



United States
Department of
Agriculture

Animal and Plant Health
Inspection Service

Veterinary Services

Updated February 2004

Veterinary Services Strategic Plan FY 2004 to FY 2008

Letter from the Deputy Administrator

This Strategic Plan outlines the strategic direction, goals, and objectives for APHIS' Veterinary Services organization for the five year period, FY 2004 to FY 2008. The plan's format has been revised from previous editions with new sections added describing who we in VS serve, our organization, and our strategy for the next five years.

This plan was crafted after a careful review of the changing context surrounding animal health during this opening decade of the 21st century. The final impact of events, such as the creation of the Department of Homeland Security, will not be known for several years, but these events were considered in developing this plan. Feedback received from a survey of VS personnel was also incorporated.

This plan also reflects changes resulting from enactment of the Animal Health Protection Act and implementation of the Animal Health Safeguarding Review. Action Plans being developed by the seven Safeguarding Issue Groups were incorporated. This plan will be revised to reflect new initiatives put forth to make the safeguarding system the one envisioned by the Review.

VS begins the next five years needing to develop the infrastructure, partnerships, and capacity necessary to effectively carry out an expanding range of activities and programs. Reflecting the importance of these concerns, a strategic goal centered around organizational effectiveness has been added to the four programmatic goals brought forward, largely unchanged, from previous editions of the VS strategic plan. By adding this goal, we are acknowledging the importance VS needs to place on addressing issues of organizational culture, human resource management, communications, technology, and flexibility.

We intend to review and update this plan annually. More important than a written document, however, will be the actions and steps taken during the next few years to position VS for its continued success. Your comments and continued feedback are greatly appreciated

Ron DeHaven
Deputy Administrator
APHIS, Veterinary Services



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Acronyms

AAVLD	American Association of Veterinary Laboratory Diagnosticians
AEC	Area Emergency Coordinator
AERO	Animal Emergency Response Organization
AHPS	Animal Health Programs Staff
AI	Avian Influenza
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
AVIC	Area Veterinarian in Charge
AVMA	American Veterinary Medical Association
BSE	Bovine Spongiform Encephalopathy
BTSCC	Bulk Tank Somatic Cell Count
CAHFSE	Collaboration in Animal Health and Food Safety Epidemiology
CDC	Centers for Disease Control and Prevention
CEAH	Centers for Epidemiology and Animal Health
CEM	Contagious Equine Metritis
CSF	Classical Swine Fever
CVB	Center for Veterinary Biologics
CWD	Chronic Wasting Disease
DHS	Department of Homeland Security
DOD	Department of Defense
DOI	Department of Interior
EIA	Equine Infectious Anemia
EMRS	Emergency Management Response System
END	Exotic Newcastle Disease
EPA	Environmental Protection Agency
EVA	Equine Viral Arteritis
FAD	Foreign Animal Disease
FAS	Foreign Agricultural Service
FAO	Food and Agriculture Organization
FEMA	Federal Emergency Management Agency
FMD	Foot-and-mouth disease
FSIS	Food Safety Inspection Service
GDB	Generic Disease Database
GPEA	Government Paperwork Elimination Act
GPRA	Government Performance and Results Act
IAEM	International Association of Emergency Managers
IS	International Services
ISA	Infectious Salmon Anemia
NAHEMS	National Animal Health Emergency Management System
NAHLN	National Animal Health Laboratory Network
NAHMS	National Animal Health Monitoring System
NAHRS	National Animal Health Reporting System
NASDA	National Association of State Departments of Agriculture
NEMA	National Emergency Response Agency
NIAA	National Institute of Animal Agriculture
NPIP	National Poultry Improvement Plan
NSS	National Surveillance System
NVSL	National Veterinary Services Laboratories
OIE	Office International des Epizooties
PPQ	Plant Protection and Quarantine
SACFAPD	Secretary's Advisory Committee on Foreign Animal and Poultry Diseases

SVC	Spring Viremia of Carp
TSE	Transmissible Spongiform Encephalopathy
USAHA	United States Animal Health Association
USDA	United States Department of Agriculture
VMO	Veterinary Medical Officer
VS	Veterinary Services
WTO-SPS	World Trade Organization, Sanitary Phytosanitary Standards

VS' Mission and Vision

VS protects and improves the health, quality, and marketability of our nation's animals, animal products, and veterinary biologics by:

- preventing, controlling and/or eliminating animal diseases, and
- monitoring and promoting animal health and productivity.

Together with its customers and stakeholders, VS employs innovative methods to achieve ever higher standards of animal health.

VS' wide-ranging responsibilities include:

- Coordinating national animal health emergency preparedness and management
- Excluding imports of unsafe animals, animal products, and veterinary biologics

- Diagnosing foreign and domestic animal diseases
- Monitoring the health and disease status of US livestock and poultry
- Certifying animals, animal products, and veterinary biologics for export
- Delivering scientific and economic information, policy advice, risk assessment and other data to address challenges faced by animal producers and stakeholders
- Certifying quality assurance methods used in animal production
- Providing standards for safe, potent, and effective animal vaccines
- Directing national programs to eradicate selected animal diseases

Who We Serve

The American people benefit from the work of VS in a variety of ways. Improvements in animal health provide consumers with plentiful, safe supplies of animal products at reasonable prices. Licensed and inspected veterinary biologics manufacturers assure animal owners that vaccines for their animals will be available and effective.

VS works on a daily basis with livestock producers, veterinarians, and other animal health professionals to implement disease control and eradication programs. Manufacturers of veterinary biologics receive guidance from VS on their production processes. Businesses engaging in international marketing of animals and animal products are assisted by VS and the greater APHIS community in negotiations of trade rules and in the provision of diagnostic testing and health certification.

International organizations, foreign governments, and businesses also refer to VS' expertise and animal health information. VS and APHIS' IS participate on international working groups undertaking initiatives affecting animal health and trade.

The livestock and poultry industries in the US are valued at over \$100 billion. While the overall number of farms is decreasing, there are still nearly 1 million farms raising cattle

in the US. VS certifies over 1 million cattle and pigs, 40 million aquaculture species, and 170 million poultry for export annually. The CVB has over 100 licensed establishments and over 2500 licensed products.

VS consults with and receives input from its stakeholders through a variety of means. An Animal Health Safeguarding Review was commissioned by APHIS to provide recommendations on ways to improve the safeguarding system. The review was carried out by the NASDA. Many VS stakeholders participated on Review committees.

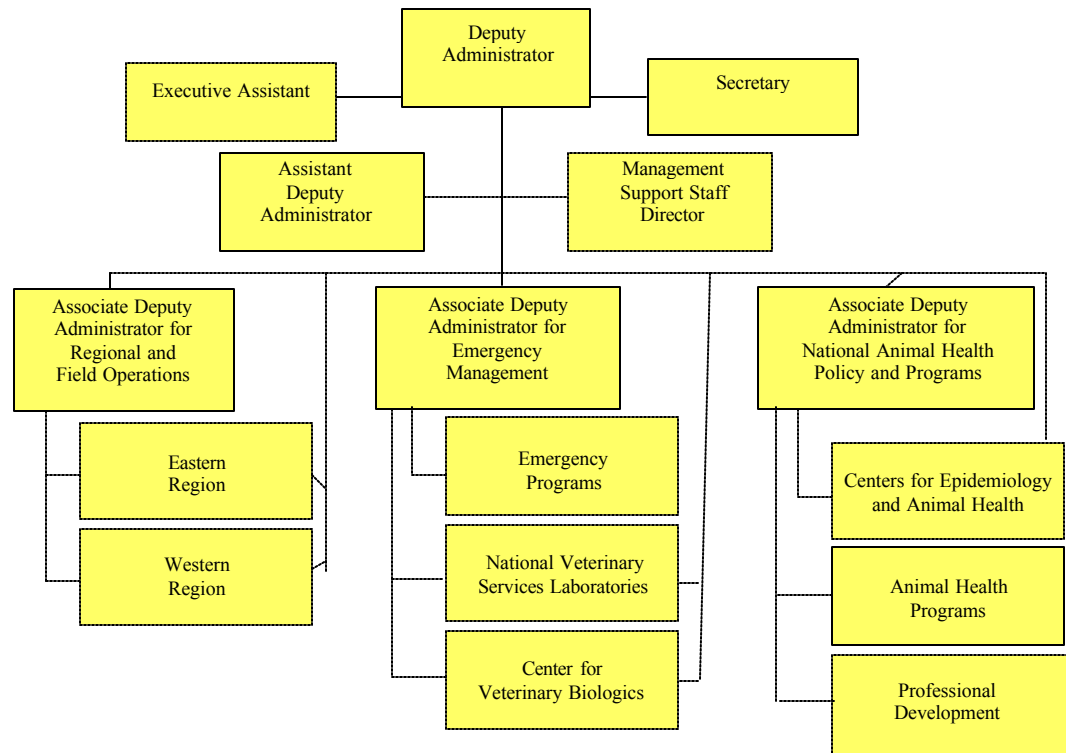
The VS Deputy Administrator holds quarterly conference calls with state animal health officials including State Veterinarians and Laboratory Directors as well as members of the AAVLD. Top VS officials also participate on the APHIS Administrator's monthly call with NASDA officials. The CVB holds an annual public meeting with its stakeholders. Input provided at these sessions is used to improve VS operations and procedures.

VS also receives resolutions from the NIAA and the USAHA which recommend actions in a number of VS program areas. The SACFAPD also provides important input. Finally, VS participates on numerous working groups which discuss aspects of VS' work.

Who We Are

VS employs professionals with a range of scientific, technical, and administrative skills. In 2003, VS' permanent employees numbered nearly 1600. Veterinary Medical Officers comprise approximately one-third of this permanent workforce and Animal Health Technicians an additional 20 percent. VS also employs an array of other specialists including: animal caretakers, budget analysts, biological technicians, computer specialists, economists, entomologists, epidemiologists, geographers, management analysts, microbiologists, statisticians, spatial analysts, and other administrative and animal health support specialists.

The VS infrastructure is nationally distributed. VS has field offices overseeing activity in each of the 50 states and major ports of entry. VS also has personnel and offices in Puerto Rico and in US territories. VS field personnel are located strategically to best serve VS' customers. VS disease eradication and control activities, export certification, and surveillance all take place primarily at these field locations. Overseeing these field offices are regional offices located in Raleigh, North Carolina and Fort Collins, Colorado.



VS maintains headquarters facilities in Riverdale, Maryland and Washington, DC. These headquarters offices establish much of the program policy and regulatory development for the organization. These offices also liaison with other federal agencies, members of the Executive branch, and Congressional offices.

The CVB located in Ames, Iowa regulates veterinary biologics. These regulations ensure that available products are pure, safe, potent, and effective.

The NVSL provide diagnostic services which support foreign animal disease identification; control and eradication programs; and export. The NVSL operate facilities in Ames, Iowa and Plum Island, New York.

The CEAH in Fort Collins, Colorado administers the NAHMS and other surveillance efforts for VS. The CEAH also develops technology applications; maintains key databases; conducts epidemiological, economic, and spatial analysis; and carries out trade risk assessments.

VS accomplishes much of its work through partnerships with state, federal, and international animal health counterparts; private veterinarians; US animal industries; wildlife agencies; and academia.

Many of the statutory authorities underpinning VS' work were consolidated into the Animal Health Protection Act during 2002. VS also derives authorities from the Virus-Serum Toxin Act. Recently, the Agricultural Bioterrorism Protection Act added responsibilities for overseeing agents or toxins deemed a severe threat to animal health.

VS is funded through a number of line item appropriations granted by Congress. VS operating funds from appropriations totaled approximately \$210 million in FY 2003. VS also collects user fees for some of its services.

VS maintains an active website – <http://www.aphis.usda.gov/vs>. Updates are provided on VS programs and electronic copies of various VS forms are also available. An annual report highlighting VS accomplishments is included on the VS website.

Strategic Outlook

Animal health issues and VS' activities are in the public eye to a degree not experienced in decades. The finding of BSE in Washington State in December 2003 which followed the finding of BSE in Canada in May brought home to the American public the risk of animal diseases; a risk raised earlier by the 2001 FMD outbreak in the United Kingdom. The continuing spread of West Nile virus across the United States in 2002 and 2003 along with outbreaks of monkeypox and SARS in 2003, also fueled this interest.

These events occurred not long after the September 11, 2001 terrorist attacks and anthrax scares which had elevated the priority and immediacy of homeland security, biosecurity, and agroterrorism prevention. The creation of a new DHS, the largest government reorganization ever undertaken, demonstrates the emphasis being placed on safeguarding the homeland from terrorist and other threats. Food security has become a prominent focus of government activities.

VS' implementation of the comprehensive Animal Health Safeguarding Review, conducted by the NASDA, is underway. Actions that VS takes now to enhance infrastructure, streamline communications, establish a NSS, and create a NAHLN will impact VS for many years to come. As stated in the Safeguarding report, "US biosecurity is a national, military, and food security issue, and concern

is rightly growing over the country's thin line of defense."

Consumer-driven agriculture is also forcing change. US consumers are increasingly vocal about defining what is produced, how food production takes place, and with what effects. As the retail grocery industry continues to consolidate, that industry is improving its ability to listen to and shape consumer opinion, and to influence how food is produced, processed, and distributed. The top five US food retailers control almost 50 percent of US food sales, and one of them—WalMart—topped the Fortune 500 list in 2002 as the largest corporation in any industry. The restaurant industry has recently used its influence to drive animal welfare requirements and impose restrictions on the use of antibiotics in animal production.

Animal agriculture is increasingly an industry of extremes with large "mega" operations co-existing with "hobby" farms. Niche marketing of animal products as organic, free-range, or all-natural is moving animal agriculture from a commodity to a differentiated product business. Aquaculture production continues to increase and provide competition to livestock producers. Some predict that, worldwide, fish farming will overtake cattle ranching as a source of food by 2010.

Wildlife issues represent a growing area of concern. Growth in wildlife populations due to government and

"We are today a Nation at risk to a new and changing threat"

President
Bush

“Farmers today operate in a global, technologically advanced, rapidly diversifying, highly competitive environment that is driven by increasingly sophisticated consumers.”

Secretary Ann Veneman

private conservation initiatives along with increased interest in domestic rearing of traditionally wild animals, has led to more interactions between wildlife and domestic livestock.

Accelerating personal travel has continued to further raise the stakes for animal disease control. Travelers are now exploring the far reaches of the planet on “ecotours”. Tourism has also become an important source of income for rural areas. In the United Kingdom, tourism industry losses exceeded agricultural losses following that country’s FMD outbreak. This dependence of rural areas on other sources of income raises challenges regarding the appropriate response to take during animal health emergencies.

Trade expansion is a centerpiece of USDA policy. Domestic consumption has limits and 96 percent of the world’s population lives outside the US. The US has recently concluded free trade agreements with Central America and Singapore and is actively engaged in negotiations with Australia, Chile, Morocco, and the Southern African Customs Union.

Globalization of trade, movement of people and agricultural products, and rapid urban population growth around the globe create new opportunities for reemergence and spread of infectious diseases, including those resistant to antibiotics. Changing weather patterns, intensive agriculture, and limited genetic diversity in farm animals may exacerbate those conditions.

New strategies and tools, some based on advances in biotechnology, are emerging to enhance animal health and fight disease. Molecular biology and high throughput genome sequencing are shedding light on how genes of microbes and infected animal hosts are involved in disease. Transgenic animals, cloning applications, and transplantation of animal organs into humans also hold potential to improve animal and human health. Rapid diagnostic tools and new veterinary biologics—some using current technologies, and some based on genetics—are also advancing and attracting international attention.

Certain pharmaceutical products, such as antibiotics and pesticides, may decline in use and not be replaced due to high research and development costs or low consumer acceptance. The ongoing international debate regarding genetically modified organisms in food clearly demonstrates that the public wants credible and objective scientific information to evaluate new technologies.

Animal agriculture and animal health are increasingly connected to other national policy areas as well: energy, environment, and public health, to name but a few. Energy policy has a vitally important impact on agriculture, and there is opportunity for agriculture to contribute solutions to US efforts to meet our country’s energy needs. Fulfilling society’s demands for improved environmental quality requires redefining agricultural

“output” to include environmental amenities, and improved water and air quality. Coordinating animal health and public health initiatives remains a public mandate for VS.

Other trends continue to generate fundamental uncertainty, and represent issues around which VS may prepare for various scenarios. Animal welfare and environmental conservation are established social issues, but it is unclear to what extent these issues will lead to more profound changes in agricultural production. Food retailing has the potential to become more global, but uncertainties remain whether consumers will accept globalization. Similarly, genetic technologies will advance but to what extent remains uncertain. Some experts predict that a genetic-based “life sciences” revolution, of similar magnitude to the digital information revolution, will help create new synergies among animal health and other industries. Finally, the role of the federal government vis-à-vis the 50 states is still evolving, even more so in the wake of September 11th.

National animal health programs will continue to operate through an evolving balance of centralized federal authority and state and local control of events and entities in their own territories.

Public sector management presents its own set of challenges, and the next decade will be no different. The Congressional Budget Office projects federal budget deficits for the next several years, signaling stagnant discretionary income for many federal agencies. Even with budgetary constraints, VS must find innovative ways to recruit and hire skilled people, in multiple disciplines, who represent the diverse American population. The Bush Administration has placed renewed emphasis on the Federal Activities Inventory Reform Act that mandates ongoing review of each agency’s inventory of commercial activities, to ensure the work is inherently governmental and could not be performed by the private sector.

Guiding Principles

In 1998, VS undertook an extensive “futuring” effort. An outcome of that effort was a set of principles guiding how VS would define its activities and operate as an organization. The continued relevance of these principles was noted by reviewers of the animal health safeguarding system and by VS personnel responding to a strategic planning survey. One shortcoming noted was the lack of a principle regarding the value VS places on its people; such a principle has now been added.

What We Do

Comprehensive Animal Health Approach	Recognize the spectrum of animal health needs from endemic disease to epizootic diseases and from program diseases to emerging disease situations. VS actions and involvement across these spectrums will vary. Opportunities exist for VS to increase its involvement in those diseases which fall on the spectrum between endemic and traditional program diseases
Right Data at the Right Time	Develop a comprehensive approach to animal health monitoring and surveillance which can address needs in trade support, regionalization, quality assurance, and emerging animal health issue identification
Public Service	Utilize VS’ animal production expertise and resources (field force, laboratories) to address veterinary public health and environmental issues
Animal Kingdom	Recognize that linkages between livestock, wildlife, and companion animals in animal health, public health, and food safety require VS to consider the needs of <u>all</u> animals.

How We Act

Collective Work Force	Recognize that VS personnel are only part of a core animal health staff in the US. Strengthen the VS organization by reducing internal fragmentation. Continue to build solid partnerships with the other members of the core animal health staff (i.e., state, federal, and international counterparts; private veterinarians; industry personnel; and academia).
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Valuing People	Value the contribution of VS personnel in achieving the VS mission and provide personnel with a work environment that enhances their development and satisfaction.
Technology for Today and Tomorrow	Maintain worldwide leadership in applying technology to animal health issues.
Flexibility	Demonstrate greater flexibility in the VS management culture, leadership style, and in the development of new initiatives.
Visibility	Take advantage of specific expertise in the area of public affairs to increase VS visibility.
New Funding Approaches	Be increasingly innovative in finding funding sources to support the VS organization and its activities

Strategy for FY 2004 – FY 2008

VS begins the next five years needing to develop the infrastructure, partnerships, and capacity necessary to effectively carry out an expanding range of activities and programs. This strategic focus parallels the early 1990s when VS focused on developing “the basic organization” and shifted funding from specific disease eradication programs to general surveillance. VS expects to play an expanded and more visible role in the animal-human health interface. VS will also continue to see the highly competitive international trade arena influencing the way that domestic animal health events are addressed.

VS’ infrastructure and capacity needs have both an internal and external dimension and work will be needed in both. Key aspects of internal capacity building include: human resources, organizational dynamics, and flexibility. Key aspects of external capacity building include: strategic partnerships with other agencies and stakeholders. As part of a broad effort to maximize the potential of its employees and leadership, VS will need to recognize the increasingly multidisciplinary nature of our organization, develop succession/career planning in all job series, improve the orientation of new employees, improve incentives

and recognition to maintain our highly skilled workforce, and continue to develop leadership potential at all levels of the organization. Priorities must be clearly communicated throughout the organization but flexibility must be built in for implementing these priorities at various points in the organization.

Externally, VS will continue to expand networks currently being developed to address diagnostics and emergency response. VS will also need to develop innovative models for working in partnership with new entities. In the past, VS has been able to rely on its close programmatic interface and shared regulatory responsibilities with the State Veterinarians to create consistency and standards in approaches taken to address animal health concerns. VS has a different relationship with State Fish and Game agencies and with other federal agencies such as the DHS and FEMA and organizations such as the AAVLD and IAEM. Additional models of cooperation will need to be developed and refined with these organizations to ensure consistency and define VS’ leadership role.

Goals and Objectives

VS' goals are aligned with the APHIS' goals and with the needs of VS' stakeholders. Achievement of these goals requires broad interaction of all VS program, staff, and scientific units and extensive partnering with other federal and state agencies, private industry, and academia.

Goal 1: Protect the United States from the occurrence of adverse animal health events. (*Adverse animal health events can result from the real or perceived impacts of diseases, pests, vectors, toxins, or natural disasters on public health, productivity, or trade*)

Goal 2: Monitor the health and productivity of our nation's animal populations and monitor the health-related attributes of animal products and veterinary biologics

Goal 3: Enhance the health status of our nation's animal populations by anticipating and responding to new or emerging threats and managing, controlling, or eradicating those already identified.

Goal 4: Expand the domestic and international marketability of our nation's animals, animal products, and veterinary biologics

Goal 5: Create a highly effective animal health organization.

Among VS' goals, Goal 1, *Protect the U.S. from the occurrence of adverse animal health events*, is paramount. Addressing disease incursions and improving response capabilities join Goal 1 activities as key areas for VS over the next five years.

Completing the eradication of brucellosis, bovine tuberculosis, and pseudorabies remains a high priority as does initiating eradication and control programs for CWD and Johne's disease.

VS added a new organizational goal to this strategic plan to emphasize the importance of building a VS organization that is able to address the increasing scope of its activities. Work on achieving this goal will also be emphasized during the next five years.

For each of its five goals, VS has identified a number of objectives. These objectives are listed below. Table 1 (page 15) summarizes these goals and objectives in a single matrix. More detailed descriptions of these objectives are provided in the Appendix. Also included in the appendix are the general performance expectations for each objective during the FY 2004 to FY 2008 time period. Specific performance measures will be provided annually in separate VS Performance Plans.

Goal 1: Protect the United States from the occurrence of adverse animal health events.

Safeguarding the health of America's animals has always been central to the VS mission. VS will continue to exercise vigilance in protecting our nation's animals from disease. To enhance our safeguarding capabilities, VS will continue to foster partnerships within the APHIS and USDA and with other federal agencies, states and industry.

- Objective 1.1: Prevent incursions of adverse animal health events by managing the importation of animals, animal products and veterinary biologics
- Objective 1.2: Collaborate internationally to maintain awareness of international animal health events and improve global animal health
- Objective 1.3: Improve readiness to respond to disease incursions
- Objective 1.4: Prevent the introduction and establishment of nonindigenous invasive species capable of harming US animal populations

Goal 2: Monitor the health and productivity of our nation's animal populations and monitor the health-related attributes of animal products and veterinary biologics

Information regarding the health status, productivity, and health-related attributes of US animal populations, animal products, and

biologics is in high demand. Public concerns about diseases that affect both animals and people only reinforce the need for accurate, timely, and thorough information. To expand the effectiveness of its monitoring activities, VS will continue to build ties to state governments, industry, public health agencies, and other governmental and private groups. VS' monitoring network will be broad and inclusive. VS will seek out and employ innovative technology to bolster its monitoring efforts.

- Objective 2.1: Rapidly detect and evaluate foreign and emerging animal diseases including those with public health/food safety implications
- Objective 2.2: Track and report levels of endemic animal diseases including those with public health/ food safety implications
- Objective 2.3: Conduct facility inspections to ensure compliance with animal health regulations and program standards
- Objective 2.4: Increase and improve capabilities to identify and trace animals and animal products nationwide
- Objective 2.5: Improve pharmacovigilance (post licensing monitoring) for veterinary biologics
- Objective 2.6: Improve laboratory diagnostic services, products, and training to support animal disease surveillance

Goal 3: Enhance the health status of our nation's animal populations by anticipating and responding to new or emerging threats and managing, controlling, or eradicating those already identified.

VS will continue to work to ensure that America's animals are the healthiest in the world. To reach this goal, VS will not only effectively manage its existing animal health programs, but will build its capacity for responding to new threats. VS will enhance its emergency response capabilities by developing innovative and adaptive strategies, infrastructure, and partnerships.

- Objective 3.1: Respond effectively to adverse animal health events and continue to improve the national animal health emergency response capabilities
- Objective 3.2: Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs
- Objective 3.3: Ensure the availability of quality veterinary biological products for diagnosis, prevention, and treatment of animal diseases
- Objective 3.4: Reduce the incidence and spread of serious animal diseases including those with public health/food safety implications
- Objective 3.5: Eradicate animal diseases that pose a threat to public health and/or the national economy

Goal 4: Expand the domestic and international marketability of our nation's animals, animal products, and veterinary biologics.

VS shares with the greater APHIS community an expanding commercial protection role. This role requires VS to respond to and help negotiate science-based animal import requirements ensuring that America's animal, animal product, and veterinary biologic exports are protected. VS uses leading-edge science, high technology, and proactive communication to maintain market accessibility.

- Objective 4.1: Improve market access and promote timely and efficient certification for exports of US animals, animal products, and veterinary biologics
- Objective 4.2: Certify animal production facilities as using processes designed to enhance the quality and safety of their animal-derived food products
- Objective 4.3: Provide disease-status certification for animals entering domestic or international trade
- Objective 4.4: Improve diagnostic testing associated with the marketing of animals and animal products

Goal 5: Create a highly effective animal health organization.

Only with a strong, effective organization can VS hope to achieve its other goals. Keys to VS creating this type of organization are: eliminating internal fragmentation, creating a culture which fosters a

greater degree of employee appreciation, excelling in communication, and valuing flexibility.

- Objective 5.1 Recruit, develop, and retain a competent, committed, and diverse workforce that provides high quality service
- Objective 5.2 Improve internal and external communications to

increase awareness and enhance cooperation and coordination

- Objective 5.3 Utilize information technology effectively
- Objective 5.4 Implement administrative and management approaches which maximize flexibility while retaining accountability

Table 1: Matrix of VS Goals and Objectives

<p>Goal 1: Protect the United States from the occurrence of adverse animal health events. (<i>Adverse animal health events can result from the real or perceived impacts of diseases, pests, vectors, toxins, or natural disasters on public health, productivity, or trade.</i>)</p>	<p>Goal 2: Monitor the health and productivity of our nation’s animal populations and monitor the health-related attributes of animal products and veterinary biologics.</p>	<p>Goal 3: Enhance the health status of our nation’s animal populations by anticipating and responding to new or emerging threats and managing , controlling, or eradicating those already identified.</p>	<p>Goal 4: Expand the domestic and international marketability of our nation’s animals, animal products, and veterinary biologics.</p>	<p>Goal 5: Create a highly effective animal health organization</p>	
<p>1.1 Prevent incursions of adverse animal health events by managing the importation of animals, animal products, and veterinary biologics</p>	<p>2.1 Rapidly detect and evaluate foreign and emerging animal diseases including those with public health/food safety implications.</p>	<p>3.1 Respond effectively to adverse animal health events and continue to improve the national animal health emergency response capabilities.</p>	<p>4.1 Improve market access and promote timely and efficient certification for exports of US animals, animal products, and veterinary biologics.</p>	<p>5.1 Recruit, develop, and retain a competent, committed, and diverse workforce that provides high quality service.</p>	
<p>1.2 Collaborate internationally to maintain awareness of international animal health events and improve global animal health.</p>	<p>2.2 Track and report levels of endemic animal diseases including those with public health/food safety implications.</p>	<p>3.2 Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs.</p>	<p>4.2 Certify animal production facilities as using processes designed to enhance the quality and safety of their animal-derived food products.</p>	<p>5.2 Improve internal and external communications to increase awareness and enhance cooperation and coordination.</p>	
<p>1.3 Improve readiness to respond to disease incursions.</p>	<p>2.3 Conduct facility inspections to ensure compliance with animal health regulations and program standards.</p>	<p>3.3 Ensure the availability of quality veterinary biological products for diagnosis, prevention, and treatment of animal diseases.</p>	<p>4.3 Provide disease-status certification for animals entering domestic or international trade.</p>	<p>5.3 Utilize information technology effectively.</p>	
<p>1.4 Prevent the introduction and establishment of nonindigenous invasive species capable of harming US animal populations.</p>	<p>2.4 Increase and improve capabilities to identify and trace animals and animal products nationwide.</p>	<p>3.4 Reduce the incidence and spread of serious animal diseases including those with public health/food safety implications.</p>	<p>4.4 Improve diagnostic testing associated with the marketing of animals and animal products.</p>	<p>5.4 Implement administrative and management approaches which maximize flexibility while retaining accountability.</p>	
	<p>2.5 Improve pharmacovigilance (post-licensing monitoring) for veterinary biologics.</p>				<p>3.5 Eradicate animal diseases that pose a threat to public health and/or the national economy.</p>
	<p>2.6 Improve laboratory diagnostic services, products and training to support animal disease surveillance.</p>				

Appendix

Details about VS Objectives

This Appendix provides detailed descriptions of each VS strategic objective. Included in this Appendix are details about which specific VS activities are encompassed by each objective and information about key approaches planned for achieving each objective over the FY 2004 to FY 2008 time period. A general expectation of performance during this time period is also provided.

Objective 1.1: Prevent incursions of adverse animal health events by managing the importation of animals, animal products and veterinary biologics

VS establishes and administers import regulations for animals, animal products and veterinary biologics. These regulations incorporate the results of risk assessments examining the disease status of the exporting country, information about the country's surveillance systems and other infrastructure, and site visits. VS trains and certifies state and federal diagnostic laboratories to conduct import/export testing. VS works cooperatively with PPQ, IS, and other agencies to ensure that its import requirements are enforced.

Programs/activities included

- Import regulations and procedures
- Animal/animal product tracking
- Pre-clearance activities
- Animal import testing
- Global animal health intelligence
- Trade risk assessments
- Inspector training

Key approaches FY 2004 – FY 2008

The creation of the DHS has significantly changed the environment in which VS carries out its import functions. VS continues to set the specific quarantine, testing, and other conditions under which animals, animal products, and veterinary biologics can be imported. Agricultural border inspectors are now a part of the DHS. New

protocols for training and interacting with these inspectors will need to be developed. VS will also need to work with the DHS to implement improvements recommended in the Animal Health Safeguarding Review regarding exclusion activities.

Within VS additional steps will be taken to improve exclusion efforts. VS will review its border facilities and identify and implement improvements needed in security, infrastructure, and procedures. A review of off-shore clearance activities for animals and animal products will also be conducted. Additional training may be needed for VMOs, AHTs, AVICs, and others to carry out some of the Animal Health Safeguarding Review recommendations.

VS will continue to work with IS to improve reporting of global animal health information. IS is currently implementing the International Safeguarding Information Program which is designed to place IS personnel (both Foreign Service Officers and Foreign Service Nationals) in many new locations around the world. The role of individuals placed in these positions will be to gather specific pest and disease information requested by VS and PPQ and to enter the information into a database. Information obtained through the International Safeguarding Information Program will complement efforts VS already has underway to monitor electronic news sources for indications of

disease problems. Early warning regarding animal health events will improve VS' prevention and preparedness activities. VS and IS will continue to collaborate on identifying risk pathways for known and emerging diseases. IS will also expand collaboration with international animal health organizations (OIE, ORISA), attend more regional OIE meetings, and increase collaboration on trainings, seminars, and workshops. These activities will enable IS to provide better information to VS. IS personnel will also continue to assist countries in controlling and eradicating diseases. These control and eradication efforts will reduce the risk of spread of these diseases in the U.S.

VS will continue working with Canada and Mexico to coordinate exclusion activities for North America. Steps have already been taken regarding BSE and other TSEs. TSE activity is also being coordinated with the FDA. Joint efforts for other diseases of concern will be enacted as needed.

VS and other APHIS units are working with HHS to implement the provisions of the Public Health Security and Bioterrorism Preparedness Response Act. This Act requires increased notification

and controls on the movement of agents or toxins deemed to be a threat to animal or plant health and to animal and plant products. Enforcing this Act will also require collaborating with the AAVLD.

VS has completed work on a competitive ELISA for piroplasmosis and it has been accepted as an OIE approved method for trade. Work on this more sensitive test was done in response to a USAHA resolution. Over the next five years, VS plans to follow up with similar tests for dourine and glanders. VS is close to completing a developmental project on validation of a PCR for CEM. This test will decrease the time necessary to make a diagnosis of a FAD. VS will also continue to evaluate fluorescence polarization assays and "phase-shift" technologies.

During the next five years, VS will implement a new electronic permit system. This ePermits system should improve customer service and allow better tracking of products imported into the US.

Performance Expectations

No adverse animal health events will occur in the US due to the legal importation of animals, animal products, and veterinary biologics.

Objective 1.2: Collaborate internationally to maintain awareness of international animal health events and improve global animal health

Promotion of transparency in global animal health information allows all countries to take appropriate steps to protect themselves from disease events. Providing assistance to improve global animal health reduces the threat of adverse animal health events in the United States.

Programs/activities included

- Sanitary International Standards Team
- OIE Collaborating Centers (CEAH, CVB, and NVSL)
- OIE Reference Laboratory (NVSL)

Key approaches FY 2004-2008

The Animal Health Safeguarding Review recommended that the APHIS expand its participation in international animal health discussions and activities. VS' current international activities take place under the auspices of the OIE in concert with IS. IS has a permanent staff member providing liaison with the OIE, FAO, and other international organizations.

The OIE facilitates inter-governmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that scientifically justified standards govern international trade in animals and animal products. The OIE aims

to achieve this through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

VS plays an active role in the OIE's standard-setting activities. Staff participate in the various OIE Commissions and Working Groups, where OIE positions, policies, and standards are developed. These include the International Animal Health Code Commission (which develops health standards to ensure the safety of international trade in animals and animal products); the Foot-and-Mouth Disease and Other Epizootics Commission; the Fish Diseases Commission; the Working Group on Wildlife Diseases; and the Ad-hoc Groups on Animal Welfare, Animal Production Food Safety, and Avian Influenza; and several other disease specific expert groups.

VS' CEAH is a collaborating center of the OIE for Animal Disease Surveillance and Risk Analysis. The CVB and NVSL participate as collaborating centers for the Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas through their involvement in the Institute for International Cooperation in Animal Biologics. The NVSL also serves as an OIE reference laboratory for numerous diseases. As collaborating centers and reference laboratories, VS provides training, consultation, and other services to OIE member

countries. A NVSL employee serves as a member of the OIE Standards Commission on behalf of VS and the North American continent.

Recently, VS participated on an OIE Ad Hoc Committee formulating a definition for avian influenza.

The CEAH will be assisting the OIE in improving informatics tools within the OIE. A new Vaccine Manager in the CVB will be responsible for collaborating with international partners, both governmental and vaccine manufacturers, to provide information concerning a list of vaccines that may be used in the event of a foreign animal disease outbreak. The NVSL will continue to assist foreign countries by providing diagnostic services, training, and reagents as well as collaborating with them on work plans to maintain a disease-free status.

VS and IS will continue to assist countries in developing their capacity to control animal disease and improve animal health. Assistance in the areas of risk assessment, surveillance methodology, and geographic

information systems will be offered by VS in collaboration with IS, other federal agencies, and universities. Collaborations on surveillance methodology are underway in Bosnia/Herzegovina and Uruguay. CEAH is also developing a template and approach for the evaluation of surveillance systems which will be used beginning in FY 2004.

VS will also continue to increase the involvement of the USAHA, the Animal Agriculture Coalition, the NIAA, and individual industry associations in global standard setting activities. VS will continue to encourage participation of state and industry personnel at international meetings and in preparing comments and developing consensus based approaches to new or updated Code Chapters.

Performance expectations

The probability of a foreign animal disease incursion will be reduced due to increased awareness of international animal health events and efforts made to improve animal health worldwide.

Objective 1.3: Improve readiness to respond to disease incursions

VS continues to prepare for potential incursions of high risk diseases. A set of emergency management guidelines is under development. Systems for collecting and storing baseline information critical to managing disease incursions are also being developed. VS is also modernizing its emergency management and laboratory facilities.

Programs/activities included

- National Animal Health Emergency Management System Guidelines
- NAHMS
- National mapping project
- National tick survey
- Emergency Management Operations Center
- Laboratory modernization

Key approaches FY 2004-2008

The National Animal Health Emergency Management System Guidelines Series will include 10 sets of operational procedures guidelines, three sets of guidelines outlining strategies for dealing with highly contagious, nonhighly contagious, and vector-borne diseases, respectively; a number of sets of guidelines focusing on various types of facilities; a set of guidelines on the roles and responsibilities of AERO personnel; and a field investigations manual.

Three of the ten draft operational procedures documents have been written, edited, and reviewed by federal and state veterinarians;

members of the APHIS' animal health emergency response teams; officials of other federal agencies; representatives of industry; and additional experts. The comments of these individuals are being evaluated and incorporated into the drafts. Two of the three disease strategy documents, the AERO document, and the field investigations manual have been drafted and are undergoing internal staff review. The draft facilities guidelines are under development. These facilities guidelines draw on the expertise of veterinary professionals in zoos and feedlots as well as in poultry, dairy, and other agricultural environments.

VS is working to improve the availability of baseline information needed to respond to a disease incursion. VS is also developing approaches for analyzing diverse data for trends and indications of potential disease threats. Through the NAHMS, baseline information is available for commodity specific demographics (producers and animals), marketing patterns, biosecurity, and vaccination practices. Baseline information is especially needed for equine, poultry and alternative livestock, including captive cervids and bison. The NAHMS program is developing a plan to address this need. Through increasing the amount and quality of information in its disease control related databases (the GDB and EMRS), VS will be better able to determine exclusion strategies. Information from all of these sources can be used to predict impacts of

disease incursions and is helpful in developing strategies to manage disease events. VS also continues to improve a FMD model which simulates the spread of FMD under various control scenarios. A new Animal/Animal Products Tracking System will provide VS with real-time information on animal movements.

VS has several mapping and spatial analysis projects underway which will contribute to baseline information. The National Mapping Project is focused on mapping first points of animal concentration (feedlots, livestock markets, and slaughter operations) across the US. A cadre of VS personnel have been trained in GIS software and are beginning to enter data on these facilities into a central database. VS is collaborating with state animal health officials on this project as many states have developed or are developing their own spatial databases. VS is also developing national distribution data and interactive maps for tick species of veterinary importance. VS is evaluating the potential for invasive tick species to become established in the US by integrating tick distributions with environmental data.

A new Vaccine Manager at the CVB will be responsible for coordinating

and managing a database that contains real time data on vaccines and diagnostic test kits available for response to a foreign animal disease. Additionally, VS will be involved in a study called for in the Farm Bill to determine vaccine storage availability in case of disease incursion.

The APHIS is upgrading its Emergency Management Operations Center located at its headquarters facility in Riverdale, MD. Modernization efforts are also underway at the Ames campus. These efforts will increase biocontainment facilities for diagnostics, biologics, and agriculture research increasing VS' efficiency and effectiveness in responding to a disease incursion. The Automated Information Management System being developed for the Ames campus will also allow for improved readiness. The inventory system and biologics portions of the system are currently under development.

Performance expectations

Necessary guidelines, information, facilities, systems, and research will be in place allowing VS to quickly contain and eliminate a disease incursion.

Objective 1.4: Prevent the introduction and establishment of nonindigenous invasive species capable of harming U.S. animal populations

VS has a long-standing program to prevent the establishment of cattle fever and its vector, the cattle fever tick, in the continental US. VS has also recently initiated work to address a broader range of nonindigenous invasive species.

Programs/activities included

- Cattle fever ticks
- Invasive species

Key approaches FY 2004-2008

The Cattle Fever Tick program relies on horseback patrol and systematic quarantine to prevent the establishment of cattle fever and its vector, the cattle fever tick.

Continuing efforts to prevent establishment have been complicated in recent years by unfavorable climatic conditions in Texas, extremely low water levels in Falcon Reservoir, high infestation rates on Mexican livestock along the border, increasing numbers of feral exotic ungulates along the border, the presence of pesticide resistant ticks in Mexico, and EPA review of the chemical of choice for cattle fever tick control, coumaphos. New activities planned over the next five years include expanding studies of pesticide resistant tick populations; evaluating moving the tick border further south; developing innovative techniques for determining resistance; evaluating alternative chemicals for the control of fever ticks; and filling a tick epidemiologist position. Work on pesticide resistance and evaluation of

alternative chemicals will be done in collaboration with the ARS.

VS will also be devoting resources to address nonindigenous invasive species. Training programs will be developed and implemented for port inspection personnel that specifically target detection and methods to prevent entry of invasive species that threaten animal agriculture. An aggressive public education campaign to convey the risks and control requirements associated with invasive species that threaten the US animal industry will be undertaken. Outreach programs, such as a separate web site to disseminate information to industry, state and local governments, and the public will be developed. Meetings with stakeholders, industry, and consumers will be held to increase awareness of the potential harmful effects of invasive species. Methods to research and identify potential invasive species and their pathways of introduction into the US will be developed. Risk analyses processes will be used to determine the potential environmental and animal and human health damage levels associated with identified invasive species. VS will also collaborate with other APHIS units and additional federal agencies to develop emergency management and eradication strategies for those invasive species found established in the US.

Invasive species of arthropods will be cataloged and guidelines

developed to eradicate and/or control their impact on farm-raised animals. Import regulations will be developed to exclude identified and known invasive species. VS will collaborate with the ARS, the FDA, industry, Tribes, PPQ, IS, and other countries in developing approaches for excluding invasive species.

Performance expectations

Cattle fever tick outbreaks occurring outside the quarantine zone will be eliminated in less than 12 months.

Surveillance programs will identify new incursions of invasive species. Invasion pathways will be identified and exclusion programs developed to eliminate those pathways. New regulations will be developed to prevent introduction of known invasive species not already covered by existing regulations.

Objective 2.1: Rapidly detect foreign and emerging animal diseases including those with public health/food safety implications

Rapid detection of foreign and emerging animal diseases is an essential component of the VS animal health safeguarding system.

Programs/activities included

- FAD investigations
- Accredited veterinarians
- Emerging animal health issues tracking system
- NAHLN
- NAHMS
- Pilot projects on syndromic surveillance and CAHFSE
- Disease specific surveillance – AI, CSF, ISA, SVC, TSE
- FAD training courses

Key approaches FY 2004-2008

The Animal Health Safeguarding Review made numerous recommendations for changing VS surveillance activities. Of particular concern, was the disaggregated nature of current VS surveillance efforts. Action plans are being developed to respond to the Safeguarding Review recommendations and begin the transition of surveillance activities within VS from a collection of stand alone efforts to a NSS that provides integrated, comprehensive, and coordinated surveillance. Three critical action plans have been developed to support the newly appointed Assistant Deputy Administrator for surveillance. These action plans call for creating a common vision for the NSS, establishing a national surveillance

unit, and establishing a national surveillance steering committee. Proposals to create a national surveillance steering committee recognize that creating a NSS will require VS to form formal linkages with many groups ranging from private practitioners to foreign government agencies, and including relevant state and federal government agencies, the national diagnostic laboratory network, public health agencies, industry, academia, and animal health professional organizations. A national surveillance steering committee will help set specific national surveillance goals, provide input to surveillance plans, and be the primary communication route to and from the groups that they represent.

VS is also moving to increase the training available to accredited veterinarians so that they can continue to play a key role in the identification of foreign and emerging issues. Accredited veterinarians must be knowledgeable and aware of the dangers of foreign and new emerging diseases. They must be able to recognize these diseases and educate their clients so that biosecurity is maintained. Accredited veterinarians must also know the reporting procedure so there is immediate collaboration with VS for proper specimen submission and resource notification. Accredited veterinarians who work as market veterinarians play an especially key role as livestock markets may serve as sites for

widespread dissemination of disease. VS has initiated the production of new veterinary accreditation training materials. Over the next five years, new training modules will be produced to meet the continuing education requirement of the accredited veterinarian. Through a special grant in 2003, VS will be working with veterinary colleges to determine resources needed to enhance training in foreign animal diseases for their students of veterinary medicine.

VS will continue to revamp existing targeted surveillance efforts and explore new methods for detecting foreign and emerging animal diseases. CSF surveillance in the US was recently refocused to emphasize clinical observations and virus isolation. VS is providing RT-PCR technology to many labs for rapid CSF diagnosis. VS is collaborating with a firm in Maine to perform surveillance testing for detecting ISA in the Gulf of Maine. As the NAHLN develops, VS expects to include a system for secure communication and reporting of potential outbreaks of targeted diseases. A newly developed adverse event reporting system for veterinary biologics may also provide early indications of animal health problems. VS is collaborating with researchers at Kansas State University on a pilot project testing the viability of a syndromic surveillance system. Under this system, veterinary clinics in Kansas will report on occurrences of various syndromes such as acute non-neonatal diarrhea, abortion/birth defects, and unexpected feed refusal

or weight loss. The NAHMS ongoing monitoring portfolio (BTSCC, sentinel feedlot, and CAHFSE) will be expanded. Additional feedlot consultants will be added to the sentinel feedlot effort and the CAHFSE will be expanded to include dairy as well as swine.

VS will continue to collaborate with other federal agencies to improve sharing of information on potential foreign or emerging diseases issues. VS collaborates with the Joint Subcommittee on Aquaculture to address foreign and emerging aquatic animal diseases. VS is working closely with the FSIS to ensure that FSIS veterinarians are aware of and report unusual clinical signs observed at slaughter. VS will continue to maintain a liaison position at the CDC in Atlanta to foster sharing of emerging disease information.

VS continues to work with manufacturers, the ARS and other research agencies, and animal industry groups to facilitate the licensing of diagnostic tests used in the detection of foreign and emerging animal diseases. A diagnostic test kit for CWD was licensed to be used as a screening test in white-tail deer, mule deer, and elk during the hunting season. VS has committed to an aggressive timetable to validate rapid diagnostic tests being developed by the ARS for eight diseases (FMD, CSF, AI, END, African swine fever, Rinderpest, Lumpy Skin Disease, and Contagious Bovine Pleuropneumonia). The validation

plan will ensure that these new tests are effective in real-world settings. Training has already been provided to laboratories in real-time PCR for AI and END; deployment of these assays is currently in process. Training has also been provided in real-time PCR for CSF, FMD, and vesicular stomatitis. As part of the CSF surveillance program, NAHLN laboratories will assist in completing the validation of the CSF assay with deployment targeted for April 2004.

FMD assays are targeted for deployment by July 2004. Assays developed by ARS can be used only with a single sample. VS is in the process of developing a method to scale up for high-volume sampling.

Performance expectations

Foreign and emerging diseases will be detected prior to their becoming widespread throughout the US.

Objective 2.2: Track and report levels of endemic animal diseases including those with public health/ food safety implications

The Animal Health Safeguarding Review recommended that VS restructure its surveillance activities to create a more comprehensive, coordinated, and integrated surveillance system.

Programs/activities included

- Disease specific surveillance: Bovine tuberculosis, brucellosis, CWD, EIA, Johne's, Pseudorabies, Scrapie, West Nile virus
- NAHMS
- NAHRS
- CAHFSE
- Antibiotic resistance

Key approaches FY 2004-2008

VS actions to create a NSS are described above in objective 2.1. The NSS will address surveillance issues for endemic diseases.

VS will continue to refine its data collection systems. The Johne's disease program will be using tissue and serum samples collected for the tuberculosis and brucellosis slaughter surveillance programs as a monitoring method to get estimates on national and regional prevalences of Johne's disease among cull cattle. VS will continue to work with university and industry collaborators to develop new surveillance approaches for pseudorabies and other diseases. VS will work with WS to enhance surveillance in wildlife populations.

NAHMS national and targeted studies will be used to provide national and regional estimates of disease incidence for new diseases facing VS including CWD. Data collected by the GDB and NAHMS provide information which can be used to develop best management practices for disease eradication and control programs.

A collaboration in animal health and food safety epidemiology (CAHFSE) that includes the FSIS and the ARS was initiated in 2003. This effort entails collecting samples from sentinel farms and slaughter facilities chosen to be representative of production/ slaughter within a particular commodity. The initial focus for this effort will be the pork industry and will include surveillance for antimicrobial resistance as well as other animal health topics.

VS will continue to license and maintain a high level of quality for diagnostic test kits used in monitoring endemic animal diseases.

VS has created several new positions to improve coordination of surveillance activities: a National Surveillance Coordinator and a FSIS liaison. Additional positions will be created at the NVSL and at the CEAH. In addition, several working groups, including a field implementation team are being developed or are already in place.

Performance expectations

Accurate monthly reports of surveillance activities and diseases detected will be produced and surveillance levels will be sufficient

to detect disease occurrence at predefined levels facilitating disease eradication and control programs. VS will report annually on its surveillance methodologies and disease status.

Objective 2.3: Conduct facility inspections to ensure compliance with animal health regulations and program standards

VS is charged with enforcing provisions of a number of Acts and guidelines including the Swine Health Protection Act, the Agricultural Bioterrorism Act, and the slaughter horse transport guidelines. The VS field force could also be utilized to conduct compliance inspections for other federal agencies.

Programs/activities included

- Swine Health Protection Act
- Agricultural Bioterrorism Act of 2002 (select agents)
- Slaughter horse transport
- North American Foot-and-Mouth Disease Vaccine Bank manufacturers
- Livestock markets, pet food manufacturers, taxidermies
- Feed manufacturing plant inspections for FDA (proposed)

Key approaches FY 2004-2008

Enforcing the Swine Health Protection Act has been an important VS activity for many years. While the overall number of licensed garbage feeders has declined, the practice of garbage feeding remains a method of recycling food waste. Key challenges for VS will be evaluating new technologies being proposed for treating food waste and revising regulations to remain current with these new technologies. VS has initiated a Swine Health Protection course to provide instruction in how best to inspect garbage feeding operations.

VS will be taking on a new inspection activity as it begins to oversee compliance with the select agent provisions of the Agricultural Bioterrorism Act of 2002. VS will conduct inspections to register facilities that ship and/or receive select agents. VS activity related to the Agricultural Bioterrorism Act will be conducted in collaboration with the CDC.

New slaughter horse transport regulations were finalized in December 2001. Educational materials have been distributed to owners/shippers and slaughter plant officials. VS will develop letters of intent with Canadian and Mexican officials for sharing enforcement of humane transportation provisions for commercial shipments of horses to the US.

VS will continue to conduct inspections of manufacturing sites involved with the production of FMD vaccine bulks included in the North American Foot-and-Mouth Vaccine Bank. These inspections become part of risk assessments used to determine the safety of products prepared in other countries.

VS also inspects livestock markets, pet food manufacturers, and taxidermies. To the extent that resources are available, the VS field force is well positioned to take on additional compliance inspections. Inspecting feed manufacturing plants for compliance with the FDA BSE

requirements is a possible area in which VS could assist other agencies.

VS will conduct a nonambulatory study in FY 2004 and FY 2005 fulfilling the 2002 Farm Bill directive. The study will address scope, causes, and handling practices.

Performance expectations

Compliance with the above Acts and guidelines will approach 100 percent and enforcement actions will be taken towards those facilities not in compliance.

Objective 2.4: Increase and improve capabilities to identify and trace animals and animal products nationwide

A national animal identification system is needed to improve traceback and disease eradication and control programs.

Programs/activities included

- National Animal Identification System
- Animal/Animal Product Tracking System

Key approaches FY 2004-2008

In collaboration with industry and stakeholders, VS is developing a National Animal Identification System that will meet current and future animal health needs of American agriculture. The National Identification Development Team, a group of over 70 individuals representing over 30 organizations developed the U.S. Animal Identification Plan (USAIP). This document received the endorsement of the USAHA at its October 2002 meeting. VS is working in collaboration with industry and stakeholders to finalize the plan.

A number of implementation steps will be carried out during the next few years. These steps include: identifying current methods of

identification and how those methods could be improved in the short term; developing and finalizing national standards for premises and unique animal identification; developing written national program standards and incorporating those standards into the Code of Federal Regulations; and developing the needed electronic data collection infrastructure. The NAHMS can be used as a vehicle to provide estimates of progress, compliance, and to describe identification techniques in use at the producer level.

VS is also creating an Animal/Animal Product Tracking System. This system will draw data from numerous sources, such as the ePermits system and Import/Export databases, by identifying key electronic linkages between these sources. Data from these systems will be captured on a routine basis.

Performance expectations

The national identification system will have the capability to identify all premises that had direct contact with a FAD within two days after discovery.

Objective 2.5: Improve pharmacovigilance (post licensing monitoring) for veterinary biologics

Pharmacovigilance information provides important feedback for improving the effectiveness of VS' veterinary biologics program. This information also enhances VS' ability to take regulatory action expeditiously and in a more uniform manner.

Programs/activities included

- Pharmacovigilance (formerly vaccinovigilance)

Key approaches FY 2004-2008

VS published draft *Guidelines on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports*. This draft was developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products. This international document will be used as final guidance for US veterinary biologics licensees, permittees, and applicants in conjunction with new federal rules and regulations for adverse event reporting. VS will partner with representatives of the international working group to ensure that the adverse event reporting methods developed in the US meet or exceed international standards. VS will also collaborate with the FDA to develop similar methods for receiving adverse event reports, entering data, summarizing data, and analyzing adverse events regarding the pharmacovigilance program. VS will also cooperate with the FDA and the CDC by sharing information

regarding cases involving humans adversely exposed to veterinary biologics.

VS published a proposed rule defining methods and objectives for the mandatory reporting of adverse events pertaining to veterinary biologics. VS is addressing comments received on this proposed rule and will have a final rule published in FY 03 for implementation in FY 04. Developing the details of the reporting structure, database management, data analysis, and the reporting of summary information back to stakeholders will be an ongoing objective. Emphasis will be placed on integrating the information received from this program and activity into the national safeguarding initiative when applicable.

VS has hired an epidemiologist to develop and manage the national pharmacovigilance program as it pertains to veterinary biological products. This program will be fully developed over the next five years.

Performance expectations

VS will monitor the baseline of adverse events from fiscal year 2005 through 2008 to determine trends. From this data, VS will be able to provide better information to veterinary biologic users (veterinarians and consumers) regarding the efficacy and safety of certain products. The information

obtained from this post-marketing surveillance program will be used to: assess if product performance in the field is equivalent to prelicensing testing; substantiate or modify label

claims and warnings; and provide feedback to regulatory authorities regarding licensed and permitted veterinary biological products.

Objective 2.6: Improve laboratory diagnostic services, products, and training to support animal disease surveillance

VS is in the process of developing a NAHLN to address diagnostic needs for animal disease surveillance. VS is also modernizing its laboratory facilities.

Programs/activities included

- NAHLN
- Ames Animal Health Facility Modernization Project

Key approaches FY 2004-2008

The Animal Health Safeguarding Review made several recommendations regarding the role of the NVSL in a national surveillance system. VS is acting on these recommendations.

In collaboration with the AAVLD and CSREES, VS recently established a pilot of the NAHLN. Among the elements of the planned NAHLN system are: the development of standardized, rapid diagnostic techniques which can be used at the state, regional, and national level; modern equipment and experienced personnel trained in the detection of emergent, foreign, and bioterrorist agents; national training, proficiency testing, and quality assurance; and upgraded facilities meeting biocontainment requirements. As part of the pilot NAHLN, twelve state diagnostic laboratories received funding to be used for the purposes stated above. Specifically, VS provided NAHLN laboratories with training in the standard nomenclature to be used in

the pilot lab results reporting tool. The NAHLN laboratories also received training in sensitive methods for distinguishing viruses such as AI, END, CSF, and FMD. VS anticipates that training in additional techniques will be offered, and the number of NAHLN laboratories will increase significantly by FY 2009, attaining a broader pool of expertise to tap for surge testing capacity in an outbreak.

Having adequate laboratory space available at the appropriate biosafety level is essential to conducting diagnostic activities within VS. With DOD appropriations, VS began construction in December 2002 on a facility to relocate laboratories from leased space to the main APHIS site in Ames, Iowa. This effort was incorporated into the Modernization Project and is now referred to as the Consolidated Laboratory – Phase 1 project with a target completion date of June 2004. With other appropriated funds, construction began in the fall of 2003 for the High Containment (BSL-3AG) Large Animal Housing Facility, associated infrastructure, and miscellaneous support structures which are targeted for completion in 2006. In addition, planning/design are well underway for the remainder of the National Centers for Animal Health Modernization Project. This project will bring VS' NVSL and CVB together in one facility with the ARS' National Animal Disease Center which will enhance

collaboration. Subject to appropriations, construction will begin on the Low Containment (BSL-2) Large Animal Facility, the Consolidated Laboratory Building – Phase 2, and the balance of the infrastructure in FY 2005 with completion of the entire project targeted for 2007.

A Memorandum of Understanding was signed between VS and the AAVLD to solidify the cooperative relationship already realized by the two organizations. The

Memorandum clarifies mutual goals and objectives while promoting and enhancing animal health diagnostic services in the US. Quarterly conference calls will continue to be held to enhance the lines of communication.

Performance expectations

The Ames Modernization project will be completed. The NAHLN concept will be expanded.

Objective 3.1: Respond effectively to adverse animal health events and continue to improve the national animal health emergency response capabilities

In 2003 alone, VS responded to an outbreak of END in poultry in California, the continued westward movement of West Nile virus, an isolated case of BSE discovered in Canada, followed by confirmation of BSE in the US due to the importation of a cow from Canada.

Programs/activities included

- AERO
- AECs
- EMRS
- Response to adverse animal health events – AI, BSE, END, ISA, SVC, and West Nile virus

Key approaches FY 2004-2008

APHIS' animal health emergency response capabilities have been reviewed by outside groups, most recently by the Animal Health Safeguarding Review Response Committee. Areas for improvement have also been suggested by members of the task forces assigned to deal with the low pathogenic AI and END outbreaks. VS is in the process of implementing the recommendations put forth by these groups.

The potential extensive distribution of an animal disease across the US requires integrated, coordinated, yet flexible response mechanisms that are locally based, but nationally coordinated. A broad, rapidly spreading disease, or the intentional introduction of a disease in several locations, could quickly outpace the

capabilities of the former Regional Animal Disease Eradication Organization (READEO). VS plans to build upon the successes of READEO as it moves to implement a national animal health emergency response organization based on the Incident Command System – the AERO. A document describing AERO Role and Responsibilities was drafted in 2002. Complementing this AERO organization is the recently issued *Federal Emergency Response Plan for Foot-and-Mouth Disease and Other Highly Contagious Diseases* which identifies how all federal agencies can assist in a disease emergency.

Accredited veterinarians will play important roles in the response to disease incursions. Those accredited veterinarians interested in a role on the response team will be specially trained through an accredited veterinarian supplementary training program. After completion of the program, accredited veterinarians will receive certification as members of the AERO. These individuals will also receive appropriate operational manuals as resource materials.

VS continues to gain experience through responses to current disease outbreaks. The Incident Command System has been utilized in responses to AI, BSE, and END. The outbreak Emergency Management Response System continues to be refined as it is used to respond to current outbreaks. Geographic information capabilities

were one of the features recently added to the system. VS worked with vaccine manufacturers concerning the production of a vaccine for ISA. Several strategies were used to prepare a vaccine that could be used at the appropriate time to attempt to limit the movement of the disease. In response to an outbreak of SVC in farm-raised koi, the states of North Carolina and Virginia have requested APHIS assistance with epidemiology, surveillance, and indemnification. The goal is to contain the disease through rapid detection and depopulation of susceptible fish at risk of spreading the disease or that have been infected with or exposed to SVC. Effective management of SVC requires more extensive surveillance nationally. VS will enhance state and federal laboratory diagnostic capabilities and initiate international and interstate movement requirements to reduce the risk of disease spread.

VS continues work to ensure that tools needed to respond to an adverse animal health event are available. A new VS Vaccine Manager will have real-time data on vaccines and diagnostic test kits available for response to a foreign animal disease. Expertise gained during the AI outbreak and CWD situation on rapidly licensing diagnostic test kits and veterinary vaccines for use in animal health events will be applied to future outbreaks. In addition, VS is in the process of developing a PCR test for use on bacterial select

agents; this test could become important during a response to a bioterrorist event. VS will also work to address issues of data access and quality which surfaced during the END response.

VS has created additional positions within the regions devoted to emergency management, AECs. These positions will work with state animal health officials and emergency management officials at the state and federal level to update emergency response plans and liaison with other agencies and organizations. VS has also created a position devoted to compensation issues. This compensation specialist will work to develop consistent compensation policies. The specialist will also continue recent work looking at the potential for risk management tools, such as insurance, to supplement indemnity programs.

VS participates on the NAHEMS Steering Committee. The NAHEMS committee brings together industry, state, federal, and other organizations to steer the development of a comprehensive emergency management system within the US.

Performance expectations

The AERO will be fully designed, staffed, and trained. The accredited veterinarian program will be augmented.

Objective 3.2: Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs

VS is collaborating in the development of a NAHLN which will address diagnostic needs for routine animal disease surveillance (see objective 2.1) as well as diagnostic capacity for investigations and control and eradication programs.

Programs/activities included

- NAHLN (pilot NAHLN, CWD Contract laboratories)

Key approaches FY 2004-2008

Under the NAHLN concept, state laboratories could provide a significant surge capacity during a disease outbreak. State laboratories could assist in defining herds for depopulation, delimiting the extent of the outbreak, and conducting follow-up surveillance to determine “free status”.

In addition to the 12 NAHLN laboratories, VS has worked with state laboratories to address surveillance needs for CWD and scrapie. As of January 2004, approval has been given to 26 state laboratories to assist with testing for CWD and scrapie, both animal nervous system disorders. Between these two networks (NAHLN and CWD), laboratories in 26 states are available to assist VS in providing necessary Federal animal diagnostic services. Agreements are also being offered to additional laboratories allowing them to assist VS with END surveillance testing and

potentially increasing the number of states participating in this overall network.

VS and the AAVLD are partnering with the CDC to enlist state veterinary diagnostic laboratories into the CDC Laboratory Response Network. VS will serve as the gatekeeper for the veterinary diagnostic laboratory connection to this wider network. NVSL’s Diagnostic Bacteriology Laboratory has received approval from the LRN to conduct diagnostic testing for *Clostridium botulinum*, *Francisella tularensis*, and *Yersinia pestis*. NVSL had previously been approved for *Bacillus anthracis* and *Burkholderia spp.* The LRN laboratories function as confirmatory laboratories for other diagnostic laboratories and will process overflow samples in the event that a bioterrorist event were to occur.

VS has engaged veterinary biologics manufacturers in a dialogue about assistance needed from that sector in the event of a foreign animal disease. The regulated industry has agreed to work with VS to provide vaccines, diagnostic test kits, and laboratory space for use in case of an outbreak.

Performance Expectations

The role of state laboratories in providing surge capacity and other diagnostic services will continue to be developed.

Objective 3.3: Ensure the availability of quality veterinary biological products for diagnosis, prevention and treatment of animal diseases

VS ensures the purity, safety, potency, and efficacy of vaccines and diagnostics through the issuance of product licenses, the establishment of standards, and inspection of products and facilities. VS has licensed veterinary biologics for 197 animal diseases.

Programs/activities included

- Biologics licensing
- Biologics inspection/testing

Key approaches FY 2004-2008

VS has responded to emerging animal diseases with expedited reviews and inspections for new veterinary biologics. VS has also used its authority to conditionally license products needed in the field. These products have a reasonable expectation of efficacy and by allowing the conditional licensure (for example, of West Nile vaccine), numerous animals were protected from risk.

VS is using a risk-based approach for the inspection and testing of veterinary biologics. Efforts and resources are focused on investigations and compliance with the Virus-Serum-Toxin Act. Administrative inspection will be implemented to allow on-site facility

inspections to focus more on observations and audits of veterinary biologics.

Accreditation of VS' CVB laboratory facilities to ISO 17025 standards will enhance consumer and stakeholder confidence in CVB test results and testing aids for the regulated industry. The CVB is also increasing the review of test summary documents prepared by the regulated industry.

Within VS, stronger collaboration between the CVB and NVSL will be fostered. One area of work will be developing appropriate validation criteria for laboratory accreditation.

VS will continue to partner with industry representatives to ensure that quality veterinary biologics are available for the diagnosis, prevention, and treatment of animal disease.

Performance expectations

Needed biologics will be available to meet diagnostic, treatment, and preventative needs for existing programs and for emergency program needs.

Objective 3.4: Reduce the incidence and spread of serious animal diseases including those with public health/food safety implications

VS cooperates with state officials and industry to reduce the incidence and spread of a number of animal diseases. Accredited veterinarians may also participate in disease management and control programs as provided for in certain state plans.

Programs/activities included

- Johne's disease
- National low pathogenic AI program
- NPIP
- EIA, EVA

Key approaches FY 2004-2008

VS has a number of ongoing disease control programs which will continue during the FY 2004 to FY 2008 timeframe.

Johne's disease

VS published the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program in April 2002. Major program components include: educational, management/control, and herd classification (34 states in full compliance in FY 2003), and advisory committees (42 states have active advisory/working groups in FY 2003). Johne's disease was a major component of the NAHMS Dairy 2002 study and is the subject of a followup study in 2004. In FY 2003, VS provided over \$1,400,000 in cooperative agreements and grants for research and educational activities in 20 different states. Risk factor information gathered through

NAHMS studies will be incorporated into certification programs and producer educational materials. Also, a project on Johne's culturing methods is currently underway at NVSL.

Key activities during the next 5 years for Johne's disease include: establishing a Johne's disease demonstration project in each major dairy state (currently in 18 States), increasing farm surveillance by providing funds to states to increase producer participation in the Voluntary National Bovine Johne's disease control program, and developing interstate and international movement controls aimed at protecting producers from Johne's disease.

National low pathogenic AI program

VS is proposing the establishment of a national low pathogenic AI program for H5 and H7 virus subtypes. Both the Transmissible Diseases of Poultry Committee of the USAHA and the NPIP have outlined a low pathogenic AI program framework.

The initial approach of a national low pathogenic AI program would be to eliminate the low pathogenic AI viruses that are circulating in the live bird markets in the Northeast region through depopulation, temporary closure of markets, and cleaning and disinfection of market facilities. Traceback to live bird market suppliers and depopulation

and cleaning and disinfection are also anticipated. Separate program activities will be implemented for layer, broiler, and turkey commercial operations. An indemnity component has been proposed in the program for both live bird market depopulation activities and for supplier flocks found infected.

NPIP

The NPIP is a cooperative industry-state-federal program through which new technology can be effectively applied to the improvement of poultry and poultry products throughout the country. The provisions of the Plan, developed jointly by industry members and state and federal officials, establish standards for the evaluation of poultry breeding stock and hatchery products with respect to freedom from hatchery-disseminated diseases. The NPIP has active control programs for *Salmonella pullorum*, *Salmonella gallinarum*, *Salmonella enteritidis*, *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, and *Mycoplasma meleagridis*.

Plans for the next five years include development of a H5/H7 AI surveillance program for commercial broilers, turkeys, and table egg layers. This expansion into the commercial industry will mean a vast change in how the NPIP will approach its activities. The full impact of this change on the NPIP mission and its needs will not be fully realized for a number of years.

EIA

VS will be presenting/proposing a new approach to EIA testing. Under this new approach, all primary EIA testing will be done by ELISA format. Positive samples would be forwarded to an "EIA Reference Laboratory" and further confirmation of unequivocal samples would be done at the EIA National Referral Laboratory (the NVSL or Gluck Equine Research Center, University of Kentucky). In addition, VS continues to work to develop a national EIA certification program through the proposed rulemaking process. VS has drafted a budget and completed a cost benefit analysis for the industry for such a program.

EVA

VS has issued an Advanced Notice of Proposed Rulemaking and Request for Comment which presented the issues surrounding EVA and a spectrum of potential regulatory programs. Comments received clearly favored a voluntary control program which would include import testing of stallions and semen for EVA and notification of state animal health officials in the state of destination for positive stallions and semen. The final draft of the new EVA UM&R is scheduled to be published in February of 2004. Educational materials continue to be developed and delivered on EVA.

Performance expectations

Progress will be made on all of the current disease control programs.

Objective 3.5: Eradicate animal diseases that pose a threat to public health and/or the national economy

VS cooperates with state officials and industry to eradicate animal diseases that pose a threat to public health and/or the national economy.

Programs/activities included

- Brucellosis
- Tuberculosis
- Pseudorabies
- Scrapie
- CWD (in farmed cervids)

Key approaches FY 2004-2008

Several longstanding eradication programs are expected to achieve their goals in the next five years (brucellosis and pseudorabies). Other programs will continue to make progress.

NAHMS national studies will be used to measure progress and compliance with many programs, identify ways to get information to producers, and identify management practices affecting program goals and effectiveness. The GDB will continue to house key programmatic data.

Brucellosis

As progress continues towards the final eradication of brucellosis from US domestic livestock, VS is placing more emphasis on surveillance activities and the testing of herds that are adjacent, contact, or community herds to assure that the last affected herd is found. Milk samples are obtained from all dairy herds at least twice a year and tested for

brucellosis. Vaccination continues to be used for high-risk herds of cattle, bison, and elk.

Management of brucellosis continues to be an issue in Yellowstone National Park and in the Greater Yellowstone Area. The APHIS is working in cooperation with other agencies to develop a brucellosis elimination plan for the Greater Yellowstone Area. This plan will include elk, and will be complex in scope. Research is continuing on RB51 vaccine in anticipation of its use in the Yellowstone bison as part of the bison management plan.

The potential for infected feral swine to infect the domestic swine herd continues to be a concern. Research is being conducted to provide additional information to control the spread of this disease from wild populations. In addition, feral swine management plans will be developed for each state to ensure that feral swine do not become a source of disease transmission.

Tuberculosis

VS will eradicate bovine tuberculosis through four major strategies: 1) eradicate tuberculosis from the remaining pockets of infection in the domestic livestock populations, 2) work with wildlife agencies to control and eradicate tuberculosis from the wildlife population in order to prevent transmission of the disease from wildlife to domestic livestock, 3) increase laboratory and

diagnostic support to increase testing capacity and to incorporate new methods and technology, and 4) maintain and enhance increased levels of surveillance to ensure that unknown or new incidences of tuberculosis can be eliminated before they spread.

The Bovine Tuberculosis Eradication Program works cooperatively with the state animal health agencies and the national livestock industry to achieve the eradication of bovine tuberculosis from domestic livestock in the US, and prevent its recurrence through continued disease monitoring and surveillance and safe import policies. Program activities include conducting investigations for tuberculosis on livestock herds identified through slaughter surveillance, tracing exposed animals moving from infected herds, testing possible source herds for infections, and conducting area tests. Infected herds are depopulated when feasible. For those herds that cannot be depopulated, test and slaughter procedures are implemented to free those herds of tuberculosis. The program also includes oversight of state programs for state designations of state status, training in tuberculosis epidemiology and eradication procedures, and certification of veterinarians to conduct tuberculosis tests.

The most significant issues facing the Bovine Tuberculosis Eradication Program today are new cases of bovine tuberculosis found in large dairies and the endemic foci of bovine tuberculosis in free-ranging white-tailed deer in Michigan.

Mycobacterium bovis in free-ranging white-tailed deer in Michigan has been linked to at least 24 outbreaks of bovine tuberculosis in domestic livestock. Wild animal surveys have been conducted and extensive surveys are being planned.

Extensive area testing of domestic livestock will continue. This testing may eventually involve the entire state and possibly surrounding states.

The inability to depopulate large *M. bovis*-infected dairy herds or free them of disease also has been an important deterrent to tuberculosis eradication in the US. At best, VS has been able to limit the disease to a few herds.

VS will be initiating a new proficiency testing program for laboratory certification in the Bovigam test, the first serological test for tuberculosis.

Pseudorabies

The US has nearly achieved the goal of eradicating pseudorabies from the domestic swine herd. Sporadic cases of pseudorabies are eliminated and circle and epidemiological testing are completed within 60 days. Most states have achieved Stage IV or Stage V status.

Enhanced surveillance testing will continue to assure that any remaining infection is identified. New surveillance approaches, such as meat juice testing, are being utilized to achieve these surveillance goals. Feral swine management plans will be developed in each state to ensure that pseudorabies is not transmitted

from feral swine to the domestic herd.

Scrapie

VS is working to eradicate scrapie from the US. Keys to achieving this eradication include: maximizing surveillance at slaughter and through testing of at risk flocks, aggressively pursuing epidemiologic investigations, and increasing education and enforcement efforts to achieve compliance with identification and recordkeeping requirements. The Code of Federal Regulations will be updated to match established policies and the Scrapie Eradication Uniform Methods and Rules will be reviewed annually and updated. Laboratory capacity will be increased to meet program needs. The GDB will be enhanced to include new data capture and retrieval techniques. A national prevalence study for scrapie in goats will be undertaken.

Chronic wasting disease

CWD was first detected in farmed animals in the US in 1997. By the end of 2002, the disease had been identified in farmed elk or deer herds in eight states. VS is working to eliminate CWD from captive cervid herds in the US. VS is also assisting states and Tribes in conducting surveillance in wildlife populations

and in controlling and managing the disease in wildlife.

VS received new line item funding for a CWD program in the FY 2003 budget. VS is using this funding to implement key elements of the CWD program: surveillance, traceback, depopulation, and herd certification. VS has expanded its contract group for CWD testing to 26 laboratories and has approved 3 rapid ELISA based test kits for CWD.

Congress requested that the USDA and the DOI work together to create a national plan to assist the states and Tribes in addressing CWD in both farmed and wild animals. Budgets and an implementation approach have been developed for this national plan. Implementation of this plan is proceeding as budgets allow.

Performance expectations

Brucella abortus will be eradicated from the bovine population and *Brucella suis* and pseudorabies will be eradicated from the swine population of the US. Plans will be in place for preventing crossover of *Brucella suis* and pseudorabies from feral swine.

Progress will be made in eradicating bovine tuberculosis, scrapie and CWD.

Objective 4.1: Improve market access and promote timely and efficient certification for exports of U.S. animals, animal products, and veterinary biologics

VS works closely with IS and the FAS to open overseas markets for US animals, animal products, and veterinary biologics. VS issues export certificates and approves laboratories within the US for export testing. IS personnel overseas facilitate the entry of animals and animal products into their respective countries and work to resolve any animal health issues that impact trade.

Programs/activities included

- Animal/animal product inspection/certification
- Veterinary accreditation
- Trade issues resolution and management
- International harmonization
- Market support mechanisms (annual animal health report, regional prevalence of trade significant diseases, applied studies)

Key approaches FY 2004-2008

The export environment for US animals, animal products, and veterinary biologics has become increasingly competitive. This competitive atmosphere puts a great deal of pressure on export activities within the APHIS. Key initiatives for the next few years include: being proactive in dealing with trade issues, participating in standard setting organizations and international trade negotiations, and strengthening the veterinary accreditation program.

The APHIS has increased its participation in international standard setting organizations such as the OIE. IS, VS, and PPQ personnel regularly participate on review groups where international standards are developed. VS was involved in the creation of the Committee of the Americas for the Harmonization of Registration and Control of Veterinary Medicines which seeks to coordinate technical information for the registration and control of veterinary medicines. VS also participates actively in the Veterinary International Cooperation on Harmonization which is working to harmonize quality test requirements and post licensing monitoring procedures for veterinary biologics. VS also continues to discuss a Mutual Recognition Agreement for marketing of veterinary biologics with the Europeans.

The APHIS has become involved earlier in bilateral and other negotiations promoting trade agreements and international harmonization. The APHIS has also begun to hold strategy sessions with other countries prior to the annual OIE meeting to develop consensus on US supported positions.

Working through IS, VS will tap into the FAS Technical Issues Resolution Fund and other funds as needed to resolve trade issues. These funds can support risk assessment

workshops, technical exchanges, or fact-finding trips needed to arrive at scientifically valid risk assessments. VS will also utilize all the resources available for trade dispute resolution from bilateral discussions to informal dispute resolution at the WTO-SPS committee and/or the OIE, to formal dispute resolution at the OIE.

A new Trade Initiative Resolution Manager at the CVB is responsible for expediting the review and certification of documents submitted by the veterinary biologics industry which are intended for exportation and/or registration of USDA licensed veterinary biologics in foreign countries. Inherent to this position is a commitment to agency and stakeholder customer service through information availability and collaboration.

VS is working to increase the international credibility of its veterinary accreditation program. Some importing countries have questioned the US use of private practitioners to certify the health of animals being exported and to provide information for product exports. Import authorities in those countries worry about potential conflict of interests for private

veterinarians providing certificates for their clients. Often these other countries rely solely on the services of official regulatory veterinarians. Proposed changes in the National Veterinary Accreditation Program are designed to strengthen the credibility of the program by providing additional and continuing education and regular contact between VS and the accredited veterinarians. The proposed use of electronic health certificates by accredited veterinarians will also provide greater efficiency, accuracy, and security of export documents.

VS is exploring the feasibility of regionalization/zoning for specific diseases. Regionalization/zoning could be an important tool in preserving markets and market share during disease outbreaks and for endemic diseases. The establishment and maintenance of disease-free zones requires the collaboration of industry and government.

Performance expectations

Additional markets will be opened to US animals, animal products, and veterinary biologics.

Objective 4.2: Certify animal production facilities as using processes designed to enhance the quality and safety of their animal-derived food products

VS is initiating certification programs designed to improve the quality of animal derived food products.

Programs/activities included

- Trichinae

Key approaches FY 2004-2008

The Trichinae Certification Program is a pre-harvest pork safety program that will provide documentation of swine management practices which minimize risk of exposure of swine to the zoonotic parasite *Trichinella spiralis*. The program establishes a set of criteria that enable producers to market swine which are not considered a risk to human health due to exposure to this parasite. In states performing the pilot study for this program, the services of accredited veterinarians, working under contract, are being utilized for farm visits. This program is seen as a model for future on-farm animal agriculture food safety programs.

The Trichinae Certification Program has been developed as a cooperative effort among USDA agencies (APHIS, AMS, ARS, CSREES, and FSIS), the National Pork Board, and the pork processing industry. Each of these entities had input on the structure of the program and each

performs a key role in the administration of the program.

USDA regulations to govern this program have been drafted and are going through the internal US government review process. Once these regulations have been reviewed and published, the Trichinae Certification Program will become an official USDA program available to the entire US pork industry. This goal is expected to be reached in 2005.

VS will collaborate with IS and the FAS to promote these programs overseas with trading partners and gain acceptance for their legitimacy.

Performance expectations

The current pilot Trichinae program will be completed and a voluntary program will be launched within the pork industry. The program will be expanded through marketing of the production benefits to the pork industry and through the development of trade agreements with export partners. The OIE/Codex Alimentarius will recognize the Trichinae Certification Program as a valid program to mitigate animal health risks.

Objective 4.3: Provide disease-status certification for animals entering domestic or international trade

VS has several ongoing programs which provide disease status certification for animals entering trade.

Programs/activities included

- Aquaculture (multiple diseases)
- Sheep (scrapie)
- Cattle (anaplasmosis, bluetongue, brucellosis, Johne's disease, tuberculosis)
- Captive cervids (CWD)

Key approaches FY 2004-2008

The health status of US animals and the disease status of individual states is determined from specific disease surveillance programs, NAHMS studies, and NAHRS reporting. VS also has specific certification programs designed to document the status of US animals for certain disease conditions. Accredited veterinarians play a role in carrying out these certification programs. Testing and movement requirements for animals entering trade are based on the results of these surveillance and certification programs.

Aquaculture

VS operates a National Aquatic Animal Health Certification and Inspection Program. This program includes aquatic animal health certification, farm inspection, and procedures for approving laboratories for export testing. Under certain conditions, VS can certify disease freedom for OIE

notifiable diseases of fish. During the next five years, VS will increase the number of states with voluntary certification programs from 13 to 38 and institute a National Aquaculture Improvement Plan.

Sheep

VS collaborates with state and industry to oversee the Scrapie Flock Certification Program. The intent of the program is to monitor the flocks to identify flocks that are free of scrapie. Flocks may be certified by enrolling in the program and following program requirements. Program requirements include: identification of animals in the flock; inspection of the animals by state or federal regulatory officials; record keeping which tracks acquisitions, departures, births, and deaths; and immediate reporting of scrapie-suspect animals to the proper animal health officials. Animals from certified flocks are eligible for export to many countries and are a valuable source for replacement of breeding animals in other flocks.

Cattle

The Voluntary Bovine Johne's Disease Control Program provides minimum requirements for a state program to identify herds of low risk with *M. paratuberculosis* infection. These Standards will be used to identify positive and negative herds, establish management guidelines, and establish national criteria for state status programs. The intent of

this program is that it be industry driven, assuring maximum participation by cattle producers, and eventually producers of other species, whose animals may also be affected by Johne's disease. Although the management concepts work for other species, serologic tests for sheep, goats, and cervids and culturing methods for sheep are not reliable.

Captive cervids

VS is currently developing a proposed rule to establish a national herd certification program for susceptible farmed deer species for CWD. Once it is established, this

certification program will identify requirements for fencing, identification, and surveillance. Herds will be certified after meeting program requirements and having five years of surveillance with no evidence of disease.

Performance expectations

US disease status certification programs will be accepted by US trading partners leading to increased numbers of US animals in trade.

Objective 4.4: Improve diagnostic testing associated with the marketing of animals and animal products

VS approves laboratories within the US for export testing. VS also develops testing methods and protocols.

Programs/activities included

- Laboratory approval
- Methods development
- Quality Assurance Plan
- Official Methods Program

Key approaches FY 2004-2008

Major initiatives over the next five years include continued work on quality assurance at the NVSL and CVB and the development of an Official Methods Program. Both of these efforts will assist VS in establishing credibility for its diagnostic testing programs.

*Quality assurance is an integral component of the missions of the NVSL and CVB. The purpose of quality assurance is to provide an effective measure of good laboratory practices, support laboratory findings from legal or other challenges, exemplify the national and international leadership that both organizations provide, and contribute to the overall credibility of both NVSL and CVB findings. The NVSL's overall goal is to apply the ISO 17025 standard to the full range of their activities and to eventually seek accreditation for all of them. However, the initial focus is on assuring that all laboratory employees have received basic training in good laboratory practices. Concurrently work will begin

towards accreditation of the following five high-risk priority areas: TB, import testing on horses, vesicular diseases, transmissible spongiform encephalopathies, and fraudulent blood samples. Through the AAVLD, VS will continue to assist other diagnostic laboratories with their quality assurance efforts.

VS will lead the development of an Official Methods Program and assure that the diagnostic methods used meet or exceed international standards. VS will collaborate with NAHLN laboratories to identify which tests should be developed as part of the Official Methods Program. Initial efforts will focus on validation of rapid diagnostic tests being developed by the ARS and others.

VS will continue to certify state and federal laboratories to perform various diagnostic testing techniques. VS will establish a new organizational unit that will focus on proficiency testing and laboratory approval activities. This will be a core element of the NAHLN.

VS will continue to work with IS and the FAS to ensure US laboratory results are accepted by trading partners.

Performance expectations

US laboratory results will be accepted by trading partners for US exports.

Objective 5.1 Recruit, develop, and retain a competent, committed and diverse workforce that provides high quality service

A high quality workforce is at the core of any high performing, successful organization.

Programs/activities included

- Workforce planning
- Diversity/Civil rights initiatives
- Continual learning
- Orientation programs
- Mentoring
- Outreach/recruitment
- Employee recognition

Key approaches FY 2004-2008

The Animal Health Safeguarding Review identified shortcomings in VS' human resource management. Actions will be identified and implemented during the next five years to address these shortcomings.

Improvements will be needed in recruitment, development, recognition, and succession planning in order to ensure that VS has the workforce necessary to carry out its mission. A culture change is needed within the organization to foster a greater degree of employee appreciation.

Continual learning will be emphasized and learning contracts will be in place for all employees. CD-rom and other methodologies will be utilized to provide technical, managerial, and other training. VS will develop and use long-term training opportunities (e.g., with

university degree programs) as a magnet to help attract new recruits and retain good employees. VS will establish a career development ladder for each new recruit that includes alternatives for advancement (supervisory as well as nonsupervisory). Temporary duty assignments will become part of the culture as will mentoring programs. Recruitment and outreach is ongoing, but must become increasingly creative to identify and develop outstanding candidates. Management accountability is crucial.

VS will partner with universities and other training organizations to provide training opportunities for employees and encourage a diverse pool of potential recruits. When necessary, VS will not be afraid to look outside for fresh ideas.

Performance expectations

VS will have an enthusiastic, committed, and diverse workforce prepared for future challenges. VS will have qualified leadership candidates well versed in APHIS programs, committed to public service, and grounded in skills necessary to manage a federal workforce. Candidates for employment will see VS as an employer of choice.

Objective 5.2 Improve internal and external communications in order to increase awareness and enhance cooperation and coordination

VS communicates to a wide array of stakeholders located both within and outside the US. The VS organization itself is geographically dispersed, and thus communication strategies must be tailored to meet these diverse needs. Effective communications are essential for maintaining a quality relationship with internal and external stakeholders.

Programs/activities included

- Annual highlights report
- Outreach
- Employee feedback
- Communication technology
- International and stakeholder communication
- Relationships with accredited veterinarians
- Collaboration and partnerships with other organizations

Key approaches FY 2004-2008

The Animal Health Safeguarding Review made numerous recommendations related to communication. The basics are in place, but improvements are needed within the VS organization itself, and certainly externally to our stakeholders. VS will publish a report on the status of animal health in the US on an annual basis. The first ever report will be available mid-year 2004 and will cover calendar year 2003.

Accountability for improving and sustaining communication successes

is necessary at many levels within the organization, and should be coordinated. Communication should be valued. The entire VS workforce should have knowledge of the VS mission and goals, as well as be able to easily obtain information on issues pertinent to mission area responsibility. There should be a forum for routine feedback from all employees, and value placed on that information. Communication technology will be expanded as a tool to reach both internal and external customers.

As an organization, there is value in assuring our stakeholders, both within the US and abroad, have access to current and timely information in times of crisis, as well as in regard to routine issues. Frequent and succinct marketing of VS is taking shape and will be expanded. VS should be prepared to communicate information in different forums, languages, and geographic areas.

Improved electronic communication between field and region and field and headquarters will be developed including the ability to pull reports and transmit data electronically.

VS will collaborate with industry groups, other federal and state agencies, and international partners to assure free flow of critical information. Particular focus will be on international trading partners and those involved with Homeland Security. Collaboration with IS and

the FAS should be maximized. Partnerships will be maintained with other Federal Agencies whose responsibilities also intersect with animal health such as FSIS, FDA and DOI (Bureau of Land Management, and Wild Horse and Burro Program).

Changes proposed for the National Veterinary Accreditation Program will allow regular communication by electronic means and development of a one-on-one relationship between VS field VMOs and accredited veterinarians. This will foster better

information exchange and a closer personal relationship.

Performance expectations

VS employees will understand their role as a part of the entire organization. Marketing and outreach will be an accountable activity for many within VS, as will open communication to and from employees. Trading partners will be able to approach VS with a firm background and current information.

Objective 5.3 Utilize information technology effectively

VS' information technology systems are critical in allowing VS to carry out its programs and activities. VS personnel must be equipped and trained to take maximum advantage of the benefits information technology has to offer.

Programs/activities included

- Information technology infrastructure and planning
- Geographic information systems
- Database systems: GDB, Veterinary Accreditation Database, EMRS, NAHLN, Animal/Animal Product Tracking System
- Government Paperwork Elimination Act
- Automated Information Management System

Key approaches FY 2004-2008

The Animal Health Safeguarding Review identified a number of areas in which VS could enhance its activities by utilizing improved information technologies. Several key needs identified in the Review were: assuring compatibility between information technology systems developed at the federal level with state systems, providing leadership in setting information technology standards, enhancing the use of geographic information systems, and addressing the issue of confidentiality. Projects addressing these issues will be worked on during the next several years.

The VS information technology infrastructure will be reviewed as necessary to assure that sufficient information technology support resources are available to meet the identified needs and that those resources are working collaboratively to integrate and link major information technology systems throughout VS. VS is also looking at creating data quality manager positions in each region. The data quality manager would review surveillance data entered into the GDB to provide assurance that monthly/quarterly reports based on this data are complete and comprehensive. Increased use of the data in the GDB for determining program status and making decisions about program direction will also help assure that steps are taken to improve the quality of the data. Training needs for personnel within the region will also be identified and the data quality manager will assist in providing this training. During responses to adverse animal health events, the data quality manager will oversee data entered into the Emergency Management Response System.

The GPEA process will be used as a stepping stone to incorporate information technology within VS workflow processes and gain efficiencies. Electronic animal health certificates, web-based reservations for animal import centers, electronic permits, and electronic access to VS memorandums are just a few results expected from this process.

VS will provide leadership in setting standards and establishing electronic linkages with key collaborators. Existing and newly developed VS databases will be modified so that electronic interactions with stakeholders are enabled. Animal identification information will be integrated into existing and new databases. Collaboration with states, NIAA, and industry will be needed to achieve this goal. VS will replace legacy Laboratory Information Management Systems with systems designed to enable electronic interaction with customers, field and laboratory staff, and other systems. Major modifications will be made to the veterinary accreditation database. In addition, improved methods for communicating with accredited veterinarians will be developed.

Capabilities for working with spatial data will be improved. VS is developing interactive mapping capability via the web and will be utilizing this capability to provide information to the VS organization and other stakeholders. VS has also trained a cadre of field personnel in GIS software.

VS will also implement systems enabling the tracking of inventory; chain of custody; and disposition of biological agents, diagnostic samples, veterinary biologic product samples, chemicals and reagents at VS laboratories. VS will also continue to collaborate with Sandia National Laboratories to implement adequate Cyber Security measures at its laboratory facilities. These tracking systems will bring VS into compliance with USDA Security Policy and Procedures and quality assurance program requirements. Real-time inventories and location information for select agents held at the NVSL and CVB are now accessible to APHIS Management through the newly developed Integrated Item Tracking System (IITS). Plans are in place to expand the system to include other agents as well.

Performance expectations

VS will take maximum advantage of information technology to streamline processes and improve its ability to carry out its animal health mission.

Objective 5.4 Implement administrative and management approaches which maximize flexibility while retaining accountability

Flexibility is needed in implementing VS programs. National and local interests often move in different directions and the local VS program manager must negotiate these shifting priorities.

Programs/activities included

- Strategic management
- Program analysis and planning
- Administrative process review

Key approaches FY 2004-2008

VS has long been an organization focused on specific disease eradication goals. Until recently, there was neither incentive nor practical reason to consider management approaches to address change elements. VS now works together with other state/federal agencies, as well as private industry to accomplish goals, making it crucial to have the flexibility to change quickly and fluidly as our own goals change and as the goals of our stakeholders dictate.

VS will review business models from companies in the private sector as well as successful federal agencies. VS will use these models to shape change elements and build flexible leadership fluent in change. Budgeting strategies such as Activity Based Costing will be reviewed and implemented. Administrative processes will be reviewed as part of the GPEA initiative and streamlined. Pay banding will be evaluated.

VS will proactively approach emerging diseases and response to animal health incidents by reviewing staffing levels, Incident Command training, and fostering a group dedicated to change. VS will better showcase its resources ready to lead change.

Through collaboration with stakeholders, VS will gain perspective on effective management approaches. Outside groups and academia may be used to provide third-party insight.

VS will continue to improve its GPRA performance reporting system. Performance measures will be developed for all major VS programs/activities and progress toward meeting these performance measures will be reported quarterly and reviewed by VS leadership.

Performance expectations

VS will be able to respond to changes in program direction seamlessly and without fear. VS will create a managerial environment in which the traditions of the organization are respected, new methodologies flourish, new approaches are encouraged, and continual improvement in personal and organizational performance is emphasized.