CFIA Evaluation of the Zoning for Foreign Animal Disease Control in the US

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TABLE OF CONTENTS

INTRODUCTION ........................................................................................................................................... 5

PART 1 - REVIEW OF THE VETERINARY INFRASTRUCTURE OF THE UNITED STATES FOR ZONING ........................................................................................................................................................ 6

1. LEGAL AUTHORITY ........................................................................................................................... 6
   a. Federal authority: United States Department of Agriculture (USDA) ............................................ 6
      i. Legislation on prevention, control and eradication of animal diseases ..................................... 6
      ii. Regulations governing quarantine and interstate movement of animals .................................. 6
      iii. Zoning within a state ............................................................................................................. 6
      iv. Reporting ................................................................................................................................... 7
      v. Emergency power for control of exotic disease outbreaks ................................................... 7
      vi. Compensation ....................................................................................................................... 7
   b. State authority .................................................................................................................................. 7

2. ORGANIZATIONAL STRUCTURE .................................................................................................. 9
   a. Veterinary Services, United States Department of Agriculture ..................................................... 9
      i. Surveillance, Preparedness and Response Services Organizational Structure (SPRS) ........ 12
      ii. National Import Export Services (NIES) .............................................................................. 13
      iii. Science Technology and Analysis Services (STAS) ........................................................... 17
      iv. Program Support Services (PSS) ....................................................................................... 19
   b. State Veterinary Services ........................................................................................................ 19
   c. Accredited veterinarians .............................................................................................................. 21
   d. Stakeholders ................................................................................................................................ 22

3. HUMAN AND MATERIAL RESOURCES ...................................................................................... 23
   a. Personnel .................................................................................................................................... 23
   b. Education and training ............................................................................................................ 23
   c. Monitoring and audit programs ................................................................................................... 24
      i. Strategic plans: objectives and priorities ................................................................................. 24
      ii. Performance assessment ........................................................................................................ 24
      iii. Compliance ......................................................................................................................... 25
   d. Budget and finances ............................................................................................................... 25
   e. Material resources ....................................................................................................................... 25

4. EMERGENCY PREPAREDNESS ................................................................................................. 26
   a. Contingency planning ............................................................................................................... 26
      i. Federal emergency plans ...................................................................................................... 26
ii. APHIS emergency plans ................................................................. 26
iii. State emergency plans ................................................................. 28
b. Livestock traceability: animal and premises identification .............. 28
c. Internal movement controls .......................................................... 29
d. Surveillance and reporting of epidemiological information ............. 29
i. Passive surveillance ................................................................. 29
ii. Active surveillance ............................................................... 30
e. Laboratory support .................................................................. 30

PART 1 - CONCLUSIONS ................................................................. 32

PART 2 - PROCEDURES FOR ZONING AND MAINTAINING ZONE INTEGRITY ........................................ 33
1. SUSPECT PHASE ......................................................................... 34
   a. Triggers .................................................................................. 34
   b. Field investigation .................................................................. 34
2. INVESTIGATION PHASE .......................................................... 35
   a. Sampling ................................................................................ 35
   b. Diagnosis ............................................................................. 35
3. ACTIVATION PHASE ................................................................. 36
   a. Decision to activate Incident Management Team ..................... 36
   b. Reporting .............................................................................. 36
   c. Movement Controls ............................................................... 37
4. ACTION PHASE ........................................................................ 38
   a. Initial activities ...................................................................... 38
      i. Biosecurity .......................................................................... 38
      ii. Vector/wildlife control to contain them within the zone ........... 38
      iii. Epidemiological investigation/tracing .................................. 38
      iv. Initiate surveillance ........................................................... 39
      v. Disposal ........................................................................... 40
   b. Containment/Eradication activities ........................................... 40
      i. Refine boundaries of zone based on epidemiology and tracing ... 41
      ii. Zone boundary controls .................................................... 41
      iii. Surveillance in disease free zone ....................................... 41
      iv. Compensation ................................................................... 41
      v. Decontamination of vehicles ............................................. 41
      vi. Cleaning and disinfection of premises ................................. 42
      vii. Vaccination ..................................................................... 42
5. RECOVERY PHASE ................................................................... 44
a. Proof of Freedom Surveillance
b. Release of Quarantine
c. Recovery of Free Status

Part 2 - CONCLUSIONS

ABBREVIATIONS AND ACRONYMS

REFERENCES
INTRODUCTION

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA) have undertaken evaluations of each other’s capacity to contain and eradicate a foreign animal disease (FAD) outbreak via zoning (also known as regionalization). The objective is to enhance mutual understanding of each country’s processes for zoning and potentially enable the agencies to formally recognize each other’s zoning decisions in the event of a foreign animal disease (FAD) outbreak. This recognition could limit disruption of trade from disease-free zones within the affected country as well as the economic impact.

In evaluating the equivalency of zoning processes, fundamental considerations are the veterinary infrastructure of a country’s veterinary services including legal authority, organizational structure, human and material resources, and emergency preparedness measures.

The second part of the evaluation consists of reviewing the emergency response phases in the event of an incursion of a highly contagious foreign animal disease and the procedures for establishing and maintaining the integrity of infected and disease-free zones. First, is the suspect phase: the triggers and the field investigation. Second is the investigation phase involving sampling, an epidemiological investigation, diagnosis and zoning. The third phase is the activation phase: activation of an Incident Management Team, official reporting, and movement controls. The objective of the next phase, the action phase, is to define the scope of the outbreak and to prevent further transmission. Measures include biosecurity on the farms, vector/wildlife control, epidemiological investigation and tracing, surveillance, and disposal of contaminated material. Containment and eradication activities additionally include surveillance in disease free zones, compensation to encourage reporting, and measures to limit spread, such as decontamination, cleaning, disinfection, and vaccination. The final stage is the recovery phase involving the proof of freedom surveillance, release of quarantine and movement restrictions and recovery of free status.

Diseases of concern for this review are highly infectious diseases which have a significant impact on livestock population and consequently, the national economy. These include foot-and-mouth disease (FMD), classical swine fever (CSF), exotic Newcastle disease (END) and highly pathogenic avian influenza (HPAI).
PART 1 - REVIEW OF THE VETERINARY INFRASTRUCTURE OF THE UNITED STATES FOR ZONING

1. LEGAL AUTHORITY

a. Federal authority: United States Department of Agriculture (USDA)

i. Legislation on prevention, control and eradication of animal diseases

The *Animal Health Protection Act* was enacted in 2002 to better equip veterinary services to perform various animal health safeguarding activities. The *Animal Health Protection Act*, Title 7 of the United States Code (7 U.S.C.), Chapter 109, Sections 8301-8317 [1], gives the USDA authority to regulate export, import, control disease, and engage in eradication activities. All relevant items to exercise control over zoning animal health matters such as prevention, control and eradication of animal diseases, quarantine, interstate movement of animals and animal products, zoning, reporting, and emergency power for control of exotic disease outbreaks, are included in the *Animal Health Protection Act* in general terms. The shared legal responsibilities between federal and state governments are emphasized.

The Secretary of Agriculture has the authority to act in an Extraordinary Emergency. The Secretary may take action within a state after review and consultation with the animal health official of the state, only on finding that measures being taken by the state are inadequate to control or eradicate the pest or disease (Subsection 8306 (b) [1], page 37 [2]) .

ii. Regulations governing quarantine and interstate movement of animals

Interstate movement of animals and animal products is regulated at the federal level. The Secretary of Agriculture can prohibit and restrict movements of commodities at risk within the state. The Secretary has the authority to inspect and make seizures on any premises in the US (Subsections 8305 – 8307 [1]).

iii. Zoning within a state

In Title 9 of the Code of Federal Regulations (9 CFR) [3], regulation 9 CFR Part 71.1 [3] defines a free area as the states, territories, or the District of Columbia or portions not quarantined by the Secretary of Agriculture for the specific contagious, infectious, or communicable animal disease.

According to Regulation 9 CFR Part 71.2, when the Secretary of Agriculture determines that poultry or other animals in any state, territory, or the District of Columbia are affected with any contagious, infectious, or communicable disease of livestock or poultry for which a quarantine should be established or that other basis for a quarantine exists, notice will be given of that fact and a rule will be issued accordingly, placing in quarantine such state, territory, or the District of Columbia, or specified portion thereof. This allows Federal officials to designate for quarantine any portion or area of a state, including a zone. This rule will either absolutely forbid the interstate movement of the quarantined animals from the
quarantined area or will indicate the regulations under which interstate movements may be made. The phrase "that other basis for quarantine exists" allows federal officials to impose a quarantine in the event that a serious animal disease event is considered imminent but not yet proven to exist.

iv. Reporting

Regulation 9 CFR Part 161.3(f) [3] requires accredited veterinarians to immediately report to a federal officer and the State Animal Health Official (SAHO) all diagnosed or suspected cases of a communicable animal disease for which APHIS has a control or eradication program, and all diagnosed or suspected cases of any animal disease not known to exist in the US. Individual states require veterinarians licensed to practice in the state and persons in care of livestock and poultry to report reportable diseases of that state and, in many states, to report any of the OIE-listed diseases.

v. Emergency power for control of exotic disease outbreaks

The Animal Health Protection Act authorizes the Secretary to declare an Extraordinary Emergency. This would allow federal officials to hold, seize, or destroy contaminated material and to prohibit or restrict movement within the state or portion of a state.

The Secretary of Agriculture has declared an Extraordinary Emergency for at least three animal health incidents in the last ten years: exotic Newcastle disease (END) in early 2003 (four declarations, one each for California, Arizona, and Nevada, and one for Texas and New Mexico together), bovine spongiform encephalopathy (BSE) in early 2004 (for Washington State), and for avian influenza (AI) in 2004 (Texas, [4]).

Authorization for a Declaration of Extraordinary Emergency could take as little as an hour in a major emergency such as foot-and-mouth disease (FMD). When the declaration is published (a few days later) it states the actual effective date. In the meantime, during the hour or two it might take to get federal authority to act, the state has authority to act immediately.

vi. Compensation

Compensation is described in regulation 9 CFR Part 71.14 and 9 CFR Part 53 [3] at the federal level. Compensation is based on fair market value, as determined by the Secretary. Compensation can be paid at the state level also, so the federal level would pay only the difference with the market value, if there is one. If there is any violation, no compensation is paid (9 CFR 53.10 [3] and [5, 6]).

b. State authority

State-level regulations are designed to control animal movement and internal commerce. Each state has the authority to place quarantines and hold orders as necessary in the event of a disease outbreak. Animal health authorities in each state are responsible for monitoring and controlling diseases in that state’s domestic livestock and poultry. Each state may develop its own respective domestic commerce regulations.

A Memorandum of Understanding (MOU) between a state and USDA–APHIS can be signed to outline expectations and procedures for a joint response in case of an animal health emergency. At this time,
there are no signed agreements with individual states related to expectations and procedures for a joint response. The USDA-APHIS’ Veterinary Services (VS) has signed an MOU October 11, 2009 with the National Assembly of State Animal Health Officials that provides a detailed explanation of actions to be taken by the Veterinary Services and National Assembly members to ensure effective communication in the event of an investigation or initial laboratory finding of a potential high-consequence livestock disease (Appendix B [7]).
2. ORGANIZATIONAL STRUCTURE

a. Veterinary Services, United States Department of Agriculture

The Chief Veterinary Officer (CVO) (Veterinary Service Deputy Administrator) reports to an APHIS Administrator who in turn reports to the Under Secretary of Marketing and Regulatory Programs (Figures 1, 2 and 3).

The Veterinary Services (VS) has a mission to protect and improve the health, quality, and marketability of the nation's animals, animal products and veterinary biologics by preventing, controlling and/or eliminating animal diseases, and monitoring and promoting animal health and productivity. The CVO and the VS represent the veterinary authority which speaks for the country as far as official international dialogue is concerned. The VS consist of four main parts: Surveillance, Preparedness and Response Services; National Import Export Services; Science, Technology and Analysis Services; and Program Support Services.

The organizational structure of the Veterinary Services includes the key functional capabilities (Article 3.2.3, Point 3 of the OIE Terrestrial Animal Health Code [8]), namely, epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems limited to interstate movements, communication of epidemiological information, training, inspection, certification, laboratory, and field systems. These functional capabilities are portrayed in the detailed organization charts and descriptions below.
Figure 1. USDA organization chart which displays the Headquarters Organization, including the Secretary, Chief Officers, Under Secretaries, and Assistant Secretaries for various agencies within USDA [4].
Figure 2. APHIS organization which displays the Headquarters Organization, including the Programs and Offices within APHIS [4].
Figure 3. Veterinary Services organization chart which portrays the organization of the Veterinary Services and its Programs, Offices, and Centers [4].

i. **Surveillance, Preparedness and Response Services Organizational Structure (SPRS)**

The SPRS reports directly to the Deputy Administrator of the Veterinary Services. SPRS comprises the Animal Health Centers, the National Preparedness and Incident Coordination Center, the SPRS Logistics Center, the One Health Coordination Center, and the Districts (Figure 4). Six geographic Districts (Figure 5) provide leadership for the implementation of all VS surveillance, preparedness, and response field activities. Within each District, Assistant District Directors serve as the primary points of contact for State Animal Health Officials and other local stakeholders. The SPRS key services include animal health incident management; commodity business planning; disease program, surveillance, and animal disease traceability policy setting and administration; emergency preparedness; epidemiologic investigations and tracing; veterinary accreditation; and veterinary stockpiling [9].

**National Preparedness and Incident Coordination Center (NPICC)**
(formerly known as National Center of Animal Health Emergency Management (NCAHEM))

NPICC develops strategies, policies and exercises for preparedness activities, develops disease specific plans and incident management and coordination during an animal health incident, coordinates Animal Disease Traceability and the National Veterinary Accreditation Program and coordinates delivery of training to field personnel and accredited veterinarians. NPICC is responsible for supporting the Emergency Support Function (ESF) #11 – Agriculture and Natural Resources under the National Response Framework, specifically for animal health incidents. ESF #11 is coordinated by the USDA and provides the structure for coordinating Federal interagency support in an incident response.
Surveillance, Preparedness & Response Services Logistics Center (SPRS Logistics Center)

The Logistics Center is responsible for oversight of the National Veterinary Stockpile of veterinary countermeasures animal vaccines, antivirals, or therapeutic products, supplies, equipment, and response support services that states, tribes, and territories needed to respond to animal disease outbreaks. Furthermore, the Logistics Center ensures rapid deployment of the animal disease countermeasures and the availability of animal identification tags and other supplies. The deployment of the National Animal Health Emergency Response Corps when needed is a responsibility of this center.

ii. National Import Export Services (NIES)

The NIES comprises Policy, Permitting and Regulatory Services, District Field Services, Animal Import Center Services, Port Services, Agricultural Select Agent Services, and International Animal Health Standards Services (Figure 6). The NIES operates six service centers, several animal quarantine facilities, and multiple ports of entry. The NIES key services include: import animal and animal product inspection and quarantine; import and export policy setting and administration; facility inspection; health certificate endorsement; World Organization for Animal Health (OIE) representation and disease reporting; pathways analysis and risk assessment; permit issuance; pre-export inspection; and select agent registration and inspection [9].
Figure 4. Surveillance, Preparedness and Response Services (SPRS) organizational structure.
Figure 5. Districts of the Surveillance, Preparedness and Response Services (SPRS).
Figure 6. National Import Export Services (NIES) organizational structure.
iii. **Science Technology and Analysis Services (STAS)**

STAS comprises the Center for Veterinary Biologics, the National Veterinary Services Laboratories, the Center for Epidemiology and Animal Health, and Office of STAS Interagency Coordination (Figure 7). The STAS key services include: analysis of response options; animal disease modeling; animal health data acquisition, analysis, and interpretation; animal health data standards; animal health surveillance design; diagnostic capability and capacity; economic analysis; national animal health laboratory network coordination; national studies and large scale epidemiological investigations; OIE Collaborating Center; predictive modeling; risk assessments; veterinary biologics approval and monitoring regulatory activities [9].

![Figure 7. Science, Technology and Analysis (STAS) organizational structure.](image)

**Centers for Epidemiology and Animal Health (CEAH)**

The CEAH [10] explore and analyze animal health and related agricultural issues to facilitate informed decision-making in government and industry. CEAH is also the OIE Collaborating Center for Animal Disease Information Systems and Risk Analysis. CEAH is comprised of five units: Monitoring and Modeling; Information Management and Analytic Support; Surveillance Design and Analysis; Risk Identification and Risk Assessment; and Program Support and Evaluation.

The National Animal Health Surveillance System (NAHSS) [11] is a network of federal, state, industry, university, laboratory, and other partners that collaborate through surveillance to protect animal health. The goal of NAHSS is to systematically collect, collate, and analyze animal health data and promptly
disseminate vital information, especially to those partners responsible for maintaining animal health. Early detection and global risk surveillance for foreign and emerging animal diseases is a NAHSS’ goal.

The USDA initiated the National Animal Health Monitoring System (NAHMS) [12] in 1983 to collect, analyze, and disseminate data on animal health, management, and productivity across the US. NAHMS conducts national studies on the health and health management of US domestic livestock populations. These studies are designed to meet the information needs of the industries associated with these commodities, as identified by people within those industries. The swine, dairy beef and poultry commodity groups are generally studied every 5 years.

The National Animal Health Reporting System (NAHRS) [13] is designed to collect data from chief state animal health officials on the presence of confirmed World Organization for Animal Health (OIE)-reportable diseases in specific livestock, poultry, and aquaculture species in the US. Under NAHRS, participating state animal health officials report monthly on the occurrence of confirmed OIE-reportable diseases in US livestock, poultry, and aquaculture species. NAHRS reports animal disease occurrence to the OIE as required.

National Veterinary Services Laboratories (NVSL)

The NVSL [14] is responsible for diagnosis for domestic and FADs, provision of diagnostic reagents, training, and laboratory certification for selected diseases. The NVSL serves as the national veterinary diagnostic reference and confirmatory laboratory for the APHIS VS program diseases and is an OIE reference laboratory for 13 diseases, including avian influenza, FMD, and Newcastle Disease. NVSL coordinates activities; participates in methods validation; and provides training, proficiency testing, assistance, materials, and prototypes for diagnostic tests. Training of state and federal field veterinarians to detect foreign animal diseases and training for laboratory diagnosticians are functions of the NVSL. The NVSL comprises four laboratories at two locations: the Diagnostic Bacteriology Laboratory (DBL), Ames, Iowa; Diagnostic Virology Laboratory (DVL), Ames, Iowa; Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York; and the Pathobiology Laboratory (PL), Ames, Iowa. In addition, the NVSL operates the program office of the National Animal Health Laboratory Network (NAHLN). The FADDL is responsible for diagnosing and confirming FADs, training of Federal and State veterinarians in the recognition and diagnosis of FADs and is the manager of the North American FMD Antigen Bank.

The NAHLN [15] is a cooperative effort between two USDA agencies—the Animal and Plant Health Inspection Service (APHIS) and the National Institute of Food and Agriculture (NIFA), formerly the Cooperative State Research, Education and Extension Service (CSREES), and the American Association of Veterinary Laboratory Diagnosticians (AAVLD). It is a multifaceted network comprised of sets of laboratories that focus on different diseases, using common testing methods and software platforms to process diagnostic requests and share information. There are over 60 laboratories in NAHLN. The state/university laboratories in the NAHLN perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for FADs. State/university laboratories participate in the development of new assay methodologies. The NAHLN laboratories are trained, proficiency tested and follow standardized testing protocols for avian influenza (AI), bovine spongiform encephalopathy (BSE), chronic wasting disease (CWD), CSF, END, FMD, pseudorabies virus (PRV), scrapie, swine influenza virus (SIV), and vesicular stomatitis virus (VSV).

Center for Veterinary Biologics (CVB)

The CVB [16] regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention,
and treatment of animal diseases are pure, safe, potent, and effective. The CVB regulates veterinary biologics and is responsible for enforcing the *Virus-Serum-Toxin Act* [17].

### iv. Program Support Services (PSS)

PSS provides key support services for both VS personnel and stakeholders. PSS comprises the Planning, Finance and Strategy Staff, Management Support Staff (including the Professional Development Staff), the Chief Information Officer, and the Writing, Editing, and Regulatory Coordination Staff. The PSS key services include: monitoring; animal health information technology systems; guidance documents; regulatory coordination; recruitment; Secretary’s Advisory Committee on Animal Health facilitation; strategic planning; technical training; and workforce/succession planning [9].

#### b. State Veterinary Services

Cooperation exists between the USDA and individual states on several animal disease eradication, certification, disease control, and monitoring programs. The state veterinarian and the Assistant District Director establish a Unified Command to coordinate disease management. In an animal health emergency the state activates its state, regional, or local emergency operations centers to interface with other agencies within the state (page 66 [2]). The initial response is state level.

With respect to animal disease reporting, all federally accredited veterinarians and state laboratories are required to report OIE-listed diseases to the USDA (page 46 [2]).


The National Poultry Improvement Plan (NPIP) [18] is an example of federal, state, and poultry industry collaboration in low pathogenic avian influenza (LPAI) surveillance and disease programs for *Salmonella* and *Mycoplasma*. Other cooperative programs include the National Pseudorabies Eradication Program, the National Swine Brucellosis Eradication Program, the Bovine Tuberculosis Eradication Program, the Brucellosis Eradication Program, the Voluntary Bovine Johne’s Disease Control Program, the National Scrapie Eradication Program, the Voluntary Federal Cervidae Tuberculosis Herd Accreditation Program, the Federal Chronic Wasting Disease (CWD) Herd-Certification Program, and the Equine Infectious Anemia (EIA) Control Program.

Information on the following six states was used to illustrate the similarity of activities among states and their involvement and cooperation with national programs. North Carolina, Iowa, Oklahoma, Colorado, and Texas are all classified as free states in the Bovine Tuberculosis Eradication Program, the Brucellosis Eradication Program, and the National Swine Brucellosis Eradication Program, and Stage V of the National Pseudorabies Eradication Program [19].

In North Carolina [20], the Veterinary Division is under the authority of the Commissioner, Department of Agriculture and Consumer Services (NCDACS). The Veterinary Division “protects the health of the state’s livestock and poultry population through the administration of regulatory animal health programs and its diagnostic laboratory system.
Responsibilities include the surveillance, monitoring, control, and eradication of diseases; regulation of animal movements; inspections and testing on the farm and at markets and sales; providing diagnostic laboratory service to owners and their veterinarians; and conducting regulatory disease testing to facilitate interstate and export movement of animals and food products.” North Carolina has a reportable list of 30 diseases including “foreign animal diseases” as a disease entity, for which all persons practising veterinary medicine in the state must report to the State Veterinarian within two hours after the disease is suspected to exist.

The Animal Industry Bureau of the Iowa Department of Agriculture and Land Stewardship (IDALS) [21] has as its mission “to protect, safeguard, and improve animal health among all livestock industries in Iowa through animal movement regulations, exhibition regulations, import regulations, and cooperative disease control/education campaigns; to cooperatively work with academia, industry groups, and others to eradicate/control infectious and contagious diseases of importance to animal agriculture in Iowa; and to protect the animal agriculture industry FAD introductions and maintain a state of emergency preparedness sufficient to deal with disease and natural disaster concern.” The Bureau has a list of 9 reportable diseases (avian influenza, BSE, chronic wasting disease, enzootic Newcastle disease, FMD, Johne’s, pseudorabies, scrapie, and West Nile virus).

The State of Colorado [22], under the Commissioner of the Colorado Department of Agriculture (CDA), has an Animal Industry Division headed by the State Veterinarian, an Assistant State Veterinarian, a Livestock Disease Veterinarian, and two field veterinarians. The Animal Industry Division is responsible for animal health and disease control activities and laboratory services. Colorado has a reportable disease list of 33 diseases, including “vesicular diseases” as a disease entity, which must be reported to the Colorado State Veterinarian. Under the Livestock Health Act, Colorado Revised Statutes, Title 35 Agriculture, Article 50: “Any person who knows or has reason to believe that any livestock that belongs to or is in the possession of such person, or any livestock upon such person’s premises, has a reportable disease shall immediately report such disease to the State Veterinarian”. In addition to the diseases on the list, any disease of unusual morbidity or mortality that does not fit a normally expected clinical picture shall be reported.

The State of Oklahoma [23] has an Animal Industry Services under the Oklahoma Department of Agriculture, Food and Forestry (ODAFF) which covers the area of animal health, meat inspection, and dairy production inspection. Oklahoma has a reportable disease list of 87 animal and poultry diseases. Under provisions of Title 59, Oklahoma Statutes, Section 698.15, the State Board of Agriculture declares and requires the following actions regarding contagious or infectious diseases of domestic animals by any person engaged in the practice of veterinary medicine: (1) listed reportable diseases shall be immediately reported to the State Veterinarian, and (2) the name, location and species for the disease identified must be provided. In addition, diseases not confirmed or diagnosed as a listed reportable disease shall be reported if the following clinical symptoms are exhibited: (1) sore mouth or muzzle, especially if accompanied by foot, udder, vulva, or skin lesions resembling blisters or vesicles; (2) encephalitis (central nervous system) conditions in all animals and avian species; (3) high death loss, especially over a short period of time in animals more than several weeks old; (4) reproductive problems; and (5) any highly unusual condition or unusual symptomatology of any kind. The State maintains its bovine brucellosis, tuberculosis, pseudorabies, and swine brucellosis free status, surveillance and import restrictions, and monitors and/or
maintains surveillance for trichomoniasis, tuberculosis, bovine babesiosis, Johne’s disease, anthrax, pullorum-typhoid under the National Poultry Improvement Plan (NPIP), pseudorabies, scabies, screwworm, malignant catarrhal fever, and all vesicular diseases.

The Texas Animal Health Commission (TAHC) [24] has as its mission: to protect the animal industry from, and/or mitigate the effects of domestic, foreign and emerging diseases; to increase the marketability of Texas livestock commodities at the state, national and international level; to promote and ensure animal health and productivity; to protect human health from animal diseases and conditions that are transmissible to people; and, to prepare for and respond to emergency situations involving animals. TAHC works to protect the health of all Texas livestock. The TAHC works to protect the health of both domestic and exotic Texas livestock. The TAHC has a reportable disease list of 67 species-specific and multiple-species diseases. Under the Texas Administrative Code, Title 4, Part 2, Chapter 45, Rule 45.2, a veterinarian, a veterinary diagnostic laboratory, or a person having care of an animal must report the existence of reportable diseases to the TAHC within 24 hours after diagnosis.

c. Accredited veterinarians

The Veterinary Services maintains a list of active federally accredited veterinarians who assist with disease exclusion and control during non-emergencies, however, the accredited veterinarians can be called upon for emergency disease responses. For the most part though, accredited veterinarians perform official diagnostic tests, inspections, treatments and vaccinations, and submit diagnostic specimens to designated laboratories.

Accredited veterinarians must satisfactorily complete a core orientation program presented by the APHIS VS Area Office of the state in which they wish to perform accredited duties, as well as any required state-specific training. Veterinarians must indicate their accreditation category: Category I includes all animals except food and fibre species, horses, birds, farm-raised aquatic animals, all other livestock species, and zoo animals that can transmit exotic animal diseases to livestock; Category II includes all animals. Accreditation must be renewed every 3 years. Accredited veterinarians must complete APHIS-approved supplemental training for re-accreditation: 3 units for Category I veterinarians and 6 units for Category II veterinarians (9 CFR Parts 160, 161 [3]). The training is available online at no charge [25].

Federal legislation allows for the establishment of standards of conduct for accredited veterinarians: accreditation could be suspended or revoked if there is a violation. An accredited veterinarian shall perform the functions of an accredited veterinarian only in a state in which the accredited veterinarian is licensed. The tasks to perform are clinical examinations, animal identification, export certification, official seals application and removal, blood sampling, and application of cleaning and disinfection plans. The regulations concerning accredited veterinarians are published in 9 CFR Parts 160, 161, 162 [3]. The regulations require accredited veterinarians to be able to develop appropriate biosecurity protocols, as well as cleaning and disinfection protocols, to control communicable disease spread. These skills are necessary to control or prevent the spread of diseases encountered within the normal course of veterinary practice. In the event of an FAD outbreak, accredited veterinarians would follow biosecurity measures and cleaning and disinfection protocols developed at the state or federal level. A National Veterinary Accreditation Program Reference Guide, July 2011 [26], details the involvement of accredited veterinarians in control and eradication programs, animal health emergency management, movement controls, disease surveillance, laboratory submission, cleaning and disinfection, and animal identification. Additionally, the National Veterinary Accreditation Program (NVAP) [27] details the compliance requirements and regulations pertaining to the responsibilities of the accredited veterinarian.
d. Stakeholders

Mechanisms are in place for collaboration/interaction with all stakeholders, including state governments and industries. There is legal provision in the *Animal Health Protection Act* (109, Sec. 8310) [1] on cooperation among stakeholders to carry out operations or measures for animal health protection, including different federal agencies, states or political subdivisions of states, national governments of foreign countries, local governments of foreign countries, and domestic or international organizations, domestic or international associations. All decisions or policy changes involve a regulatory change, which includes a consultation process with all stakeholders, including industry representatives.
3. HUMAN AND MATERIAL RESOURCES

a. Personnel

There are 83,730 veterinarians registered in the US: 546 are permanent veterinarians at the national level; 369 are field veterinarians; 11 are in Emergency Management and Diagnostics and 31 are in the National Veterinary Service Laboratory. 67,000 veterinarians are federally accredited. The Veterinary Services employ 179 full-time veterinarians in the Eastern Region and 184 full-time veterinarians in the Western Region [2]. In 2001, APHIS established the National Animal Health Emergency Response Corps (NAHERC) [28] as an additional resource to supply veterinary personnel for emergencies.

Between FY 2002 and FY 2005, funds for the veterinary services more than doubled. It resulted in approximately 300 additional permanent staff (20% increase) to address, at least partially, the under staffing noted in the review of the National Association of State Departments of Agriculture (NASDA). Personnel were added in key positions in surveillance and emergency response.

b. Education and training

It is apparent that the VS of the USDA strongly encourages continuing education and training of federal and state veterinarians, especially in the area of FAD preparedness and animal disease control and eradication. The VS offers FAD training courses, courses in epidemiology, emergency response, FAD agents, scrapie surveillance, brucellosis, tuberculosis, Johne's disease, pseudorabies, and poultry diseases. Federal veterinarians must achieve a designated number of continuing education hours, ensuring that the VS consists of fully-trained personnel capable of responding quickly and adequately to emergency situations (page 72 [2]). NPICC has a responsibility for planning and coordinating delivery of training of field personnel for readiness to respond to an animal disease outbreak as well as training of private veterinary practitioners to work cooperatively with federal and state veterinarians.

There is over 250 specially trained state or federal veterinarians, known as Foreign Animal Disease Diagnosticians (FADDs). On average, 160 participants are trained in FAD diagnostics each year. The FADD course is a 2-week classroom and laboratory course that provides training in identifying and diagnosing FAD diseases in poultry and livestock, and in the investigation of potential foreign and emerging animal diseases. Foreign Animal Disease Practitioner (FADP) courses for APHIS field Veterinary Medical Officers and state veterinarians are 1-week classroom and laboratory courses to demonstrate necropsy techniques, sampling, and FAD investigation (pages 74, 75 [2]).

The National Veterinary Accreditation Program certifies private veterinary practitioners to work cooperatively with federal veterinarians and state animal health officials. Continuing education is a requirement for private veterinarians to maintain accreditation (page 72 [2]). A great proportion of the core group of veterinarians (80%) are the accredited veterinarians, who would be in the front lines of the response. Mechanisms are in place to monitor this group and to ensure that proper training is provided for rapid detection and response.

There are 28 veterinary medical schools in the US accredited by the American Veterinary Medical Association (AVMA) (page 21 [2]).
c. Monitoring and audit programs

i. Strategic plans: objectives and priorities

According to the VS Strategic Plan 2006-2011 [29], the Veterinary Services is responsible for protecting and improving the health, productivity, quality, and marketability of animals, animal products, and veterinary biologics by monitoring animal health and conducting surveillance for animal diseases; preventing, controlling and/or eliminating zoonotic and animal diseases; and partnering with domestic and global stakeholders. Priorities are to improve and streamline the regulatory processes, to resource the National Surveillance Unit and complete national surveillance objectives, to complete the eradication of brucellosis and tuberculosis, to improve LPAI/HPAI surveillance, to establish the National Veterinary Stockpile, to continue development of the National Animal Health Laboratory Network, to complete National Veterinary Services Laboratories (NVSL) accreditation, to support new technologies that improve productivity, to increase the number of veterinary biologics available, and to improve VS information technology.

The Veterinary Services 2015 Project, One Health Strategic Direction [30] has the aim to have the VS lead in the animal health component of One Health. The goals in this One Health strategic plan include the alignment of VS policy, programs and infrastructure with the plan’s vision, building collaborations and partnerships in the OH community and building new skill sets to support and integrate the One Health principle.

ii. Performance assessment

In 2000, APHIS established a cooperative agreement with the National Association of State Departments of Agriculture Research Foundation (NASDA) to coordinate an assessment of capabilities of the US, state governments, and the livestock industry to protect US livestock from animal diseases. The NASDA report was published in October 2001 as the National Animal Health Safeguarding Review [31]. It included domestic detection and surveillance, exclusion committee, international information, and response.

The mission of the exclusion committee was to review all facets of efforts to prevent incursions of FADs into the US, from gathering international animal health information, promulgating import regulations, and physical inspection activities at ports of entry, to domestic surveillance and monitoring systems.

There are six strategic goals that guide USDA’s core performance measures: to enhance international competitiveness of American agriculture; to enhance the competitiveness and sustainability of rural and farm economies; to support increased economic opportunities and improved quality of life in rural America; to enhance protection and safety of the Nation’s agriculture and food supply; to improve the Nation’s nutrition and health; and to protect and enhance the Nation’s natural resource base and environment.

Different types of reviews and audits are done regularly to evaluate the efficacy and adequacy of the Veterinary Services, and changes are made according to findings and recommendations. Different sources of funds are available to ensure proper response in case of an emergency, and there is good collaboration with other stakeholders. The states are a crucial player of the VS if an emergency situation should occur. Based on recommendations of previous reviews, many discussions and working collaborations were implemented to improve communication and to harmonise efforts.
iii. Compliance

APHIS Investigation and Enforcement Services unit investigates violations of VS regulations and coordinates with the Office of General Counsel to prosecute these violations. USDA’s Office of the Inspector General conducts periodic independent audits of the VS programs to ensure compliance with program objectives [2, 32, 33].

d. Budget and finances

The budget for VS was, from 2001 to 2007 respectively (in millions of US dollars): 272, 260, 518, 344, 335, 261, and 296. The budget difference between 2001 and 2007 is 9%. Some of the budget comes as transfers from the Commodity Credit Corporation (CCC), a government-operated corporation that stabilizes farm income and prices. The budget for Emergency Management and Diagnostics (EMD) went from 2.6 million in 2001 to 9.4 m in 2007. As an example, CCC transfers for AI (low/highly pathogenic avian influenza) amounted in 2002 to $84.4 m, in 2004 $15.4 m, in 2006 $37.2 m, and in 2007 $8.2 m. while a transfer of $ 214 m for END occurred in 2003 (pages 23, 24 [2]).

Funds are provided to state cooperators through grants and cooperative agreements. In an animal health emergency VS may obtain additional funds from other unobligated sources as determined by the Secretary of Agriculture. The Deputy Administrator of Veterinary Services can send a written request to the Secretary for CCC funds to respond to an emergency pest, disease threat, or outbreak affecting US agricultural commodities (page 22 [2]).

e. Material resources

The VS operates or staffs six Animal Health Districts, four hub locations (Fort Collins, Colorado; Ames, Iowa; Raleigh, North Carolina; and Riverdale, Maryland), six NIES Service Centers, 17 NIES Northern Border Ports, 11 NIES Southern Border Ports, three NIES Animal Import Centers (Los Angeles, Miami, and New York) and six NIES Air and Sea Ports [9]. In FY 2008 APHIS operated 4273 vehicles and 44 aircraft. The operating costs of the vehicles in FY 2008 were over $8.3 million (page 72 [2]).

The National Veterinary Services Laboratory (NVSL) [14] provides diagnostic services for domestic and foreign animal diseases, responds to animal health emergencies, assists in managing the National Animal Health Laboratory Network (NAHLN) and serves as an international reference laboratory. It comprises four laboratories at two locations, the Diagnostic Bacteriology Laboratory (DBL), Ames, Iowa, Diagnostic Virology Laboratory (DVL), Ames, Iowa, Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York and the Pathobiology Laboratory (PL), Ames, Iowa.

Research responsibilities in relation to animal health and veterinary public health matters are conducted in Agriculture Research Service (ARS) laboratories. In FY 2008 had a budget of $74 million for livestock protection research and $104 million for food safety research (page 35 [2], [34]).

For communication, there is the VS Process Streamlining System (VSPS) [35] which provides a consistent and standard method of capturing data at all levels. Information is shared among stakeholders, which include VS personnel, accredited veterinarians, state officials, importers, and exporters. The National Animal Health Laboratory Network (NAHLN) Information Technology System [15] is setup to standardize data, maximize the efficiency of data transfer, report laboratory results in the event of an animal disease outbreak, enhance surveillance programs and recognize emerging issues. The system is available in all NAHLN laboratories.
4. **EMERGENCY PREPAREDNESS**

a. Contingency planning

i. **Federal emergency plans**

Contingency plans are available at all levels of intervention and follow national standards included in the National Incident Management System. Once VS identifies an animal health incident the Agency activates its response system following National Incident Management System standards [36, 37], which employ an Incident Command System (ICS) at the incident level. In the event of a major animal health emergency in the US, ICS makes it possible for the appropriate local, state, and federal governments and their private sector partners to respond in a coordinated, mutually supportive manner to define the nature of the disease outbreak or other emergency, initiate an appropriate response, eliminate or control the disease or other hazard, and help facilitate recovery (page 65 [2]).

The ICS provides a managerial and organizational structure to accomplish the objectives in the incident action plan. In any given animal health incident, one of three levels of response (local, state, and federal) may be appropriate and commensurate with the severity of the outbreak or other emergency. Industry agricultural officials as well as non-agricultural personnel from government (for example, the Federal Emergency Management Agency (FEMA) through the National Response Framework (NRF) [38] and the private sector are included to accomplish national-level crisis management, response coordination, consultation, and consequence management (page 65 [2]).

The NRF [38] was developed in response to the Homeland Security Presidential Directive to align federal coordination structures, capabilities, and resources into a unified, all-hazards approach to domestic incident management (page 66 [2]). The NRF presents the guiding principles that enable all response partners to prepare for and provide a unified national response to disasters and emergencies. It establishes a comprehensive, national, all-hazards approach to domestic incident response. A second edition of the National Response Framework became available in 2013, while the first edition was released in 2008. It describes how communities, tribes, states, the federal government, private sectors, and non-governmental partners work together to coordinate national response; describes specific authorities and best practices for managing incidents; and builds upon the National Incident Management System (NIMS) [36], which provides a consistent template for managing incidents.

ii. **APHIS emergency plans**

Extensive coordination efforts are in place to ensure continual collaboration between all stakeholders in emergency response. Emergency preparedness and response are done in partnership with various governments and stakeholders: federal, state, tribal, local, industry, and other private sector cooperators. APHIS coordinates the efforts mounted jointly by the federal government and the governments of affected states. Each year VS provides FAD and emergency response training to federal and state veterinarians, program specialists, and others [39].
The Surveillance, Preparedness and Response Services (SPRS) [40] is an integrated system for dealing with animal health incidents in the US. For preparedness and incident management, The SPRS develops and distributes emergency response guidelines based on the National Incident Management System and the Incident Command System for responding to a foreign animal disease or pest, and providing incident goals, objectives, strategies, procedures, and timelines; coordinates investigations and disseminates information about suspected outbreaks of foreign animal diseases; manages the National Animal Health Emergency Response Corps (NAHERC), a reserve of veterinarians and animal health technicians who can assist state and federal response efforts during an animal health event; and supports continuity of business planning through cooperative agreements with universities. For interagency coordination, the SPRS identifies resources and clarifies roles in the event of an animal emergency through participation in interagency and international working groups and permanent assignments at other Federal agencies; develops methods and techniques to obtain and analyze surveillance information within USDA and APHIS; leads the implementation of the joint USDA/Department of Homeland Security foreign animal disease modeling analysis center, and contributes funding to additional modeling efforts through cooperative agreements; and coordinates development and deployment of emergency disposal and decontamination tools through international, federal, state, industry and academic working groups and partnerships. The SPRS Logistics Center manages the National Veterinary Stockpile (NVS) of vaccines, supplies, equipment, field tests, vaccines, and support services) to ensure states have the resources to fight catastrophic animal disease outbreaks.

NVSL provides APHIS’s laboratory services. The NVSL provides a wide variety of information and services including the diagnosis of domestic and FADs, support of disease control and eradication programs, reagents for diagnostic testing, training, and laboratory certification (pages 64, 65 [2]).

APHIS has developed agent-focussed response plans and guidelines for FMD, CSF, END and HPAI [41-44] and for other diseases including African swine fever (ASF), Rift Valley fever (RVF), and peste des petits ruminants (PPR). These plans address agent-specific issues within the emergency response, such as initial field investigations; local disease control, health and safety, and special eradication activities; and interagency coordination.

To minimize the danger of a catastrophic multi-state FAD outbreak, APHIS, in cooperation with its state and industry partners, is expanding the US’ ability to respond to any animal emergency by developing locally based, nationally coordinated Animal Emergency Response Organizations at the state level. APHIS has designed these organizations, which draw upon the principles of the Incident Command System, to integrate easily with each state’s emergency management system as well as the National Response Framework (NRF). The NRF directs federal government agencies to mobilize for such emergencies (pages 65, 66 [2]).
iii. **State emergency plans**

A primary role of state government is to supplement and facilitate local efforts before, during, and after incidents. The state provides direct and routine assistance to its local jurisdictions through emergency management program development and by routinely coordinating these efforts with federal officials. States must be prepared to maintain or accelerate the provision of commodities and services to local governments when local capabilities fall short of demands.

Under the Framework, the term “state” and discussion of the roles and responsibilities of states typically include similar responsibilities that apply to US territories and possessions, and tribal governments. Under the *Stafford Act* [45], states are also responsible for requesting federal emergency assistance for communities and tribal governments within their jurisdiction. In response to an incident, the state helps coordinate and integrate resources, and applies them to local needs.

In an animal health emergency, including the outbreak of a highly contagious or significant zoonotic disease, the state activates its state, regional, or local emergency operations centers (EOCs), as needed, to interface with local governments, other state agencies, and the private sector. The State Veterinarian and the Assistant District Director (ADD) establish a Unified Command, which serves as the focal point for coordinating the disease management decision-making process (page 66 [2]).

An example of a Memorandum of Understanding (MOU) (Appendix 4 [2]) for the state role in animal emergency exists although no agreement has yet been signed. The MOU defines that the state and APHIS will work together in a unified command response organization, using the National Incident Management System. The operational activities under the program may include information dissemination, biosecurity measures, disease investigation, surveillance, vaccination, quarantine, valuation and compensation, depopulation, disposal, cleaning and disinfection, and evaluation for repopulation through use of sentinel animals. The state may have to mobilize additional resources from within the state. An MOU between VS and the National Assembly of State Animal Health Officials was signed October 11, 2009 on the communication of an initial investigation or laboratory finding of a high consequence livestock disease (Appendix B [7]).

**b. Livestock traceability: animal and premises identification**

Specific regulations pertaining to identification of certain cattle over two years of age and swine in interstate commerce are located in 9 CFR Parts 71.18 and 71.19, respectively. Specific regulations exist pertaining to the identification of animals for the control of certain diseases, that is, the identification of cattle for tuberculosis (9 CFR Part 77) and brucellosis control (9 CFR Part 78), identification of swine for brucellosis (9 CFR Part 79) and pseudorabies control (9 CFR Part 85), identification of sheep and goats for scrapie control (9 CFR Part 79), and identification of poultry for exotic Newcastle disease (END) control (9 CFR Part 82). General regulations for the traceability of US livestock moving interstate when animal disease events take place are found in 9 CFR Part 86, which was issued by the USDA on January 9, 2013 [46].

The rule of 9 CFR Part 86 establishes minimum national official identification and documentation requirements for the traceability of livestock moving interstate. The species covered in the proposed rule include cattle and bison, sheep and goats, swine, horses and other equines, captive cervids (e.g., deer and elk), and poultry. The covered animals moved interstate, unless otherwise exempt, would have to be officially identified and accompanied by an interstate certificate of veterinary inspection (ICVI) or other movement document. Livestock moved interstate to a custom slaughter facility or entirely within Tribal land are exempt from the regulations.
Cattle: the official identification requirements for interstate movement apply to all sexually intact cattle and bison 18 months of age or over, female dairy cattle of any age and dairy male cattle born after March 11, 2013, cattle and bison of any age used for rodeo or recreational events, and cattle and bison used for shows or exhibitions, unless exempt as indicated in 9 CFR Part 86.4 (b) 1 (i) A to D and (ii) for cattle and bison moved interstate direct to a slaughter establishment or to a livestock facility and then to a slaughter establishment, where they are harvested within 3 days of arrival. The ICVI is required for all interstate movement with the exemption that: 1) they are moved directly to a recognized slaughtering establishment, or directly to an approved livestock facility and then directly to a recognized slaughtering establishment, and they are accompanied by an owner-shipper statement; 2) moved directly to an approved livestock facility with an owner-shipper statement and do not move interstate from the facility unless accompanied by an ICVI; or for some other situations indicated in 9 CFR Part 86.5 (c).

Swine: The traceability rule for swine is based on the existing regulations for swine in 9 CFR Part 79.19 without change in the requirements for interstate movement of these animals.

Sheep and goats: The traceability rule requires that sheep and goats moved interstate must be officially identified prior to the interstate movement unless they are exempt from official identification requirements under 9 CFR Part 79.

Poultry: Poultry that are required to be officially identified for interstate movement must be identified by sealed and numbered leg bands in accordance with the National Poultry Improvement Plan (NPIP) regulations (9 CFR Parts 145 through 147) or a group/lot identification number (GIN) when it may be used. Poultry moving interstate must be officially identified prior to interstate movement unless: as agreed to by the states or tribes involved in the movement; the poultry is from a hatchery to a redistributor or poultry grower; or the shipment is from a redistributor to a poultry grower and the person responsible for receiving the chicks maintains a record of the supplier of the chicks. Poultry moved interstate must be accompanied by an ICVI unless: they are from a flock participating in the NPIP and are accompanied by the documentation required for participation in that program; they are moved directly to a recognized slaughtering establishment; they are moved under permit in accordance with 9 CFR Part 82 pertaining to END, and other reasons indicated in 9 CFR Part 86.5 (g).

c. Internal movement controls

Interstate movement regulations of live animals and poultry are included in 9 CFR Part 71 [3] which give provisions for movement, animal identification during interstate commerce, and provisions on maintaining sanitary conditions in facilities and means of conveyance. Each state has the authority to place quarantines and hold orders in the event of a disease outbreak.

d. Surveillance and reporting of epidemiological information

i. Passive surveillance

In 2012, APHIS conducted 586 investigations of suspected FADs or emerging disease incidents in 47 states and Puerto Rico. Of these, 475 were vesicular complaints, 275 in equids, 152 were in bovids, 18 in goats, 13 in sheep, 9 in pigs, 5 in alpaca and 3 in deer. Of the 586 investigations of suspected FADs, 36 resulted in a confirmed FAD finding, all 36 were diagnosed as vesicular stomatitis.

ii. Active surveillance

APHIS has partnered with other federal and state agencies and the commercial poultry industry in conducting surveillance for AI for many years. All commercial poultry flocks are tested for avian influenza through industry, state and federal efforts. The USDA tests wild birds for avian influenza in cooperation with the states and Department of the Interior. The National Poultry Improvement Plan (NPIP) H5/H7 LPAI Monitored Program requires the testing of meat-type chickens (broilers, roasters, Cornish, and fryers), commercial table-egg layers, meat-type turkeys, meat-type waterfowl and game birds, and raised-for-release waterfowl and game birds. Screening tests are performed in 129 NPIP-authorized laboratories throughout the country [48].

Active surveillance is being done for classical swine fever in high-risk states (Florida and Texas) and in Puerto Rico, high-risk herds such as waste feeders, feral swine, and in sick pig submissions to veterinary diagnostic laboratories [49]. There is currently no active surveillance for END or FMD [50].

e. Laboratory support

The National Veterinary Services Laboratories (NVSL) [14] is an OIE reference laboratory for 13 diseases such as vesicular stomatitis, END and HPAI. It received international accreditation to ISO 17025, ISO 17403 and ISO Guide. NVSL’s responsibilities include diagnosing domestic and FADs; providing diagnostic support for disease control, disease eradication, and animal-health monitoring programs; testing samples from animals for import and export; training APHIS and other US and international personnel; certifying US laboratories to handle the testing for selected diseases; and acting as a comprehensive reference laboratory. NVSL is responsible for laboratory certification at state and university levels to conduct official testing for certain diseases. The NVSL is the official reference laboratory for FAD diagnostic testing and study in the US. The NVSL trains and proficiency tests the NAHLN member laboratories either annually or semi-annually. Tests include standardized screening methods for the currently targeted diseases in the NAHLN (AI, END, FMD, CSF, PRV, BSE, SIV, CWD, scrapie, and VS). NAHLN laboratories perform screening assays and forward any suspect or positive samples to the appropriate section of the NVSL for confirmatory testing. The NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD investigations in the US. NVSL has a Quality Assurance Program that requires laboratories within NVSL and NAHLN to demonstrate technical competence in testing and calibration in accordance with international standards. Various external agencies conduct audits on a regular basis, including regulatory agencies and an independent accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC). NAHLN laboratories participate in yearly validation of testing procedures that include certification to monitor the ability of the organizations and staff to conduct these tests.

The National Animal Health Laboratory Network (NAHLN) [15] is part of a national strategy to coordinate the capabilities of federal, state, and university diagnostic laboratories. It is comprised of 61 state and university laboratories. NVSL validates positive or unexpected results. The NAHLN labs can do rapid tests such as for CSF, FMD, END, and AI. NAHLN initiated a surveillance program for CSF in 2006. This surveillance program targets sick pig submissions to veterinary diagnostic laboratories, slaughter swine with high risk of CSF exposure, feral swine, swine populations with high risk of CSF exposure in Florida, Texas and Puerto Rico and FAD investigations. NAHLN does not have a surveillance program for HPAI, however, many of the NAHLN laboratories are involved in AI testing for VS and state surveillance programs. Personnel in AI-approved NAHLN laboratories maintain current training and proficiency testing and this is the case for FMD-approved and END-approved NAHLN laboratories. NAHLN Methods Technical Working Group, established in July 2006, consists of personnel from NAHLN laboratories and NVSL. The working group provides input on various aspects of methods approval and validation. In addition, NAHLN is a participating member of the Integrated Consortium of Laboratory Networks, a multi-
department and multi-agency effort led by the Department of Homeland Security (DHS). This group identifies gaps in surveillance and diagnostic efforts of national importance, and develops mechanisms for collaborating and sharing information and resources.

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) [51] administers an accreditation program for public veterinary diagnostic laboratories in North America. Collaboration is being done between US, Mexico, and Canada to harmonize tests.
PART 1 - CONCLUSIONS

- Emergency response is shared at both federal and state levels. Close collaboration between the State Veterinarian and the APHIS Assistant District Director is crucial and fundamental to manage a disease incursion. This cooperation between the USDA and the states has been occurring for many years with respect to several animal disease eradication, certification, disease control, and monitoring programs.

- The organizational structure of the VS provides for an autonomous, integrated and inclusive veterinary services which is highly capable for response to an animal health emergency.

- The VS organization possesses the key functional capabilities for the effective control of the animal health status of the US.

- The legislative authority of the *Animal Health and Protection Act* and Title 9 of the *Code of Federal Regulations* permits the VS to have control over animal health in cooperation with state authorities.

- The human and material resources of the VS and state animal health services are adequate to respond properly to an FAD incursion and zoning approach.

- The continuing education and training programs of federal, state, and accredited veterinarians in the area of FAD preparedness, animal disease control, and eradication are exemplary and the basis for competence of the veterinary services.

- The capability to promptly detect incursion of disease is supported by active and passive surveillance and a strong laboratory network. The laboratory network in the US is well coordinated and can adequately provide high quality support for on-going surveillance, prompt detection, and appropriate capacity during an outbreak situation.

- The traceability capability establishes minimum national official identification and documentation requirements for the traceability of livestock moving interstate.

- The veterinary infrastructure of the United States has the capability to detect and respond promptly to new incursions of highly infectious disease on its territory. Reporting to trading partners, including Canada, and to the international community would be done in a timely manner.

- Zoning of FAD incursions in the US would be supported by a competent, effective and capable veterinary infrastructure.
PART 2 - PROCEDURES FOR ZONING AND MAINTAINING ZONE INTEGRITY

Figure 8. Zones established in the event of an FAD outbreak.

Part 2 reviews the eradication phases which are conducted if a highly infectious foreign animal disease is detected in part of the country and the zoning procedures applied to differentiate the disease status of the infected zone from the disease-free rest of the country.

APHIS defines a Control Area (CA) similar to the OIE definition of infected zone (Figure 8). The CA includes both an Infected Zone (IZ) and a buffer zone (BZ). The IZ would have its perimeter at least 3 km beyond the perimeters of an Infected Premises (IP), whether a presumptive positive or confirmed positive premises. The perimeter of the BZ would be at least 7 km beyond the perimeter of the IZ [52]. Numerous factors, however, are considered in determining the size of a CA as presented in Table 3-1 of the APHIS Foreign Animal Disease Framework Response Strategies [52] and Table 5-5 of the USDA APHIS FMD Response Plan: The Red Book and the respective documents for CSF, HPAI (Table 5-4) and ND [41-44].

A containment vaccination zone (CVZ) is an emergency vaccination zone inside the CA. The CVZ may include all of or part of an IZ and/or the BZ [52].

A surveillance zone (SZ) outside and along the border of the CA would be established to ensure the rapid and effective containment of disease with a focus on premises with the highest risk of infection. The width of the SZ would be at least 10 km [52].

Free area (FA) is defined is a territory not included in the CA and represents an area in which this subpopulation of animals has a disease free status. The FA contains the SZ [52].

A protection vaccination zone (PVZ) is an emergency vaccination zone outside the CA and may be subject to movement control and surveillance requirements as well as biosecurity procedures [52].
In a highly contagious foreign animal disease (HCFAD) outbreak there are six types of premises designations. An infected premises (IP) is a premises where a presumptive positive case or confirmed positive case exists as determined by laboratory results, clinical signs, and case definition. A contact premises (CP) is a premises with susceptible animals that may have been exposed to the FAD agent. A premises that is contiguous to an IP may be classified as a CP. A suspect premises (SP) is a premises under investigation due to the presence of susceptible animals reported to have clinical signs of an FAD. An at-risk premises (ARP) is a premises with susceptible animals but none have clinical signs of an FAD and an ARP is located within an IZ or BZ. A monitored premises (MP) is a premises which is an ARP but meets a set of criteria to move susceptible animals or animal products out of a CA by permit. A vaccinated premises (VP) is a premises where emergency vaccination has been performed. A free premises is a premises outside a CA, it can be located within a SZ or elsewhere in the FA [52].

The diseases of interest for zoning are highly contagious diseases in which rapid response and physical containment of infected premises is crucial for the control of the disease. Zoning would be the best approach. For that evaluation, four diseases were reviewed, FMD, CSF, HPAI and END. They are considered typical examples where zoning would be highly beneficial for disease control and trade purposes.

1. SUSPECT PHASE

a. Triggers

A highly contagious foreign animal disease (HCFAD) is one that spreads rapidly from animal to animal and, if given the opportunity, from herd to herd. Transmission can occur via direct and indirect modes. An HCFAD may be recognized by greater than normal morbidity or mortality per unit time (high incidence rate or high attack rate), where morbidity could be characterized by a loss of production even without overt signs of clinical disease. Foreign animal diseases such as FMD, CSF, END, and HPAI are considered highly contagious and would require a rapid and coordinated response to control and eliminate the agent.

A suspect case is an animal that has clinical signs consistent with a highly contagious FAD. Cattle, pigs, sheep and goats are susceptible to FMD, pigs to CSF and poultry to END and HPAI. Livestock owners or managers, private veterinarians, and federal and state veterinarians are the initial detectors of an HCFAD. FMD is typically recognized by vesicular signs whereas mortality may be the prominent sign of CSF, END and HPAI.

b. Field investigation

When livestock producers or veterinary practitioners suspect an HCFAD, they notify the State Veterinarian or the Assistant District Director (ADD). Depending on whether the suspect case is of high suspicion, categorized as Priority 1, the ADD notifies the Veterinary Services (VS) District Office and the National Preparedness and Incident Coordination Center (NPIC).

A Foreign Animal Disease Diagnostician (FADD) is assigned to conduct an investigation of the disease, including animal investigation and laboratory testing. This has to be initiated within 8 hours of receiving the initial report. The Director of the National Veterinary Services Laboratory (NVSL) reports the FAD test results to VS, NPICC, ADD for the state of the National Animal Health Laboratory Network (NAHLN), and the ADD for the state of sample submission. The FADD informs the owner and veterinarian [7].
2. INVESTIGATION PHASE

The FAD/EDI investigation period is defined as the time from when the investigation is initiated until the FAD/EDI is ruled out by a FADD field investigation, NVSL laboratory diagnostic testing or study results or by VS case definitions. The objectives of the investigation include a veterinary assessment consisting of a differential diagnosis, classification as to low, intermediate or high suspicion of an FAD, and designation of the priority of the diagnostic sample and provision of the presumptive and definitive diagnostic testing results as rapidly as required by the priority designation of the diagnostic sample.

The procedures for investigating an FAD are laid out in a VS Guidance 12001.1 [53, 54]. The Area District Director (ADD) and State Animal Health Official (SAHO) will initiate a timely investigation of all reported suspect FADs and assign the most readily available FADD to complete an investigation. The ADD and/or SAHO will assign a FAD/EDI Case Coordinator(s) to assist with investigation support, communications, and Emergency Management Response System (EMRS) data entry, as required by the location, scale, complexity, or urgency of the investigation.

During the investigation of a suspected HCFAD or emerging disease incident (EDI), an FADD will use clinical signs, history, and professional judgement to determine the likelihood of the existence of an HCFAD or EDI. The assessment of a suspect HCFAD will include taking a history of clinical and epidemiological findings, performing physical examinations, performing necropsies, collecting diagnostic specimens, investigating trace backs and trace forwards, and recommending intrastate and interstate quarantines.

a. Sampling

Sample collection and diagnostics is briefly described in Section 5.4 of the respective Response Plans for FMD, CSF, END and HPAI [41-44]. The Foreign Animal Disease (FAD) Investigation Manual, FAD PReP Foreign Animal Disease Preparedness and Response Plan [55] provides detailed information on field kit components, protective equipment, sample collection, necropsy procedures, investigation procedures, diagnostic sample prioritization and preparation of diagnostic specimens for shipping.

b. Diagnosis

The classification of an FAD/EDI investigation as high suspicion indicates that the disease situation is consistent with a FAD/EDI and inconsistent with an endemic disease. With an intermediate suspicion, the assessments are consistent with either an FAD/EDI or endemic disease. With a low suspicion, the assessments are consistent with an endemic disease and inconsistent with a FAD/EDI. Upon classification to rank and prioritize the differential diagnosis in terms of the magnitude of suspicion for a foreign animal disease, the FADD, ADD and SAHO designate the priority of sample submission and contact the VS and NPICC. For investigations which are classified as high suspicion, diagnostic sample submissions are categorized as priority 1. The sample collection, transportation and diagnostic testing are conducted rapidly any day of the year and at any time of the day. Priority 2 sample submissions which arrive on a weekday or a Saturday during business hours are submitted to testing while submissions received after hours are processed the next weekday. Priority 3 designated sample submissions are treated as with routine surveillance samples [54].

The NVSL (two locations NVSL Ames (Iowa) and NVSL FADDL (Plum Island, New York) and the NAHLN are responsible for the diagnostic testing and studies. Two sets of diagnostics samples may be obtained, one set for the NVSL and the other set for the NAHLN laboratory. When a second set of diagnostic samples cannot be obtained, then the samples are submitted to the NVSL [54].
Information collected during the investigation includes, but not limited to, the clinical signs, lesions observed, herd/flock morbidity and mortality rates, duration of signs, species affected and the incident history of the herd/flock [54].

3. ACTIVATION PHASE

a. Decision to activate Incident Management Team

The APHIS Administrator is the federal executive responsible for the management of an incident such as an outbreak of FMD, CSF, END and HPAI. The APHIS Administrator will delegate much of the actual management of the incident to the Veterinary Services Deputy Administrator and APHIS Emergency Management Leadership Council (EMLC). The VS Deputy Administrator and EMLC will establish an APHIS Incident Coordination Group to oversee the staff functions associated with the incident at the APHIS headquarters level. The Incident Coordinator will work closely with the personnel in charge of establishing operations of the incident response at the Area Command (AC) or Incident Command Post (ICP) in the field and coordinate with the APHIS Multiagency Coordinating Group (MAC). The APHIS MAC Group provides support, coordination and assistance with policy-level decisions and is formed as the incident expands in size requiring off-scene coordination and support (Chapter 3 [56]).

The ADD and the affected state SAHO will initially serve as the Co-Incident Commanders for the unified Incident Command Post. The ADD and SAHO may be relieved by a VS Incident Management Team Incident Commander if there is a delegation of authority to the VS Incident Management Team. When more than one incident is occurring at the same time, more than one Incident Command (IC) may be established. An Area Command (AC) may be established. The AC will be responsible for managing coordination of all the incidents, along with the ADD and state officials. Furthermore, the NCAHEM Incident Coordination Group Plan (NCAHEM is now known as NPICC) provides a framework for incident management, including, elaborating: the procedures and protocols for executing APHIS Emergency Operations Center (AEOC) operations; coordination of the process for Level I (highest resource requirement), Level II and Level III (events; the organizational structure of the APHIS Incident Coordination Group (ICG) and its capabilities for incident response and coordination; the procedures for investigating a potential foreign animal disease or emerging disease incident; the roles and responsibilities of the ICG and NPICC personnel for incident management and continuity of operations; the provisions for delegation of authority for an incident; the relationship of NPICC with other Veterinary Services (VS) and APHIS departments, district offices, and Federal agencies involved in the response and the interaction among these organizations; and the process for requesting and distributing funds to support the incident response (Chapter 1 [56]).

b. Reporting

The NVSL Director, upon positive, suspect or inconclusive laboratory results, immediately contacts the VS Deputy Administrator, the VS Associate Deputy Administrator for Emergency Management and Diagnostics, the NPICC or VS District Office, the ADD for the state of the NAHLN, and the ADD for the state of the sample submission. Upon this notification from the NVSL Director, the NPICC or VS District Office coordinates a conference call within 2 hours. The FADD notifies the producer, owner and the veterinarian [53, 54]. Cases of clinical illness that are found to be presumptive positive, based on the current case definition for FMD at NVSL FADDL will be reported to the affected States, other States, Tribal Nations, industry, other Federal agencies, trading partners, and the World Organization for Animal
Health (OIE) [57]. The Emergency Management Response System (EMRS) FAD/EDI is a web-based database to record FAD/EDI investigations. EMRS manages information such as the case information, movement controls, permitting actions, epidemiological investigations, disease surveillance, laboratory test results, vaccine inventory, and vaccinated animals [58].

c. Movement Controls

The Incident Commander, Disease Surveillance Branch (Operations Section), and Situation Unit (Planning Section) coordinate to establish an IZ and BZ within 12 hours of the identification of the index case. Controlled movement orders and 24-hour standstill notices are implemented. The movement controls within the state are under the SAHO. State officials quarantine susceptible animals, animal products, and potentially contaminated fomites such as conveyances, and implement movement control in the form of a permit system. Implementation of quarantine and the administration of a permit system for movement control would be described in each state’s animal health emergency response plan. Federal officials initially quarantine the entire affected state; the quarantine remains in place until the disease is eradicated or an effective Control Area smaller than a whole state is implemented. The USDA would impose a federal quarantine on interstate commerce from the infected state(s) and request the infected and adjoining states to provide resources to enforce the quarantine (Section 5.10 [41-44]).

The CA, consisting of the IZ and the BZ, would be established to ensure the rapid and effective containment of the disease. Initially, multiple counties or the entire state under the authority of the SAHO, a Tribal Nation or multiple states would be declared a CA and be subject to movement restrictions. All susceptible animal movements would be stopped for a period long enough to determine the scope of the disease outbreak. The potential modes of transmission (e.g., aerosol, water, direct contact, fomites, vectors, etc.), characteristics of the agent, terrain, the pattern of livestock/poultry movements, livestock/poultry concentrations, weather, prevailing winds, the distribution and movements of susceptible wild and feral birds and animals, and processing options (livestock/poultry and livestock/poultry products), are considered when determining the minimum size and shape of the CA (Section 3.1.3 [52]).

In an outbreak of an HCFAD, the CA would encompass the perimeter of all presumptive or confirmed positive premises and include as many of the contacts as the situation requires logistically or scientifically. The boundary of the CA is at least 10 km beyond the perimeters of the presumptive or confirmed infected premises. The boundaries can then be modified (either expanded or reduced) as new information becomes available (Section 3.1.3 [52]).

A CA would be established within 12 hours of the identification of the index case, either a presumptive positive premises or confirmed positive premises (Section 5.10 [41-44]). Presumptive positive or confirmed positive premises are those that have at least one animal that is classified as having a presumptive positive or confirmed positive case of the HCFAD in question (Section 5.2.2 [41-44]).

A zoning plan describing free zones and CAs would be developed and implemented during the first week of the outbreak. Included would be the process of collecting all relevant information to defend a zoning plan to trading partners and the OIE. The zone would be set up and measures to maintain the zones established as soon as the disease situation has stabilized adequately.

Animals of the IP, CP and SP are quarantined and controlled movement orders are applied (Section 5.10 of [41-44]). Movements of susceptible species out of a CA from IP, SP and CP premises is prohibited except under circumstances such as to slaughter as determined by the IC. Movements out of the CA of non-susceptible livestock from premises with susceptible species, vehicles, equipment and other fomites from premises with susceptible species are controlled by permitting and appropriate biosecurity procedures. Movements out of the CA for non-susceptible livestock from premises without susceptible
species are not controlled. Within a CA, movements of susceptible species are allowed under permit approved by the IC if the premises is not an infected premises (IP), contact premises (CP), or suspect premises (SP). Permitting of susceptible animal movements within the CA is used for any ARP and MP and for movement out of the CA, a MP is allowed by permit approved by the IC. For movement of susceptible animals and animal products out of the CA, the permitting considers national and international standards, biosecurity measures and risk assessment recommendations (Tables 5-5 to 5-7 or Tables 5-6 to 5-8 Section 5.10.2 [41-44]).

4. ACTION PHASE

a. Initial activities

i. Biosecurity

Biosecurity procedures to prevent the spread of diseases such as FMD, CSF, END and HPAI have as a response goal to ensure that the biosecurity procedures are implemented within 12–14 hours of identifying the index case to prevent the spread of the disease. A biosecurity plan is implemented for all infected premises, contact premises, suspect premises, checkpoints and livestock and poultry facilities within the CA (Section 9.1 [59-61]).

The Animal Biosecurity and Disease Prevention Group, Disease Support Branch, Operations Section of the Incident Management Team is responsible for ensuring that appropriate biosecurity measures are implemented during an animal health emergency response to prevent the transmission of the disease agent to uninfected premises and/or animals on the same premises. These biosecurity measures are employed during the movement of personnel and materials necessary for such animal health activities as surveillance, vaccination, appraisal, depopulation and disposal (Sections 1.1 and 3 [62]).

ii. Vector/wildlife control to contain them within the zone

A wildlife management plan is developed as soon as possible after identification of the index case. An assessment of risk posed by wildlife is conducted within 7 days of confirmation of the index case (Section 5.18 [41-44]). A VS animal health policy in relation to wildlife has been elaborated [63].

Diseases such as FMD, CSF, END and HPAI can be transmitted mechanically by mice, vultures, and other vectors. Biosecurity measures are put in place to ensure that mechanical vectors do not have contact with infected swine herds or flocks or other infected material (Section 5.18.2 [41-44]).

iii. Epidemiological investigation/tracing

A team of advisors is deployed to the incident site to prepare an epidemiological assessment within 24 hours of arrival. Epidemiological techniques would be used to understand the characteristics of the disease and outbreak characteristics, to identify risk factors associated with the disease occurrence, to provide information for decisions on control measures, and to evaluate their effectiveness. The FMD, CSF and HPAI Epidemiological Investigation and Tracing SOPs [64-66] and the NAHEMS Guidelines: Surveillance, Epidemiology and Tracing [58], detail this part of the investigation.

Within 96 hours of identifying the index case, the goal of the epidemiological investigation is to characterize the nature of the outbreak, identify the risk factors and develop mitigation strategies. Other
goals include a goal of assigning premises classification and priority of investigation within 6 hours of identifying potential IPs or CPs through tracing and a goal of identifying all additional CPs within 24 hours of identifying the IP or initial CP. Trace-back and trace-forward information is ideally collected for at least 28 days of FMD and CSF and 21 days for END and HPAI. Tracing includes all movements from the premises including susceptible livestock or poultry, non-susceptible species, animal products, vehicles, crops and grains and people. Tracing considers the modes of transmission for the disease and any role of wildlife. The boundaries of the CA are modified when tracing and other epidemiological information becomes available (Section 5.5 [41-44]). Epidemiological investigation and tracing SOPs are available for FMD, CSF and HPAI [64-66].

Tracing would include all movements from the premises including susceptible livestock, non-susceptible livestock, animal products, vehicles, crops/ grains, and people. Tracing would consider potential modes of transmission and possible contact with wildlife. The goal is to identify all contact premises within 24 hours of identifying the infected premises or initial contact premises (Section 5.5.2 [64-66]).

The critical period is a minimum of two maximum incubation periods before the onset of clinical signs which is 28 days in the case of FMD and CSF and 21 days for poultry infected with HPAI (Section 5.5.3 [64-66]) or END (Section 5.5.3 [44]).

A case definition would be defined within 24 hours of the first presumptive case or confirmed positive case (index case). The case definition is modified on an ongoing basis based on additional information or changing needs of the eradication effort, as described in the Case Definition Development Process SOP [67]. The nature of the highly contagious disease is characterized, risk factors are identified, and mitigation strategies are developed within 96 hours of identifying the index case. Within 6 hours of identifying a potential infected premises or contact premises through tracing activities, premises are classified and priority of investigation is assigned (Section 5.10.3 Epidemiological Response Procedures for FMD and CSF and Section 5.5.2 Epidemiological Investigation for END and HPAI [41-44]).

iv. Initiate surveillance

Surveillance plans are implemented within 48 hours of confirmation of an outbreak. The surveillance plan defines the present extent of the outbreak, quickly detects unknown IPs, and considers the susceptible wildlife population.

In the initial 72 hours post outbreak, with the objective to detect the IP quickly, three goals are set: establish the BZ designation and the boundary of the CA, create a list of premises with susceptible herds, flocks and according to species in the CA, and determine the boundary of the SZ and its surveillance plan. Surveillance is conducted on each premises within the IZ and BZ for at least 28 days for FMD, CSF and END (Appendix F for FMD, Appendix D for CSF and END, [42-44]) and for at least 14 days for HPAI (Appendix E for HPAI, [41]). According to these surveillance guidance plans, the frequency of surveillance inspections/samplings varies with the disease, whether commercial or non-commercial (backyard for HPAI and ND) premises, whether the premises represents either a CP, SP, or MP versus an ARP, and in the case of CSF whether the CSF agent is acutely highly pathogenic, mildly pathogenic or established mildly pathogenic.

Depending on the availability of resources to intensively survey premises for FMD and CSF, a number of questions, which vary with the two diseases, on the disease outbreak, disease epidemiology, susceptible species in the CA, agent pathogenicity, livestock operations, and the amount of movements of animals, animal products, things, and people on and off premises are answered to indicate the level of sampling within herds (Section 5.3.2 and Appendix D (CSF) and F (FMD) [42, 43]). For FMD, sampling schemes
and sampling frequency are elaborated for commercial and non-commercial premises in the IZ and BZ for the CP, SP and MP and for the ARP and in the SZ for SP and FP with susceptible species (Appendix F [42]). For CSF, sampling schemes and sampling frequency are elaborated for both commercial and non-commercial premises for acutely, mildly and established mildly pathogenic virus in the IZ and BZ for the CP, SP and MP and for the ARP and in the SZ for SP and FP (Appendix D [43]).

For END and HPAI, specific surveillance schemes for each zone (IZ, BZ and SZ) and premises designation for commercial and backyard flocks are elaborated (Section 5.3.2 and 5.3.3 and Appendix D (END) and Appendix E (HPAI) [41, 44]).

v. Disposal

Disposal of contaminated material and carcasses is to be done in a manner which does not allow the disease agent to spread, has a limited effect on the environment, and preserves animal protein, where possible. It is done as soon as possible after the depopulation of susceptible animals on the premises. The disposal of carcasses, animal and poultry products, litter, bedding, feedstuffs and products of the veterinary response efforts, infected with, exposed to, or contaminated with the disease agent may be by on-site burial, off-site burial, composting, landfills, rendering, digestion, or incineration (Section 5.14 [41-44]). An SOP for disposal focuses on the responsibilities of personnel, evaluation of sites, selection and execution of methods, and disposal of waste materials for a HCFAD affecting livestock animals and poultry [68]. The NAHEMS Guidelines: Disposal, additionally elaborates on disposal methods in the event of an HCFAD incursion [69].

b. Containment/Eradication activities

A stamping-out policy is the primary strategy for all HCFAD that would be implemented on all infected premises and appropriate contact premises. Stamping-out involves the depopulation of clinically affected and in-contact susceptible animals. For FMD there are four response strategies: stamping-out, stamping-out modified with emergency vaccination to slaughter, stamping-out modified with emergency vaccination to live and emergency vaccination to live without stamping-out. For CSF the strategies are: stamping-out, stamping-out modified with emergency vaccination to kill, stamping-out modified with emergency vaccination to slaughter and stamping-out modified with emergency vaccination to live. If emergency vaccination is used, a Containment Vaccination Zone (CVZ) would be established in the infected zone, the buffer zone, the entire control area or a part of the buffer zone. For the FMD strategies of stamping-out modified with emergency vaccination to live and emergency vaccination to live without stamping-out and the CSF strategy of stamping-out modified with emergency vaccination to live, a Protection Vaccination Zone (PVZ) would be established in which targeted vaccination of non-infected animals is conducted. Vaccinated animal identification, movement controls, traceability and a scalable permitting system may all be required (Section 4.3 [42, 43] and [70, 71]). For END and HPAI, emergency vaccination to kill and emergency vaccination to live may be considered in specific circumstances. Similarly to FMD and CSF, vaccination occurs within a CVZ or a PVZ (Section 5.16 [41, 44] and for HPAI [72]).

The time goal is to complete the depopulation or euthanasia within 24 hours of classifying the premises as an IP and in many cases the susceptible livestock or poultry on CP (Section 4.3.1.2 for FMD and CSF [42, 43] and Section 4.3.1 for END and HPAI [41, 44]).

Given the challenge of an FMD outbreak, the containment and eradication strategies may change over the phases of the outbreak and according to the size, location and other characteristics of the outbreak and the vaccine availability. Proposed strategies are formulated for six types of outbreak: focal, moderate regional, large regional, widespread or national, catastrophic and North American. Phase 1 represents
the time from confirmation of the first FMD case until the extent of the outbreak has been reasonably estimated, with a goal of less than 96 hours to transition to Phase 2. During Phase 2, characterization of the FMD outbreak as to one of the six types is made [73].

i. **Refine boundaries of zone based on epidemiology and tracing**

The perimeter of the IZ is at least 3 km beyond perimeters of presumptive or confirmed IP and that of the BZ, at least 7 km beyond the perimeter of the IZ. Several factors are considered in determining the size of the CA. The IZ and BZ which comprise the CA are redefined as the outbreak continues. The width of the SZ is a minimum of 10 km zones (Tables 5-4 and 5-5 for CSF and END [43, 44] and Tables 5-3 and 5-4 for FMD and HPAI [41, 42]).

ii. **Zone boundary controls**

Movement out of a CA with respect to susceptible animals/poultry, susceptible animal/poultry products, non-susceptible animals from premises with susceptible species, equipment, and vehicles is prohibited or under permit (Sections 5.10.2 and 5.10.3 [41-44]).

iii. **Surveillance in disease free zone**

For FMD and CSF, enhanced passive clinical surveillance with testing of suspect cases, surveillance in slaughter plants and enhanced surveillance in markets and shows is conducted in the FA (Attachment 3 A [74, 75]). With respect to CSF, the existing ongoing targeted active and passive surveillance in the FA would be increased (Section 3.1 [74]). For END and HPAI, active investigation of flocks with suspicious signs, increased slaughter serological surveillance, and the limited use of sentinel flocks are conducted. Doubling of the frequency of testing of flocks for HPAI as stated in the National Poultry Improvement Plan surveillance is put in place (Attachment 3A [76, 77]).

iv. **Compensation**

Regulations support payment of compensation for animals and birds depopulated, articles and means of conveyances destroyed, and any restriction on movement of animals, articles and means of conveyances by the authorities to prevent the spread of animal disease. APHIS appraisal resources, and valuations for indemnity, provide fair compensation for losses which helps to ensure the quick and full cooperation of the owners of affected livestock. Such cooperation is central to rapid disease control and eradication. APHIS appraisal resources include published valuations and an APHIS Emergency Management Compensation Specialist. The appraisal of animals is based on the fair market and determined by the meat, egg production, dairy or breeding value of such animals. Title 9 CFR Part 53 describes the policies for providing indemnity to an owner of animals and/or materials requiring destruction as a result of the incursion of an animal disease (Section 5.21 [41-44] and [5]).

v. **Decontamination of vehicles**

Cleaning and disinfection (C&D) of vehicles and heavy machinery that have been used on contaminated premises must occur before removal from the premises, as detailed in the FMD and HPAI SOPs on cleaning and disinfection (Attachment 15.F [78], Attachment 15.D [79] and Section 7.7 [80]). For an HPAI outbreak, instructions for C&D of manure trucks are included (Attachment 15.E [79]).
vi. Cleaning and disinfection of premises

Cleaning and disinfection is done on any premises on which a highly contagious disease agent is presumed or confirmed to exist, within 48 hours of disposal of infected and susceptible animals. The goals are to remove, inactivate, reduce or destroy pathogenic agents on the infected premises and to prevent the off-site spread of these agents (Section 15.1.2 [78, 79]). Details of the C&D of premises, slurry pits, and equipment are given in the FMD and HPAI SOPs on cleaning and disinfection (Attachments [78, 79] and Sections 7.8 to 8 [80]).

vii. Vaccination

FMD

The SAHO, Tribal Official, and the APHIS VS Deputy Administrator must agree on the decision to vaccinate before activating the North American Foot and Mouth Disease Vaccine Bank (NAFMDVB). The NAFMDVB Guidelines uses a decision tree and decision matrix of outbreak and mitigation factors to assist with the decision on vaccine use versus only stamping-out or stamping-out with additional culling measures (e.g., ring or continuous culling, culling of premises to arrest spreading of the outbreak). The NAFMDVB Guidelines details the access to the vaccine bank, field use, vaccinate identification and records, disease control measures in the vaccination zone, and the distribution or sharing of the vaccine if the FMD outbreak involves more than one Tripartite country (Canada, Mexico and United States of America). The strategy of stamping-out modified with emergency vaccination to slaughter involves the depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals and subsequent slaughter of the vaccinated animals. The strategy of stamping-out modified with emergency vaccination to live involves allowing the vaccinated animals to live out their productive lives and the strategy of emergency vaccination to live without stamping-out is used in a situation of a widely disseminated outbreak and insufficient resources for the required amount of stamping-out (Sections 4.3.2 to 4.3.6 and Appendix D [42]).

Emergency vaccination occurs within a CVZ or a PVZ and all animals receiving emergency vaccination on a vaccinated premises (VP) may be subject to vaccinated animal identification, vaccinated animal traceability and DIVA (Differentiating Infected and Vaccinated Animal) testing. VP is another premises designation but is only in use if emergency vaccination is employed. DIVA tests are used to differentiate infected herds from vaccinated herds, less suitable for individual animal differentiation. The National Veterinary Stockpile, maintained by the Surveillance, Preparedness & Response Services (SPRS) Logistics Center provides the logistical support for the NAFMDVB and delivery of the vaccine to the IC. The FMD vaccinations are not administered more than 28 days after the last known case of FMD is detected (Sections 5.16 and 5.17 [42] and [81]).

CSF

The use of emergency vaccination strategies is determined by the IC, the SAHO and VS Deputy Administrator.

The strategy of stamping-out modified with emergency vaccination to kill involves depopulation of the clinically affected and in-contact susceptible swine and vaccination of at-risk swine, with subsequent depopulation and disposal of vaccinated swine. The other two strategies employing vaccination are similar except the vaccinated swine are sent to slaughter or allowed to live out their productive lives (Sections 4.3.2 to 4.3.6 [43]).

A marker vaccine can be used which permit the use of DIVA diagnostic tests so that field-infected and vaccinated swine can be distinguished. In a focal CSF outbreak though, a modified live virus (MLV)
vaccine is used in an inner ring vaccination program where vaccinates are subsequently depopulated. The MLV vaccine can confer immunity within 4 – 5 days whereas the marker vaccine requires 2 doses with an effective onset of immunity in 14 – 21 days. All emergency vaccination occurs within a CVZ or a PVZ and swine on a VP may be subject to vaccinated animal identification, vaccinated animal traceability and DIVA testing. No new vaccinations are given more than 28 days after the last known case of CSF is detected (Section 5.16 [43]).

HPAI

The IC evaluates the need for HPAI vaccination. The SAHO, Tribal Official and APHIS VS Deputy Administrator make the decision on vaccination and may use a decision matrix. Stamping-out is the primary strategy but emergency vaccination to kill or to live can be used. With vaccination, DIVA testing is a requirement involving an appropriate choice of vaccine and diagnostic test. The decision to vaccinate takes in number of considerations, especially the disease epidemiology and distribution, the poultry demographics, proximity of high-value genetic birds, risk of zoonotic infection and impact on international trade. A decision tree for emergency vaccination is additional tool. Vaccination occurs in a CVZ or a PVZ and the premises are designated VP, all vaccinated birds are identified with specific and permanent identification. When vaccine is used, surveillance continues to assess the vaccination effectiveness and detect any antigenic change. No new vaccinations are given more than 42 days after the last known new case of HPAI is detected (Section 5.16 [41]).

END

The IC evaluates the need for HPAI vaccination. The SAHO, Tribal Official and APHIS VS Deputy Administrator make the decision on vaccination and may use a decision matrix. As with HPAI, stamping-out is the primary strategy for controlling and eradicating an outbreak of END but emergency vaccination to kill or to live may be considered. The decision to vaccinate takes in number of considerations, especially the disease epidemiology and distribution, the poultry demographics, proximity of high-value genetic birds, risk of zoonotic infection and impact on international trade. Vaccination occurs in a CVZ or a PVZ and the premises are designated VP, all vaccinated birds on the VP may be subject to vaccinated animal identification and traceability. The decision to cease emergency vaccination is made by the IC, SAHO and the APHIS VS Deputy Administrator, based on national and international standards (Section 5.16 [44]).

NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A: Foot-and-Mouth Disease, NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix B: Vaccination for Classical Swine Fever and NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix C: Vaccination for High Pathogenicity Avian Influenza [70-72, 82] provide the characteristics of the available vaccines, strategies for vaccine use, and factors to consider when designing an effective vaccine program. For HPAI, Appendix I [41] describes the available AI vaccines and Appendix E [42] provides information on FMD vaccines including that of their potency and immunological responses.
5. RECOVERY PHASE

a. Proof of Freedom Surveillance

Surveillance for proof of disease freedom, starts 21 days after depopulation of the last IP (FMD Appendix F, CSF Appendix D, END Appendix D, HPAI Appendix E [41-44]).

In the IZ, BZ and SZ, an inter-herd design prevalence of 1% (census testing of herds if the number of premises is small) is employed for FMD and highly pathogenic CSF surveillance of commercial herds. An intra-herd design prevalence of 5% in which both clinically sick pigs and randomly selected pigs is employed for highly pathogenic CSF whereas for FMD the intra-herd design prevalence depends the surveillance methodology, diagnostic sensitivity, and chosen confidence level. The sampling frequency is once during a 3 month period (Appendix F for FMD and Appendix D for CSF [42, 43] and the respective SOPs Attachment 3A [74, 75]).

For END and HPAI, an inter-flock design prevalence of 5% (census testing of flocks if the number of premises is small) and intra-flock testing of 5- or 11-bird pools (5-bird pools in the case of HPAI) selected from each group of 50 or less dead birds is employed for commercial premises and with a sampling frequency of once during a 3 month period (Appendix D for END, Appendix E for HPAI [41, 44] and the respective SOPs Attachment 3A [76, 77]).

b. Release of Quarantine

Quarantine and movement restrictions are maintained until at least 28 days have elapsed since the decontamination of all confirmed IP and negative results of surveillance activities (Section 6.1.4 [42, 43]) or 21 days have elapsed in the case of END and HPAI (Section 6.1.3 [41, 44]). The IC develops a plan to specify procedures by which quarantined premises are evaluated for disease freedom and how the quarantine is released, by sections, risk or in its entirety.

For FMD and CSF, restocking of IPs occurs after the minimum 28 day period, but the period of premises vacancy may be longer based on the environmental conditions, the execution of the cleaning and disinfection procedures and the outbreak circumstances. Restocking requires that animals are subject to clinical inspection every 3 days for the first 14 days and once per week thereafter up to 28 days. At 28 days after the last animals are introduced, each animal is clinically inspected and samples tested for FMDV or CSFV antibodies (Section 6.2 [42, 43]).

For END and HPAI, restocking of IPs occurs after a minimum 21 day vacancy, the period may be decreased if external heat is used to raise the temperature of the poultry houses sufficiently to inactivate the virus. The restocking with birds requires weekly testing by rRT-PCR (real-time reverse transcriptase polymerase chain reaction) for the presence of virus, with the last test conducted at least 21 days after placement of the birds. Environmental conditions, a longer vacancy period, and buildings which are not amenable to cleaning and disinfection, influences the IC’s restocking timeframe decision (Section 6.2 [41, 44]).

c. Recovery of Free Status

The United States would declare freedom from the disease once the obligatory waiting period (OIE requirements) had elapsed with no new cases and would apply to the OIE for recognition of free status. FMD, CSF, END and HPAI free status would require a formal submission detailing policy, eradication
procedures, surveillance, monitoring and tracing of vaccinates, if vaccination was used, and veterinary infrastructure (Section 6.1.6 [42, 43] and Section 6.1.5 [41, 44]).

For the recovery of free status in a previously free country where stamping-out is the response strategy, a waiting period of 3 months after the last case is an OIE requirement for FMD, CSF, END and HPAI (Sections 6.1.1.1 [41, 44] and Section 6.1.2.1 [42, 43]). For CSF, the 3 month waiting period also applies where a stamping-out policy with emergency vaccination is practiced, that is, 3 months after the last case and the slaughter of all vaccinated animals or without the slaughter of vaccinated animals if such animals can be satisfactorily distinguished from infected pigs. Similarly for FMD, a 3 month waiting period is required where a stamping-out policy and emergency vaccination is practiced, that is, 3 months after the slaughter of all vaccinated animals. The waiting period for FMD is increased to 6 months after the last case or the last vaccination in the latter response strategy in which slaughtering of vaccinated animals is not done (Section 6.1.2.1 [42, 43]).
Part 2 - CONCLUSIONS

- Zoning in the event of an FAD incursion has received a high degree of preparedness by the USDA through the development of very detailed response plans, SOPs, guidelines, ready reference documents, strategic plans, industry manuals and other documentation.

- Upon the identification of a suspected FAD incursion, a rapid response of diagnostic investigation is initiated.

- The investigation phase entails sampling and diagnostic procedures, clinical examinations, epidemiological assessments, tracing, case definitions, and epidemiological methods to characterize the outbreak and the risk factors in a thorough and timely manner.

- Following the identification of a presumptive or a confirmed positive case, zoning is initiated with the establishment of a Control Area (CA) comprising infected and buffer zones, and a surveillance zone, based on the assessment of epidemiological factors, agent characteristics, livestock/poultry demographics, weather, susceptible wildlife, and livestock/poultry marketing.

- The management of the FAD incident is highly organized for maximum control and efficiency of the operations put in place.

- The Emergency Management Response System is used to collect and report epidemiological data, including movement tracing information, locally and nationally, for timely information downloads and data entry.

- Movement controls into and out of an Infected Zone are effectively enforced by state and federal authorities while in the larger CA, movements are allowed under permit if the premises is not an Infected Premises, Contact Premises or Suspect Premises.

- The containment and eradication activities within the CA ensure rapid control of the outbreak and are accompanied with a vaccination strategy, when it is deemed necessary.

- Epidemiological tracing and surveillance within and outside the CA provides the evidence and data to confidently assess any reduction of the CA and to confirm the status of the disease-free area.

- Zoning procedures for an FAD incursion in the US are highly rigorous for the prompt containment and eradication of the disease and for the protection and maintenance of disease-free areas.

- Proof of freedom and return free status is readily demonstrated through the assessment of the eradication measures and the evaluation of the surveillance statistics to show that, at an acceptable level of confidence, infection is present in less than a specified proportion of the population.
ABBREVIATIONS AND ACRONYMS

7 USC - Title 7 United States Code
9 CFR - Title 9 Code of Federal Regulations
AAVLD - American Association of Veterinary Laboratory Diagnosticians
AI - Avian Influenza
AHPA - Animal Health Protection Act
APHIS - Animal and Plant Health Inspection Service
ARP - At-Risk Premises
ASF - African swine fever
AVMA - American Veterinary Medical Association
BSE - Bovine spongiform encephalopathy
BZ - Buffer Zone
C&D – cleaning and disinfection
CA - Control Area
CCC - Commodity Credit Corporation
CDA – Colorado Department of Agriculture
CEAH - Centers for Epidemiology and Animal Health
CFR – Code of Federal Regulations
CP - Contact Premises
CSF – Classical Swine Fever
CSREES - Cooperative State Research, Education and Extension Service
CVB - Center for Veterinary Biologics
CVO - Chief Veterinary Officer of the United States
CVZ - Containment Vaccination Zone
CWD - chronic wasting disease
DF - disease freedom
DIVA - differentiation of infected from vaccinated animals
EDI - emerging disease incident
EMD - Emergency Management and Diagnostics
EMLC - Emergency Management Leadership Council
EMRS - Emergency Management Response System
END - enzootic Newcastle disease
EOC - Emergency Operations Center
EPP - expected percentage of protection
EQS - Emergency Qualifications System
ESF - Emergency Support Function
FA - Free Area
FAD - foreign animal disease
FAD PreP - Foreign Animal Disease Preparedness and Response Plan
FADD - Foreign Animal Disease Diagnostician
FADDL Foreign Animal Disease Diagnostic Laboratory
FADP - Foreign Animal Disease Practitioner
FEMA - Federal Emergency Management Agency
FMD - foot-and-mouth disease
FMDV - foot-and-mouth disease virus
FP - Free Premises
HCFAD - highly contagious foreign animal disease
HPAI – highly pathogenic avian influenza
IC - Incident Command
ICG - Incident Coordination Group
ICP - Incident Command Post
ICS - Incident Command System
ICVI – interstate certificate of veterinary inspection
IDALS – Iowa Department of Agriculture and Land Stewardship
ILAC - International Laboratory Accreditation Cooperation
IMT - incident management team
IP - Infected Premises
IZ Infected Zone
LPAI - low pathogenic avian influenza
MAC - Multiagency Coordinating group
MOU - Memorandum of Understanding
MP - Monitored Premises
NACC - National Chicken Council
NAFMDVB - North American Foot-and-Mouth Disease Vaccine Bank
NAHEMS - National Animal Health Emergency Management System
NAHERC - National Animal Health Emergency Response Corps
NAHLN - National Animal Health Laboratory Network
NAHMS - National Animal Health Monitoring System
NAHRS - National Animal Health Reporting System
NAHSS - National Animal Health Surveillance System
NAI - notifiable avian influenza
NASDA - National Association of State Departments of Agriculture
NCDACS – North Carolina Department of Agriculture and Consumer Affairs
NCAHEM - National Center for Animal Health Emergency Management (replaced by NPICC)
NIES - National Import Export Services
NIFA - National Institute of Food and Agriculture
NIMS - National Incident Management System
NPICC – National Preparedness and Incident Coordination Center
NPIP - National Poultry Improvement Plan
NRF - National Response Framework
NVAP - National Poultry Improvement Plan
NVS - National Veterinary Stockpile
NVSL - National Veterinary Services Laboratories
ODAFF – Oklahoma Department of Agriculture, Food and Forestry
OIE - World Organization for Animal Health
PSS – Program Support Services
PVZ - Protection Vaccination Zone
rRT-PCR – real-time reverse transcriptase polymerase chain reaction
SAHO - State Animal Health Official
SPRS – Surveillance, Preparedness and Response Services
STAS – Science, Technology and Analysis Services
SOP - standard operating procedure
SP - Suspect Premises
SZ - Surveillance Zone
TAHC - Texas Animal Health Commission
USDA - United States Department of Agriculture
VMO - Veterinary Medical Officer
VP - Vaccinated Premises
VS - Veterinary Services
VSPS - Veterinary Services Process Streamlining system
VSTA - Virus-Serum-Toxin Act
VZ - Vaccination Zone
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