Newcastle infection.
- Poult enteritis of all kinds (necrotic/ulcerative, hemorrhagic and non-specific).
- MG and MS outbreaks in breeders and commercials.
- *Ornithobacterium rhinotracheale* (OR) in turkey breeder and commercial flocks with variable mortality. High mortality with little response to antibiotics occurred in cases where infection followed an outbreak of bordetellosis.
- Turkey viral hepatitis in young turkeys still recycles (as many as 10 times) on some of the premises.
- Low incidence of musculoskeletal disorders has been observed. Many cases of osteomyelitis due to *Actinomyces pyogenes* have been observed.
- Cases of avian influenza, serotype H7N3, have been experienced in commercial turkeys. The use of autogenous vaccine at 3.5 and 7 weeks of age under a supervised program controlled the spread of the infection very successfully in the region.

A report of the health status and other concerns of the ratite industry was presented by Dr. Karen Hicks-Alldredge, Sweetwater, TX. The USDA has approved 48 facilities across the United States for ostrich slaughter. Ostrich are being slaughtered under voluntary USDA inspection. Ostrich, emu, and rhea are not amenable species; and, therefore, do not require inspection. However, restaurants and consumers want an inspected product. State inspection of ostrich, emu, and rhea is also available in some states. Approximately 8,000 ostriches will be slaughtered in 1995 and an anticipated 50,000 in 1996. The USDA is not inspecting emu or rhea at this time. Product research has been the emphasis of the ostrich and emu industries this past year.

III. Status reports

The following report on NVSL Diagnostic Bacteriology activities was presented by Dr. Lee Ann Thomas, APHIS-VS/NVSL:

*Salmonella* serotyping of chicken and turkey isolates continues to constitute a large proportion of those salmonellae submitted to the National Veterinary Services Laboratories (NVSL). Of 21,175 isolates submitted from July 1994 through June 1995 to the NVSL, 12,576 (58%) were isolated from either chickens or turkeys. Approximately 88% of these isolates were identified as being the result of monitor/surveillance activities or environmental testing. *Salmonella enteritidis* remained the most common serotype associated with chickens, whereas *Salmonella brandenburg* was the most common serotype associated with turkeys. Both of these findings are biased as a result of specific surveillance or monitoring activities. For instance, 77% of all brandenburg isolates were submitted from West Virginia.
REPORT OF THE COMMITTEE

A liquid egg survey was initiated in October 1994. This survey was designed in order to assess the overall prevalence of *Salmonella* and *Salmonella enteritidis* in nonpasteurized egg pools and to determine if there had been changes in the type and frequency of phage type. After 45 weeks of the survey, 165 (19%) of samples were positive for *Salmonella enteritidis* and 249 (29%) were positive for other *Salmonella*. This is in comparison to the survey that was conducted in 1991 where 15% and 38% of samples were positive for *Salmonella enteritidis* and other *Salmonella*, respectively. The most common phage types identified to date are 13a, 8, and 4. These have been identified on 60, 44, and 17 occasions, respectively.

A report of Newcastle disease investigations and outbreaks was presented by Drs. Kelly Preston and James Pearson, APHIS-VS/NVSL. Since 1971 velogenic Newcastle disease virus (V-NDV) has been isolated from pet birds in the U.S. Every year except 1978, 1990, and 1991. Isolations in FY 95 include an isolation of V-NDV in November 1994 from a finch in a quarantine center in California, an isolation of viscerotropic velogenic Newcastle disease (WND) virus from a Kingfisher in a Quarantine center in California in March, 1995, and an isolation of WND virus from an Amazon parrot in US Customs in California in March, 1995. There were no isolations of VNDV from domestic poultry.

A report on avian influenza was presented by Dr. James E. Pearson, National Veterinary Services Laboratories. The complete avian influenza report by Dr. B. S. Pomeroy can be found later in this report. The following are additional details concerning the AI laboratory findings during the period of October 1, 1994, to September 30, 1995.

As reported by Dr. Pomeroy, avian influenza (AI) surveillance in fiscal year (FY) 1995 detected infections in two commercial turkey flocks caused by H5 and H7 subtypes. H5N2 AI virus was isolated in Minnesota and H7N3, in Utah. The virus was characterized at the National Veterinary Services Laboratories (NVSL) as being nonpathogenic by chicken inoculation and amino acid profile at the cleavage site of the hemagglutinin glycoprotein.

The interstate testing for ratites is still in place, but the number of positives submitted to the NVSL for typing has decreased in the last year, which may reflect a decrease in movement. As reported by Dr. Pomeroy, virus and antibodies to AI virus, subtypes H5 and H7, were detected in ratites from four states in FY 1995. The only virus isolated was subtype H7N3 from an emu from Texas in April 1995. The virus was characterized at the NVSL as nonpathogenic by chicken inoculation and amino acid profile at the cleavage site of the hemagglutinin glycoprotein. Rheas from Illinois and Indiana had antibodies to H5N2 AI virus. Antibodies to H7N3 were detected in an emu and ostrich from Texas and to H7N1 in an emu from Tennessee.

Two rounds of live-bird market (LBM) surveillance were conducted in FY 1995, October/November 1994 and February/March 1995. A total of 3,525 samples were collected from LBMs in 11 northeastern states. One hundred
sixty-nine (H7N2 subtype AI viruses were recovered from 20 markets in New York (89 isolates) and 6 markets in New Jersey (80 isolates). All 169 H7N2 viruses were characterized as being nonpathogenic by chicken inoculation and amino acid profile at the cleavage site of the hemagglutinin glycoprotein. Three of the 20 markets in New York were positive for the H7N2 virus on retest at least one time following cleaning and disinfection. One market in New Jersey was positive on retest four times and another market, three times. In July 1995, antibodies to H5N2 were detected in sentinel birds in a botanica in Dade County Florida; no virus was isolated. The subtype and frequency of isolation of other influenza A viruses is covered by Dr. Pomeroy.

No isolations of influenza A viruses were made from imported pet birds in FY 1995.

In support of the H5N2 AI control program in Mexico in 1995, the NVSL characterized a total of 25 viruses. Eight of the 25 viruses met the criteria for classification as being highly pathogenic by chicken inoculation and/or by amino acid sequence at the cleavage site of the hemagglutinin glycoprotein. The highly pathogenic viruses were from the states of Puebla and Queretaro. The remaining 17 isolates were characterized as being nonpathogenic and represented all 11 states where H5N2 virus has been isolated, including the states of Puebla and Queretaro. In August 1995, Mexican officials reported the isolation of nonpathogenic H5N2 virus in several premises of commercial chickens in three states bordering the United States: Coahuila, Tamaulipas, and Nuevo Leon. This represents the first isolation of H5N2 AI virus from chickens in these states, although positive serology was reported more than a year ago.

During FY 95, 3240 vials of AI antigen/antiserum were supplied by NVSL. This was enough reagents to perform 388,800 tests. This is supplied at no cost to encourage surveillance. If NVSL did charge for the reagents, the cost would have been $189,000, which would cover cost of production.

A report on avian import activities was prepared by Dr. Keith Hand, and presented by Dr. Kelly Preston, APHIS-VS.

Poultry and Hatching Eggs. There were 7,539,037 poultry, 375,955 including day-old chicks, and 12,544,134 hatching eggs imported into the United States during fiscal year (FY) 1995. This is a significant increase from FY 94. There were 10,500 goose eggs imported as well as 510 exhibition game fowl.

Commercial Birds. Importation of commercial birds continues to be at much lower levels than in the mid 1980's. The Wild Bird Conservation Act restricts the importation of most species of birds. This resulted in the importation of many of the non-prohibited species such as finches and other song birds. There were 84,618 commercial birds released during FY 95.

Pet Birds. There were 589 pet birds imported into the United States during FY 95. All pet birds covered under the Wild Bird Conservation Act were required to have a U.S. Fish and Wildlife exemption prior to importation.

Confiscated Birds. A total of 882 birds were either confiscated or aban-
doned by their owners and placed in quarantine. One confiscated lot of two Amazon parrots was destroyed in San Ysidro because of an isolation of exotic Newcastle virus.

**Ratite importation.** A total of 22,092 ostrich eggs were placed in privately owned bird quarantine facilities. From these imported eggs, 6,992 (31.6%) chicks were released at the end of quarantine.

During October 1994, 75 farms were inspected in Africa by USDA-APHIS officials. Currently, the value of ratites and their eggs is only about 10 percent of their peak value. Because of this decline, very few importers are interested in importing ratites or ratite hatching eggs. No recent requests have been received to inspect farms overseas.

During FY 1995 there were no ostrich chicks quarantined at the New York or Miami Animal Import Centers. Two shipments of cassowaries, totaling 13 were quarantined and released from the Hawaii Animal Import Center.

**Avian Imports. FY 1993, 1994, and 1995**

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<th>FY 1993</th>
<th>FY 1994</th>
<th>FY 1995</th>
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<tr>
<td>Poultry and day old chicks</td>
<td>6,282,363</td>
<td>2,725,542</td>
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<td>Poultry hatching eggs</td>
<td>17,593,184</td>
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<td>Ratites</td>
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<tr>
<td>Hatched ostrich chicks</td>
<td>15,556</td>
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<td>Ostrich chicks</td>
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<tr>
<td>Emu</td>
<td>1,238</td>
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<tr>
<td>Cassowaries</td>
<td>0</td>
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<td>13</td>
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<td><strong>Total</strong></td>
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<td>12,902,160</td>
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The National Poultry Improvement Plan report prepared by A. R. Rhorer, USDA,APHIS,VS, was presented by Dr. Otis Miller, USDA,APHIS,VS.

**Pullorum-Typhoid Status:**

In Calendar Year 1994, there were 40 isolations/outbreaks of *Salmonella pullorum* reported to the Poultry Improvement Staff. These isolations were reported from 7 States. All of the 40 isolates were standard pullorum. During calendar year 1995 from January to October 16, there were 8 isolations of *Salmonella pullorum*. These isolations were reported by 3 States. Of the 8 isolates, 2 were intermediate, 1 was variant and 5 were standard pullorum. Of the 5 standard pullorum isolates, 1 was atypical (ornithine negative). This atypical isolate was identified as *Salmonella gallinarum* on the Analytical
TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES

Profile Index (API). There have been no official isolations of *Salmonella gallinarum* since 1988 in any poultry and no isolations in commercial poultry since 1980. This atypical pullorum was isolated from a flock of non-release quail.

One hatchery and its supply flocks were responsible for 35 isolations in 1994. Investigations were completed on approximately 250 shipments from the suspect hatchery. All suspect flocks that were capable of being traced from the source hatchery were serologically tested. All reactors to the serological tests were submitted for further testing to Authorized Laboratories or destroyed.

In 1994-95 there were 31 isolates in bantam chickens, 10 in standard chickens, 3 in game chickens, 1 in game birds and 3 in mixed breeds.

The number of birds in *Salmonella pullorum* positive flocks were as follows:

<table>
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<th>Number of birds</th>
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<td>&lt; 5 birds</td>
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<tr>
<td>&gt;5</td>
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<td>&gt;15</td>
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<td>&gt;500</td>
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</tr>
<tr>
<td>Total</td>
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NATIONAL POULTRY IMPROVEMENT PLAN

The following is a thumbnail sketch of the proposed rules that were published in the federal register. The proposed rules were proposed changes to the provisions of the National Poultry Improvement Plan that were approved at the 1994 biennial conference in Nashville, Tennessee.

1. A new U.S. *S. enteritidis* Clean classification for primary meat-type breeding chickens was approved.
2. Protocol for bacteriological examination of baby chicks was established.
3. Various changes in sample sizes were approved for Official Mycoplasma serological tests.
4. A federally licensed SE ELISA was accepted as a NPIP approved serological test.
5. A colony lift assay was added as part of the NPIP approved bacteriological examination protocol.
6. Established the maximum number of serum plate positive samples for *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, and *Mycoplasma*...
REPORT OF THE COMMITTEE

*meleagridis* that will be examined using the hemagglutination inhibition (HI) and or the serum plate dilution (SPD) test.

(7) Require a representative sample of male birds from meat-type chickens and waterfowl, exhibition poultry and game birds be serologically sampled for pullorum-typhoid.

Pullorum-Typhoid Clean State:
California - October 1994
Oregon - October 1994

**NPIP Mycoplasma Survey:**
Does your State permit the use of F-strain Mycoplasma gallisepticum vaccine in commercial layers?

<table>
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<tr>
<td>Total</td>
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If the answer to number 1 is yes, how long has your State permitted the use of F-strain in commercial layers? (years)

<table>
<thead>
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<th>Percent</th>
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<td>83.3</td>
</tr>
<tr>
<td>25</td>
<td>1</td>
<td>8.3</td>
<td>91.7</td>
</tr>
<tr>
<td>30</td>
<td>1</td>
<td>8.3</td>
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<tr>
<td>Total</td>
<td>12</td>
<td>100.0</td>
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</tr>
</tbody>
</table>

Does your State permit the use of apathogenic vaccines for Mycoplasma gallisepticum in commercial poultry?
## TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES

<table>
<thead>
<tr>
<th>yes/no</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>14</td>
<td>43.8</td>
<td>43.8</td>
</tr>
<tr>
<td>no</td>
<td>18</td>
<td>56.3</td>
<td>100.0</td>
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<tr>
<td>Total</td>
<td>32</td>
<td>100.0</td>
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</tr>
</tbody>
</table>

How long has your State permitted the use of a pathogenic vaccines for *Mycoplasma gallisepticum* in commercial poultry? (years)

<table>
<thead>
<tr>
<th>years</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>7.7</td>
<td>15.4</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>7.7</td>
<td>23.1</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>15.4</td>
<td>38.5</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>30.8</td>
<td>69.2</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>7.7</td>
<td>76.9</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>7.7</td>
<td>84.6</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>15.4</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Does your laboratory bacteriologically examine suspect birds?

<table>
<thead>
<tr>
<th>yes/no</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>21</td>
<td>42.0</td>
<td>42.0</td>
</tr>
<tr>
<td>no</td>
<td>29</td>
<td>58.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Does your laboratory conduct Polymerase Chain Reaction (PCR) based tests on suspect birds?

<table>
<thead>
<tr>
<th>yes/no</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>9</td>
<td>18.4</td>
<td>18.4</td>
</tr>
<tr>
<td>no</td>
<td>40</td>
<td>81.6</td>
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<tr>
<td>Total</td>
<td>49</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
REPORT OF THE COMMITTEE

Does your laboratory have ELISA capabilities for MG, MS and MM?

<table>
<thead>
<tr>
<th>yes/no</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>29</td>
<td>58.0</td>
<td>58.0</td>
</tr>
<tr>
<td>no</td>
<td>21</td>
<td>42.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Does your laboratory conduct the hemagglutination inhibition test on MG, MS, and MM plate reactors?

<table>
<thead>
<tr>
<th>yes/no</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>28</td>
<td>57.1</td>
<td>57.1</td>
</tr>
<tr>
<td>no</td>
<td>21</td>
<td>42.9</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>49</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

III. Update on USAHA committees of interest

The following report of the activities of the Salmonella committee was submitted by Dr. K. V. Nagaraga, University of Minnesota:

The Salmonella Committee met at 1:30 p.m., Monday, October 30, 1995. Fifty-nine members and guests were present. There were ten papers and two videos shown.

Dr. Lee Ann Thomas from NVSL presented Serotyping results for Salmonella isolates from animals and related sources for July 1, 1994, through June 30, 1995. There were 21,552. Forty percent of the total number of isolates were from chickens. There were 8,6773 isolates from chickens submitted. The most frequently identified serotype included Salmonella enteritidis, S. heidelberg, S. hadar, S. kentucky, S. typhimurium, S. braenderup, S. istanbul, S. schwazzengrund, S. montevideo.

Dr. Lamichhane presented a paper on colony lift immunoassay for detection of Salmonellas. This method can help to quantify Salmonellas within 18-24 hours.

Dr. Diane Holder and coworkers presented a 24-hour filter monitor procedure for isolation of Salmonella. This method will detect and can help quantify salmonella within 18-24 hours.

Dr. Lamichhane presented a paper on colony lift immunoassay for detection of Salmonellas. This method can help to quantify Salmonellas within 18-24 hours.

Drs. Richard Gast and Steven Benson of USDA-ARS in Georgia reported on virulence, intestinal colonization and organ invasion in chicks experimentally infected with Salmonella enteritidis phage Type 4 and other phages Types found in poultry and humans in the United States. Significant differences in
virulence were evident within the set of phage type 4 isolates examined. Their data suggest that, although some phagetype 4 isolates apparently possess heightened virulence and colonizing abilities, the differences between phage types do not appear to be of sufficient magnitude or consistency.

Dr. Saeed and his colleagues from Indiana reported that strains of Salmonella enteritidis phage type 8 that expressed different fimbrial classes. Results of their study suggest that cecal colonization in laying hens by S. enteritidis may involve surface expression of fimbrial proteins. This protein may mediate local attachment to chicken granulosa cells and may be also involved in elicitation of humoral immune response against S. enteritidis.

Dr. Kinde and coworkers reported on result of an epidemiological investigation of SE phage type 4 in egg laying hens in Southern California. Their study indicated the source of infection to be a nearby creek which passes beside the ranch. The creek was entirely supplied by a "treated" effluent from municipal sewage treatment plant.

Dr. Don Franco from APPI showed a video. The video highlights specific recommendations that were observed that resulted in a marked decrease in the incidence of contamination and ultimately served as an educational tool for members of the association.

Dr. Ed Mallinson from Maryland presented a video which he produced entitled "Partners in Progress: Growing and Testing for Healthy Poultry". It is available to those wishing to have a copy.

An update from the Feed Safety committee was presented by Dr. M. S. Cover of Maryland:

One of the primary goals of the Feed Safety Committee is to reduce the microbiological load in the final feed for food animals. The recent actions by F.S.I.S. and other governmental agencies has strengthened the resolve to accomplish this. The Feed Safety Committee has emphasized the need for the feed industry to adopt H.A.C.C.P. type programs. Every feed mill should have such a program. It is clear that such a program must be patterned to fit the milling procedures at the particular mill. Likewise, similar H.A.C.C.P. or Good Management Practices are requirements in the production. The Committee in 1994 approved Best Management Practices for Salmonella Risk Reduction in Broilers and Turkeys. A similar program entitled "Integrated Guidelines for Table Egg Producers" has been approved.

In order to identify progress in the reduction of pathogens, especially salmonella, in final feed it is necessary to establish a baseline of the prevalence in feed. Therefore, two specific sampling plans have been established by the committee. One plan will establish a U.S.A.H.A. baseline study by having voluntary sampling by the industry. Specific procedures have been established for sampling, testing and interpretation. Also, there are special procedures in this monitoring to fully protect the source of the samples. This is extremely important in order to obtain to cooperation of the industry. The other monitoring program is a routine plan which will indicate progress in
reducing the presence of microbiological pathogens in feed over time.

In the area of feed transportation, guidelines have been prepared. Sanitation GMP's for trucks, rail cars, etc. as well as sampling plans for empty transport tanks have been prepared.

A number of integrated poultry companies are now working H.A.C.C.P. programs in the production of feed. GMP's in the live production area have been used for sometime in most areas. In the pork industry, great progress has been made in most of these areas under the direction of Dr. Beth Lautner.

IV. Disease control and exports

Dr. Tom Holder delivered the report of an ad-hoc committee appointed to determine if the Committee could assist the APHIS Import/Export staff in negotiating language on export certificates that is more specific and reasonable. One state had poultry product embargoed because of laryngotraechitis in commercial broilers.

Import certificates from all importing countries were summarized as related to poultry products. A list of the top 25 importing countries was received from the Foreign Agriculture Service. Present wording and suggested wording was circulated to several states for their review. Most agreed that more specificity is needed on disease definition, geography, and time.

A committee meeting was held on October 31, 1995, and as a result the following resolution was passed by the committee:

BACKGROUND INFORMATION: Infectious poultry diseases are sometimes used as trade barriers by countries importing poultry and poultry products from the United States. During the Spring of 1995, one poultry producing state reported several cases of infectious tracheitis and as a result, poultry product was embargoed by an importing country. Many import certificates are broad, vague and non-descript regarding disease definition, geographical distribution, and time. The poultry industry would like changes in the wording of these certificates.

RESOLUTION: The Transmissible Diseases of Poultry Committee of the USAHA recommends that APHIS import-export staff work with the poultry import-export subcommittee in continued negotiations with poultry importing countries regarding poultry and poultry products.

Dr. E. T. Mallinson presented the results of a national poultry laboratory utilization survey conducted by Drs. R. J. Eckroade (University of Pennsylvania), Dr. L. Van der Heide (University of Connecticut), and Dr. E. T. Mallinson (University of Maryland). The survey was stimulated by reports suggesting that confidentiality issues and/or regulatory responses to certain diagnoses were a deterrent to optimal laboratory usage. The causes for these decreases were distributed evenly across the USA. This was an important concern because maintenance of strong poultry diagnostic laboratory systems has traditionally been a key element in modern poultry production, health improvement, and disease surveillance.
The following survey results are provided as potentially useful information for the short- and long-term planning activities of laboratory directors, avian diagnosticians, and state and federal veterinarians.

Survey forms distributed ................................................................. 140
Survey forms returned ...................................................................... 57
Laboratories reporting diagnostic case load stability or increases .. 22
Laboratories reporting diagnostic case load decreases .................. 35

Table 1. Survey results: The 35 laboratories reporting *decreased* diagnostic case loads.

<table>
<thead>
<tr>
<th>Probable causative factors cited*</th>
<th>Number of laboratories</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client concerns about confidentiality and/or regulatory issues</td>
<td>16</td>
<td>46</td>
</tr>
<tr>
<td>Changes in laboratory personnel</td>
<td>11</td>
<td>31</td>
</tr>
<tr>
<td>Existence of laboratory fees</td>
<td>9</td>
<td>26</td>
</tr>
<tr>
<td><strong>External</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreases in poultry populations or businesses in service area</td>
<td>15</td>
<td>43</td>
</tr>
<tr>
<td>Existence of other sources of diagnostic service</td>
<td>14</td>
<td>40</td>
</tr>
</tbody>
</table>

*Single laboratories often cited more than one cause for their case load *decreases.*
Table 2. Survey results: Practices and policies believed to stabilize or increase laboratory usage.

<table>
<thead>
<tr>
<th>Desirable practices and/or policies cited</th>
<th>Number of laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial flocks</strong></td>
<td></td>
</tr>
<tr>
<td>Strong liaison with corporate poultry veterinarians</td>
<td>10</td>
</tr>
<tr>
<td>Well-trained, competent laboratory personnel</td>
<td>7</td>
</tr>
<tr>
<td>Confidentiality of diagnoses and/or perception that regulatory responses will be fair and even handed</td>
<td>7</td>
</tr>
<tr>
<td>State-of-art services available</td>
<td>7</td>
</tr>
<tr>
<td>Clarity and timeliness of reporting</td>
<td>5</td>
</tr>
<tr>
<td>Ability to provide flock management and medication recommendations</td>
<td>5</td>
</tr>
<tr>
<td>Involvement in NPIP and other monitoring programs</td>
<td>5</td>
</tr>
<tr>
<td>Field staff available for further follow-up work/epidemiology</td>
<td>2</td>
</tr>
<tr>
<td><strong>Specialty or hobby flocks</strong></td>
<td></td>
</tr>
<tr>
<td>Promotion of laboratory use/availability by Extension Service agents</td>
<td>11</td>
</tr>
<tr>
<td>Absence of laboratory fees</td>
<td>4</td>
</tr>
<tr>
<td>Less regulatory fear</td>
<td>3</td>
</tr>
<tr>
<td>Prompt, understandable laboratory reports</td>
<td>3</td>
</tr>
<tr>
<td><strong>Cage pet birds/aviaries</strong></td>
<td></td>
</tr>
<tr>
<td>Promotion of laboratory use/availability by Extension Service agents</td>
<td>9</td>
</tr>
<tr>
<td>Strong liaison with pet bird clinicians/practitioners</td>
<td>6</td>
</tr>
<tr>
<td>Skill with diseases of exotic avian species</td>
<td>4</td>
</tr>
</tbody>
</table>

V. Subcommittee reports

The report of the subcommittee on Avian Influenza was presented by Dr. B. S. Pomeroy. This report includes data from questionnaires sent to State Veterinarians and laboratory results reported by NVSL-USDA-APHIS-VS.

INDIVIDUAL STATES

Responses to the questionnaires were received from 32 states. No corrections were suggested in Table 1 (pages 516-518, 1994 USAHA Proceedings) Avian Influenza Serotypes isolated from Turkeys, Chickens and other domestic fowl in the United States or based on serology (1964-1994).
TRANSMISSIBLE DISEASES OF POULTRY
AND OTHER AVIAN SPECIES

TURKEYS

According to state reports and the NVSL laboratory report, the incidents of AI in turkeys were reported from 7 states with significant losses reported from outbreaks in two states. Virus isolations were made from turkeys in these two states (Minnesota and Utah), (Table 2).

Iowa

Turkey flock was identified with H1N1.

Michigan

Turkey flock was identified with H1N1.

Minnesota

Minnesota has continued its extensive monitoring programs of turkey and broiler flocks in 1995. Positive AGPT samples were submitted to NVSL as well as swabs for virus isolations. In the 94 AI season the first flock was identified in June and the last flock in November, 1994. Eight flocks on six farms with 200,000 birds were identified with H5N2, H6 and H7N1. No significant losses were reported.

The first flock of the 1995 avian influenza season was identified in a small flock of bronze turkeys on a game farm with H5N2 with no significant loss and H1N1 in two breeder flocks in January and February 1995. Then the next flock was reported with H9N2 in August and this was the beginning of an extensive outbreak that is still in progress. As of October 2, 36 flocks on 22 farms have become infected with H9N2. Some flocks were detected on the surveillance program at slaughter plant, others showed mild to severe signs and the estimated loss is approximately $1 million. Two breeder flocks on one farm were reported infected with H10N7 with drop in egg production in one flock. The H9N2 outbreak came after large migrations of gulls, blackbirds and waterfowl in August with commingling with turkeys on range.

Isolates of H9N2 typed at NVSL were considered non-pathogenic by laboratory tests.

North Carolina

H1N1 was identified serologically in four laboratory submissions involving breeder flocks with drop in egg production.

North Dakota

Flock was identified serologically with H10N7.

Utah

This state experienced an extensive outbreak with H7N3 beginning the end of March and also involved extensive use of H7 vaccine beginning in late June. Approximately 4 million birds were at risk in the valley and are raised on range. The flocks under 12 weeks of age that became infected experienced 5-10% mortality while flocks over 12 weeks had little loss. Flocks marketed in early stages of the disease experienced high condemnations from airsacculitis and septicemia - toxemia. Approximately 2 million birds were involved in 229 flocks on 60 farms. The economic impact was estimated at $1.5 million. The valley will be completely depopulated before repopulation.
REPORT OF THE COMMITTEE

occurs in 1996.

Isolates of H7N3 were typed at NVSL and considered non-pathogenic by laboratory tests.

Utah has had previous experiences with outbreaks of AI with H4, H6 and H10.

Wisconsin
H1N1 was identified serologically as well as H6N1.

CHICKENS
No commercial chicken flocks were reported infected with avian influenza.

BACK YARD FLOCKS
No backyard flocks were reported involved with avian influenza.

LIVE POULTRY MARKETS (NVSL)
Veterinary Services surveyed live bird markets and isolations were made from a variety of species mostly from chickens and guinea fowl but other species yielded AIV. H3N8 was identified once in Connecticut. Florida identified serologically the infection in chickens of H5N2 but no isolations were made and birds depopulated and premise repopulated with no evidence of reinfection. Numerous isolations were made from birds and environment in live bird markets in New Jersey, H2N2, H3N2, H3N3, H3N8, H4N6, H7N2, H10N7, H11N3, H11N9. New York reported a number of isolations, H2N2, H3N8, H6N8, H7N2. Pennsylvania reported the isolation of H2N3 from a duck. (Table 3).

The serotypes tested for pathogenicity at NVSL were considered non-pathogenic.

OTHER FOWL (NVSL)
NVSL reported the presence of antibodies in samples of waterfowl. Ibis from Illinois; duck from Maryland; duck from Pennsylvania, swan from Washington; and goose and swan from Wisconsin. No tissues were submitted (Table 4).

RATITES (NVSL)
Serum samples from emus, rheas and ostriches were submitted from 9 states as well as samples for pathogenicity tests from one state. Serotypes identified were H1, H4N8, H5N2, H7N1, H7N3, H9N2, H10, H12N5. H7N3 virus was identified from an emu from Texas (Table 5).

PATHOGENICITY TESTS
All isolates from U.S. sources tested at NVSL were considered non-pathogenic.
TRANSMISSIBLE DISEASES OF POULTRY
AND OTHER AVIAN SPECIES

USE OF AVIAN INFLUENZA VACCINE - TURKEYS
Minnesota reported the use of H1 and H6 vaccines in FY 95. H9 is currently being used. North Carolina reported extensive use of H1 vaccine in breeder flocks as well as Ohio. No reports were received from several states that received H1 vaccines. Utah made extensive use of H7N3 vaccine in 238 flocks.

SUMMARY
Avian influenza was identified serologically or by virus isolation in the following species and states.

Turkeys
- Iowa: H1N1
- Michigan: H1N1
- Minnesota: H1N1, H5N2, H6, H9N2, H10N7
- North Carolina: H1N1
- North Dakota: H10N7
- Utah: H7N3
- Wisconsin: H1N1, H6N1

Chickens
No commercial flocks

Live Poultry Markets
- Connecticut: H3N8
- Florida: H5N2
- New Jersey: H2N2, H3N2, H3N3, H3N8, H4N6, H7N2, H10N7, H11N3, H11N9
- New York: H2N2, H3N8, H6N8, H7N2
- Pennsylvania: H2N3

Other Fowl
NVSL reported the presence of antibodies in samples from waterfowl from five states.

Ratites (NVSL)
NVSL reported the presence of antibodies in samples from emus, rheas and ostriches from seven states and identification of H7N3 isolate from an emu in Texas.

Table 1, Avian influenza serotypes isolated from turkeys, chickens and other domestic fowl in the U.S. or based on serology. (1964-1995).
Table 1. Avian influenza serotypes isolated from turkeys, chickens and other domestic fowl in the U.S. or based on serology (1964-1995).

<table>
<thead>
<tr>
<th>State</th>
<th>Year First Identified</th>
<th>Hemagglutinin Antigens Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Turkeys</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>1964</td>
<td>H1, H5, H6, H9</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>1965</td>
<td>H6</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>1965</td>
<td>H1, H2, H5, H6, H9; 1995; H1, H6</td>
</tr>
<tr>
<td>Minnesota</td>
<td>1966</td>
<td>H1, H2, H3, H4, H5, H6, H7, H8, H9, H10, H13; 1995: H1, H5, H6, H9, H10</td>
</tr>
<tr>
<td>Washington</td>
<td>1967</td>
<td>H6</td>
</tr>
<tr>
<td>Oregon</td>
<td>1970</td>
<td>H6, H7</td>
</tr>
<tr>
<td>Iowa</td>
<td>1971</td>
<td>H1, H2, H4, H5, H6; 1995: H1</td>
</tr>
<tr>
<td>Colorado</td>
<td>1972</td>
<td>H1, H5, H7, H9</td>
</tr>
<tr>
<td>Ohio</td>
<td>1975</td>
<td>H1</td>
</tr>
<tr>
<td>South Dakota</td>
<td>1978</td>
<td>H1</td>
</tr>
<tr>
<td>Texas</td>
<td>1979</td>
<td>H5, H7, H9</td>
</tr>
<tr>
<td>Indiana</td>
<td>1980</td>
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</tr>
<tr>
<td>Missouri</td>
<td>1980</td>
<td>H1</td>
</tr>
<tr>
<td>Kansas</td>
<td>1980</td>
<td>H1</td>
</tr>
<tr>
<td>North Dakota</td>
<td>1981</td>
<td>H5, H6, H10; 1995: H10</td>
</tr>
<tr>
<td>Arkansas</td>
<td>1981</td>
<td>H1</td>
</tr>
<tr>
<td>North Carolina</td>
<td>1982</td>
<td>H1, H4; 1995: H1</td>
</tr>
<tr>
<td>Virginia</td>
<td>1983</td>
<td>H1, H2, H4, H5, H10; H4; 1995: H1</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1983</td>
<td>H1, H5</td>
</tr>
<tr>
<td>Michigan</td>
<td>1985</td>
<td>H1, H9; 1995: H1</td>
</tr>
<tr>
<td>Utah</td>
<td>1985</td>
<td>H6, H4, H10; 1995: H7</td>
</tr>
<tr>
<td>Nebraska</td>
<td>1988</td>
<td>H1</td>
</tr>
<tr>
<td>New York</td>
<td>1988</td>
<td>H9</td>
</tr>
<tr>
<td>Illinois</td>
<td>1991</td>
<td>H1</td>
</tr>
<tr>
<td>Florida</td>
<td>1991</td>
<td>H9</td>
</tr>
<tr>
<td>Maryland</td>
<td>1993</td>
<td>H5</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>1994</td>
<td>H6</td>
</tr>
<tr>
<td><strong>Chickens</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alabama</td>
<td>1975</td>
<td>H4</td>
</tr>
<tr>
<td>Minnesota</td>
<td>1978, 88</td>
<td>H6, H9</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1983, 86</td>
<td>H1, H2, H5</td>
</tr>
<tr>
<td>Maryland</td>
<td>1983, 84</td>
<td>H5, H9</td>
</tr>
<tr>
<td>New Jersey</td>
<td>1983, 86</td>
<td>H5</td>
</tr>
<tr>
<td>Virginia</td>
<td>1983</td>
<td>H2, H4, H5, H7</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>1986</td>
<td>H5</td>
</tr>
<tr>
<td>New York</td>
<td>1986</td>
<td>H5</td>
</tr>
<tr>
<td>Ohio</td>
<td>1991</td>
<td>H1, H2</td>
</tr>
<tr>
<td>Michigan</td>
<td>1992</td>
<td>H1, H6</td>
</tr>
<tr>
<td>Delaware</td>
<td>1993</td>
<td>H5</td>
</tr>
</tbody>
</table>
## TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES

<table>
<thead>
<tr>
<th>State</th>
<th>Year First Identified</th>
<th>Hemagglutinin Antigens Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Live Poultry Markets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td>1980</td>
<td>H1, H5</td>
</tr>
<tr>
<td>Florida</td>
<td>1986</td>
<td>H4, H5; 1995: H5</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>1986</td>
<td>H5</td>
</tr>
<tr>
<td>New Jersey</td>
<td>1989 Turkey</td>
<td>H9</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>1986</td>
<td>H5</td>
</tr>
<tr>
<td>Delaware</td>
<td>1990 Duck</td>
<td>H2, H5</td>
</tr>
<tr>
<td>New Jersey</td>
<td>1991 Guinea Fowl</td>
<td>H2, H5, H6</td>
</tr>
<tr>
<td></td>
<td>1992 Pheasant</td>
<td>H12</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1993</td>
<td>H5; 1995: H2</td>
</tr>
<tr>
<td><strong>Chickens -Dealer/ Backyard</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flocks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td>1983</td>
<td>H5</td>
</tr>
<tr>
<td>Ohio</td>
<td>1986</td>
<td>H5</td>
</tr>
<tr>
<td>Georgia</td>
<td>1987</td>
<td>H5</td>
</tr>
<tr>
<td>Maryland</td>
<td>1993</td>
<td>H1, H3, N8, H4</td>
</tr>
<tr>
<td>Maryland</td>
<td>1994</td>
<td>H5</td>
</tr>
<tr>
<td><strong>Other Species</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1969</td>
<td>Ducks H1, H3, H5, H10</td>
</tr>
<tr>
<td>Minnesota</td>
<td>1974</td>
<td>Geese NA</td>
</tr>
<tr>
<td></td>
<td>1974</td>
<td>Guinea Fowl NA</td>
</tr>
<tr>
<td></td>
<td>1980</td>
<td>Pheasants H3, H7, H8</td>
</tr>
<tr>
<td>New York</td>
<td>1978</td>
<td>Ducks H3, H4, H5, H6, H11</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1983</td>
<td>Guinea Fowl, Quail H5</td>
</tr>
<tr>
<td>Maryland</td>
<td>1984</td>
<td>Ducks, Guinea Fowl H3, H5</td>
</tr>
<tr>
<td></td>
<td>1984</td>
<td>Chukar H5</td>
</tr>
<tr>
<td></td>
<td>1984</td>
<td>Ducks H4</td>
</tr>
<tr>
<td>Washington</td>
<td>1985</td>
<td>Pheasant H9</td>
</tr>
<tr>
<td>Virginia</td>
<td>1985</td>
<td>Ducks, Swans, Geese H2, H5, H7</td>
</tr>
<tr>
<td>Oregon</td>
<td>1986</td>
<td>Quail, H5</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1986</td>
<td>Guinea Fowl H1, H6 H11</td>
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<td></td>
<td>1986</td>
<td>Guinea Fowl, Chukar H5</td>
</tr>
<tr>
<td>Georgia (Dealer)</td>
<td>1987</td>
<td>Guinea Fowl, H5</td>
</tr>
<tr>
<td>Maryland</td>
<td>1987</td>
<td>Ducks, Geese H9</td>
</tr>
</tbody>
</table>

NA=Not Available
<table>
<thead>
<tr>
<th>State</th>
<th>Year First Identified</th>
<th>Hemagglutinin Antigens Identified</th>
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<tbody>
<tr>
<td>Wisconsin</td>
<td>1988</td>
<td>Pheasant H9</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1988</td>
<td>Geese H1, H6, H11, H12</td>
</tr>
<tr>
<td>North Carolina</td>
<td>1988</td>
<td>Ducks H6</td>
</tr>
<tr>
<td>Connecticut</td>
<td>1990</td>
<td>Pheasant H4</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>1990</td>
<td>Pheasant H10</td>
</tr>
<tr>
<td>California</td>
<td>1990</td>
<td>Quail H1, H4</td>
</tr>
<tr>
<td>Maryland</td>
<td>1991</td>
<td>Quail H6 or H1, H5, H6</td>
</tr>
<tr>
<td>Arkansas</td>
<td>1992</td>
<td>Quail H5, H6, H7, H9, H10</td>
</tr>
<tr>
<td>New Jersey</td>
<td>1993</td>
<td>Guinea fowl H5, Duck H3</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>1993</td>
<td>Pheasant H5</td>
</tr>
<tr>
<td>New York</td>
<td>1993</td>
<td>Pheasant, Guinea fowl, Duck H5</td>
</tr>
<tr>
<td>Michigan</td>
<td>1993</td>
<td>Ducks, Geese H5, H11</td>
</tr>
<tr>
<td>Ohio</td>
<td>1993</td>
<td>Muscovy duck H1</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>1993</td>
<td>Duck H10</td>
</tr>
<tr>
<td>Maryland</td>
<td>1994</td>
<td>Pheasants H3, H5, H11</td>
</tr>
<tr>
<td>Maryland</td>
<td>1994</td>
<td>Duck, Geese H3, H5</td>
</tr>
<tr>
<td>Ratites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>1993</td>
<td>Rheas, Emus H5, H7; 1995: Emu H7</td>
</tr>
<tr>
<td>North Carolina</td>
<td>1993</td>
<td>Rheas H7</td>
</tr>
<tr>
<td>9 States</td>
<td>1993</td>
<td>Serological evidence</td>
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<tr>
<td>16 States</td>
<td>1994</td>
<td>Serological evidence</td>
</tr>
<tr>
<td>7 States</td>
<td>1995</td>
<td>Serological evidence</td>
</tr>
</tbody>
</table>
Table 2. Presence of avian influenza virus (AIV) or AIV-specific antibodies in gallinaceous birds other than those in live-bird markets. (NVSL, October 1, 1994 to September 30, 1995)

<table>
<thead>
<tr>
<th>State</th>
<th>Species</th>
<th>Isolate Subtype</th>
<th>Antibody Subtype</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iowa</td>
<td>Turkey</td>
<td></td>
<td>H1N1</td>
<td>4/95</td>
</tr>
<tr>
<td>Michigan</td>
<td>Turkey</td>
<td></td>
<td>H1N1</td>
<td>2/95</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Turkey</td>
<td>H5N2</td>
<td>H1N1</td>
<td>3/95</td>
</tr>
<tr>
<td></td>
<td>Wild Turkey</td>
<td></td>
<td>H5N2</td>
<td>11/94</td>
</tr>
<tr>
<td></td>
<td>Turkey</td>
<td>H9N2*</td>
<td>H6</td>
<td>11/94</td>
</tr>
<tr>
<td></td>
<td>Turkey</td>
<td></td>
<td>H9N2</td>
<td>8/95, 9/95</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Turkey</td>
<td></td>
<td>H1N1</td>
<td>4/95, 5/96, 6/95, 8/95</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Turkey</td>
<td></td>
<td>H10N7</td>
<td>8/95</td>
</tr>
<tr>
<td>Utah</td>
<td>Turkey</td>
<td>H7N3*</td>
<td>H7N3</td>
<td>4/95, 6/95, 8/95</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Turkey</td>
<td></td>
<td>H1N1</td>
<td>1/95</td>
</tr>
<tr>
<td></td>
<td>Turkey</td>
<td></td>
<td>H6N1</td>
<td>2/95</td>
</tr>
</tbody>
</table>

* The isolates were associated with respiratory disease and mortality in turkeys.
### Table 3. Presence of avian influenza virus (AIV) or AIV-specific antibodies in birds from live bird markets. (NVSL, October 1, 1994 to September 30, 1995)

<table>
<thead>
<tr>
<th>State</th>
<th>Isolate subtype*</th>
<th>Number(s) Isolated</th>
<th>Antibody Subtype</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut</td>
<td>H3N8</td>
<td>1</td>
<td></td>
<td>4/95</td>
</tr>
<tr>
<td>Florida</td>
<td></td>
<td></td>
<td>H5N2</td>
<td>7/95</td>
</tr>
<tr>
<td>New Jersey</td>
<td>H2N2</td>
<td>32</td>
<td></td>
<td>10/94-8/95</td>
</tr>
<tr>
<td></td>
<td>H3N2</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H3N3</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H3N8</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H4N6</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H7N2</td>
<td>89</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H10N7</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H11N3</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H11N9</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td>H2N2</td>
<td>17</td>
<td></td>
<td>10/94-4/95</td>
</tr>
<tr>
<td></td>
<td>H3N8</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H6N8</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H7N2</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>H2N3</td>
<td>1</td>
<td></td>
<td>1/95</td>
</tr>
</tbody>
</table>

* Most AIVs were recovered from chickens and guinea fowl. Other sources that yielded the AIVs were pheasants, partridges, waterfowl, turkeys, quail, and the environment.

### Table 4. Presence of antibodies to avian influenza virus in waterfowl and miscellaneous bird species. (NVSL, October 1, 1994 to September 30, 1995)

<table>
<thead>
<tr>
<th>State</th>
<th>Species</th>
<th>Antibody Subtype</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illinois</td>
<td>Ibis</td>
<td>H1, H10, N1, N7, N8</td>
<td>4/95</td>
</tr>
<tr>
<td>Maryland</td>
<td>Duck</td>
<td>H1, H11, H12, N1-9</td>
<td>4/95</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Duck</td>
<td>H1N1, H11N6</td>
<td>1/95</td>
</tr>
<tr>
<td>Washington</td>
<td>Swan</td>
<td>H9</td>
<td>3/95</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Goose</td>
<td>H10, N2, N8</td>
<td>7/95</td>
</tr>
<tr>
<td></td>
<td>Swan</td>
<td>H1, H2, H5, H6, H9</td>
<td>8/95</td>
</tr>
<tr>
<td></td>
<td></td>
<td>H12, N1-4, N8, N9</td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Presence of antibodies in ratites (emus, rheas, and ostriches) to avian influenza virus subtypes. (NVSL, October 1, 1994 to September 30, 1995)

<table>
<thead>
<tr>
<th>State</th>
<th>Ratite Species</th>
<th>Antibody Subtype</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut</td>
<td>Rhea and emu</td>
<td>H10, N4, N7</td>
<td>10/94</td>
</tr>
<tr>
<td>Georgia</td>
<td>Emu</td>
<td>H10</td>
<td>11/94, 1/95</td>
</tr>
<tr>
<td>Iowa</td>
<td>Emu and rhea</td>
<td>H10, N1, N3, N4, N6, N7, N8, N9</td>
<td>5/95</td>
</tr>
<tr>
<td>Illinois</td>
<td>Rhea</td>
<td>H5N2</td>
<td>4/95, 8/95</td>
</tr>
<tr>
<td>Indiana</td>
<td>Rhea</td>
<td>H5N2</td>
<td>8/95</td>
</tr>
<tr>
<td>Kansas</td>
<td>Rhea</td>
<td>H4N8</td>
<td>7/95</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Ratite sp.</td>
<td>H1, H8, H10, N1, N4, N7</td>
<td>7/95</td>
</tr>
<tr>
<td></td>
<td>Rhea</td>
<td>H8, H10, N1, N4, N7</td>
<td>4/95</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Emu</td>
<td>H7N1</td>
<td>11/94</td>
</tr>
<tr>
<td>Texas</td>
<td>Emu</td>
<td>H1, H10, H12, N5</td>
<td>7/95</td>
</tr>
<tr>
<td></td>
<td>Ostrich, emu</td>
<td>H12N5</td>
<td>6/95</td>
</tr>
<tr>
<td></td>
<td>Emu, ostrich</td>
<td>H7N3 (also H7N3 virus was isolated from an emu)</td>
<td>4/95</td>
</tr>
<tr>
<td></td>
<td>Emu</td>
<td>H9N2</td>
<td>4/95</td>
</tr>
</tbody>
</table>

Tom Mickle, Select Laboratories, Gainesville, Georgia reported on progress on development and licensure of a recombinant avian influenza-fowl Pox vaccine.

In April 1995, Select Laboratories submitted a license application to the Biologics, Biotechnology and Environmental Protection section, Veterinary Biologics, Animal Plant Health Inspection Services, USDA, for an Avian Influenza-Fowl Pox Vaccine, Live Fowl Pox Vector. Along with the application, protocols for several essential experiments were submitted for review and comment. These protocols included several safety studies, non-reversion to virulence studies, and efficacy experiments.

A Master Seed virus has been prepared and quality control tested at
REPORT OF THE COMMITTEE

Select. The Master Seed stock virus is currently being tested at the National Veterinary Services Laboratories in Ames, Iowa. Authorization to produce three prelicensing serials has been received from Veterinary Biologics. Shipment to Mexico of 20,000 doses of the recombinant Avian Influenza-Fowl Pox Vaccine, Live Fowl Pox Vector, product code 1061.RO, has also been approved.

Laboratory studies will be conducted at the National Institute of Forestry and Agricultural Research in Toluca, Mexico, beginning in November. Four experiments have been planned to examine safety and efficacy. Following the satisfactory completion of the laboratory studies, field trials may be approved.

Also, field trials using the prelicensing serials of the recombinant avian influenza-fowl pox vaccine may be approved for the United States.

Dr. Eduardo Rivera-Cruz presented an update on the current situation with avian influenza in Mexico. He reviewed the results of laboratory challenges of inactivated avian influenza vaccines, described the signs and lesions of high path AI as seen in Mexico, and presented information on the progress of the eradication program now under way.

A Summary of Pathobiologic and Molecular Epidemiologic Findings From Experimental Studies in Chickens with Mexican Avian Influenza Viruses was presented by David E. Swayne and Michael L. Perdue, Southeast Poultry Research Laboratory, Athens, GA.

The development of an avian influenza outbreak during 1993-94 in commercial poultry of Mexico was of great concern to the U.S. government and poultry industry, and to international trading partners. Initially, the outbreak had low mortality rates and was primarily a respiratory disease (3). However, in December, 1994, mortality rates for layer-type chickens increased and lesions compatible with highly pathogenic (HP) avian influenza (AI) were reported (3).

In our laboratory several H5N2 Mexican avian influenza virus (AIV) isolates have been inoculated into chickens to answer some elemental questions concerning virologic and pathologic aspects, especially in relation to the diagnostic testing, pathobiology and molecular epidemiology of isolates. The following is a summary of research information for 1995.

1. Individual H5N2 Mexican AIV isolates varied greatly in pathogenicity for chickens. A/ck/Queretaro/95 (Q1/95) and A/ck/Puebla/8623-607/94 (P11/94B) produced the greatest number of ill chickens, exhibited cytopathic effect (CPE) and cleaved HA in trypsin-free chicken embryo fibroblast cultures, and had a two basic amino acid insert (Arginine-Lysine) at the hemagglutinin cleavage site (I) (Pearson and Senne, personal communication). Q1/95 was highly lethal (8 of 8 inoculated birds), but P11/94B had low to moderate lethality rates (0-4 of 8 inoculated birds) in pathotyping tests using White Plymouth Rock (WPR) chickens. Consequently, Q1/95 and P11/94B met U.S. Animal Health Association criteria for eradication (5), and could be...
categorized as HP and potentially HP, respectively. A/ck/Hidalgo/26654-1368/94 (H5/94) was of low pathogenicity (LP), and A/ck/Jalisco/14589-660/94 (J12/94) and A/ck/Mexico/26654-1374/94 (M5/94) were non-pathogenic (apathogenic).

2. Both oral and cloacal swabs were good samples for isolation of Mexican AIVs from experimentally-inoculated chickens during the acute stage of the infection (3 and 5 days postinoculation).

3. Both agar gel precipitin (AGP) and hemagglutinin-inhibition (HI) tests were effective in detecting AIV infections in chickens experimentally inoculated with Mexican AIVs.

4. Pathogenesis of Mexican AIV infections in chickens varied with individual AIV isolates. Parent stock and two 14-day-old-embryo-derived P11/94B viruses (ED-7 and ED-9) produced 29-50% mortality in White Leghorn (WL) hens. For AIV variants recovered from hens that died following inoculation with P11/94B stock or ED-9 AIVs, 75% of isolates were highly lethal in standard WPR pathotyping tests. Multiple passages of P11/94B AIVs in hens shortened the mean death times from 6.8 to 4.6 days. P11/94B AIV inoculated chickens had gross lesions compatible with HP AI ("fowl plague-like") and included severe hemorrhage of leg shanks, necrosis of the comb and wattles, edema of the head and neck, and necrosis and inflammation in the adrenal gland, brain, heart and pancreas (4). LP Hidalgo/94 AIV parent stock and derivatives produced a few lesions in the respiratory system and kidney (4), but did not produce lesions compatible with HP AI.

5. The sequence analysis of the HA1 coding region of the hemagglutinin gene for eight Mexican AIV isolates has resulted in following conclusions.

a. The Mexican outbreak was the result of the introduction of H5N2 viruses not closely related to the H5N2 viruses of the Northeast U.S. outbreak of 1983 (Figure 1; series I) nor recent European H5 AIVs (Figure 1; series IV). The Mexican isolates were most closely related to the 1991 H5N2 shorebird virus isolated by Dr. Robert Webster, St. Jude’s Children’s Hospital (Figure 1; RT91 of series III). The Mexican isolates were related to the Pennsylvania (CP93), Florida (CF93) and Texas (ET93 and ET931B) AIVs isolated in 1993 (Figure 1; series III). This suggests the Mexican and 1993 U.S. isolates had a common progenitor most likely an AIV circulating in migratory shorebirds.

b. The Mexican outbreak had two separate lineages of virus (Figure 1). Based on date of isolation, geographic location, and sequence homology, the AIVs of the first lineage (Jalisco lineage) appeared in late 1993/early 1994 (J12/94, Q1/95, H5/94 and M5/94 isolates) and the second lineage in late 1994 (P11/94C, P12/94, P11/94A and P11/94B isolates).

c. High pathogenicity was associated with specific changes at the hemagglutinin cleavage site (originally reported by APHIS, NVSL and
confirmed by ARS, SEPRL and St. Jude's Children's Hospital); i.e. insert of 2 basic amino acids (arginine and lysine) and a substitution of lysine for glutamic acid at AA (-3) position. A similar amino acid sequence has been previously reported for highly pathogenic field viruses isolated from turkeys in Ireland in 1983 (TI83) and turkeys in England in 1991 (TE91), and a similar insert was found in a highly pathogenic AIV variant (ET931B) obtained following laboratory passage of A/emu/Texas/93 (ET93) in 14 day-old chicken embryos at SEPRL (2). The commonality of this insertion and substitution suggests distinct mutational event(s) that could occur in other H5 AIVs of low pathogenicity.

d. Highly pathogenic AIVs were located in both lineages of Mexican AIVs; i.e. Jalisco and Puebla lineages (Figure 1). This suggests two separate and rapid mutation events for high pathogenicity, one for each of the two lineages of Mexican AIVs. There is a significant possibility of additional Mexico AIVs of low pathogenicity mutating and becoming highly pathogenic.
REPORT OF THE COMMITTEE

Dr. C. W. Beard, Southeastern Poultry and Egg Association, presented the report of an ad-hoc subcommittee charged with developing recommendations for responses to the threat of H5 or H7 avian influenza. The subcommittee presented the following recommendations:

1. Provide a vaccine "safety net" against H5 and H7 influenza.

   There needs to be available, with minimal lag time, inactivated oil emulsion vaccine against H5 and H7 avian influenza viruses. The regulatory and financial details remain unresolved but should present no insurmountable obstacles. APHIS would retain control of the use of the vaccine would be intended only as a "safety net" for the industry should eradication efforts prove to be ineffective or impractical. Steps will be initiated to determine the quantity of reserve vaccine antigen which would be appropriate and to establish the priorities of use in the different types of poultry; i.e., primary breeders, multiplier flocks, table egg layers, turkeys, etc.

2. Increase avian influenza antibody surveillance.

   It is the recommendation of the subcommittee that each state have a continuing serologic surveillance program of adequate magnitude to detect the presence of AI antibodies that could result from mild, non pathogenic strains of virus. The timely detection of H5 or H7 antibodies in sera or yolk will greatly facilitate the accomplishment of Objective 3. An important ingredient in the successful accomplishment of adequate surveillance will be the continued availability of antigen and reference antisera to perform the tests. It is suggested that USDA-APHIS continue to make these reagents available at no cost to the poultry laboratories. The use of sera from processing plants will greatly aid in maintaining a continuing surveillance. The use of sera submitted as part of the NPIP will be useful to monitor the AI status of breeders.

3. Provide recommendations to the industry regarding low path H5 and H7 AI introductions.

   A worst-case scenario would be the introduction of a low path H5 or H7 virus which would be allowed to spread in the industry because it was undetected or because it caused no major disease and no effort was made to control it. After a period of time the virus would undergo the necessary genetic changes and become highly pathogenic as it did in Pennsylvania and more recently in Mexico. The recommendation is to provide guidance to the industry on what their response should be to keep this scenario from becoming reality. The methods used by the industry to accomplish this goal must be tailored to fit the different geographic areas because of differences in poultry type, concentrations, remoteness, and the number of companies involved. Improved biosecurity practices will likely be a part of the program as will quarantine and slaughter by processing.


   It is the recommendation of the subcommittee that a fourth symposium be held in late Spring or early Summer of 1997. It should be under the sponsorship of USAHA as have the first three symposia. The emphasis of the
symposium should be to exchange research information and control strategies with the participation of researchers, regulatory officials, and industry representatives. It now appears that the threat from AI and the potential it has for causing severe losses in the world’s poultry is steadily increasing. There is a great need for mapping out agreed-upon intervention strategies to cope with the disease without unjustified trade restriction penalties. For the symposium to be held in 1997 efforts should soon begin to assign responsibilities, finalize the location, and initiate efforts to obtain the necessary funding.

In order to ensure the continued availability of AI test reagents, the following resolution was approved:

**BACKGROUND INFORMATION:** Whereas avian influenza serologic surveillance is necessary to detect the presence of mild but potentially highly pathogenic avian influenza infections due to H5 or H7 viruses, it is very important that plentiful supplies of high quality agar gel precipitin test antigens and reference antisera be available. These reagents have been provided by the NVSL as evidenced by their distribution of over 300,000 test quantities of these reagents in the last year. These reagents were provided at no cost to the testing laboratories. There is now discussion that these reagents cost approximately $185,000, which may need to be recovered by charging for the reagents in the future. This action will likely severely curtail AI surveillance activities by laboratories and therefore could interfere with the rapid detection of AI introductions.

**RESOLUTION:** Therefore, this association strongly urges that the NVSL of APHIS continue to provide the high quality reagents at no cost to the testing laboratories.

The report of the subcommittee on Mycoplasmosis was presented by Frederic J. Hoerr.

Sporadic cases of mycoplasmosis caused by *M. gallisepticum* and *M. synoviae* continue to occur although no major epornitics have been identified in the past year. The general trend continues in which MS-positive broiler breeders in the U.S. are kept in production rather than depopulated.

The use of live attenuated mycoplasma vaccines was reviewed. The subcommittee recommends that attenuated vaccines be used only as specified on the label.

The sensitivity of the rapid plate agglutination test for *M. synoviae* to detect acute infection was reviewed. Ancillary tests such as ELISA, culture, and PCR should be used as necessary to identify acute infections of *M. synoviae*.

The National Veterinary Services Laboratory and the Southeastern Poultry and Egg Association were commended for efforts leading to the availability of control antisera for avian mycoplasma testing. Know positive and negative control sera for *M. gallisepticum, M. synoviae,* and *M. meleagrisidis* are now available from NVSL for both the rapid plate agglutination test and the he-
magglutination inhibition test. With the support of the SEPEA, chicken sera of variable titer to MG and MS, as well as negative controls are now available monthly from the laboratory of Dr. Stanley Kleven (Georgia).

Dr. Lloyd Lauerman (Alabama) reported on studies to identify mycoplasma isolates from ratites originating from the laboratories of Dr. Stanley Kleven (Georgia) and Dr. Richard Chin (California) The isolates share no biochemical or serological identity to know avian mycoplasmas. Preliminary analyses by PCR and RFLP indicate the possibility of four or more strains. The pathogenicity of these isolates for chickens or turkeys is not currently known.

Dr. John Fischer (Georgia) reported on Mycoplasma gallisepticum in house finches in the eastern U.S.

The epornitic of conjunctivitis in house finches (Carpodacus mexicanus) that was first reported in early 1994 in suburban Washington, DC has expanded throughout much of the eastern United States and Canada. Affected birds have been reported in Connecticut, Delaware, Georgia, Kentucky, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia, Nova Scotia, Ontario, and Quebec.

Disease is characterized grossly by bilateral or unilateral eyelid swelling often accompanied by ocular and nasal exudates. Microscopic lesions consist of lymphoplasmacytic inflammation with hyperplasia of the lymphoid and epithelial tissue of the conjunctiva, often with keratitis and rhinitis. Mycoplasma gallisepticum (MG) was detected in affected birds by culture and polymerase chain reaction, and serologic testing identified antibodies against MG. MG also was isolated from house finches without lesions. Limited molecular studies of house finch MG isolates suggested that they differ from strains commonly associated with disease in domestic poultry.

Experimental work has been performed at the Southeastern Cooperative Wildlife Disease Study and the Poultry Diagnostic and Research Center at the College of Veterinary Medicine, The University of Georgia; and at the National Wildlife Health Center of the National Biological Service. Conjunctivitis, rhinitis, and antibodies against MG developed in house finches experimentally inoculated with MG derived from a field case, and young domestic turkeys and chickens developed severe airsacculitis when inoculated with the same isolate. Additional experimental work currently includes inoculation of other passerine species, study of the pathogenesis of experimental MG infection of house finches, and studies of MG transmission between chickens and house finches.

This disease currently appears confined to house finches. The effects on house finch populations are unknown; however, large percentages of affected birds are frequently reported in areas involved in the epornitic. There is potential for continued spread of MG in house finches through social and migratory behavior, and a potential for persistence of MG infection in house finch populations through possible transovarial transmission as occurs in domestic poul-
The threat of the spread of this pathogen to other passerine species or domestic poultry remains a concern and points to the need for continued tight biosecurity on poultry premises.

The report of the subcommittee on infectious laryngotracheitis (ILT) was presented by Dr. H. M. Ghori, subcommittee chair. Whereas ILT is a highly contagious disease of chickens and whereas eradication is not practical, the subcommittee recommends that the name be changed from Infectious Laryngotracheitis Eradication subcommittee to Infectious Laryngotracheitis subcommittee. And further, the ILT subcommittee has established the following mission statement—"Assess the current status of ILT and develop recommendationsto the poultry industry and regulatory agencies". Secondly, the subcommittee asks individual states to develop guidelines for reporting ILT to state officials or consider removing ILT from the reportable disease list.

The report of the subcommittee on infectious bronchitis virus (IBV) was presented by Dr. Syed Naqi, subcommittee chair.

IBV infection continues to be one of the most common and economically significant infections of both commercial broiler and layer chickens. In broilers, IBV mainly causes respiratory problems, whereas in laying hens it reduces both egg production and egg quality, thus decreasing the number of saleable eggs from affected flocks. Prevalence of nephrotropic IBV strains in the USA remains quite low compared to pneumotropic IBV.

One of the major impediments to the control of IBV infection in the field continues to be the prevalence of multiple serotypes and antigenic variants of the virus. Since IBV immunity is serotype specific (although some cross-protection between serotypes may occur), knowledge of the prevalent serotype(s) on a premises becomes highly important in the selection of an appropriate vaccine. Recognizing this need, two different methods for serotype identification, one utilizing specific monoclonal antibodies (MAbs) and the other applying PCR technology, were developed in the last few years.

The panel of MAbs currently used in the USA (available from the College of Veterinary Medicine, Cornell University) consists of two IBV group-reactive MAbs, and three serotype-specific MAbs which recognize Massachusetts (Mass), Connecticut (conn) and Arkansas (Ark) serotypes, respectively. The PCR-based assays developed at the University of Georgia and the University of Delaware can recognize IBV serotypes, Mass, Conn, Ark, JMK, Gray, Florida, SE17, Georgia variant, Delaware variant 92-072, California variant, and Texas variant (PP14).

Antigenic variants arising from both wild- and vaccine-type IBV remain an important cause of bronchitis outbreaks in vaccinated chickens. Although most of the variants seem to cause short-term problems, some can persist and ultimately spread to other regions. A good example of the latter type is the Delaware variant 92-072. This variant, first recognized in layers in Delmarva
in 1990 and later in Delaware broilers in 1992, has since been isolated from chickens in several Eastern states, including Pennsylvania and North Carolina (the virus identification was based on PCR and virus neutralization tests). A live virus vaccine prepared from this variant is now available for use in Delmarva, Pennsylvania and North Carolina. Different antigenic variants of IBV have become established in other areas of the USA with large concentrations of chickens, such as Georgia (GA variant) and California (CA variant).

**Research needs and recommendations:**

1) IBV is a difficult virus to control in the field because of its highly contagious nature, and its tendency to continually undergo antigenic change. Since there is evidence that live IBV vaccine viruses can give rise to antigenic variants in the field, there is need for the development of recombinant IBV vaccines which may induce protective immunity without the risk of the generation of variant viruses. Such vaccines should eventually replace the live virus vaccines in the field. At that stage, possible approaches to the eradication of IBV might be considered.

2) Research should be encouraged in the development of additional reagents and techniques for the serotype-specific diagnosis of IBV and variant strains. However, since the standard test for IBV serotyping is still the virus neutralization test, the latter should be made available to the poultry industry through a central agency such as National Veterinary Services Laboratory, Ames Iowa.

3) The respiratory immunity in chickens must be aggressively researched. Such research should address both the basic aspects of the respiratory immunity as well as practical approaches such as methods of vaccine delivery and development of adjuvants for the stimulation of the mucosal immune system.

**VI. Old and new business**

The Committee approved a recommendation that the 4th International Symposium on Avian Influenza be held in 1977 under the sponsorship of USAHA.

Discussion was held on implementation of the resolution that the APHIS import-export staff work with the poultry import-export subcommittee in continued negotiations with poultry exporting countries regarding poultry and poultry products. It was decided that the Committee Chair should appoint a subcommittee on Government Relations to carry out this recommendation as well as to maintain a liaison with other appropriate governmental agencies.

**VII. Subcommittees**

A. Avian Influenza: C.W. Beard; B.C. Easterday; D. Halvorson; H. N. Lasher; J.E. Pearson; V. Sivanandan; Richard D. Slemons; D. E. Swayne; S. Trock; R. Webster; R.J. Eckroade, Vice Chair; B.S. Pomeroy, Chair.
TRANSMISSIBLE DISEASES OF POULTRY
AND OTHER AVIAN SPECIES

B. Food Safety: J.-W. Colby; R.J. Eckroade; D. Hill; G.T. Holder; G.E. Kolb; S. McCarter; A. Matalib; P.E. Poss, Chair.

C. Infectious Bronchitis: C.W. Beard; H.N. Lasher; M. Opitz; H.L. Shivaprasad; P. Woolcock; S. Naqi, Chair.

D. Infectious Laryngotracheitis Eradication: W.C. Baisley; F.J. Hoerr; G.T. Holder; H.N. Lasher; E.M. Odor; H.M. Ghori, Chair.

E. Mycoplasmosis. G.T. Holder; S.H. Kleven; E.T. Mallinson; H.M. Opitz; B.S. Pomeroy; H.W. Towers; R. Yamamoto; F.J. Hoerr, Chair.

F. Ratite Industry: R. Angel; K. Coldwell; F. Golan; H. L. Rubin; J.P. Sanders; H.L. Shivaprasad; S.A. Vezey; K.D. Hicks-Alldredge, Chair.

G. Broiler Industry: G.T. Holder, Chair.

H. Table Egg Industry: G.L. Waters, Chair.

I. Turkey Industry: G.Y. Ghazikhanian, Chair.

J. Program committee. R. J. Eckroade; F.J. Hoerr; R.E. McCapes; P.E. Poss; G.T. Holder, Chair.
REPORT OF THE COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE

Chairman: Dr. Beth Lautner, Des Moines, IA
Vice Chairman: Dr. Joseph Annelli, Ellicott City, MD

Dr. Gary A. Anderson, KS; Dr. Greg BeVier, MO; Mr. Don Benson, SD; Dr. George W. Beran, IA; Mr. Neal Black, MN; Mr. Philip E. Bradshaw, IL; Dr. John R. Cole, GA; Dr. John M. Cunningham, NE; Mr. Eric Dee, IA; Dr. E. Gerald Duhamel, NE; Mr. Robert Dykhuis, MI; Dr. Gene A. Erickson, NC; Dr. Anthony M. Gallina, PA; Mr. Don D. Gingerich, IA; Dr. Larry M. Granger, MI; Dr. Mark Hammer, VA; Dr. D. L. Harris, IA; Ms. Jody Hauge, ND; Dr. Howard Hill, IA; Dr. Wade L. Kadel, KY; Dr. Charles L. Kanitz, IN; Dr. John P. Kluge, IA; Mr. James W. Leafstedt, SD; Dr. Charles E. Massengill, MO; Mr. John McNutt, IA; Dr. William L. Mengeling, IA; Dr. Rita D. Michaels, MO; Dr. F. J. Mulhern, MD; Dr. Phillip A. O’Berry, IA; Dr. Richard E. Omohundro, AZ; Dr. Roy A. Schultz, IA; Mr. Gary Simpson, CO; Mr. James W. Stocker, NC; Dr. Paul Sundberg, IA; Dr. David G. Thawley, MN; Dr. H. Wesley Towers, DE; Dr. Mahlon W. Vorhies, KS; Mr. Fred Wise, IN; Dr. James C. Wright, AL.

There were 47 people attending with 19 of the 41 members present.

Dr. Kelly Lager presented a summary of the 2nd International Symposium on PRRS held in Copenhagen, Denmark. This was a follow up to the one held in Minnesota in 1990 and covered the history of the disease which was traced back to 1985 in the U.S. While the clinical observation would indicate that PRRS has an immunosuppressive effect, experimental evidence does not support this. So far there is no definitive answer to the immunosuppressive nature of PRRS. Diagnosis is by IFA, SVN, IPA, and ELISA. The commercial ELISA is comparable to the IF and therefore becoming the "gold standard" for the U.S. Problems with serology are antigenic differences in viruses and a decrease in antibody titer over time. Serum is the tissue of choice for virus isolation, however alveolar macrophages may be the best. There is currently a vaccine available. The respiratory form of the disease is of major concern in the U.S. but in Europe the respiratory form appears milder. Virus can be spread in semen. Aerosol and airborne transmission may not be as easy as it was once thought. One case report was presented on the elimination of PRRS from a 400+ sow herd with management changes on the farm.

Dr. Joe Annelli reviewed the changes in APHIS with the development of National Animal Health Program Staff. The Swine Health Protection Program has recently undergone a reevaluation to review the risks associated with waste food feeding. It has been proposed to develop a risk-based inspection/certification program. This would allow APHIS to move from the current framework of inspection of cooking of regulated food waste to a risk based inspec-
 tion/certification system based on an assessment of variables for each premises. The risk factors would include risks of Foreign Animal Disease and potential public health concerns. A management plan would be developed based on the level of risk. The AVIC or State Veterinarian would review the resulting management plan. It has been proposed to have an annual review of the farm to recertify. Pilot studies are being developed currently. There has been increased interest in waste food feeding due to increased concern about costs and availability of landfills.

Dr. Michael Westendorf presented the Food Waste Recycling Symposium to be held at Harrah's Marina, Atlantic City, New Jersey, January 22 and 23, 1996.

Dr. Robert Teclaw presented an overview of the National Trichina Pilot Project. The U.S. is the lowest cost producer of pork and can expand markets internationally. The idea persists in the minds of consumers that trichina is a problem. The trichina testing program is a certification program based on an ELISA test of a representative sample of a herd. There are 4 main goals of the National Trichina Pilot Project: to test the efficacy of the ELISA test, determine risk factors associated with trichina infection, the determination of national prevalence and to determine control and avoidance strategies. Results so far indicate that seroprevalence of infection is low.

Dr. Scott Wells presented the 1995 National Animal Health Monitoring System Swine Survey. Ninety-one percent of the hog inventory and seventy-two percent of the hog producers are represented by the States included in the program. The purpose was to provide a snapshot of the U.S. pork industry. When the data collection is completed it will be presented in descriptive fact sheets.

The remainder of the program focused on swine research, education, and surveillance priorities.

Dr. Howard Hill presented the practitioner perspective. The focus of the presentation was on the changing swine industry. Some changes are toward larger but fewer operations, from reaction to health management, odor and nutrient control is becoming important. Resources should be focused on economically important diseases. This importance is not only for disease losses but impact on marketability of pork. There is a need for health monitoring systems for physiological systems.

Dr. James McKean gave the University perspective and listed PRRS as the primary disease of concerned and elucidated methods to mitigate the effect. Production characteristics such as regionalization, wide variation in the size of herds, producers' goals and resources differences, variations in self interests, hog density and disease transmission variations, and market access and contracts will determine actions. Individual versus area spread diseases need to be dealt with differently.

Dr. Jim Collins gave the diagnostic laboratory perspective. The role of the diagnostic lab is in regulatory diseases, international commerce, recognition
of emerging diseases, research, and training. He identified targeting resources to quality control programs to reduce interlaboratory variation and new diagnostic test implementation. Changing production methods are changing disease patterns. A better look at the cost-benefit of diagnostic studies such as herd profiling is needed.

Dr. Dale Polson of NOBL Laboratories gave the allied industry perspective. One area of education is to stress the population disease dynamics including epidemiology, statistics, production economics and animal management. Disease surveillance is important to protect U.S. producers and consumers plus increasing access to world markets. There is a need to link and network laboratories, Federal, State, and private diagnostic labs. Monitoring should be for food safety concerns plus significant animal production efficiencies. The methods of surveillance could include PigMon, serum or meat juice monitoring, and input surveillance of feed and breeding stock. Production surveillance was discussed contrasting private vs. mandated, optimal inputs for national databases, and tools for surveillance (i.e., production software and surveys). Research concerns were salmonella reduction, trichina, toxoplasmosis and yersinia and those of economic impacts on animal production.

Dr. Annelli discussed a vision for future APHIS activities. New areas include an increased emphasis on enhancement of global trade, quality assurance/certification programs, rapid investigation, identification, and analysis of emerging animal health issues.

Dr. Beth Lautner reviewed the research priority setting agenda of NPPC. This list was as follows: (1) PRRS vaccines, (2) PRRS epidemiology, (3) SEW issues, (4) TGE differentiation, (5) Ileitis, (6) PRV evaluation of vaccines and serology, (7) Mycoplasma, (8) Regionalization, and (9) Ileitis.

The Chairperson established a Health Monitoring Subcommittee and asked for volunteers to serve on this subcommittee. Three resolutions were passed by the committee. These were:

RESOLUTION 1: The potential presence of trichinae has an impact on the image of U.S. pork, both domestically and internationally. Though the number of human cases and the incidence in swine has declined over the last several decades, elimination of trichinosis would improve product sales. In addition, trichinosis in swine continues to be a barrier to expanding U.S. pork exports. To address these health and economic issues, USDA and the National Pork Producers Council have collaboratively initiated the National Trichinae Research Project (NTRP) in January 1995. The goals of the NTRP are to evaluate the utility of an ELISA serologic test for determining herd trichinae status at the farm level and to evaluate the risk factors for the presence of trichinae.

Be it resolved that, the USAHA Transmissible Diseases of Swine Committee strongly urges USDA to expand the National Trichinae Research Project to
REPORT OF THE COMMITTEE

conduct a national trichinae prevalence survey of breeding and market swine, evaluate "at risk" swine populations, develop regional and herd certification pilot projects, and gain international acceptance of U.S. trichinae testing methodology.

RESOLUTION 2: The USAHA Transmissible Diseases of Swine Committee urges APHIS to develop, in cooperation with the subcommittee on health monitoring, an ongoing surveillance program for diseases of high priority to the pork industry, report on their national incidence, prevalences, geographic distribution and trends, and develop economic models based on optional level of diseases.

RESOLUTION 3: The Transmissible Diseases of Swine Committee urges APHIS to work with OIE to develop methods to uniformly enforce disease reporting, surveillance, and monitoring.
COMPARISON OF NORTH AMERICAN PPDS IN VIVO: CAUDAL FOLD TESTING

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Introduction

The purpose of this project was to compare the tuberculin purified protein derivatives (PPDs) used for caudal fold skin testing (CFT) of cattle for tuberculosis eradication programs in Canada, Mexico, and the United States of America (U.S.). There are differences in the PPD production protocols used in Canada, Mexico, and the U.S., including the original source of the AN5 strain of Mycobacterium bovis and the agent used to precipitate protein. Mexico, like most other tuberculin producing countries, uses trichloroacetic acid, while Canada and the U.S. use ammonium sulfate. The original source of the AN5 strain of M. bovis used for tuberculin production in Canada and Mexico was Lelystad, The Netherlands, while the U.S. source was Weybridge, United Kingdom. Comparing skin test results of North American PPDs will provide information important to current and potential trade agreements.

Materials and Methods

A herd of Charolais and Limousin cattle in the state of Sonora, Mexico was selected for use in this project. A single cervical skin test, using Mexican PPD, had been conducted six months prior to the current study, and bovine tuberculosis had been confirmed in the herd by isolation of M. bovis from
COMPARISON OF NORTH AMERICAN PPDS
IN VIVO: CAUDAL FOLD TESTING

tissue samples. Single lots of *M. bovis* PPDs from Canada (Agriculture and
Agri-Food Canada), Mexico (ProNaBIVE), and the United States (USDA) were
used. A total of 327 cattle were caudal fold tested: 286 in three PPD combina-
tion groups (Canada & Mexico, Canada & U.S., and Mexico & U.S.), and 41
cattle in which PPD from a single country was injected in both caudal folds
(Canada & Canada, Mexico & Mexico, and U.S. & U.S.). Cattle were ran-
domly assigned to PPD groups as they entered chutes for testing, and for
each PPD combination group the placement of PPDs was alternated for left
and right caudal folds. The CFT was conducted according to USDA, Veteri-
nary Services Memorandum 552.15 (dated 28SEP82), except that PPDs were
placed in both caudal folds. After review and standardization of individual in-
jection and reading (palpation) techniques, one USDA veterinary epidemiolo-
gist and three certified veterinarians of the TB Eradication Committee in the
state of Sonora performed all skin tests. To further control for differences in
individual technique, the same veterinarian performed both the injections and
skin test readings on an individual animal. The skin tests were read at 72-hr
post-injection, and the veterinarians were blind to which PPDs had been used
in individual animals. Palpation results were analyzed statistically by t-tests
of z transformations of proportions or by Chi-square tests of 2 x 2 tables.

Two months after conducting the CFT, a subpopulation of tested cattle
were slaughtered. This subpopulation included 54 cattle that had discrepant
skin test results (one side positive and the other negative), 18 cattle that had
negative results on both sides, and three cattle that had large positive results
on both sides. A standard set of samples was collected from the head, tho-
racic, and abdominal regions of each animal, whether or not lesions were
observed. Samples were also collected from the carcass lymph nodes, liver
and spleen if lesions were observed in those regions. Each sample was split
and submitted to the USDA, National Veterinary Services Laboratories, Diag-
nostic Bacteriology Laboratory, for culture, and Pathobiology Laboratory, for
histopathology. A lesion was reported as "compatible for mycobacteriosis" on
histopathology when the lesion was observed to be characteristic of *M. bovis*
infection and contained acid fast organisms. All samples were cultured, re-
gardless of histopathology results. A sample was negative by culture if *M.
bovis* was not isolated, and negative by histopathology if compatible lesions
were not observed.

Results

The full data report for this study will appear in a manuscript to be submit-
ted for journal publication.

For each animal, the palpation results of the skin tests performed in the
left and right caudal fold were compared. Either the results agreed (both posi-
tive or both negative) or they were discrepant (one positive and one negative).
The results for individual cattle in each PPD combination group were pooled
to determine the overall agreement between the two PPDs tested in each
In cattle receiving the same PPD in both caudal folds (Canada & Canada, Mexico & Mexico, or U.S. & U.S.), CFT palpation results agreed 86-93% of the time; the small number of discrepant results observed in each group was not statistically significant. The amount of agreement of CFT results in individual cattle tested with PPD combination groups (Canada & Mexico, Canada & U.S., and Mexico & U.S.) ranged from 76-85%. In the Mexico & U.S. PPD group, the number of cattle in which CFT results in left and right caudal folds disagreed was statistically significant, most being Mexico positive and U.S. negative.

In the subpopulation of cattle that were slaughtered, a few were positive for *M. bovis* by culture and had lesions compatible for mycobacteriosis on histopathology. Large positive CFT results had been observed in both caudal folds for each of these animals. One animal, which was from the group with discrepant CFT results (Mexico positive, Canada negative), was found on histopathology to have lesions compatible for mycobacteriosis, but *M. bovis* was not isolated from sample cultures. Other mycobacterial species were cultured from the group of cattle with negative CFTs as well as the group with discrepant CFT results. The other mycobacteria identified in the cultures included *M. avium*, *M. terrae*, *M. fortuitum*, and Runyon Group IV mycobacteria.

**Discussion**

The objective of this study was to compare performance of the North American PPDs in side-by-side caudal fold skin tests in individual cattle. In the various PPD combination groups, the CFT results agreed in 76-85% of the cattle. Some discrepant CFT results were observed in each PPD combination group, but reached statistical significance only in the Mexico & U.S. PPD group. When discrepant palpation results were observed, the size of the positive reactions was relatively small; there were no instances in which a large positive reaction on one side was accompanied by a negative reaction on the other. This demonstrates the similarities of the three PPDs regarding the size of the skin test response in individuals, as well as the difficulties in identifying infected individuals with small skin test responses.

The results of this study must be evaluated in light of our knowledge of the disease and the limitations of tuberculosis diagnostics, including skin testing, culture, and histopathology. The true infection status of individual cattle in this population was not known. Because the sensitivity of caudal fold testing is generally regarded as only about 80%, it is possible that even in individual animals where CFT results of two PPDs agreed, they might both be in error. It is also important to note that cattle reported as negative by culture and histopathology may actually have been infected - the organism may have been missed in sampling or assay.

The slaughter data adds important information regarding interpretation of
COMPARISON OF NORTH AMERICAN PPDs IN VIVO: CAUDAL FOLD TESTING

the skin test results. When *M. bovis* is not isolated, nor compatible lesions observed, in tissue samples from cattle with positive skin tests, it is often suggested that the skin test response may be due to cross reacting mycobacteria. However, in this study other mycobacterial species were isolated from some CFT negative animals, and positive CFTs were not always associated with the detection of other mycobacterial species. In this study Mexican PPD was associated with a greater number of positive CFTs than Canadian or U.S. PPD, however, it should not be assumed that these were false positives. In such cases it is possible that the organism may be present but not detected by culture or histopathology, and data should be evaluated with the advantages and limitations of both techniques in mind. Additionally, it is important to note that there are differences between the three countries regarding use of histopathology data for eradication program purposes, and in some circumstances only a positive culture is considered definitive.

Skin testing has been very useful to identify herds infected with *M. bovis*. In the current study of a high prevalence herd the amount of agreement observed between PPDs would appear to ensure comparable results. When used to identify a low prevalence herd, or infected individuals within a herd, the limitations of skin testing come into play, and the amount of disagreement between PPDs observed in this study may or may not be important, depending on how the test results are to be used. Further interpretation of the data should be made cautiously, with limitations of tuberculosis diagnostic techniques in mind. Implications of this data for import/export activities will be left to eradication program staff in each participating country.
In May 1994, due to tuberculosis concerns, the USDA proposed a rule (Docket No. 93-014-1, Cattle From Mexico) in the Federal Register to amend the requirements regarding importation of Mexican steers and spayed heifers into the U.S. In response to that proposal, on August 10, 1994, the U.S. State Veterinarians of the four border states with Mexico (Arizona, California, New Mexico and Texas) signed a “Consensus Document” in which they requested the proposed rule be withdrawn and replaced with a regulation incorporating recommendations stated in the document. In order to assure that infected Mexican cattle would not be exported to the U.S., the Consensus Document was written to provide a greater incentive for Mexican states to implement an effective tuberculosis eradication program than would be afforded by the USDA proposal.

The Consensus Document provided for a phase-in, over time, of three stages (Control/Preparatory Phase, Eradication Phase and Free) of progressively stricter requirements for a bovine tuberculosis eradication program. In order for a Mexican state to continue its eligibility to export steers and spayed heifers to the U.S., they would have to comply with the criteria for each stage. The Bi-National Tuberculosis Committee (BNC-made up of U.S. and Mexican regulatory veterinarians, border state veterinarians, industry representatives and research representatives) would review every state’s application for each stage and decide to approve or remove official state status. Annual state reviews, to determine compliance with the requirements and monitor program progress, would be conducted by tuberculosis technical personnel, under the direction of the BNC.

For various reasons, the USDA proposed rule was withdrawn in February 1995, without a substitute proposal being submitted at the time. Meanwhile, the states of Texas and New Mexico adopted the Consensus Document as part of their bovine tuberculosis state regulations. The new state regulations, effective March 1, 1995, gave the Mexican states until September 1, 1995, to fulfill the Stage 1 requirements of the Consensus Document. States not meeting these standards by the deadline would be unable to move neutered cattle into Texas and New Mexico. The BNC, in support of these new state regulations, initiated individual reviews of the tuberculosis programs in the
REPORT ON REVIEWS OF MEXICAN STATES' TUBERCULOSIS PROGRAMS

Mexican states that requested such reviews.

Technical review teams, led by the Texas Animal Health Commission (TAHC) and USDA:APHIS:VS veterinary liaisons to Mexico, Drs. Bill Brown and Cindy Gaborick, respectively, visited each state for two-to-three days. The teams ranged from four-to-seven people and included BNC members and other representatives of regulatory agencies and industry organizations. Activities included in the reviews were examinations of records and observations of tuberculin testing, animal identification and inspection procedures at slaughter establishments (i.e., slaughter surveillance), activities at animal health/movement inspection stations and laboratory activities. With the help of an extensive questionnaire, an evaluation of the overall tuberculosis program in each state was made, with specific assessment of achievement of the Stage 1 requirements of the Consensus Document. Stage 1 state status requires the existence of the following six items:

1. Functional State Animal Disease Committee with State/Federal/Industry Representatives
2. State Regulatory Authority to Implement and Enforce a Tuberculosis Eradication Effort
3. Agreement Between the State/Federal/Industry to Accept the Norma Official Mexicana (NOM) (i.e., the Mexican federal regulation counterpart to the U.S. Uniform Methods and Rules for Bovine Tuberculosis Eradication) as the Minimum State Standard
4. Functional Infrastructure of Veterinary Expertise and Authority Sufficient to Apply All Aspects of the Tuberculosis Eradication Program
5. Initiated Systematic, Organized, Large-Scale Area Testing and Begun Implementation of Effective, Reliable Slaughter Surveillance
6. Implemented Educational Aspects of the Tuberculosis Eradication Program

After a review is conducted, a written report of the findings and recommendations of the review team is submitted to the BNC. Based on this information, the BNC then votes on whether or not to approve the state for Stage 1 status. This decision is passed on to the TAHC and the New Mexico Livestock Board, who have agreed to accept the recommendations of the BNC.

From June-September, 1995, 12 state reviews were conducted in the northern and central Mexican states of Tamaulipas, Coahuila, Nuevo Leon, Sonora, Chihuahua, Durango, Zacatecas, San Luis Potosi, Aguascalientes, Sinaloa, Baja California Norte and Jalisco (listed in order of visitation). Two more reviews, in Veracruz and Yucatan, are planned for October. As of September 30, 1995, of the 31 states and one federal district in Mexico, only the above 14 states had requested reviews.

In general, the reviewers noted the same tuberculosis program weaknesses in many of the states. The major recommendations made to address these recurrent findings were the following:
1. Review Tuberculin Testing Procedures
2. Intensify Area Testing
3. Improve and Expand Slaughter Surveillance
4. Conduct Thorough Epidemiologic Investigations
5. Address the Tuberculosis Problem in Dairy Herds
6. Follow the NOM

The caudal fold tuberculin test procedures observed were of particular concern with regard to obtaining accurate test results (Note- comparative cervical and single cervical testing were uncommon in most states and were not observed). Varying lengths and gauges of needles, with assorted tuberculin injection techniques, were noted. Automatic syringes were popular in some states. Subcutaneous, instead of intradermal injections, were common. The number of reported caudal fold responders was very low, generally lower than the number of expected false-positive reactions. In one state, there were zero reported responses out of 86,202 caudal fold tests performed. In another state, only one caudal fold response was reported out of 107,420 tests conducted. In addition, animal identification with official silver eartags was often lacking. The reviewers stressed the necessity of a good caudal fold tuberculin test, consisting of the intradermal injection of 0.1 ml of bovine PPD and the recording of any visible or palpable reaction as a positive response. Training, addressing correct tuberculin testing equipment and procedures, is definitely needed. In response to this need, the TAHC produced a videotape demonstrating tuberculin testing techniques, for distribution to the Mexican states by the National Commission for the Eradication of Bovine Tuberculosis and Brucellosis (CONETB) in Mexico City, Mexico.

Only Sonora has progressed very far in area testing, having tuberculin tested 98% of their cattle herds once and almost one-third of their herds twice. The other states are not as advanced in their area testing and will need to intensify testing if they hope to fulfill the Stage 2 requirement of the Consensus Document, requiring completion of area testing of at least 75% of all beef and dairy cattle (this requirement may only pertain to testing of adult breeding animals but it, and other Stage 2 criteria, need further future clarification by the BNC/Texas/New Mexico).

Of the six Stage 1 requirements, deficiencies were most often noted in implementation of effective, reliable slaughter surveillance. Slaughter surveillance was being conducted in only some of the plants. In some slaughtering establishments with inspection for tuberculous lesions, not all of the cattle were inspected and/or only very superficial inspections were performed. In addition, identification procedures to correlate the hide, carcass, head, viscera and pluck to an individual animal were often non-existent or inadequate to enable accurate determination of the particular animal in which a lesion was found and subsequent tracing of that animal back to its herd of origin. If any tracing could be done, in many cases the trace would dead-end at an
animal lot. Eartags were not being collected to aid in tracebacks. Two states had not made any laboratory submissions for confirmation of tuberculosis in suspicious tuberculous lesions found during routine slaughter surveillance. Laboratory submissions for tuberculosis confirmation in Baja California Norte and Sonora far exceeded those in other states. Training is needed to ensure a thorough inspection for tuberculous lesions, with a functional correlation system of animal parts and adequate records to enable successful tracebacks.

Epidemiologic investigations were sometimes found to be non-existent or if conducted, performed inconsistently. The importance of accurate traces to infected herds of origin was stressed by the reviewers, as was tracing in and out of infected herds and testing of adjacent herds.

The prevalence of tuberculosis in Mexican dairy herds is estimated to be quite high. In part, due to the lack of indemnity for reactor animals, dairy producers are reluctant to test their herds or, if tested, producers are averse to slaughtering tuberculin reactors. Consequently, in regard to dairies, the states are generally not applying the strict requirements in the NOM. However, the NOM has been revised, and the updated version, available soon, reportedly provides special tuberculosis program concessions for dairies. In practice currently, if a dairy herd is tested for tuberculosis, it may or may not be quarantined when reactors animals are found. Often times infected herds are not being compelled to undergo repeat testing. If not slaughtered, reactor animals usually are not segregated from the rest of the herd. The tuberculosis problem in dairies needs to be addressed. If immediate slaughter of tuberculin reactors is not a viable option, then management factors should be instituted to decrease the risk of disease spread to other animals and humans.

In light of the fact that Texas has excluded importation of Mexican Holstein crossbred steers and spayed heifers, in addition to Holstein steers and spayed heifers excluded due to a USDA requirement, one state was particularly concerned about potential tuberculosis dissemination by dairy crossbred animals (physically indistinguishable from beef breeds) entering beef herds or feedlots. A Mexican veterinarian proposed the permanent identification of dairy origin calves so that there would be no mistaking their lineage.

The final recurring recommendation made was to follow the procedures listed in the NOM. Reasons for not complying with the NOM included unavailability of equipment (e.g., silver eartags and correct size and gauge of needles for tuberculin testing), misunderstanding of requirements, uncooperative producers (e.g., those averse to herd testing, slaughter of tuberculin reactors and using official eartags) and lack of training/knowledge (e.g., still using the old skin thickness measurement method for interpreting caudal fold tests). Considering that the NOM is obligatory in all of Mexico and that Stage 1 requirements of the Consensus Document included acceptance of the NOM as the state minimum tuberculosis standard, then the states should be applying the NOM, at least as the minimum standard.
The reviewers had many compliments for the Mexican tuberculosis programs. The animal movement controls in place in the states were impressive. Support for the tuberculosis programs was evident, with producers shouldering much of the economic burden for the programs. State support was particularly visible in Durango and San Luis Potosi. Excellent promotional/educational activities had occurred in some states. The people who worked in the tuberculosis campaigns were enthusiastic, candid about their programs and open to suggestions for improvement.

Based on the findings and recommendations of the review teams, the BNC and subsequently, the states of Texas and New Mexico, have made a decision concerning the state status of eight reviewed states. Tamaulipas, Coahuila, Nuevo Leon, Sonora and Chihuahua have been granted approval for Stage 1 status. Tamaulipas was initially denied approval, due to deficiencies in slaughter surveillance but submitted evidence of sufficient progress in this area after the review visit was conducted. Durango, Zacatecas and San Luis Potosi have received Provisional approval for Stage 1 status due to immature slaughter surveillance programs. These programs must be developed and expanded by early 1996 in order to maintain recognition of Stage 1 status.

Aguascalientes, Sinaloa, Baja California Norte and Jalisco were recently reviewed and, as of September 30, had not been discussed by the BNC. Due to major deficiencies in three of these states, the reviewers recommended approval of Stage 1 status for Baja California Norte only. Inadequate area testing and slaughter surveillance was found in Aguascalientes. The slaughter surveillance program was weak in Sinaloa. Jalisco lacked the functional infrastructure and authority to apply all aspects of the tuberculosis eradication program and had not initiated large scale area testing.

In conclusion, based on reviews in 12 Mexican states, the tuberculosis eradication program is progressing in Mexico. Some states are significantly more advanced in their programs than others. Training is needed to assure accurate tuberculin testing and slaughter surveillance programs. Area testing needs to be intensified to meet Stage 2 requirements of the Consensus Document. All eight states discussed by the BNC were recognized as having achieved Stage 1 status. Three of these were provisional recognitions, due to immature slaughter surveillance programs. Of the four more states reviewed, only one was recommended for Stage 1 status approval by the review teams. The other three were found deficient in varying areas. Two additional states are scheduled for review in October. The advances in the Mexican bovine tuberculosis eradication program are to be commended and continued progress is strongly encouraged.
REPORT OF THE COMMITTEE ON TUBERCULOSIS

Chairman: Dr. Bob R. Hillman, Boise, Idaho
Vice Chairman: Dr. Dennis Thompson, Sacramento, California

The Committee on Tuberculosis met on Wednesday, November 1, 1995 from 1:30 P.M. to 5:30 P.M. and Thursday, November 2, 1995 from 1:30 P.M. to 6:15 P.M. Eighteen papers and reports were presented to over 85 committee members and guests.

Dr. Mitchell Essey, Cattle Diseases and Surveillance Staff, presented a report on the Status of the United States Bovine Tuberculosis Eradication Program for Fiscal Year 1995. Dr. Essey reported that two states, North Carolina and Kansas, gained Accredited-Free Status and Virginia reverted to Modified Accredited Status, bringing to 44 the number of Accredited-Free States at the end of fiscal year (FY) 1995. A total of nine infected herds were accountable, of which two were newly infected and seven were carried over from previous years. The two new herds included one dairy herd in Wisconsin and one beef herd near El Paso, Texas. The Texas herd was most likely infected by association with Mexican origin steers. No herds were depopulated during FY 1995. Cattle imported from Mexico reached an all time high with 1,600,000 head imported, which was 400,000 head greater than the previous high. A total of 136 tuberculosis cases were detected at regular slaughter, a drop of 78% from the high of 613 cases reported in FY 1992. Of 201 cases completed during FY 1995, 63% traced to Mexico, the lowest percentage in almost a decade. All indicate advancements in Mexico's tuberculosis eradication program.

There were ten known *M. bovis* infected captive cervid herds during FY 1995, which included two newly detected herds (one each in New York and Michigan) and eight herds carried over from previous years. Four cervid herds were depopulated and two were released from quarantine, bringing to four the total number of herds remaining quarantined. There is one quarantined herd in each of the following states: Colorado (elk), Texas (elk), Missouri (elk), and South Carolina (deer). Federal indemnity became available for tuberculous cervidae in June 1995. The indemnity rate for cervidae is the same as that for cattle and bison, up to $750.00 for reactors and $450 for exposed animals.

Dr. Armando Mateas, Director of the Mexican National Brucellosis and Tuberculosis Program, presented a status report on the Mexican Tuberculosis Program. Dr. Mateas reviewed the basic components of the Mexican program which includes State Committees, Norma Oficial Mexicana (UM&R), reliance on Accredited Veterinarians, animal movement controls and slaughter house surveillance. Currently Mexico has 32 state coordinators, 163 district supervisors, 8 regional laboratories and 20 support staff working in the program.
REPORT OF THE COMMITTEE

From January through September, 1995, 2,255,700 tuberculin tests were performed. The goal is to test three million head. During the same period, 425 herds were certified as Accredited Free and 2,118 herds were certified as first test herds.

When slaughter surveillance yielded tuberculous lesions and the blue eartag number was provided to Mexico, they were able to trace 91.5% of such cattle to the herd of origin. They were able to trace back only 18% of cases when the blue eartag was not recovered.

Slaughter surveillance disclosed 440 lesioned animals out of 858,588 animals slaughtered. Eight laboratories reported 317 histopathology compatibly cases and 74 culture positive cases out of 1,152 samples received.

Dr. Ron Rogers, Domestic Diseases Control Section, presented a report on Canadian Tuberculosis Program. Dr. Rogers reported that all Canadian Provinces are Tuberculosis Free except Ontario, which had a resurgence of tuberculosis on a premises which had been depopulated because of tuberculosis in 1992. After the premises was repopulated, the new herd was tested in 1994. A number of animals exhibited large skin responses. Responders were destroyed, but no M. bovis was isolated. The herd was depopulated. No tuberculosis infected cattle have been discovered in 1995.

Dr. Rogers reported that Canada is employing DNA fingerprinting as an epidemiological tool to aid in determining the possible origin and spread of tuberculosis in livestock and other species.

Dr. Rogers also reviewed the Canadian Captive Ungulate Program, which was implemented in 1988 to protect the Canadian cattle population from potential risk posed by the unknown health status of ranched cervidae and bison. Under this program, ranched cervidae and bison are tested every three years for bovine tuberculosis and brucellosis. If bovine tuberculosis or brucellosis are discovered, all susceptible animals on the premises are destroyed. Since the inception of this program 20 cervid herds have been depopulated because of bovine tuberculosis. Eighteen of these herds were in Alberta. As a result of the outbreak in Alberta, movement controls were initiated in 1991. All ungulates, except cattle, sheep, goats and swine are required to move on permits issued by Alberta officials.

Dr. Hector Campos, Co-Chairman of the Bi-National Tuberculosis Committee, reported on the activities of that Committee during the last year. The Bi-National Tuberculosis Committee met in Cancun, Mexico on June 13, 1995. In that meeting the main topics included an evaluation of reviews of several Mexican state programs; a report on lesions and brucellosis serology of cattle slaughtered in Texas; and the Texas and New Mexico proposed rules for importation of Mexican steers.

On June, 28, 1995, members of the Bi-National Committee participated in the Open Forum on Tuberculosis and Brucellosis, hosted by the Texas Animal Health Commission, in San Antonio, Texas. On October 7 and 8, 1995 several members of the committee visited the School of Veterinary Medi-
TUBERCULOSIS

cine and Zoosanitary Regulatory Unit in Mexico City.

On October 29, 1995, the Bi-National Tuberculosis Committee met here at Reno to discuss the report of the review groups that had visited fourteen Mexican states to determine if the states met the criteria for Stage One of the Consensus Document. The committee also discussed the need to include brucellosis in the activities of the committee. The committee determined that brucellosis should be included and recommended that the Chairman of the Committee on Brucellosis of the USAHA be included as a member of the Bi-National Committee.

Dr. Scott Hurd presented a report on Tuberculosis in the El Paso Milkshed-Current Field Research Projects. Tuberculosis in the El Paso milkshed is still a significant problem. Most of the U.S. quarantined herds are in this area. Many herds have been on and off quarantine for at least 10 years. The human tuberculosis rate in El Paso is reported to be three times higher than the national average. The El Paso area is a major port for Mexican cattle imports. The neighboring city of Juarez, Mexico also has 9 large dairies that are infected with tuberculosis. The El Paso area represents a milieu of tuberculosis problems, therefore a broad analysis and description of the problem is indicated. APHIS, in cooperation with the Texas Animal Health Commission and Texas A & M University, has begun a series of projects to address hypotheses relative to this problem. These questions and projects are as follows:

1. Is there any difference in management, location or other factors that put some herds at risk for continued tuberculosis infection? In November 1993 a case-control study of quarantined and non-quarantined dairy herds in the southwestern U.S. was initiated. An extensive survey was conducted on 7 quarantined or previously quarantined herds and 27 control herds in Texas, New Mexico, California and Arizona. Control herds were defined as those with greater than 500 milk cows and no history of TB quarantine. A variety of factors were examined including herd size, source of original herd, replacement stock, number and history of hired workers, neighboring livestock and distance from the U.S.-Mexican border. Analysis of these factors suggests that proximity to the border is a significant factor. This was the only variable that was statistically significant.

2. Is there a spatial relationship to explain infection, such as soil, water, wind or vectors? Logistical regression analysis suggests the closer any El Paso dairy is to a particular Mexican dairy the greater the herd's risk of being quarantined.

3. Are there certain disease dynamics in large herds that preclude the success of any test and removal program? What is the role of herd size, herd expansion, culling rates, and test sensitivity on disease spread and maintenance? A computer simulation model is being developed to model a 5,000 animal dairy. Using different assump-
REPORT OF THE COMMITTEE

tions about test sensitivity and specificity, prevalence rates, and disease spread, researchers can simulate the time it would take to detect and remove all infected animals in a herd, and determine if it is possible given our current tools.

4. Is the same subtype of \textit{M. bovis} causing the problems in Juarez, Mexico and the U.S.? Plans are underway to get Mexico's assistance in obtaining lesions from dairy animals slaughtered in Juarez. These would be sent to NVSL and Texas A&M for subtyping and comparison with U.S. isolates.

5. What is the role of humans in transmission of \textit{M. bovis} to animals and vice-versa? Preliminary plans have been made with the health department to conduct speciation on all Mycobacteria complex positive cases to determine how much of the human tuberculosis is caused by \textit{M. bovis} and evaluate the risk humans pose to cattle.

6. What is the role of vectors (rodents, birds, dust, cattle) in transmitting disease between herds? Plans are underway with Texas A&M, TAHC and Animal Damage Control to collaborate bird and environmental testing during the next year.

Dr. William H. Brown, Bi-National Office of the Texas Animal Health Commission, reported on Slaughter Surveillance of Cull Mexican Cows and Bulls in Texas Slaughter Plants. Dr. Brown reported that cattle from Mexico enter Texas under various permits and testing regimens, depending on category of cattle (i.e. steers, spayed heifers, or sexually intact). Disease testing is not required for direct shipment of slaughter cattle. A two-fold project was initiated on Mexican slaughter cattle to determine the prevalence of brucellosis and tuberculosis and provide an accurate method for traceback to the Mexican state and herd of origin.

Cattle from thirteen Mexican states are represented in the project. The results of the project disclosed that 34 TB lesioned cattle were found in 65,233 cattle slaughtered, for a prevalence rate of 0.05%; and 214 brucellosis reactors and suspects were found in 65,233 cattle slaughtered, for a prevalence of 0.33%. The 34 TB lesioned cattle originated in six Mexican states, with the majority originating in Coahuila and Nuevo Leon. The 214 brucellosis reactors and suspects originated from eleven of the thirteen Mexican States.

Dr. L. Garry Adams, Texas A&M University reported on the status of the Texas Cattle and Deer Tuberculosis Management Plan. Representatives from a number of Texas agencies have collaborated in the development of a management plan to address the re-emergence of tuberculosis in Texas. This plan consists of regulatory, education and research solutions to prevent and manage bovine tuberculosis. The plan addresses the cause of tuberculosis, causes for re-emergence in animals, impacts of TB, and presents solutions.

Dr. Adams reported that solutions to the Texas TB problem include Public Health, Regulatory, Education and Training and Research components. The paramount goal of the plan is to eradicate bovine tuberculosis from the live-
Dr. Cindy Gaborick, Bi-National Tuberculosis Committee technical representative, presented a report on Reviews of Mexican States’ Tuberculosis Programs. Dr. Gaborick reported that there were a number of weaknesses and strengths in various state programs and concluded that the tuberculosis eradication program is progressing in Mexico. The full text of this report will be published in the proceedings.

Dr. Joe Templeton, Texas A&M University, presented a Summary of BTB Testing in Cattle, Cervidae and Zoo Animals at the Texas A&M University BTB Laboratory. Dr. Templeton reported that since their laboratory began testing cervidae for tuberculosis in 1994, the laboratory has expanded the service to cattle producers and zoos. In cervids, the BTB test is used as developed by the University of Otago in New Zealand. In cattle and zoo animals, whole blood lymphocyte cultures are compared to isolated lymphocyte cultures. When whole blood lymphocyte culture results are equal to or better than what is observed with isolated lymphocytes, subsequent tests are conducted using whole blood. Cattle BTB tests described in this report were conducted with whole blood cultures. Between May 15, and October 21, 1995 the laboratory conducted 765 cervidae tests, 1,018 cattle tests and 193 zoo tests.

Dr. Templeton reported that in cattle tested by BTB, where post-mortem M. bovis culture results and caudal fold test results were available the following results were obtained:

Caudal Fold Test Versus Culture Results.
- Specificity - 34.8%
- Sensitivity - 93.7%
- Efficiency - 77.9%

BTB Versus Culture Results.
- Specificity - 95.7%
- Sensitivity - 93.7%
- Efficiency - 94.2%

Dr. Belinda S. Lawler Goff, USDA/ARS/NADC, presented a paper entitled Comparison of North American PPD’s in vivo: Caudal Fold Testing. This project compared the tuberculin purified protein derivatives (PPD’s) used in caudal fold skin testing of cattle for tuberculosis eradication programs in Canada, Mexico and the United States. The text of this paper will be published in the proceedings.

Dr. Thomas A. Ficht reported on The Use of Molecular Markers in Typing Mycobacterium bovis isolates from Texas and Mexico. Dr. Ficht reported that molecular probes were used to characterize bovine M. bovis isolates from around Texas. IS6110 is an insertion element found only in M. tuberculosis complex organisms which can duplicate itself and insert at random sites.
within the *M. bovis* genome. Typically *M. bovis* isolates have from 1-5 copies of IS6110. Analysis of 95 Texas and Mexican *M. bovis* isolates identified up to 80% with a single copy of IS6110. The remaining 20% of the isolates contained 2-5 copies of IS6110. This is an unusually high number compared with previous studies which showed a strong correlation between multiple copies of IS6110 and isolation from wildlife. Overall, 18 different IS6110 profiles were identified in the Mexican and Texas isolates. A second probe, designated DR (direct repeat) was used to increase the ability to distinguish among strains. Using both probes, 32 different genomic profiles were characterized. The use of these profiles permitted a better description of the distribution of *M. bovis* isolates around Texas and Mexico. Overall, nonclustered isolates were found to be geographically distributed throughout Texas and Mexico and presumably represent recrudescence. Clustered isolates, characterized by multiple isolates, were also found to be geographically distributed throughout Texas and Mexico and suggest active transmission and movement of infected animals.

Dr. Mark A. Schoenbaum, USDA/APHIS/VS, presented the results of a study on the Comparison of Testing Protocols, Including a Gamma Interferon Test, for Bovine Tuberculosis in Two Infected Cattle Herds in Texas. The objectives of the study were to describe two cases of bovine tuberculosis and the testing of the herds with conventional tuberculin and gamma interferon tests. Meat inspectors in Texas detected bovine tuberculosis in two carcasses during routine inspection of adult cattle. Investigation by regulatory veterinarians led to two unrelated infected herds in Texas, a dairy and a beef herd. Officials tested the herds with the caudal fold tuberculin test. They tested positive cattle with an in-vitro cellular assay and in one herd, the comparative cervical tuberculin test. The producers ultimately elected to destroy the herds. Officials detected *Mycobacterium bovis* infection in 22% and 24% of the cattle on extensive postmortem examination. The sensitivity of the caudal fold tuberculin test for postmortem detection of tuberculosis was 86% and 94.5%. Positivity to the gamma interferon or comparative cervical test was associated with postmortem detection of tuberculosis (p < 0.0001) indicating that supplemental testing of caudal fold positive cattle may improve discrimination of infected animals. The results of supplemental tests did not appear correlated to the extent of visible lesions among the cattle detected to be tuberculous. The gamma interferon and comparative cervical tests performed equivalently in one herd. The different methods of calculating the gamma interferon test result did not appear to alter the results greatly. The study discusses the weaknesses of the gold standard, the need for monitoring slaughter surveillance, and the potential use of the gamma interferon test in place of the comparative cervical test in the U.S. eradication program.

Dr. Jere L. Dick, AVIC - New Mexico, reported the Results of Statewide Milk Ordinance Testing In New Mexico Dairy Cattle. Dr. Dick reported that there are 160 dairies in New Mexico. Records indicated that only 29/160
TUBERCULOSIS

(18%) of the herds had been tested within the past three years, as is required by the Pasteurized Milk Ordinance (PMO). Twenty-one of these herds had been tested during an area test of the Las Cruces/El Paso milkshed in 1994. This meant that only 8/160 (5%) of New Mexico dairies were complying with the PMO. The last complete statewide test had been conducted in 1985. Officials recognized that there were a significant number of risk factors within the state of New Mexico, including:

2. History of dairy heifers being raised next to Mexican steers, which have a higher risk of being infected.
3. Immigrant labor force used widely on dairies as milkers/calf feeders, who have a higher incidence of TB, and in turn expose cattle.
4. Rapidly expanding dairy populations, which provides an excellent susceptible population for TB to become established.
5. Slaughter surveillance which may be inadequate, at early or low prevalence levels, to detect infection.

In the spring of 1994, Veterinary Services and the New Mexico Livestock Board tested 21 dairies in the Las Cruces/El Paso milkshed. One tuberculosis infected dairy was disclosed on this area test. This factor led officials to initiate the PMO testing in the spring of 1995.

Forty-two accredited veterinarians tested 123,135 cows on 113 dairies in the spring of 1995. They discovered 2,106 CF responders. Comparative cervical testing by Veterinary Medical Officers identified 74 suspicious animals. All of these animals were slaughtered, a thorough postmortem conducted, and tissues submitted for histopathology and culture to NVSL. Two animals were found to have compatible lesions, but cultures were negative. One of these herds has been retested, with negative results. The other is scheduled for retest.

Dr. Robert Meyer, Regional Tuberculosis Epidemiologist, presented a report of a recent study to evaluate the specificity of the IDEXX M. bovis Gamma Interferon Assay. Almost 1,500 dairy cattle with a negative tuberculin test history were tested with the IDEXX Assay. Results indicated a specificity between 90% and 97.8%, depending on the bovine/avium cutoff ratio selected and on the number of assays conducted in series on samples having an initial ratio of 1.3 or higher.

Dr. Dan Baca, epidemiologist for the Texas Animal Health Commission, reported that only two dairies near El Paso and one elk herd are currently quarantined in Texas. Three dairies were released from quarantine during the past year. Tuberculosis was confirmed in a beef herd as a result of slaughter surveillance. Exposure was probably from M-branded steers. That herd has been depopulated. Dr. Baca also informed the Committee about new Texas regulations which implement the Cervid UM & R. Those regulations exceed UM & R guidelines in some significant areas. These include samples from hunter killed cervids and required change of ownership tests for cervids at
REPORT OF THE COMMITTEE

livestock markets.

Dr. Jack Rhyian, of the National Veterinary Services Laboratory, and Dr. Mitchell Essey, Staff Veterinarian for Veterinary Services, described how a small group of inoculated llamas and controls were tuberculin tested at three different sites of injection. Test results indicate use of bovine and avium tuberculins appropriately classified llamas.

Mr. Bob Frost, representing the International Llama Association, reiterated that there is no known tuberculosis in llamas or alpacas in North America. He stated that results of research projects by USDA/Argentina and NVSL are being evaluated. Serologic tests and tuberculin injection sites are being analyzed.

Dr. Mitchell Essey was asked to explain the requirements for approval of diagnostic tuberculosis tests. A number of committee members believe that a standard protocol for evaluation of tests is necessary so that potential producers of tuberculosis tests have a full knowledge of the requirements for approval at the beginning of test development.

The lack of such a protocol has resulted in a great amount of disagreement among committee members regarding status of the Gamma Interferon Assay. The Committee discussed requesting the Scientific Advisory Subcommittee (SAS) to develop a standard protocol. However, such action would result in a delay in further research since the SAS would have to bring their recommendations to the next meeting of the Committee on Tuberculosis for approval.

In order to address the immediate problem in a timely manner, the Committee established a special subcommittee. The special subcommittee is charged with the following:

1. Develop a guideline for the evaluation and approval of an official tuberculosis test, especially the Gamma Interferon test.
2. Identify data gaps present in the current knowledge of the test.
3. Facilitate development of research projects which address those data gaps and provide information necessary to thoroughly and accurately evaluate the test.
4. Compile results of research projects and present these results for deliberation by the full Committee, at the 1996 annual meeting.

The Committee recommended that representatives of the following agencies participate in this special subcommittee: Veterinary Services (Epidemiologist), ARS, CEAH, NVSL, Veterinary Biologics, Texas Animal Health Commission, Texas A&M, AAVLD and IDEXX. Dr. Dick Sherron, Texas Animal Health Commission was appointed as chairman of the special subcommittee.

The Committee also recommended that the guideline developed by the special subcommittee be presented to the Scientific Advisory Subcommittee to serve as a potential template for development of a standard protocol for approval of all tuberculosis tests. The SAS was charged with presentation of
The Committee considered nine recommendations and adopted six. Five of those pertained to changes in the Uniform Methods and Rules for Cervids (Cervid UM&R) and the sixth requests completion of a study by Veterinary Services (VS). The following recommendations were adopted.

I. Revise Part II, H. - Reporting of tests, in the Cervid UM&R to reflect the following changes.

A report of all tuberculosis tests (SCT, CCT, and BTB) shall be submitted in accordance with the requirements of cooperating State and Federal officials. The BTB test and other in vitro laboratory test results shall be reported by the authorized testing laboratories. This report shall include the identification of each animal by earatag number (or tattoo), age, sex and breed, and a record of the size of the response, where indicated, and the test interpretation. Summary supporting BTB test data shall be included in reports submitted to State and Federal officials and full supporting data be submitted on a case by case basis.

II. Revise Part II M. 3. a. - Retest schedules for high-risk herds

If bovine tuberculosis is confirmed in the exposed animal(s), the remainder of the receiving herd shall be classified as an infected herd, and handled according to Part II L. 2. of these Uniform Methods and Rules. -tested with the SCT test by State or Federal veterinarians. The BTB test may be used, provided that it is used simultaneously with a whole herd SCT test. All animals positive to either test shall be classified as reactors.

III. Revise Part II M. 3. b.

If negative to the test, the exposed animals will subsequently be handled as if they were part of the infected herd of origin for purposes of testing, quarantine release, and the five annual high-risk tests also the. The remainder of the herd shall be tested at the time of the initial investigation and retested in 1 year with the SCT. Supplemental diagnostic tests may be used if needed.

IV. Add the new wording below to Part I - Definitions, and Part III - Herd Status Plans to create the new status of Surveyed Herd.

Part I - Definitions

Surveyed Herd-A herd on which identification records are maintained for animals over one year of age that are slaughtered and inspected for tuberculosis at an approved State or Federal slaughter facility or an approved laboratory, or tested negative for tuberculosis in accordance with requirements for interstate movement. The initial qualifying total herd size is the annual average of animals over one
REPORT OF THE COMMITTEE

year of age during the initial test period, which period shall not exceed three years. The animals slaughtered or tested negative for tuberculosis in accordance with the requirements for interstate movement must be identified to the herd, and the number of animals in the sample must be at a rate to detect infection at a 2% prevalence level with 95% confidence. For maintenance of Surveyed Herd status, the sample must be evenly distributed over a three-year period and no less than half must be officially inspected at slaughter. (see appendix 4)

PART III - HERD STATUS PLANS

Surveyed Herd plan for Cervidae

1. Requirements-For a herd to be eligible for Surveyed Herd status, identification records must be maintained on animals over one year of age slaughtered, inspected and found negative for tuberculosis at an approved slaughter facility or at an approved diagnostic laboratory or tested negative for tuberculosis in accordance with the requirements for interstate movement. The initial qualifying total herd size is the annual average of animals over one year of age during the initial test period, which period shall not exceed three years. A Surveyed Herd must identify animals over one year of age at slaughter or tested negative for tuberculosis in accordance with the requirements for interstate movement at a rate to detect infection at a 2% prevalence level with 95% confidence evenly distributed over a three year period and no less than half must be slaughter inspected.

2. Maintenance of Surveyed Herd Status-For Surveyed Herd status to be renewed, an annual report shall be submitted by the person, firm or corporation responsible for the management of the herd to the cooperating State or Federal official prior to the anniversary date. This report shall give the number of animals currently in the herd and the number of animals over one year of age identified and slaughtered at a State or Federally approved slaughter facility or tested negative for tuberculosis in accordance with the requirements for interstate movement during the preceding year. The number of slaughter inspections or tested negative for tuberculosis in accordance with the requirements for interstate movement reported in any given year must be at least 25% of the number required to initially qualify a herd of this size for Surveyed Herd status, provided, however, that during each consecutive three-year period, 100% of the initial qualifying total shall be achieved in order to maintain Surveyed Herd status.

3. Additions

Herd additions must originate directly from one of the following:

   a) an Accredited or Qualified Herd
   b) a Surveyed or Monitored Herd provided that the individual
TUBERCULOSIS

animals for addition were negative to an official tuberculosis test conducted within 90 days prior to entry.

c) A herd not meeting the requirements of (a) or (b) in this section. Individual animals for addition must be isolated from other members of the herd of origin and must have negative results to two official tests for tuberculosis, conducted at least 90 days apart, provided that the second test was conducted within 90 days prior to movement to the premises of the Surveyed Herd. The additions must be kept in isolation from all members of the Surveyed Herd until they are negative to an official tuberculosis test conducted at least 90 days following the date of entry.

Animals added under (c) shall not receive Surveyed Herd status for sale or movement purposes until they are negative to a retest 90 days after entry.

V. Make the changes depicted below to Part I - Definitions, Part II - Recommended Standards, and Part III - Herd Status Plans. All of the changes in V. pertain to Monitored Herds.

PART I - DEFINITIONS

Monitored Herd-A herd on which identification records are maintained for animals over one year of age that are slaughtered and inspected for tuberculosis at an approved State or Federal slaughter facility or an approved laboratory. The initial qualifying total herd size is the annual average of animals over one year of age during the initial test period, which period shall not exceed three years. The animals slaughtered must be identified to the herd, and the number of animals in the sample must be evenly distributed over a three-year period, at a rate to detect infection at a 2% prevalence level with 95% confidence. This rate would require a maximum number of 148 animals. (see appendix 1)

PART II - RECOMMENDED STANDARDS (MINIMUM REQUIREMENTS)

G. Interstate or International Movement

7. Cervids less than twelve months of age, that originate from and were born in Qualified, Monitored or Surveyed Herds, may move without further tuberculosis testing, provided they are accompanied by a certificate stating that such cervids originated from such herds and have not been exposed to cervids from a lower status herd.

8. Institutions that have been accredited by the.... (Note, this is the beginning of current paragraph 7. If this recommendation is implemented, what is currently paragraph 7. would become paragraph 8.)
PART III - HERD STATUS PLANS

A. Accredited Herd plan for Cervidae
   1. Animals To Be Tested-Testing of herds for accreditation or reaccreditation shall include all Cervidae and all other hoof stock over 12 months of age and animals under 12 months of age that are not natural additions, except such animals born in and originating from Accredited Herds.

C. Qualified Herd plan for Cervidae
   1. Animals To Be Tested-Testing of herds for qualification shall include all Cervidae over 12 months of age and any animals under 12 months of age that are not natural additions except such animals born in and originating from Accredited or Qualified Herds. All natural additions shall be individually identified by official eartag and be recorded on the test charts as members of the herd at the time of the herd test.
   2. Qualifying Standards-To meet the requirements for Qualified Herd status, the herd must be administered, within a seven-month period, one official test for tuberculosis with results indicating no evidence of bovine tuberculosis. The Qualified herd status remains in effect for 12 months following the qualifying test.
   3. Additions-Herd additions must meet the criteria defined in part III, Section B(3).
      Herd additions must originate directly from one of the following:
      a) an Accredited or Qualified Herd
      b) a Monitored or Surveyed Herd provided that the individual animals for addition were negative to an official tuberculosis test conducted within 90 days prior to entry.
      c) A herd not meeting the requirements of (a) or (b) in this section. Individual animals for addition must be isolated from other members of the herd of origin and must have negative results to two official tests for tuberculosis, conducted at least 90 days apart, provided that the second test was conducted within 90 days prior to movement to the premises of the Monitored Herd. The additions must be kept in isolation from all members of the Monitored Herd until they are negative to an official tuberculosis test conducted at least 90 days following the date of entry. Animals added under (c) shall not receive Qualified Herd status for sale or movement purposes until they are negative to a retest 90 days after entry.
TUBERCULOSIS

(Note, if the new status of Surveyed Herd is adopted, it is intended that it have equivalent status to a Monitored Herd with regards to additions to herds of various status. This includes changes to Part III, A., 3., b.)

VI. USAHA recommends to APHIS, Veterinary Services, to develop and implement a field project, in close concert with industry, that will compare current equipment used in application of the CCT in cervids with other types of constant pressure calipers.

Evaluation of the results of that project then needs to be provided to the Scientific Advisory Subcommittee for their review prior to the 1996 USAHA meeting.

The Committee considered six resolutions and approved four pertaining to the following topics:

1. Requests USDA compile specific data re test and laboratory results pertaining to cervids, and requests that the Scientific Advisory Subcommittee be provided that data for analyses;
2. Expansion of the role of the Binational Tuberculosis Committee to include Brucellosis;
3. Deletion of charges for USDA, FSIS to conduct inspection of cervidae at USDA inspected abattoir;
4. Adding definitions and responsibilities of a Designated Tuberculosis Epidemiologist and Individual Herd Plan to the Cervid UM&R.
During the 1995 fiscal year (FY), real progress can be documented toward the final eradication of bovine tuberculosis. The three areas that have been barriers to eradication; tuberculosis in Cervidae, tuberculosis in large dairies, and tuberculosis in Mexican-origin feedlot animals, have shown measurable improvement during the past 12 months. Federal regulations are being considered to regulate the interstate movement of Cervidae in accordance with the Uniform Methods and Rules (UM&R). The United States is working, in cooperation with the Mexican government and the United States/Mexico Bi-National Tuberculosis Committee, to identify all cases of tuberculosis attributed to Mexican-origin cattle in the United States and to review the tuberculosis program status of the various Mexican States. Herd plans to eradicate tuberculosis infection have been implemented for the three tuberculosis-infected herds in the El Paso milkshed.

During FY 1995, the National program added Kansas and North Carolina to the list of States that are Accredited-Free and removed Virginia’s Accredited-Free status. There were nine herds in the United States known to be infected with bovine tuberculosis this FY. Of these, seven herds were carried over from the previous FY and two were detected during FY 1995. The newly detected herds consisted of one beef herd in Texas and one dairy herd in Wisconsin.

Mexico continues to make strides toward the eradication of bovine tuberculosis. FY 1995 realized the first strong evidence that the Mexican eradication efforts were resulting in a decrease in the number of cases of tuberculosis from Mexican-origin feedlot cattle. Before 1995, a direct, linear association was seen with comparing the number of cases of tuberculosis to the numbers of Mexican-origin feedlot animals imported over the previous two fiscal years. With no changes in import practices or in the status of the Mexican tuberculosis program, 517 cases of tuberculosis were expected during 1995. Since only 136 cases of tuberculosis were seen during 1995, it can be assumed that the ban on Holstein imports and the implementation of the Mexican tuberculosis program during June 1993 had a direct effect on reducing the observed number of cases in 1995 from the expected value.
BOVINE TUBERCULOSIS ERADICATION PROGRAM:
FISCAL YEAR 1995

In accordance with resolutions by the United States Animal Health Association (USAHA) in 1994, the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is considering regulations that decrease the risk of tuberculosis exposure from imported ruminants. These regulations are based on the principle of risk-based disease regionalization prescribed by the World Trade Organization (WTO). The WTO states that regions within a country be established that reflect the risk associated with contracting tuberculosis from all livestock. The WTO also states that there can be no international trade requirement that is more restrictive than an interstate trade requirement. The implications of the WTO may require APHIS to reevaluate interstate movement regulations for regions within the United States.

During 1995, APHIS assisted the Bi-National Tuberculosis Committee by performing tuberculosis program reviews on eight Mexican States: Tamaulipas, Coahuila, Sonora, Chihuahua, Nuevo Leon, Durango, Zacatecas, and San Luis Potosi. Five of the States have met minimum program standards set by the committee. Three States, Durango, Zacatecas, and San Luis Potosi, received provisional approval and their progress will be reevaluated in January 1996. In addition, the committee recently reviewed four more States: Aguascalientes, Sinaloa, Baja California Norte, and Jalisco. The reviewers noted some deficiencies in Aguascalientes, Sinaloa, and Jalisco. Two more reviews are planned for October in the States of Veracruz and Yucatan.

During 1995, bovine tuberculosis was isolated from a free-ranging White Tail deer in Michigan. This deer was killed on a hunting preserve and had no known association with any currently infected herd. It is interesting to note that tuberculosis was diagnosed in 1977 from a free-ranging White Tail deer in the same geographic area. APHIS and the State of Michigan are currently investigating the source and extent of tuberculosis infection in this population of deer.

The submission of thoracic granulomas from slaughter animals, by USDA, Food Safety and Inspection Service (FSIS) and State meat inspection personnel is the principle method of tuberculosis surveillance in the United States. USDA, APHIS, Veterinary Services (VS) has established an optimal submission rate for surveillance of 1 sample per 2,500 animals slaughtered. APHIS and FSIS are currently investigating the feasibility of relating slaughter submissions to the actual pathology observed within a particular slaughter plant. This method would allow APHIS and FSIS to better evaluate the effectiveness of surveillance in plants and areas where its need is greatest.

APHIS continues to work with FSIS to increase the level of information management between the two agencies and FSIS has been included in every organizational meeting and training initiative conducted by APHIS during this fiscal year. There are plans to grant FSIS access to the Tuberculosis Information Management System (TIMS) so FSIS managers can receive quicker feedback on the status of slaughter submissions. TIMS enhancements were
implemented during 1995 and will allow Regional and Area APHIS personnel to more closely monitor slaughter submissions and to target problem areas during the FY. The testing of this system is just being completed and implementation of the system on a National level is planned for the first quarter of FY 1996.

The inclusion of individual animal identification devices with slaughter samples is essential for the traceback of tuberculosis infected animals to their herds of origin and substantially increases the likelihood of a successful tuberculosis investigation. Since 1990, there have been 177 slaughter investigations of cases that could not be traced to Mexico, and the average of untraceables over the past 10 years there has been 60 cases per year. Most of these cases are due to Mexican-origin cattle, but there is evidence that some cases are related to tuberculosis infection in domestic cattle herds.

FSIS is working to increase the submission of identification devices with the surveillance samples collected by its inspectors. An increase in the collection of identification will help in resolving the country of origin of such cases. However, in many instances the subsequent tuberculosis investigation may end at the primary dealer or feedlot.

Currently there are only three tuberculosis-infected herds in the El Paso milkshed. During 1995, two herds were released from quarantine by the test and removal method. The depopulation of tuberculous herds is the most effective method for eliminating the disease. In such large herds, depopulation is rarely an economically acceptable option for either the Government or the herd owner. However, one of the remaining herds does plan to depopulate during the first quarter of FY 1996. Clean-up plans for the remaining herds in the milkshed have been implemented, which employ new testing methods and schedules meant to enhance the eradication of tuberculosis in these large dairies. The success of the eradication efforts in the El Paso milkshed is tempered by the re-appearance of tuberculosis in herds previously released from quarantine. The rate of reinfection in such herds is estimated at 30 percent and appears to increase as herd size increases. Fortunately there have been no such cases since 1991.

On July 24, 1995, indemnity was authorized for cases of bovine tuberculosis in Cervidae. Indemnity rates for cervid tuberculosis were established at $750 for reactor animals and $450 for those tuberculosis-exposed. This rate is the same rate that is paid for cattle and bison.

APHIS, the International Llama Association (ILA), and the Republic of Argentina, cooperated in a tuberculosis in llama project that was completed during FY 1995. This project is under review for publication in the scientific literature. The results of this study indicate that tuberculin tests are an effective method to diagnose tuberculosis in llamas. APHIS is also supporting research initiatives aimed at developing improved diagnostic techniques for bovine tuberculosis at Colorado State University, Cornell University, and Texas A&M University.
Figure 1 — FY 1995 began with 42 States plus the U. S. Virgin Islands having Accredited-Free State status for tuberculosis. During the year, Kansas and North Carolina achieved Accredited-Free status by meeting all standards of the UM&R. Six States plus Puerto Rico have Modified-Accredited status. The Accredited-Free status of Virginia was removed during FY 1995.

There were nine tuberculosis infected herds on record in FY 1995. Seven of these were carried over from previous fiscal years and two were newly detected in FY 1995.

Figure 2 — This map shows the distribution of ten captive cervid herds on record during FY 1995, which have had bovine tuberculosis confirmed in one or more animals. Two of the herds were newly detected during FY 1995 and eight were carried over from previous FY’s. These herds are located in eight States, seven of which are Accredited-Free of bovine tuberculosis.

Figure 3 — This figure shows the species distribution of infected Cervidae herds during FY 1995. It includes 3 deer herds (30 percent), 6 elk herds (60 percent), and 1 mixed deer and elk herd or exotic exhibits (10 percent).

Figure 4 — This figure depicts the numbers of imported Mexican steers since 1986. In 1995, 1,597,434 feedlot-type animals were imported from Mexico. This represents an increase of 415,606 animals from the 1994 level, and is the highest number of importations on record.

Figure 5 — This figure depicts slaughter investigations of feedlot origin since 1986. In 1995, there were 195 feedlot investigations, a decrease of 54 cases over 1994. The proportion of feedlot investigations that traced to Mexico has remained at a relatively constant 70 percent over a 10-year period. Even though the percentage has remained uniform, the 1995 data shows an overall decrease in the absolute number of cases traced to Mexico.

Figure 6 — This graph represents the cases of tuberculosis per 10,000 animals imported, based on the average number of feedlot type animals imported from Mexico during the previous two FY’s. During FY 1995, there were 1.25 cases of tuberculosis per 10,000 Mexican imports, a 64 percent decrease over the previous FY. This rate was chosen to depict an average time spent following import prior to slaughter for Mexican-origin cattle.

Figure 7 — Between 1986 and 1994, the number of cases of tuberculosis was directly associated with the numbers of feedlot cattle imported from Mexico during the previous two FY’s. The number of cases of tuberculosis in 1995 was 381 cases less than what the previous model would have predicted. This decrease is related to the ban on Holstein imports and the implementation of the Mexican tuberculosis program.

Figure 8 — Since 1990, 177 slaughter investigations in 8 States were not traced, but were probably of Mexican origin. Of these investigations, 69 (39 percent) were in 5 Accredited-Free States. Kentucky had 19 investigations since 1990, but the majority of these cases originated throughout the United States and were only able to be traced to a broker in Kentucky who sold them through electronic bidding.
Figure 9 — None of the nine herds on record in FY 1995 were depopulated. Four herds were released from quarantine, three from Texas and one from Puerto Rico.

Figure 10 — During the period 1985-1994, there were 82 tuberculous herds detected, of which 57 (70 percent) were depopulated. Twenty-one of the remaining herds have been released from quarantine following testing and the slaughter of reactors, or are still being tested. Four herds remain under quarantine for tuberculosis.

Figure 11 — Suspicious tuberculous lesions or thoracic granulomas were submitted by meat inspection personnel from 2,949 slaughter cattle in FY 1995. Of these, 136 (5 percent) were positive for tuberculosis on laboratory examination. Only 2 (1.5 percent) of the positive cases were adult cattle with the balance of 134 cases being immature feedlot animals.

Distinct progress was made during this FY toward the eradication of bovine tuberculosis. The National challenge that we face is to overcome all remaining obstacles and to achieve the tuberculosis eradication goal. This will require that all factions of industry and the State and Federal Governments remain firmly committed to the eradication of tuberculosis from this country.

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Bovine tuberculosis State status and location of 9 tuberculosis-infected cattle herds.

- Accredited free States (44) plus Virgin Islands.
- Modified accredited States (6) plus Puerto Rico.

Fiscal Year 1995
Bovine tuberculosis State status and location of 10 tuberculosis-infected cervid herds.

Accredited free States (44) plus Virgin Islands.

Modified accredited States (6) plus Puerto Rico.

Fiscal Year 1995
Distribution of infected Cervidae herds.

FY 1995 (by type of establishment)

Mixed/Exhibit (10%)

- 6 Elk Herds
- 3 Deer Herds
- 1 Exhibits or Mixed Herds

- 2 newly infected herds
- 8 herds carried over from last fiscal year

Elk (60%)

Deer (30%)

figure 3
Imported Mexican steers

1986 — 1995

figure 4
Closed slaughter investigations of feedlot origin.

- Closed Feedlot Cases
- Feedlot Cases of Mexican Origin

![Graph showing closed slaughter investigations of feedlot origin from 1986 to 1995.]

1986—1995

Figure 5
Cases of bovine tuberculosis as a function of imported Mexican cattle (trend/time).

Cases of Tuberculosis per 10,000 imports*.

* Based on the average number of Mexican imports during the previous 2 years.

1986—1995

figure 6
The association between cases of tuberculosis seen at slaughter and Mexican-origin feedlot cattle.

FY 1995; First effects of the Mexican tuberculosis program and the ban on Holstein imports are realized in a decrease of 381 cases from the expected amount.

* Based on the average number of Mexican imports during the previous 2 years
Location of closed slaughter investigations of cases not traced to Mexico.

FY 1990—1995

177 investigations in 8 States since 1990.

69 (39%) of these investigations were in 5 Accredited-Free States.

* The majority of these were electronic sales from throughout the United States.
Proportion of tuberculosis-infected herds depopulated

0 herds depopulated

9 tuberculosis-infected herds

* 4 herds released from quarantine this FY (3 TX, 1 PR)

Fiscal Year 1995

figure 9
Tuberculous* herds newly detected vs. herds depopulated.

* infected and exposed livestock
Suspicious lesions submitted from regular slaughter.

1986—1995

- Total lesions submitted
- Lesions of tuberculosis

Figure 11
THREE-YEAR SURVEY FOR BOVINE TUBERCULOSIS
IN HUNTER-KILLED FREE-RANGING ELK
(CERVUS ELAPHUS NELSONI)
IN NORTHWESTERN WYOMING

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Summary
Following recognition of bovine tuberculosis as a significant disease of
captive cervids, an interagency cooperative survey of hunter-killed, free-rang-
ing elk (Cervus elaphus nelsoni) for evidence of tuberculosis was initiated in
northwestern Wyoming. Lymph nodes from the heads and tonsils of 795 hunter-
killed elk were collected during October-December 1992-1994. Tissues were
examined grossly and most were examined microscopically for lesions sug-
gestive of bovine tuberculosis. Twenty-nine pools of lymph nodes that con-
tained microscopic pyogranulomas or granulomas were cultured for myco-
bacteria. Pyogranulomas were found in lymph nodes from 137 (18%) of 770
elk examined microscopically. These lesions occurred in 16-18% of juveniles,
yearling, and adult elk with no difference in prevalence between age classes.
No acid-fast bacteria were detected in sections of lymph node lesions and all
cultures for mycobacteria were negative. This survey did not detect evidence
of bovine tuberculosis in free-ranging elk from northwestern Wyoming. Long-
term surveillance for bovine tuberculosis should continue in these large, dense
elk herds.

Introduction
Eradication of bovine tuberculosis in cattle, bison (Bison bison), and cap-
tive cervids, caused by Mycobacterium bovis, is the objective of the Coopera-
tive State-Federal Bovine Tuberculosis Eradication Program in the United
States. This program is nearing completion in cattle and bison (15), but rec-
ognition of bovine tuberculosis in commercial cervid herds raised concerns
that disease in these species could significantly impact completion of pro-
gram objectives (2), and potentially destroy a growing industry. Both captive
and free-ranging cervids have been diagnosed with bovine tuberculosis in many countries of the world, and in these species, bovine tuberculosis is considered a disease of economic and public health importance (1). In 1994, captive cervids were included in the Bovine Tuberculosis Eradication Program in recognition of these concerns.

The potential for free-ranging cervids to contract bovine tuberculosis from infected captive cervids is of great concern to wildlife managers (12) and animal health officials (3). Such an occurrence was suspected when tuberculous mule deer (Odocoileus hemionus) and coyotes (Canis latrans) were found during surveys of wildlife adjacent to a Montana game-farm under quarantine for bovine tuberculosis (4,7). Recently, a free-ranging white-tailed deer (O. virginianus) from Michigan was diagnosed with bovine tuberculosis; epidemiologic investigations are still underway and the source of the infection has not yet been identified (Schmit, personal communication).

The Jackson elk (Cervus elaphus nelsoni) herd in northwestern Wyoming is estimated at 14,000-15,000 head (10). These elk primarily summer in the southern regions of Yellowstone National Park, in Grand Teton National Park, and in the Teton and Gros Ventre Wilderness areas of the Shoshone and Bridger-Teton National Forests (10). During fall they migrate to natural winter ranges in lower lying habitat, to artificial feedgrounds maintained by the Wyoming Game and Fish Department, and to the National Elk Refuge maintained cooperatively by the United States Fish and Wildlife Service and the Wyoming Game and Fish Department. Approximately 10,000-11,000 elk are fed hay in this area during the winter. Elk densities on the winter feedgrounds are high and contagious diseases, such as bovine tuberculosis probably could be maintained in these elk populations. Brucellosis is endemic in elk wintering on the feedgrounds (6,13), and serves as an example of an important livestock and public health disease established in these herds.

Bovine tuberculosis has never been diagnosed in wildlife in Wyoming. However, routine examination of sick, dead, and hunter-killed specimens submitted for diagnostic evaluation to the Wyoming Game and Fish Department and the Wyoming State Veterinary Laboratory since the 1950s does not include careful dissection and microscopic examination of all lymph nodes. Because of the growing concern about bovine tuberculosis in game farm cervids, a 3 year hunter-killed elk survey was initiated by the Wyoming Game and Fish Department and USDA-APHIS Veterinary Services, with the cooperation of Grand Teton National Park (the National Park Service), the National Elk Refuge (U.S. Fish and Wildlife Service), and the Wyoming State Veterinary Laboratory (Department of Veterinary Sciences, University of Wyoming).

Materials and methods

Elk heads were collected from hunters harvesting animals from the Jackson elk herd in Grand Teton National Park, on the National Elk Refuge, and a few from the surrounding National Forests and from the Wind River elk herd.
southeast of the Jackson herd during October-December, 1992-1994. A total of 795 elk heads were examined, including 109 juveniles, 138 yearlings, 461 adults (≥ 2-year-old), and 87 mostly adult elk, but for which age was not recorded. Seven hundred thirty-four samples were from the Jackson elk herd and 61 were from the Wind River elk herd.

The date, age, sex, a subjective evaluation of the body condition, and the hunt area or general location of the kill were noted for most animals examined. Heads were usually examined fresh; but some were frozen and thawed. Skin of the head was dissected away and lateral retropharyngeal, medial retropharyngeal, parotid, and mandibular lymph nodes and tonsils were exposed. In some cases, gunshot damage precluded collection of all nodes or tonsils. Lymph nodes were examined grossly from the capsular surfaces and on cut section and gross lesions were recorded. A portion of each node was fixed in 10% buffered formalin for histopathology and the remaining portion was preserved by freezing for possible culture.

Tissues for histopathology were embedded in paraffin, sectioned at 6 um, slides were stained with hematoxylin and eosin, and examined by light microscopy. All sections which contained pyogranulomas or granulomas were stained by the Kinyon acid-fast technique, and many were also stained by periodic-acid Schiff, Gomori’s methenamine silver, and Gram’s stain. Twenty-nine sets of pooled lymph nodes from elk with pyogranulomas or granulomas detected in lymph nodes by histopathology were cultured for mycobacteria at the National Veterinary Services Laboratories (Ames, Iowa).

Prevalence estimates for bovine tuberculosis in the Jackson elk herd of northwestern Wyoming were calculated according to Thrusfield (14). Based on data presented by Whiting and Tessaro (16) and Miller et al. (5), gross and microscopic evaluation of lymph nodes and tonsils of the head was assumed to have approximately 55% sensitivity in detecting bovine tuberculosis in elk. Considering the rarity of tuberculous lesions in juvenile and yearling elk (5,16), prevalence estimates were also made using only adult elk and assuming 65% of the elk that were not aged were adults.

Results

We did not detect bovine tuberculosis in any elk examined during this 3 year survey. Gross lesions were rare and included hemorrhage and trauma; swelling or enlargement; abscesses and nodules; discoloration; and fibrosis in lymph nodes, with most lesions occurring in the medial retropharyngeal and parotid nodes. Hemorrhage, trauma, enlargement, cysts, abscesses, and edema were found in tonsils. Most elk were judged to be in good body condition.

The most common microscopic lesions in lymph nodes were pyogranulomas which occurred in 137 (18%) of 770 elk examined. Prevalence of pyogranulomas was similar in all age classes (Table 1) and in both the Jackson and Wind River elk herd. These lesions were generally encapsu-
lated by a moderate fibrous wall which surrounded lymphocytes, neutrophils, macrophages, and a few plasma cells and multinucleated giant cells often of the Langhans' type. The centers of these pyogranulomas usually contained amorphous amphophilic debris, neutrophils, and variably sized “sulfur” granules of Splendore-Hoeppli material. These granules contained gram-negative short coccobacilli. Special stains were negative for fungi and acid-fast bacteria. Mineralization was not found in these pyogranulomas but was observed in the fibrous capsule of a few lymph nodes and within a few tonsillar crypts. Cystic or abscessed crypts were present in some tonsils.

Cultures of 29 sets of lymph nodes from elk with pyogranulomas in the nodes were negative for mycobacteria. Failure to detect bovine tuberculosis in this survey suggests that if bovine tuberculosis does exist in the Jackson elk herd, the estimated prevalence is less than 1%.

Discussion
We did not detect any cases of bovine tuberculosis in hunter-killed elk in northwestern Wyoming. A similar survey of hunter-killed elk was also negative for bovine tuberculosis in Montana (Rhyan, personal communication). It is still possible the disease is present in these populations but at such a low prevalence as to be undetectable with our sample size. If bovine tuberculosis was only recently introduced into the elk herds of the Greater Yellowstone Area it might require years before detection. Surveillance of the Jackson elk herd will continue in the future.

We found the use of hunter-killed elk heads for surveillance for bovine tuberculosis was practical and relatively efficient as suggested by Miller et al. (5). Obviously collection of heads biases the sample toward females because of the reluctance of hunters to contribute antlered heads to the surveillance effort. Whiting and Tessaro (16) did not find an overall difference in the occurrence of tuberculous lesions between male and female game-farmed elk. An attempt was made to collect adult animals in our survey, but when juveniles and yearling were presented they were also sampled. Though prevalence of lesions of bovine tuberculosis in elk increases with age; some juveniles and yearlings may have lesions (16). Concentrating on the yearling and adult age classes in hunter-killed elk tuberculosis surveys makes best use of resources.

Gross examination of lymph nodes rarely detected the small pyogranulomas which were found by microscopic examination, even when personnel experienced in detection of tubercular lesions in cattle conducted the examinations. Whiting and Tessaro (16) found gross examination alone to be approximately 90% sensitive in detecting game-farmed elk with bovine tuberculosis.

The pyogranulomas in lymph nodes detected microscopically appear to be due to chronic bacterial infection with localization in the lymph nodes. Gross inflammatory lesions draining into cervical lymph nodes were not identified in heads from which affected nodes were collected suggesting these are
incidental lesions and not clinically significant to the individual. They were found in a greater percentage of females than males but the reason for this difference is not known. Culture of a few affected nodes identified Actinomyces pyogenes, Escherichia coli, and Pasteurella spp.; Actinobacillus lignieresii has been suspected in similar pyogranulomas in elk from Colorado (9) and more recently, P. haemolytica has been cultured from these lesions in elk from Montana (Rhyan, personal communication).

Histopathologic features of these pyogranulomas were not typical of bovine tuberculosis in cervids (8,9,11) which is characterized by caseous necrosis, mineralization at the periphery of necrotic foci, fibrosis, and inflammatory cell infiltrates composed of epithelioid macrophages, giant cells, and neutrophils. Splendore-Hoeppli material has not been described in tuberculous pyogranulomas and was found in essentially every pyogranuloma or granuloma observed in our survey. Numbers of mycobacteria detected by acid-fast stains of tuberculous lesions in elk vary from rare to numerous (8, 9); no acid-fast bacteria were found in our samples and these should have been detected in at least some animals if the lesions were due to M. bovis. Failure to culture mycobacteria from lymph nodes of animals with pyogranulomas also supports the conclusion that these lesions are not due to bovine tuberculosis.

The importance of these pyogranulomas is the potential for them to be confused with gross lesions of tuberculosis. Suppurative and granulomatous lesions in lymph nodes from cervids should be examined microscopically to rule out tuberculosis.

This 3 year survey of elk in northwestern Wyoming serves as baseline evidence for the absence of bovine tuberculosis in these large free-ranging herds. The presence of bovine tuberculosis in free-ranging mule deer and coyotes from Montana adjacent to a known infected game farm and in a free-ranging white-tailed deer from Michigan with no known source of infection indicates that continued surveillance for bovine tuberculosis, especially in high density populations of free-ranging cervids is prudent.

Acknowledgments

Many individuals and agencies assisted in collection and processing of samples from this survey. Thanks to personnel of Grand Teton National Park; the National Elk Refuge; the Wyoming Game and Fish Department, including Glen Stout, Pete Thiele, Steve Kilpatrick, Norm Merz, Steve Loose, D. Abendroth, and Sandy Pistono; Veterinary Services, APHIS-USDA, including Russell Burgess, Doug Woody, Frank Enos, Mike Philo, and Richard Brewster; National Veterinary Services Laboratory, including Janet Payeur; and the Wyoming State Veterinary Laboratory including Hank Edwards, Tia Fulk, Val Welch, Ken Mills, Amy Boerger-Fields, and Eika Roher.

References

THREE-YEAR SURVEY FOR BOVINE TUBERCULOSIS

view. Vet Rec 129:5-12.


Table 1. Summary of age and sex, and occurrence of nontuberculous pyogranulomas observed microscopically in tissues collected from hunter-killed elk in northwestern Wyoming during October-December, 1992-1994.

<table>
<thead>
<tr>
<th>Age of elk</th>
<th>Sex of elk</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Sex not recorded</td>
<td>Total</td>
</tr>
<tr>
<td>----------------</td>
<td>--------</td>
<td>-------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Juvenile</td>
<td>34 (26%)</td>
<td>7 (11%)</td>
<td>60 (11%)</td>
<td>101 (16%)</td>
</tr>
<tr>
<td>Yearling</td>
<td>83 (20%)</td>
<td>50 (11%)</td>
<td>0</td>
<td>133 (17%)</td>
</tr>
<tr>
<td>Adult</td>
<td>377 (20%)</td>
<td>71 (10%)</td>
<td>1 (ND)</td>
<td>449 (18%)</td>
</tr>
<tr>
<td>Age not recorded</td>
<td>56 (14%)</td>
<td>7 (14%)</td>
<td>24 (21%)</td>
<td>87 (16%)</td>
</tr>
<tr>
<td>Total</td>
<td>550 (18%)</td>
<td>135 (9%)</td>
<td>85 (13%)</td>
<td>770 (18%)</td>
</tr>
</tbody>
</table>

1Number sampled (percent with nontuberculous pyogranulomas).

2ND - no pyogranulomas detected.
REPORT OF THE COMMITTEE ON WILDLIFE DISEASES

Chairman: Victor F. Nettles, Athens, GA
Vice Chairman: Scott Petty, Jr., San Antonio, TX

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The Committee on Wildlife Diseases met at 1:30 PM on Monday, October 30, 1995. There were more than 50 people present, including 26 members. Summaries of reports to the Committee and the Committee’s recommended actions are as follows:

1. Three-year Survey for Bovine Tuberculosis in Elk

Dr. Elizabeth S. Williams of the Veterinary Diagnostic Laboratory, University of Wyoming, presented results of a 3-year surveillance program for tuberculosis in elk in Wyoming. This work was done in collaboration with Scott G. Smith, Robert M. Meyer, and E. Tom Thorne. Following recognition of bovine tuberculosis as a significant disease of captive cervids, an interagency cooperative survey of hunter-killed, free-ranging elk (Cervus elaphus nelsoni) for evidence of tuberculosis was initiated in northwestern Wyoming. Lymph nodes and tonsils from heads of 795 hunter-killed elk were collected during October-December 1992-1994. Tissues were examined grossly and most were examined microscopically for lesions suggestive of bovine tuberculosis. Twenty-nine pools of lymph nodes that contained microscopic pyogranulomas or granulomas were cultured for mycobacteria. Pyogranulomas were found in lymph nodes from 137 (18%) of 770 elk examined microscopically. These lesions occurred in 16-18% of juveniles, yearling, and adult elk with no difference in prevalence between age classes. Acid-fast bacteria were not detected in sections of lymph node lesions and all cultures for mycobacteria were negative. This survey did not detect evidence of bovine tuberculosis in free-ranging elk from northwestern Wyoming. Long-term surveillance for bovine tuberculosis should continue in these large, dense elk herds.

638
2. Overview of Bovine Tuberculosis in Captive Cervidae

Dr. Mitchell Essey of the Cattle Diseases Staff, Veterinary Services, APHIS, USDA, gave the Committee an overview of the current situation regarding bovine tuberculosis in cervidae. From January 1991 to the present, a total of 31 captive cervid herds have been confirmed infected with Mycobacterium bovis. Of these, 21 were voluntarily depopulated by their owners. There were 10 captive herds known to be affected with M. bovis during FY 1995. This included two newly detected herds, one each in New York and Michigan, and eight herds carried over from previous years. The two new herds, plus one additional infected herd of long-standing, were depopulated during the year. Four of the FY 1995 herds were released from quarantine. Four herds remain under quarantine at this time; one each in CO, MO, SC, and TX.

Mycobacterium bovis was confirmed in one free-ranging white-tailed deer in Michigan during 1995. The investigation revealed that a hunter-killed deer from the same area was confirmed infected in 1975. Surveillance of wild deer from this area will be continued. Nevertheless, Dr. Essey stated there is no evidence of any established reservoirs of M. bovis in free-ranging wildlife populations in the United States.

Dr. Essey reported that Federal indemnity for cervidae destroyed for tuberculosis became available in June 1995. The indemnity scale is the same for cervidae as for cattle and bison.

3. Update: Surveillance for TB in Montana Wildlife

Montana State Veterinarian Dr. Clarence Siroky gave a brief update on tuberculosis surveillance in wildlife surrounding an infected elk herd. Montana has been actively looking for spread of infection in wildlife as a result of recent tuberculosis infections in game farms. In May 1995, the last tuberculosis quarantined game farm was released. Owners of this herd and one other in Montana will continue to test their animals for tuberculosis on a yearly basis for a minimum of 5 years. No infected wildlife have been found near either of these farms, but culture-positive animals were found near a depopulated elk farm as reported to the Committee last year. Continued surveillance around this farm has revealed one coyote in addition to the two mule deer and a coyote reported earlier. Genetic fingerprint analyses strongly suggest that the strain of M. bovis in wildlife was the same as that found in the captive elk. Samples from hunter-killed deer and elk will be gathered again this fall, but there are no plans to repeat a similar agency-led harvest as was done last year. There is no firm evidence that bovine tuberculosis has been established in free-ranging wildlife populations in Montana. Based on the surveillance data, the predicted prevalence rate is extremely low.

4. Blood TB Survey in Exotic Cervids in Texas

Dr. Dan Baca of the Texas Animal Health Commission (TAHC) reported on the Texas plan for tuberculosis surveillance in exotic cervids. The Com-
mission adopted regulations in June 1995 for implementation of a state program for eradication of bovine tuberculosis in cervidae. These regulations exceed the minimum standards of the Uniform Methods and Rules by (1) requiring the same entry test requirements as set for American Association of Zoos and Aquariums (AAZA) for all other classes of cervidae and (2) adoption of regulations to enhance surveillance efforts for tuberculosis in animals involved in intrastate movement.

The provisions for enhanced surveillance resulted from consideration of recommendations from the Cervid Advisory Committee appointed by the Commission to solicit input from various segments of the cervid industry, state wildlife officials, academic and scientific consultants, and TAHC staff. The adopted surveillance initiative provides for the following:

1. Definitions and criteria for “Surveyed Herd” status, which incorporates blood tuberculosis test (BTB) ELISA data collected from hunter harvested exotic deer along with commercial harvest data from state meat inspection to recognize voluntary surveillance efforts by participating producers.

2. Requirements for change of ownership test on all cervids sold at exotic livestock markets beginning September 1, 1996.

3. Exemptions from change of ownership test for animals originating from Accredited, Qualified, Monitored, and Surveyed herds.

4. The use of the BTB ELISA as a presumptive test for TB in cervids for intrastate change of ownership requirements and for surveillance in hunter harvest programs.

5. A comprehensive review of all surveillance data prior to implementation of the change of ownership test requirements to evaluate the effectiveness of voluntary industry supported efforts in providing surveillance for TB in the State herd.

The Committee recognized and commended the leadership of TAHC and the exotic cervid industry in promoting producer participation in this innovative program. The success of this program is critical to providing adequate surveillance for TB and may circumvent the need for mandatory test requirements.

5. Report on the Greater Yellowstone Interagency Brucellosis Committee

Dr. Tom Thorne of the Wyoming Department of Fish and Game gave the Committee an overview of the recent progress made by the Greater Yellowstone Interagency Brucellosis Committee. To initiate a concerted effort to manage brucellosis in the Greater Yellowstone Area (GYA), the Governor of Wyoming appointed a task force made up of cattlemen, sportsmen, and representatives from affected state agencies. The task force recognized that eradication of brucellosis was necessary and that it would require the cooperation of all state and federal agencies involved in brucellosis control and wildlife manage-
REPORT OF THE COMMITTEE

ment in the three states. Consequently, it recommended that the Governors of Wyoming, Montana, and Idaho establish an interagency brucellosis task force.

In 1993, representatives appointed by the Governors of the three states developed a mission, goal, and objectives that would fulfill the needs of the state agencies relative to brucellosis in wildlife in the GYA. It was recognized that federal agencies (National Park Service, Fish and Wildlife Service, Bureau of Land Management, Forest Service, and APHIS-Veterinary Services) had to participate because much of the brucellosis problem involves animals and habitat under federal control. These federal agencies were invited to participate with state animal health and fish and game representatives of the three states. A meeting was held in January 1994 in Bozeman, Montana, to address the problem of brucellosis in wildlife in the GYA. All affected agencies sent representatives, and there was agreement that a committee called The Greater Yellowstone Interagency Brucellosis Committee (GYIBC) should be formed. The draft goal, mission, and objectives previously agreed upon by state representatives were modified slightly and used as the cornerstone for a Memorandum of Understanding (MOU) to be signed by the Governors of the three states and Secretaries of the Departments of Agriculture and the Interior.

The GYIBC has an Executive Committee and two subcommittees: the Technical Subcommittee and the Information and Education Subcommittee. Through its Executive Committee, the charge of the GYIBC is (1) to develop options and recommendations for the Secretaries of the Interior and Agriculture, Governors, and regional administrators and Directors of member agencies in charting a management program for brucellosis-affected wildlife populations and their habitat in the GYA; (2) to provide coordination of agency responsibilities without usurping agency mandates; (3) to encourage cooperation in resolving resource problems and conflicting interests related to brucellosis in wildlife; and (4) to provide guidance and oversight to subcommittees.

The Technical Subcommittee, which serves at the direction of the Executive Committee, will, among other things, (1) develop a comprehensive, objective, and scientific base of information and recommend strategies based on common understanding of brucellosis and its impacts on the resources of the GYA; (2) serve as the scientific advisor to the GYIBC; and (3) develop a GYIBC Cooperative Brucellosis Management Plan recommending methods for the eventual elimination of brucellosis from wildlife of the GYA.

The Information and Education Subcommittee also serves at the pleasure of the Executive Committee and will develop factual information regarding the purpose of GYIBC for public distribution and will develop a brucellosis information and education strategic plan for GYIBC.

The first major accomplishment of the GYIBC was to sponsor a Symposium on Brucellosis in the GYA co-hosted by the three governors. The Sym-
WILDLIFE DISEASES

posium, held in Jackson, Wyoming, in September 1994, was successful in bringing all the issues to the forefront and allowing all major interests to participate. The first semi-official meeting of the GYIBC was held immediately after the Symposium, and subsequent meetings were held on an approximate quarterly basis. The GYIBC made several other accomplishments during its first year.

1. The most important was signing of the MOU which formalized the GYIBC by the three Governors and the Secretaries of the Interior and Agriculture.

2. The Executive Committee adopted a Position Statement that acknowledged the relationship between artificial winter feedgrounds and brucellosis and strongly recommended that winter feeding of elk be discouraged and no additional authorized or unauthorized feedgrounds be established in the GYA.

3. A Bison Quarantine Protocol was developed and adopted that would establish a mechanism by which bison could be quarantined, tested, and demonstrated free of brucellosis so that they could by removed from the area.

4. A Standardized Sample Collection Protocol for Bison also was prepared and adopted; the protocol hopefully will improve the quality and consistency of Brucella sampling and culture techniques used on bison.

5. An informational report on Risk of Transmission of Brucellosis from Infected Bull Bison to Cattle, which concluded the risk of transmission from bull bison is logically small but cannot be entirely eliminated based on existing information, was adopted.

6. In addition, news clippings, magazine articles, and other publications relevant to the topic of brucellosis in the GYA were compiled and distributed monthly to members of the Executive Committee and subcommittees and interested members of the public.

Tasks being addressed and nearing completion include (1) a public information document titled The Brucellosis Challenge, Questions and Answers on an Important Wildlife/Livestock Issue in the Greater Yellowstone Area; (2) a white paper on brucellosis in the GYA; (3) a report identifying and describing all elk and bison herd units within the GYA which will provide the basis for developing herd unit specific Brucellosis Management Action Plans; and (4) a Task Directive to prepare an Environmental Impact Statement to Address Brucellosis in the Greater Yellowstone Area which will allow the GYIBC to determine if it is necessary and appropriate to prepare a programmatic Environmental Impact Statement.

6. Preliminary Report on Brucellosis Study in Yellowstone Bison

Dr. Jack Rhyan of the National Veterinary Services Laboratories,
APHIS, USDA, gave a brief presentation on a study of the epidemiology and pathogenesis of brucellosis in bison on Yellowstone National Park (YNP). Several state and federal agencies are cooperating including APHIS, USDA; Agriculture Research Service, USDA; National Park Service, USDI; Montana Department of Fish, Wildlife and Parks; Montana Department of Livestock; Forest Service, USDA; and the Idaho Wildlife Health Laboratory. The project is a 5-year prospective study of 25 seropositive and 25 seronegative female bison and their calves. Cows will be immobilized and radiocollared; specimens to be collected will include blood, milk, swabs, and lymph node biopsies. Parturition will be monitored and placental specimens and any aborted fetuses will be collected. Bison cows and first calf crop will be monitored, and specimens will be collected three times a year for 2 years and twice a year thereafter.

Preliminary work done to date includes: (1) histopathologic and bacteriologic examination of specimens collected at slaughter from captive seropositive bulls from a South Dakota herd; (2) detailed postmortem examinations and cultures on YNP bison harvested after they left the Park last winter; and (3) initiation of a pilot study in YNP bison to refine a protocol and determine if the prospective study is feasible. Six of seven seropositive South Dakota bull bison were culture positive. All six had seminal vesiculitis, and one had severe orchitis caused by Brucella abortus biovar 1. One of three seropositive bison cows harvested after leaving the YNP last winter was culture positive. Three seropositive bulls were culture negative. An additional bison observed near the northern border of YNP was killed and submitted for necropsy because of retained placenta. Brucella abortus was isolated from multiple sites including placenta, vaginal discharge, and feces. The pilot project was begun in October with the capture of nine pregnant YNP bison. One study animal died, leaving eight radiocollared YNP bison in the pilot study.

Preliminary data suggest that culture positivity correlates with strong seropositivity. In naturally infected bulls, disseminated infection appears to occur at the time of seroconversion and frequently causes seminal vesiculitis. Furthermore, in at least the occasional YNP bison, B. abortus causes abortion and retained placenta, and organisms are shed in placenta, vaginal discharge, and feces.

7. Update on Mycoplasma gallisepticum Infection in House Finches

Dr. John Fischer of the Southeastern Cooperative Wildlife Disease Study (SCWDS), College of Veterinary Medicine, The University of Georgia, reported on the expansion of this emergent disease. The epornitic of conjunctivitis in house finches (Carpodacus mexicanus) that was first reported in early 1994 in suburban Washington, DC, has expanded throughout much of the eastern United States and Canada. Affected birds have been reported in Connecticut, Delaware, Georgia, Kentucky, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, and others.
WILDLIFE DISEASES

South Carolina, Tennessee, Vermont, Virginia, West Virginia, Nova Scotia, Ontario, and Quebec.

Disease is characterized grossly by bilateral or unilateral eyelid swelling often accompanied by ocular and nasal exudates. Microscopic lesions consist of lymphoplasmacytic inflammation with hyperplasia of the lymphoid and epithelial tissue of the conjunctiva, often with keratitis and rhinitis. *Mycoplasma gallisepticum* (MG) was detected in affected birds by culture and polymerase chain reaction, and serologic testing identified antibodies against MG. MG also was isolated from house finches without lesions. Limited molecular studies of house finch MG isolates suggested that they differ from strains commonly associated with disease in domestic poultry.

Experimental work has been performed at SCWDS and the Poultry Diagnostic and Research Center at the College of Veterinary Medicine, The University of Georgia, and at the National Wildlife Health Center of the National Biological Service. Conjunctivitis, rhinitis, and antibodies against MG were seen in house finches experimentally inoculated with MG derived from a field case, and young domestic turkeys and chickens developed severe air sacculitis when inoculated with the same isolate. Ongoing experimental work includes inoculation of other passerine species, study of the pathogenesis of experimental MG infection of house finches, and studies of MG transmission between chickens and house finches.

This disease currently appears confined to house finches. The effects on house finch populations are unknown; however, large percentages of affected birds have been reported in areas involved in the epornitic. There is potential for continued spread of MG in house finches through social and migratory behavior and a potential for persistence of MG infection in house finch populations through possible transovarial transmission as occurs in domestic poultry. The threat of the spread of this pathogen to other passerine species or domestic poultry remains a concern and points to the need for continued tight biosecurity on poultry premises.

8. Experimental Trials with House Finch MG in Songbirds

In July 1995, Dr. Chester Thomas of the School of Veterinary Medicine, University of Wisconsin, Madison, began a collaborative project with Drs. Laurie Baeten and Josh Dein of the National Wildlife Health Center. The project will investigate the host range and transmission of MG conjunctivitis among passerine species. Ten species of birds that frequent bird feeders will be exposed to the house finch-derived agent to determine host specificity.

House finches, gold finches, house sparrows, and chickadees were inoculated intraocularly into the right eye with *Mycoplasma gallisepticum*. Pre-inoculation antibody titers were negative via rapid plate agglutination (RPA) tests in all four species. Within 7-10 days, clinical signs of conjunctivitis
began to develop in the house finches. After 3 weeks, 9 of 10 house finches had conjunctivitis, and MG was isolated at necropsy from all infected individuals from at least one site. Cultures were collected from the right and left conjunctiva, upper respiratory tract, and air sacs. Positive antibody titers were observed. Three non-infected house finches were housed in the cage previously occupied by the infected birds; none of these birds developed lesions after 5 weeks exposure. None of the other three species developed ocular lesions or antibody titers. The project will be continued with trials in grackles, juncos, blue jays, mourning doves, and purple finches.

9. *Ehrlichia* and Wildlife

Dr. David Stallknecht of SCWDS gave a brief presentation on ehrlichiosis. Human ehrlichiosis caused by *Ehrlichia chaffeensis* and human granulocytic ehrlichiosis (HGE), caused by a currently unnamed *Ehrlichia* species, are two relatively new human diseases which recently have received much media attention. The epizootiology of both of these tick-borne diseases is poorly defined, but it is extremely likely that wildlife species are involved. *Amblyomma americanum* is the suspected vector with *E. chaffeensis*, and it has been shown experimentally that this agent will infect white-tailed deer. Initial work suggests that HGE is transmitted and maintained in a cycle similar to Lyme borreliosis with *Ixodes scapularis* and *Peromyscus leucopus* representing the principal vector and maintenance host, respectively. Much more work, however, is needed before we completely understand the role wildlife species play in the epizootiology of these diseases. Obtaining this knowledge will be complicated by diagnostic problems since serologic cross reactions between *Ehrlichia* species commonly occurs. Likewise, problems with isolation of these agents and specificity of polymerase chain reaction detection techniques also have been encountered.

10. Current Status of EHD/BT

Dr. Stallknecht also reported briefly on his epidemiologic studies of hemorrhagic disease in wild deer. During 1994, 18 virus isolations were made from white-tailed deer tissues sent to SCWDS. These included 17 EHDV serotype 2 isolations from Delaware, Georgia, Kansas, Mississippi, North Carolina, South Carolina, and Tennessee. BTV serotype 10 also was isolated from a deer in Georgia. To his knowledge these are the first reports of EHDV serotype 2 from Mississippi, Kansas, and Delaware and BTV serotype 10 from Georgia. As part of an ongoing serologic survey of deer populations in the southeastern United States, over 1,100 serum samples collected from hunter-killed deer were tested during 1994/95. Results were similar to the previous 3 years with most antibodies attributable to EHDV serotype 2 exposure. As in the previous years, antibodies to the BTV serotypes were detected most frequently in deer sampled in Florida and Texas. Currently, Dr. Stallknecht is working on the fifth season of this regional study.
Using these and previous data, Dr. Stallknecht's group tested a simple three-step model based on herd immunity in an attempt to explain some of the regional variation seen with hemorrhagic disease in deer populations. Results suggest that exposure to these viruses does not equate with disease, and herd immunity patterns can be used as a predictor of disease risk.

In-depth information on a recent die-off of white-tailed deer in South Dakota was provided by Dr. Sam Holland of the South Dakota Animal Industry Board. South Dakota Game, Fish and Parks officials estimate that up to 50% of the white-tailed deer herds in four northwestern counties may have been lost to epizootic hemorrhagic disease (EHD) during the summer of 1995. An estimated 9,600 deer have died. Diagnosis of EHD was made purely on history, compatible necropsy lesions, and the fact that EHD was confirmed by virus isolation from deer in areas adjacent to western South Dakota in Wyoming. No serology was done in South Dakota deer and no positive virus isolations have been made on samples submitted. While losses were reported in all counties west of the Missouri River, Gregory County in south central South Dakota also reported significant losses. Four counties east of the Missouri River had losses. The state fish and wildlife agency considered the outbreak severe enough to make reductions in the number of hunting permits issued. A total of 2,800 permits were withdrawn from the 4 hardest hit counties, and 320 permits were withdrawn from 4 counties east of the river. EHD is considered endemic in South Dakota, but 1976 was the last year the disease was responsible for reductions in the number of permits issued.

11. Challenge to Duck Plague Resolution

The Committee had been provided a copy of a letter sent from a private veterinarian to USAHA President Dr. Wesley Towers, in which the USAHA was challenged to justify its claim to being an independent, professional scientific organization. Concern was expressed because the USAHA had published a report that was jointly prepared by the USAHA Committee on Wildlife Diseases and the Fish and Wildlife Health Committee of the International Association of Fish and Wildlife Agencies on Guidelines for Responding to Duck Plague Outbreaks in Captive/Semi-Captive Flocks. The letter questioned the procedure in which the Guidelines were developed and reviewed and the role that was provided by a federal agency, the National Wildlife Health Center, USDI, in developing the Guidelines. The steps used in preparation of the Guidelines were reviewed and the Committee unanimously recommended that USAHA maintain the current position on duck plague as indicated by the USAHA Resolution and the Guidelines and that no further action on this subject appears warranted at this time.

12. Recommendation on Research Support for Brucella neotomae Vaccine

Dr. David Hunter of the Idaho Fish and Game Department reviewed the
need to explore various options in regard to oral brucellosis vaccines for wildlife. Research currently is ongoing with Strain 19 and RB51 vaccines in wildlife, but Dr. Hunter explained that these could prove unsuitable for wildlife. He presented a case for also testing *B. neotomae* as a possible oral brucellosis vaccine for wildlife because it is not considered a human pathogen and it has shown some promise on preliminary trials.

After discussion, the Committee recommended that APHIS, USDA, be urged to support research utilizing *B. neotomae* as a potential vaccine for the control of wildlife brucellosis in the Greater Yellowstone Area. This research can be concurrent with other vaccine research projects.

13. **Update on Research with RB51 Strain of *Brucella abortus***

Dr. Fred Enright of the College of Veterinary Medicine at Louisiana State University gave a brief report on the work he has been doing in collaboration with USDA, Virginia Tech, Texas A&M, the Wyoming Game and Fish Department, and veterinarians in North Dakota to evaluate the RB51 Strain as an oral vaccine in elk and swine.

They have initiated a study on a private elk ranch in North Dakota to (1) study the serological responses of elk to standard brucellosis tests and (2) to ascertain the ability of RB51 administered orally to produce immunity in elk to challenge with *B. abortus* strain 2308. To date, orally vaccinated male elk have shown no physical abnormalities, and semen cultures were negative for *Brucella* species. Females that currently are pregnant will be orally vaccinated in December. The vaccine dose is approximately $1 \times 10^{10}$ culture forming units per animal. The animals will be moved to Texas A&M in late January for mid-gestation challenge.

A study on the efficacy of RB51 as a parenteral vaccine in elk is being continued. An earlier preliminary experiment showed that RB51 inoculated into pregnant elk did not cause abortions. The current study expands the project by vaccinating calves of both sexes and comparing vaccine delivery by hand injection with ballistic inoculation. Female elk were vaccinated in May and will be challenged as sexually mature, pregnant adults. Male elk, also inoculated May 1995, are being necropsied every few months and examined bacteriologically and histologically. To date, the elk have demonstrated colonization for at least 28 days post-vaccination, and the necropsied bull elk have been culture-negative.

Dr. Enright et al. also are working with RB51 in swine with the objective to produce a vaccine for feral swine. They have established that RB51 placed in pecans and fed to domestic swine will result in rapid colonization of the organism in regional lymph nodes and that the organism is quickly eliminated within a month. RB51 is non-abortogenic in late gestational sows. Partial protection has been demonstrated against virulent *B. suis* challenge in both subcutaneous and oral vaccinates. This protection is exhibited through increased litter size, increased live/dead ratios, and decreased colonization of...
WILDLIFE DISEASES

the virulent strain among vaccinates. They are currently studying the colonization of boars by \textit{B. suis} because they believe that the boar is most likely to be the carrier in a feral swine population.

14. Attempted Communication with USDI by USAHA Regarding Brucellosis

In July 1995, USAHA President Dr. Wesley Towers wrote Mr. George Frampton, Assistant Secretary for Fish, Wildlife and Parks, of the U.S. Department of the Interior (USDA), inviting him to attend the 1995 USAHA Meeting to discuss the brucellosis problem in the Greater Yellowstone Area. This letter sought input from the USDI, notably the National Park Service, on their viewpoint on this serious problem. The Committee was upset that it appeared that no response had been provided, even if the response had been to decline the invitation.

After some discussion, the Committee voted to recommend that the incoming President of USAHA re-extend an invitation to the Department of the Interior to meet with this Association at next year’s meeting. The Committee suggests that the letter be sent to the Secretary of the Interior and that a copy of the previous invitation be included. It was also suggested that the USAHA comment favorably to the Secretary of the Interior on their recent signing of the Memorandum of Understanding in reference to the Greater Yellowstone Inter-Agency Brucellosis Committee.

Respectfully Submitted,

Victor F. Nettles, Chairman
Scott Petty Jr., Vice-Chairman
ARTICLE I - NAME

The name of this Association shall be "The United States Animal Health Association."

ARTICLE II - PURPOSE

The mission of USAHA is to be a forum for communication and coordination among State and Federal governments, universities, industry, and other groups on issues of animal health and disease control, animal welfare, food safety and public health. It serves as a clearing house for new information and methods which may be incorporated into laws, regulations, policy, and programs. It acts to develop solutions to animal health-related issues based on science, new information and methods, public policy risk/benefit analysis, and the ability to develop a consensus for changing laws, regulations, policies, and programs.

ARTICLE III - MEMBERSHIP

There shall be five kinds of members: Official, allied organization, individual, elected regional delegates, and nonvoting juniors.

OFFICIAL MEMBERSHIP

The animal health departments of each state, also the United States, and the Canadian, and Mexican governments, Puerto Rico, the Virgin Islands, and of such other governmental agencies as the Executive Committee may by a two-thirds vote approve, shall be eligible to official membership in this Association and be represented on the Executive Committee by the animal health executive official.

ALLIED ORGANIZATION MEMBERSHIP

Any nonprofit organization approved by the Executive Committee that is national in scope and actively and directly concerned with the interests and objectives of this Association as outlined in Article II--Purpose, may be elected to allied organization membership and be represented on the Executive Committee by a duly authorized member of the organization. Such organizations applying for membership shall have and shall continue to maintain no less than 50 (fifty) individual members of the U. S. Animal Health Association to qualify.
Any person engaged in animal health work for Federal, provincial, state, county, or municipal governments, and any other person interested in animal health science or milk and meat hygiene, may be elected to individual membership.

Any individual members who has maintained membership in this Association for 35 years, or if such member is at the point of retirement, for 25 years, may be elected to life membership in USAHA by the Executive Committee. Such life membership shall carry with it all the rights and privileges of regular individual membership, including receipt of the Annual Proceedings of this Association. Such life membership shall be exempt from the payment of dues. Fully retired life members, not otherwise gainfully employed in the field of animal science or health, shall also be exempt from the payment of annual meeting registration fees. All past presidents shall automatically become life members.

Members of the Executive Committee will be eligible for such life membership; but for such member, the requirements for maintaining individual membership will be waived. But the period of time for such membership will be as herein provided.

The Executive Committee may, at its discretion, confer honorary individual memberships. Such memberships shall be exempt from the payment of dues and other assessments and may be withdrawn at the discretion of the Executive Committee.

ELECTED REGIONAL DELEGATE MEMBERSHIP

Such elected regional delegates as provided for in Article V—Executive Committee shall by virtue of such election automatically become members of this organization for such term or terms as may be decided by the Executive Committee and shall pay such dues as the Executive Committee may decide.

NONVOTING JUNIOR MEMBERSHIP

Students in agriculture, medicine, veterinary medicine, vocational agriculture, or any 4-H Club member, as well as future farmers under 21 years of age are eligible to election as nonvoting junior membership.

ARTICLE IV-MEETINGS

The meetings of this Association shall be annual and special.

ARTICLE V-OFFICERS

The officers of this Association shall be: President, President-Elect, First
Vice-President, Second Vice-President, Third Vice-President, Secretary, Treasurer, Board of Directors, and an Executive Committee.

BOARD OF DIRECTORS

The Board of Directors shall consist of the officers, including the immediate Past President with the exception of the Executive Committee. It shall handle the financial, administrative, and internal affairs of the Association during such time as the Association and/or the Executive Committee is not in session. It shall handle all other duties and responsibilities as may be assigned to it by the Executive Committee or as may be provided in the Constitution. The Board of Directors shall meet immediately after the adjournment of each annual meeting of this Association and at the same place. The purpose of such meeting is to review plans for the administrative functions of the Secretary for the coming year, to give administrative guidance to the Secretary, and to approve the operations of the office of the Secretary including, upon consultation with him, the employment of an Executive Director and such other employees as may be required which are not otherwise in conflict with the Constitution and Bylaws. The Board of Directors may meet at such other times and places as it, by a majority vote, deems necessary. The Secretary shall keep minutes of all meetings of the Board of Directors, and after approval of such minutes by the President, they shall be presented to the Executive Committee at the next annual meeting of this Association.

EXECUTIVE COMMITTEE

The Executive Committee shall be composed of the executive officer representing the animal health departments of the various states, the principal animal health officer of the United States Department of Agriculture, the Veterinary Director General of Canada, the executive animal health officer of Mexico, Puerto Rico, the Virgin Islands, and of such other governmental agencies as may be approved for official membership by the Executive Committee, the elective officers of this Association, not more than eight (8) delegates at large representing the livestock industry, including poultry, and allied organization members. All past presidents in attendance not included in any other section shall be ex-officio members. For the purpose of having proper credentials, the name of the Executive Committee representative or substitute, if applicable, shall be provided to the Association Secretary by the executive officer of those entities named herein.

There shall be five districts. Said districts shall be known as (1) The Northeast: consisting of the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; (2) The North Central: consisting of the States of Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri,
Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; (3) The Southern: comprising the States of Alabama, Arkansas, Georgia, Florida, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, and the Virgin Islands; (4) The Western district: consisting of the States of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming; (5) the District-at-Large: consisting of Allied Organization Members and all Elected Regional Delegate Members.

Each district, as provided above, shall on a rotating basis, annually submit to the Nominating Committee, nominees for vacancies that shall occur in the following offices: President; President-Elect; First Vice-President; Second Vice-President; Third Vice-President. The order of rotation shall be as follows: Northeastern; Western; Southern; Region-at-Large; North Central.

In the event that an elected officer is unable to complete an elected term, the District that originally submitted the nominee shall have the opportunity to resubmit a nominee to fill the vacancy; or, the provisions of Article VII--Duties of Officers shall apply.

The elected officers shall have the authority to place before the Executive Committee applications for allied organization membership. Not more than five (5) such applications shall be presented to the Executive Committee for consideration at any annual meeting of the United States Animal Health Association.

The Executive Committee shall constitute the administrative body of this Association and shall determine its activities and policies.

All recommendations and reports of officers and committees shall be referred for consideration to the Executive Committee.

The President-Elect shall be ex-officio chairman of the Executive Committee.

The Executive Committee shall elect yearly a Secretary for the Association. The Secretary shall receive such salary and allowance as may be fixed by the Executive Committee.

The Executive Committee shall cause to be audited annually, or oftener if deemed necessary, the receipts and disbursements of the Secretary and of the Treasurer, and shall have authority to hear and determine all complaints filed before it in writing relative to the conduct of any member; and shall accept or reject applications for individual and for allied organization membership properly placed before it. Three negative votes shall disqualify for either such membership.

That, with the exception of a change in the name of this Association, upon the dissolution of this corporation or the termination of activities thereof, all remaining assets thereof shall be contributed for utilization in the advancement of research of diseases of animals, and no part of the net assets shall inure to any person or group of persons for private gain.
ARTICLE VI-PROGRAM COMMITTEE

The President, the Chairman of the Executive Committee, the Secretary, the Treasurer, and the Chairmen of the respective committees shall constitute the Program Committee. It shall be the duty of the members of the Program Committee to make the necessary arrangements and provide the program for the annual and special meetings.

ARTICLE VII-DUTIES OF OFFICERS

1. President: It shall be the duty of the President to preside at all meetings of this Association and of the Board of Directors; to appoint all committees excepting the Executive and officer faction of the Program Committee; to call special meetings of the Association whenever he considers the holding of such meetings necessary for the good of the livestock industry or upon written request of five members of the Executive Committee. The President shall be an ex-officio member of all committees.

The President shall officially represent this Association in such places and at such meetings as he, with the concurrence of a majority of the Board of Directors, deems desirable or necessary in the best interests of this Association. He may at his discretion designate a member of the Executive Committee to substitute for him. A report of such attendance shall be made annually to the membership, and all actual expenses incidental thereto shall be paid by this Association.

2. President-Elect: The President-Elect shall be chairman of the Executive Committee. In the absence of the President, he shall preside at the meetings of the Association. In the event of the absence, disability, or resignation of the President, he shall perform all duties of the President. He shall be an ex-officio member of the Executive and Program Committees and of the Board of Directors.

3. First Vice-president: The First Vice-president shall assume the duties of the President in the event of the absence, disability, or resignation of the President and President-Elect. He shall assume the chairmanship of the Executive Committee in the event of the absence, disability, or resignation of President-Elect. He shall be an ex-officio member of the Executive Committee and the Board of Directors.

4. Second Vice-president: The Second Vice-president shall assume the duties of the President in the event of the absence, disability, or resignation of the President, President-Elect, and First Vice-President. He shall assume the chairmanship of the Executive Committee in the event of the absence, disability, or resignation of the President-Elect and First Vice-President. He shall be an ex-officio member of the Executive Committee and of the Board of Directors.

5. Third Vice-President: The Third Vice-President shall assume the duties of the President in the event of the absence, disability, or resignation of the President, President-Elect, and First Vice-President. He shall be an ex-officio member of the Executive Committee and the Board of Directors.
of the President, President-Elect, First Vice-President, and Second Vice-
President. He shall assume the chairmanship of the Executive Committee in
the event of the absence, disability, or resignation of the President-Elect,
First Vice-President, Second Vice-President. He shall be an ex-officio
member of the Executive Committee and of the Board of Directors.

6. Secretary: The Secretary shall keep an accurate record of the pro-
ceedings of the Association. Whenever authorized so to do by the Execu-
tive Committee, he shall publish said proceedings and distribute them to
the members of the Association. The Secretary shall also keep an accu-
rate record of the proceedings of the Executive Committee. He shall for-
ward to each Executive Committee member a copy of each regulation ap-
proved by the Association.

He shall keep an accurate account of all Association moneys received
and disbursed. All moneys due this Association received by the Secretary
shall be promptly turned over to the Treasurer, accompanied by transmittal
information identifying the amount, the source, and such other information
as the Treasurer and the Board of Directors may require. He shall draw on
the Treasurer, on proper warrants, over his signature and that of the Execu-
tive Director, such sums as may be necessary to discharge the financial
obligations of this Association, provided however that for the payment of
incidental expenses of his office, the Secretary may draw on the Treasurer
from time to time sums not to exceed one hundred dollars ($100) at any
one time on his own authority over the sole signature on warrants signed by
the Executive Director. The President shall be furnished at the end of each
month, for his validation, a list of financial obligations satisfied during the
preceding period. He shall also present to the chairman of the Executive
Committee a list giving the name, occupation, and address of each appli-
cant for individual membership for the approval of the Executive Commit-
tee. He shall present to the Chairman of the Executive Committee for
election by that body the names of individual members eligible and apply-
ing for life membership. He shall prepare forms for applicants for allied
organization membership and shall notify each of the elected officers upon
receipt of such completed application. He shall perform such other duties
as may be authorized and prescribed by the Executive Committee. He
shall be ex-officio secretary of the Executive Committee, ex-officio secre-
tary of the Board of Directors, and an ex-officio member and secretary of
the Program Committee. He shall be bonded for not less than ten thousand
dollars ($10,000).

7. Treasurer: The Treasurer shall keep an accurate account of all
Association moneys received and disbursed. He shall receive from the
Secretary all monies of the Association paid directly to the Secretary along
with proper identification of such moneys. By and with the approval of the
Board of Directors, he shall deposit the funds of this Association in such
types of accounts as may be approved by the Board of Directors, and he
shall invest the funds of the Association or liquidate Association invest-
ments in such manner as may be approved by the Executive Committee upon
recommendation of the Board of Directors. He shall honor warrants for the
proper expenditure of Association funds furnished him by the Secretary over
his signature and that of the Executive Director. He shall honor warrants from
the Secretary on the Secretary’s own authority for incidental expenses of the
Secretary’s office in sums not to exceed one hundred dollars ($100) for any
given expenditure over the sole signature on warrants signed by the Executive
Director. He shall be given guidance and general administrative supervision
by the Board of Directors, and he shall furnish the Executive Committee with
a financial statement of the Association’s funds annually. He shall be bonded
for not less than ten thousand dollars ($10,000), and he shall receive such
salary as the Executive Committee may from time to time determine.

ARTICLE VIII-AMENDMENTS

The Constitution and Bylaws of this Association may be amended by a
two-thirds vote of the members of the Association present and voting at an
annual meeting, provided that the specific amendment to be acted upon
shall have been presented in writing at a previous annual meeting, printed
in the annual proceedings, and further provided that the amendment has
received the approval of a majority of the Executive Committee members
present and voting.

In the event of an extreme financial emergency to the association as
determined by the Board of Directors; the dues structure of the organiza-
tion may be amended immediately, solely by action of the Executive Com-
mittee at the next annual meeting, as set forth in Article V - Dues of the
Bylaws.

ARTICLE IX - COMMITTEE ON NOMINATIONS AND RESOLUTIONS

There shall be appointed annually a Committee on Nominations and
Resolutions which shall be comprised of the Association’s living immediate
past presidents from each of the five districts, and the current president of
the Northeast, North Central, Southern and Western Animal Health Asso-
ciations. The immediate past president of the United States Animal Health
Association shall serve as chairman of the committee. The purpose of the
committee shall be to receive, consider and present to the general assem-
bly nominations for officers and elected regional delegates, as well as reso-
lutions, following such procedures as are established in Articles X and XI.

ARTICLE X - ELECTION OF OFFICERS AND
ELECTED REGIONAL DELEGATES

The Committee on Nominations and Resolutions shall annually report
to the Association membership at the first morning general session. Its
recommendations for the offices of President, President-Elect, First Vice-
President, Second Vice-President, Third Vice-President and Treasurer, as
well as Elected Regional Delegates shall constitute its report. Except for the
office of Treasurer, nominations shall not originate within this committee but
shall be submitted by the appropriate region after caucus of its official and
affiliate representatives who are members of USAHA. From such caucus,
there must originate every fifth year a nominee for the office of Third Vice-
President from the district of that of the retiring President of the Association.
Annually, by caucus, two nominees for Elected Regional Delegate will like-
wise be selected and offered in nomination by each of the four regional asso-
ciations.

The recommendations of the Committee shall be posted on the regis-
tration bulletin board immediately following their presentations at the first
morning general session. Any member of the Association, at the second
general session, may propose amendments to the slate presented by the
Committee. Such amendments shall be made at a time certain specified in
the program for "Report of Action of the Committee on Nominations and
Resolutions" during that session; provided that if a paper is being presented
at that specified time, its presentation will be completed, immediately after
which the report will be read. Provided further, if the program is ahead of
schedule for that session, a recess will be taken until the time certain estab-
lished in the program for the "Report of the Action of the Committee on
Nominations and Resolutions". The Report of the Committee on Nomina-
tions and Resolutions, and proposed amendments to the report, shall be
presented to the Executive Committee for consideration. The acceptance
of the report or amendments shall constitute election.

ARTICLE XI - RESOLUTIONS

As the concluding committee report at the final session of the meeting,
the Committee on Nominations and Resolutions shall present for consider-
ation by the membership those resolutions which it has properly received
and reviewed for ambiguity and redundancy. Such resolutions must have
been submitted in proper format to the Committee by officially designated
committees of the Association, including the Executive Committee, or by
its Board of Directors. Resolutions, properly submitted, will not be altered
as to intent by the committee. Majority approval of resolutions or amend-
ments made thereto by the general membership present and voting, will
constitute acceptance.

BYLAWS

ARTICLE I-ORDER OF BUSINESS

Registration.
Call to Order.
Report of Secretary.
Report of Treasurer.
President-Elect's Address.
Reading of Papers.
Committee Reports.
Discussion.
Unfinished Business.
New Business.
Nominations and Election of Officers and eight members to Executive Committee.
Adjournment.

ARTICLE II-APPLICATIONS FOR MEMBERSHIP

Applications for individual membership shall be made in writing to the Secretary. The application shall give the name, occupation, and address of the applicant and shall be accompanied by a fee of sixty dollars ($60) which amount shall include the membership dues for one year. Applications shall be presented in proper form to the Secretary, who shall in turn submit them to the Executive Committee.

Applications for allied organization membership shall be made in writing to the Secretary on an appropriate form prepared by him. In turn, notice of receipt of such application shall be provided each of the elected officers. An individual or allied organization member may be expelled for cause by the Executive Committee. A majority vote by the members of the Executive Committee present and voting shall be required in order to expel any such member.

ARTICLE III-MEETINGS

The annual meetings shall be held in a location selected at a previous annual meeting by a majority of the members of the Executive Committee. The annual meetings shall be held in a location selected at a meeting of the geographical districts as outlined in Article V, Executive Committee, on a rotating basis as follows: North Central, Northeast, Western, Southern, and in concurrence with the executive officer of the animal health department of the state in which the meeting is proposed.

Each meeting site in the selected location shall be determined by the secretary with the approval of the Board of Directors, and in consultation with the executive officer representing the animal health department of the state in which the meeting is to be held. The Executive Committee shall be advised of said selecting at least five (5) years in advance of any annual meeting.

The annual meetings shall begin between September 15 and Novem-
The Board of Directors is authorized to select an alternate location and a site in the event that the previous selections, because of any unforeseen circumstance, become unavailable and/or unacceptable. The place for holding special meetings shall be determined by the President with due regard to the wishes of the members of the Executive Committee, the subject matter to be considered, accessibility, and the information to be obtained. The notice of time and place of holding a special meeting shall be mailed to the members at least thirty days prior to the date fixed for the special meeting.

ARTICLE IV-QUORUM

Twenty-five members of the Association shall constitute a quorum. Thirty members of the Executive Committee shall constitute a quorum, providing that the majority of those in attendance in comprised of the executive officers representing the animal health departments of their respective states.

ARTICLE IV-DUES

The dues for individual membership in this Association shall be sixty dollars ($60) per annum, payable in advance (on or before January 1st of each year) to the Secretary of the Association. The dues for nonvoting junior members shall be three dollars ($3) per annum, payable (on or before January 1st of each year) to the Secretary of this Association. The dues for official and allied organization memberships shall be three hundred dollars ($300) each per annum, payable in advance (on or before January 1st each year) to the Secretary of this Association. In the event of an extreme financial emergency to the association as determined by the Board of Directors, the dues structure of the organization may be amended immediately, solely by action of the Executive Committee, provided that such contemplated increases in dues have been furnished in writing to each member of the Executive Committee at least ninety (90) days before such action is taken.

ARTICLE VI - ALTERATION OF BYLAWS

For the purpose of changing the order of business or to facilitate important business, Articles I and III of the Bylaws, or any portion thereof, may be suspended during any single meeting by unanimous consent of the Executive Committee.

Amended November 1994
USAHA ADMINISTRATIVE POLICIES
(As adopted by the Executive Committee, October 1993)

ESTABLISHMENT AND OPERATION OF STANDING COMMITTEES

1. All members of standing committees must be paid up members of USAHA.
2. The Chairman and all members of USAHA Committees shall be appointed by the President. It is expected that member appointments will be made in consultation with Committee Chairman.
3. Efforts should be made to keep committee size between 15 and 50 members, and to maintain a geographical balance, as well as an appropriate balance of State, Federal, industry and technical members.
4. Committee Chairmen shall be appointed for a term of not more than five years, and may not be reappointed Chairman for at least one year.
5. All recommendations and resolutions shall be approved by a majority of the committee members present before the adjournment of a committee meeting.
6. All USAHA members present at committee meetings may enter into discussions. Only committee members may introduce resolutions or vote on items of business.
7. Committees shall submit reports only to the Executive Committee and Resolutions only to the Committee on Nominations and Resolutions. Committee resolutions and reports have no standing until approved by the Executive Committee.
8. Committee Chairmen may appoint subcommittees as necessary. Subcommittee members must be members of the parent committee. Subcommittees shall report only to the parent committee.

PARTICIPATION IN USAHA OF FEDERAL AGENCIES AND FEDERAL EMPLOYEES

Federal agencies and personnel have long been an integral and valuable part of USAHA. Agencies have taken part in the organization through official membership and representation on the Executive Committee. This provides the opportunity for presenting agency positions and concerns to the association.

Of undoubtedly greater value has been the individual membership and participation of numerous animal health, food safety, and research professionals from a variety of federal agencies. All disease program--related committees have long had key federal agency members who were critical to the committees' success.

A major function of USAHA is to develop and recommend policies and procedures of national disease control and eradication programs. This means that many committee findings and resolutions constitute recommendations to the appropriate federal agency which is responsible for the area of concern.
Some of these recommendations are contrary to agency policy or position. For this reason, federal employees should actively share their expertise and opinions as committee members, but should not serve as chairmen where they would be making recommendations to their employer.

A number of committees have used federal employees as assistant chairmen to good advantage. Also, committees which do not deal with federal agency policy may be chaired by federally-employed USAHA members where appropriate.

The committee strongly recommends that we maintain USAHA as a professional and technical advisory organization. We recognize that many of the Association's activities have political implications, but feel that lobbying and other political activity should be left to official, affiliate, and individual members.
100th ANNUAL MEETING
October 12-18, 1996
EXCELSIOR HOTEL
Little Rock, Arkansas

101st ANNUAL MEETING
October 18-24, 1997
GALT HOUSE HOTEL
Louisville, Kentucky

102nd ANNUAL MEETING
October 31-November 6, 1998
MINNEAPOLIS HILTON AND TOWERS
Minneapolis, Minnesota