I. Introduction

A. Disease Description

Classical Swine Fever (CSF) is a highly contagious viral septicemia affecting only swine. Also known as hog cholera, it has been eradicated from many developed nations with extensive swine production but is still endemic in much of the world. Outbreaks in countries free of CSF can have a severe impact on producers due to high swine mortality, the curtailment on exportation of swine and pork products, and from costs incurred to control and eradicate the disease.

- 1. Etiologic Agent. The etiological agent of CSF is a small enveloped RNA virus of the family Flaviviridae and genus Pestivirus, which also includes the bovine viral diarrhea (BVD) virus and border disease (BD) virus. CSF virus is stable in cool, moist, protein-rich environments (such as pork and pork products), and can survive in cured or smoked pork for up to 188 days and over 4 years for frozen pork.
- **2. Distribution**. CSF occurs nearly worldwide with the exception of the North American and Australian continents [see figure 1]. Canada has been free of CSF since 1963, and the United States was recognized free in 1978. Mexico is free of CSF in the Northern provinces that border the United States and has a control program in the other provinces; however, movement of pigs from the endemic area led to an outbreak in the northern region in 2000.

CSF is still endemic in most of Central and South America and vaccination is the chief means for control. However, Belize, Panama, Chile, Uruguay, and parts of Brazil are considered free of CSF. CSF reemerged in Cuba in 1993, and has since spread to Haiti (August, 1996) and the Dominican Republic (June, 1997).

Several major outbreaks in the European Union have occurred in past decade, particularly in Austria, Belgium, Germany, Italy, Spain, and The Netherlands. For example, between 1990 and 1998 there were 424 outbreaks of CSF in Germany. Several of the outbreaks occurred because of illegal swill feeding (waste feeding). Also, wild boars have been identified as a reservoir for CSF in Western Europe, resulting in several outbreaks in domestic pigs. Vaccination is still permitted to control CSF in most of Central and Eastern Europe.

3. Clinical Signs. The clinical manifestation of CSF depends primarily on the viral strain, as field strains vary widely in their virulence. Host characteristics also play a role, particularly the age of the host (more severe disease in young pigs), immune status, nutritional condition, and breed. Generally, CSF manifests either as an acute, chronic, or late-onset infection of swine.

Acute infection is the more 'classical' presentation of CSF and is usually seen in piglets 12 weeks-old or less. Pathological lesions are most commonly found in lymph nodes, spleen, and kidneys, and reflect those of a septicemic disorder with multiple hemorrhages of various sizes. Infarcts of the spleen are considered pathognomonic for CSF when present. Antibodies become detectable 2-3 weeks post-infection, with a practical minimum of 18 days. Several domestic disease conditions produce a similar clinical picture.

<u>Chronic infection</u> consists of three phases and is always fatal, though animals may survive 2-3 months before dying. Antibodies may only be detectable temporarily during the first month of infection but then disappear and can not be detected.

<u>"Late onset" infection</u> occurs when pregnant swine are infected with CSF virus. Infections prior to day 50 of gestation result in abortions, stillbirths, mummies, or birth of deformed piglets. The clinical signs in sows are usually mild, nonspecific, and not indicative of CSF.

For sows infected after day 50-70 of gestation, piglets will be born persistently viremic (similar to BVD viral infection in calves) and may be clinically normal for months, or may exhibit congenital tremors from birth. Eventually, at 2-11 months of age, pigs will begin to waste and become unthrifty. Persistently infected pigs shed virus constantly until they die.

4. Epidemiology. The most frequent method of transmitting CSF virus is the movement of infected pigs that appear normal. Other important sources include infected feral swine and contaminated pork and pork products. Virus can be shed in any bodily secretion and the most frequent route of infection is oronasal. Important mechanical vectors for introduction of virus into a herd include transport vehicles and people.

The rate of transmission between swine within a breeding herd is slower than the transmission rate between weaned pigs. Therefore, CSF may be present in populations of breeding stock for quite some time before it is noticed. An infected herd will be detected sooner if the infection starts in the nursery or finisher section than when the infection starts among the breeding stock.

In experimentally infected swine, the incubation period averages 7-10 days (range of 3-15 days). Under field conditions, the incubation period is approximately 2-4 weeks. The expected morbidity rates are 33-45 percent of pigs at risk. Between 15-30 percent of cases can be expected to die. [See Table 1]

5. Economic Impact. The economic impact of CSF can arise from excessive mortality, infertility, and other deleterious health effects at the herd level. A severe economic consequence of an incursion of CSF into the United States is the immediate halt to exports. The U.S. pork industry currently exports more than 14 percent of its annual production with a value of more than \$2.0 billion. The United States is the world's second largest exporter of pork.

A significant impact is the cost of disease control and eradication. U.S. costs for CSF eradication totaled more than \$140 million in 1978. This would be more than \$540 million in 1999 dollars. The direct cost of the Netherlands control program for CSF in 1983-85 was \$93 million compared to the 1997-98 Netherlands outbreak, in which costs associated with the slaughter of infected and exposed swine, production prohibitions, welfare slaughter, movement restrictions, and effects on allied industries exceeded \$2 billion.

6. Methods and Prospects for Control. Control of the CSF virus needs to occur at the animal level, herd level, and national level.

<u>Animal level.</u> With acute infection, neutralizing antibodies are detectable 2 or more weeks after infection and last several years, if not a lifetime. With chronic infection, neutralizing antibodies are detectable briefly at the end of the first month but quickly disappear. Congenitally infected pigs are persistently viremic and seldom produce specific antibodies. Maternal antibodies protect piglets against mortality for the first 5 weeks of life. They do not protect against virus replication and shedding.

Herd level. In endemic regions, the primary method for controlling CSF in herds is vaccination. The C strain is the most extensively used vaccine. It is safe to use in pregnant sows and young piglets and can be used effectively as an emergency vaccination during an outbreak. The C strain provides protection against infection as early as 5 days post-vaccination and provides protection for several years and probably life. Vaccinated sows pass maternally derived antibodies which protect piglets against mortality until 5-8 weeks of age. Maternally derived antibodies do not prevent infection and shedding of virulent virus.

Other control measures instituted at the herd level include the rigorous enforcement of biosecurity practices, particularly truck cleaning and disinfection, control of visitors, control of birds and rodents, and hygienic injection practices, i.e., not re-using syringes or needles.

<u>National level.</u> A national control policy for CSF depends on the incidence and prevalence of the infection in the domestic and wild pig populations respectively. It also depends on the pig density in the area of infection. The control of CSF in wild boar is still an unresolved problem.

The U.S. CSF emergency disease guidelines call for a three-pronged approach. Time is of the essence in the execution of these control measures. The longer the infected herd is infectious, the higher the likelihood of transmission of CSF virus to surrounding and contact herds. Therefore, the interval between diagnosis of an infected herd and subsequent pre-emptive slaughter of herds should be as short as possible.

B. Recent CSF surveillance efforts

Currently, Veterinary Services (VS) relies on three surveillance programs for detection of CSF. One is passive reporting by private practitioners (or producers, diagnosticians, slaughter plant inspectors) of suspicious cases with clinical signs similar to a foreign animal disease such as CSF. Once reported to the Area Veterinarian in Charge (AVIC), a Foreign Animal Disease Diagnostician (FADD) is dispatched to investigate the case and collect samples for shipment to the Foreign Animal Disease Diagnostic Laboratory (FADDL) at Plum Island, New York. A Lotus Notes database, Emergency Management Response System (EMRS), is used to capture administrative data on each investigation. See VS Memorandum 580.4.

The other surveillance programs rely on active serological / tissue monitoring. In the second surveillance program, specimens are collected from high risk populations such as waste feeding operations along the Texas – Mexican border. Beginning in 1998, CSF testing responsibilities were transferred from the National Veterinary Services Laboratories (NVSL) in Ames, Iowa to FADDL at Plum Island. Subsequently, serum testing has declined dramatically as the focus has shifted to testing tissue samples for antigen rather than serum for antibodies. The December 2003 CSF surveillance plan provides the rationale for this transition.

The third surveillance program came about as a result of the CSF outbreak in Hispaniola in 1997 when \$2.9 million dollars from Commodity Credit Corporation (CCC) funds were designated for CSF surveillance. See VS Notice 99-13. This Notice called for AVIC's to identify high risk premises, develop sampling plans, and build cooperation for CSF surveillance. By way of example, it was suggested that "a sample of 10 percent of the specimens collected for pseudorabies virus (PRV) testing at the lab will be submitted to FADDL for CSF testing as well." The majority of these samples are collected from breeding swine. Another \$500,000 from CCC funds was designated for CSF surveillance in FY03. Again, States were charged with and developed specific plans. However, because of the exotic Newcastle disease outbreak, efforts were diluted and a large portion of the monies were not spent.

While serology allows for the detection of surviving animals beyond the viremic stage, that method of identification of CSF in domestic slaughter swine surveillance has drawbacks:

- Serologic surveillance, either of Texas waste-feeders or PRV screening samples, does not cover other important high risk populations. If only these two populations are monitored (which are not likely to be the first infected) then the identification of the introduction of CSF into the United States could be delayed until the disease has spread to these populations.
- Serologic surveillance does not target domestic swine displaying clinical signs consistent with CSF
- Serologic surveillance at slaughter plants only target sows and boars tested for PRV, so market swine are not tested for CSF antibodies. Market swine are believed to be a more sensitive indicator of CSF virus exposure.
- Serologic surveillance for CSF antibodies does not meet the objective of early detection. Previous studies suggest that using serology could delay the detection of a CSF introduction by several months or more.
- Tag retention, tag correlation with samples, and compliance with tagging regulations for transported animals has been less than satisfactory for performing accurate trace backs.

C. Objectives for surveillance

As identified in the Swine Futures Project report, there are three surveillance objectives for foreign animal diseases such as CSF. First and foremost is the rapid detection of the CSF virus in U.S. swine (I). As part of a comprehensive surveillance plan, CSF surveillance also should entail monitoring the risk of introduction into the United States. Thus the second objective is to conduct surveillance on hazards associated with the introduction of CSF into U.S. swine (II). The third objective is to track international CSF status, particularly of neighboring countries and trading partners (III). Besides the foreign animal disease concern, there is the additional objective of conducting CSF surveillance to document freedom in order to facilitate trade (IV).

The objectives for CSF surveillance can be summarized as follows:

Objective I: Surveillance for rapid detection of CSF virus in U.S. swine.

Objective II: Monitor the risk of introduction of CSF into U.S. swine.

Objective III: Surveillance of international CSF status. Objective IV: Surveillance to document freedom of CSF.

D. Identification of end – users

Since surveillance is 'information for action,' it is important to explicitly identify the action takers (or decision makers) for each of these surveillance objectives. Further in the plan, specific users and actions will be described for each surveillance program.

For objective I, the primary action if the disease is detected will be the implementation of State-Federal control and eradication activities. The industry will be a close partner in such a situation. The action takers related to Objective I are VS Emergency Programs, VS Management Team (VSMT), AVIC's, State Veterinarians, National Pork Board (NPB), National Pork Producers Council (NPPC), State pork associations, American Association of Swine Veterinarians, FADDL, and the National Animal Health Laboratory (NAHLN).

For objective II, the primary actions arising from the detection of increased risk would be to bolster import restrictions, tighten border controls, and modify surveillance programs related to objective I. Therefore, the primary users of surveillance information related to this objective are National Center for Import and Export (NCIE), Plant Protection and Quarantine (PPQ), especially those responsible for border control, Department of Homeland Security (DHS), NPPC, and those responsible for the design of surveillance programs to meet objective I.

The findings from objective III will have a major influence on the design of surveillance programs instituted under objective II. This information will also benefit the Animal and Plant Health Inspection Services' (APHIS) International Services as well as VS representatives to the World Organization for Animal Health (OIE), NCIE, and those decision makers mentioned for objective II.

The providers of surveillance data, including producers, veterinarians, and veterinary diagnostic laboratories (VDL), are generally considered an important audience for the information generated from surveillance programs. Dissemination of information to these groups will result in greater support, participation, and improved compliance with surveillance programs.

II. CSF surveillance plans by objective

Each of the four objectives may require one or more surveillance programs. For each surveillance program developed, there will be one or more case definitions and specific characterizations of the indicators that are to be monitored over time. The determination of what surveillance programs and case definitions are needed to fulfill Objective I were based on two basic questions: 1) How will CSF enter the U.S. swine herd; and 2) After entry into U.S. swine, how will it be recognized?

Objective I: Surveillance for rapid detection of CSF virus in U.S. swine.

The initial expression of CSF in U.S. swine would be variable and unpredictable due to myriad host factors and the broad diversity of virulence among strains of CSF virus. Strains vary from high to low virulent; and symptoms range from acute death to persistent congenital infections with no apparent signs until death. Therefore, different surveillance strategies will be required to detect the different clinical manifestations (see following table).

	Clinical sign	s are	Laboratory detection
Clinical manifestation	present	noticed	of CSF antibody
Acute infection	Yes	Yes	Yes
Mild; early phase chronic infection	Yes	Not likely	Yes
Congenital persistent infection	No ¹	N/A	No

While typical CSF symptoms are not exhibited in breeding sows, congenital infections may be accompanied by reproductive losses, stillbirths, and weak born live pigs.

For acute infection, surveillance activities can be based on clinical signs, because these signs are present and likely to be noticed by producers and practitioners. For mild cases or chronic infections, where recognition of CSF symptoms is less likely, it would be prudent to develop surveillance activities based on diagnostic testing to supplement surveillance based on clinical signs.

For congenital persistent infections, effective surveillance of young pigs would be difficult and costly since no signs exist to predict infection. Surveillance activities could be based on herd level stillborn rates (or other reproductive parameters), for example in an active surveillance program based on the population of Pig Champ users. However, such an indicator may lack the specificity to be economically feasible. Furthermore, since congenitally infected pigs are immuno-tolerant to CSF virus and do not generate an antibody response (despite high viremia), laboratory based surveillance activities would have to be antigen based. This category of infection represents a critical vulnerability in the design of a comprehensive CSF surveillance system. (Of some consolation is the tendency for a portion of persistently infected pigs, upon reexposure to CSF, to become clinical and exhibit acute symptoms.)

The key point here is that there can not be a single surveillance program for the detection of CSF. There must be at least two surveillance programs in place that are based on either reporting of clinical signs or diagnostic testing of populations at risk, preferably for the detection of CSF virus or nucleic acid.

A. Target population for surveillance

The second basic question to consider is how CSF will enter the U.S. swine herd. CSF can be transmitted to U.S. swine either by direct contact with recently introduced infected pigs, exposure to contaminated pork or pork products, or via mechanical vectors such as people or pets. A likely way CSF will be introduced is via contact of susceptible U.S. swine with CSF-infected pigs that includes importation of live pigs, semen, or germplasm, or exposure to illegally transported infected pigs. Other important methods of introduction include importation of contaminated pork and pork products that may find their way to U.S. swine either via proximity to disposal sites for such products (e.g. airports, military bases, and landfills) or waste feeding sites. Mechanical vectors such as trucks, people, and pets can transmit CSF virus to susceptible swine as well. Finally, exposed feral swine can become a reservoir of CSF virus to domestic swine.

Entry routes for CSF into U.S. swine and the implications for target populations to monitor.

How will CSF enter U.S.?	Populations to monitor				
Pigs					
Imported live pigs	Seed-stock producers; herds importing pigs				
Imported semen	Boar studs; herds importing semen				
Imported germplasm	Seed-stock producers; herds importing germplasm				
Illegal movement	Producers on borders				
Pork and pork products					
Meat products	Waste feeders; herds near disposal sites for imported meat; feral				
Waste	swine				
	Waste feeders; feral swine				
Mechanical vectors					
People	Herds with visitors or workers from foreign countries; or with				
Pets	employees visiting farms in other countries.				

Each method of transmission suggests targeting a specific population of U.S. swine.

B. Surveillance programs

The following surveillance programs are proposed for meeting Objective I of CSF surveillance:

- 1. Population-based passive reporting of suspicious CSF cases;
- 2. Laboratory-based surveillance of serum and tissue submitted from sick pigs;
- 3. Active surveillance of high risk swine in Florida, Texas, and Puerto Rico;
- 4. Veterinary Medical Officer (VMO)/Animal Health Technician (AHT)-based active surveillance of registered waste feeders for CSF;
- 5. Population-based active surveillance of high risk herds; e.g., herds importing swine genetic material or near disposal areas of pork meat.

The first surveillance program covers the entire swine industry, whereas the other surveillance programs cover a specific target population. This version of the CSF plan provides details for the first four surveillance programs.

1) Population-based passive reporting of suspicious CSF cases.

Target population:

The intended coverage of this surveillance program would be any and all premises where domestic swine exist. This includes all 50 States and Puerto Rico.

Actual population:

In reality, suspicious cases of CSF (or other FAD of swine) have been reported infrequently (average of 30 FAD investigations per year). The majority of reports are initiated by private practitioners. However, many swine operations (albeit small ones) do not have a relationship with a veterinarian. Therefore, the actual population covered by the current reporting system is more limited than the target population this plan aims to cover.

Efforts to enhance reporting will be focused on high risk States. The criteria for determining a high risk State was initially taken from <u>VS Notice 99-13</u> (currently inactive) and resulted in 18 high risk States, plus Puerto Rico, being covered in the first year of implementation. The risk assessment was revisited by Dr. Tim Clouse, Center for Animal Disease Information and Analysis, to generate a risk classification of States (Appendix B).

High risk areas for CSF include those with garbage feeding operations, backyard swine operations, feral swine hunting clubs, military bases, international air or sea ports, farming operations utilizing an international labor force, and corporations engaging in international movement of swine. High risk is also a function of the number of swine in each State and the number of swine imports in each State.

The following territory will be identified as **very high risk: Puerto Rico**

The following 25 States were the identified as **high risk**:

Eastern Region	Western Region		
Florida	Arizona		
Georgia	Arkansas		
Illinois	California		
Indiana	Hawaii		
Kentucky	Iowa		
Minnesota	Kansas		
New Jersey	Missouri		
New York	Nebraska		
North Carolina	New Mexico		
Ohio	Oklahoma		
Pennsylvania	South Dakota		
Tennessee	Texas		

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Wisconsin

Washington

The remaining unlisted states will be designated **low risk**.

Case definition:

In order to improve the reporting of suspicious CSF cases in higher risk States, particularly where swine veterinarians are sparse, the following case definition was developed as a guide for what cases should be reported. A clinical description of CSF is provided. For reporting, the clinical case definition states that cases should be compatible with the clinical description and may or may not have additional clinical (necropsy findings) or epidemiological features (risk factors).

Clinical description:

Affected swine will experience a viremia characterized by persistent fever, skin discoloration, conjunctivitis, and diarrhea that is unresponsive to antibiotics. Leucopenia is a consistent clinical laboratory finding. Severity is variable. Three common forms are acute, chronic, late onset.

<u>Acute</u> – illness usually in weaned pigs under 12 weeks of age that is unresponsive to antibiotics and characterized by persistent fever, skin discoloration, conjunctivitis, hind-limb weakness and / or diarrhea

<u>Chronic</u> – characterized by three phases: sub acute infection followed by brief recovery before relapse of fever, anorexia, and wasting leading to death 1-3 months after onset.

<u>Late onset</u> –pigs born to sows infected after day 50-70 of gestation may be persistently infected and appear normal for several months before dying, or be born with congenital tremors. (Sows infected prior to day 50-70 of gestation may abort or give birth to stillbirths, mummies, or pigs with congenital defects.)

Clinical case definition for field identification of suspicious cases:

A herd exhibiting one or more of the following clinical features:

- * a herd with clinically compatible cases
- ❖ a herd with clinically compatible cases with necropsy examination demonstrating splenic infarcts, internal hemorrhages of the kidney, bladder, lymph nodes, larynx, or other evidence of septicemia.
- ❖ A herd with clinically compatible cases that in the previous three months had either imported genetic material from a foreign country, fed waste to swine, or had on-site a person recently on a farm in a foreign country.

Case classification:

A case is classified as "suspect" when it is reported as a CSF suspicious case that meets the clinical case definition. Additional case classifications can be found in the full CSF case definition (Appendix A).

Case reporting:

The case definition is to be used by those making direct observations of swine that are in a position to notice the clinical expression of CSF in U.S. swine. These include producers,

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practitioners, slaughter inspectors, and laboratory diagnosticians. A "suspect" case should be reported immediately to the State AVIC. The AVIC's responsibilities to take action are detailed in VS Memorandum 580.4 and result in a timely investigation of the herd by a FADD.

Data collection and sampling

When the FADD concurs that the herd meets the clinical case definition for CSF, the FADD will collect specimens for shipment to FADDL. At a minimum, specimens to be collected from live affected swine are serum, whole blood (EDTA or heparin), tonsil scrapings, and nasal swabs. When possible, at least one pig, and ideally five pigs, should be posted and the following tissues collected: tonsil, lymph nodes, spleen, kidney, and distal ileum.

Per VS Memorandum 580.4, EMRS must be used throughout the investigation. The AVIC, FADD, and laboratory personnel must enter all pertinent information that emerges during the investigation into the EMRS.

Analysis and reporting

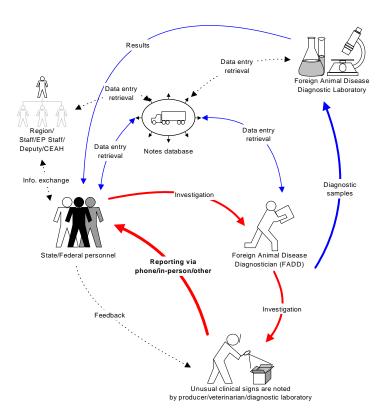
FADDL will attempt to detect CSF antigen in tonsil, spleen, and lymph node by immunohistochemistry (IHC) assays; isolate CSF virus from whole blood, tissues and tonsil scraping; and detect CSF nucleic acid by PCR from whole blood, tissues, and tonsil scraping. Serum will be screened for CSF antibody by enzyme-linked immunosorbent assay (ELISA) or immunoperoxidase assay (IP) and confirmed by immunoperoxidase neutralization test, if positive by ELISA or IP. Results will be entered into EMRS.

CSF data views will be created in EMRS for quarterly evaluation. The herd exam view should contain variables for referral control number, State, date, complaint source, species, initiation reason, # sick, # dead, # affected, total, herd size, and differential diagnosis in field. The sample / lab report view should contain referral control number, State, date, sample id, # animals sampled, # samples, sample type, disease, test type, access #, result, test interpretation.

The Centers for Epidemiology and Animal Health (CEAH) will be responsible for the routine and ad hoc analysis of CSF surveillance data collected via EMRS system. Reports should be distributed to FADDL, regional offices, National Center for Animal Health Programs (NCAHP), and National Surveillance Unit (NSU).

The following flowchart depicts the data flow for this surveillance program. A response plan developed by Emergency Management and Diagnostics stipulates the actions to be taken based on test results and investigation findings.

Flowchart A. Reporting of suspicious clinical signs by practicing veterinarians/producers/diagnostic laboratories and follow up by a Foreign Animal Disease Diagnostician (FADD)



2) Laboratory-based surveillance of serum and tissue submitted from sick pigs.

Target population:

The intended coverage of this surveillance program would be any and all premises where domestic swine exist. This includes all 50 States. Any laboratory or slaughter plant is encouraged to submit tissues from sick pigs for routine surveillance to the National Animal Health Laboratory Network. If CSF is actually suspected, then samples should be submitted to FADDL per surveillance program 1 (described previously).

Actual population:

Currently, few tissues from sick pigs are submitted to FADDL and from only a handful of diagnostic laboratories. Therefore, this plan seeks to enhance the submission of tissues from sick pigs, specifically in high risk States.

The actual population covered by this surveillance program, from which tissue samples from sick pigs will be submitted, will vary by State. It is defined by the catchment population for the two primary sources of tissue specimens – veterinary diagnostic laboratory submissions from private practitioners and condemnations at federally inspected slaughter establishments.

Case definition:

Selection criteria for laboratory submissions:

For diagnostic laboratories in the high risk States, except for Iowa and Minnesota, the following selection criteria will be used to identify eligible cases for routine CSF surveillance testing by CSF approved NAHLN laboratories.

- ❖ Any swine accession from which at least one of the following specimens can be obtained:
- Tonsil tissue biopsy, tonsil scraping, or nasal swab.

For Iowa and Minnesota veterinary diagnostic laboratories, any and all accessions that meet the above selection criteria and possess one or more of the following lesions should have tissues set aside for preparation, boxing, and shipment to a CSF approved NAHLN laboratory for routine CSF surveillance testing:

- Dramatic acute septicemias
- ❖ Abortions, particularly with congenital deformities
- Dermatitis or Nephritis (PDNS is a rule out)
- Undiagnosed central nervous system (CNS) cases (especially congenital tremors & nonsuppurative encephalitis)
- Other undefined cases that the pathologist wishes to submit

Selection criteria for slaughter condemnations:

Any and all condemnations of market swine due to erysipelas or septicemia should have tissues set aside for preparation, boxing, and shipment to a CSF approved NAHLN laboratory for routine CSF surveillance testing. Tonsil should be collected from all eligible carcasses.

Laboratory criteria for diagnosis:

Accessions that meet the selection criteria for either diagnostic laboratory submissions or slaughter condemnations that yield an inconclusive or positive result on real time rRT-PCR at a CSF approved NAHLN laboratory.

Case classification:

Cases that meet the laboratory criteria for diagnosis will be classified as a "suspect" case. Additional case classifications can be found in the full CSF case definition (Appendix A).

Data collection and sampling:

The table below provides the expected number of eligible cases meeting the defined case selection criteria for laboratory submissions. The estimates for lab submissions were obtained from the respective laboratory directors or other personnel. With the exception of Iowa and Minnesota, they reflect total swine case load. Twenty-three of the 27 high risk States have a CSF approved NAHLN laboratory. There are two States (Colorado and Louisiana) that are not high risk States but have a CSF approved NAHLN laboratory. The implementation plan details how specimens from the high risk States will be allocated to CSF-approved NAHLN laboratories.

Appendix B: Classical Swine Fever (CSF) Surveillance Plan

Expected number of laboratory submissions from high risk State

				Number of
Region	State	High R	isk NAHLN testin	g submissions
ER	O Florida	1	$\sqrt{}$	10
	Georgia	1	$\sqrt{}$	150
	Illinois	1	$\sqrt{}$	1200
	Indiana	1	$\sqrt{}$	800
	Kentucky	1	$\sqrt{}$	44
	Minnesota	1	$\sqrt{}$	1300
	New Jersey	1	$\sqrt{}$	50
	New York	1	$\sqrt{}$	10
	North Carolina	١ - ١	$\sqrt{}$	460
	Ohio	1	$\sqrt{}$	42
	Pennsylvania	1	$\sqrt{}$	174
	Puerto Rico	1		N/A
	Tennessee	1	$\sqrt{}$	50
	Wisconsin	1	$\sqrt{}$	12
	Subtotal			4302
WR	Arizona	٦	\downarrow	14
	Arkansas	1	1	N/A
	California	1	$\sqrt{}$	250
	Hawaii	1		N/A
	Iowa	1	$\sqrt{}$	800
	Kansas	1	$\sqrt{}$	150
	Missouri	1		1000
	Nebraska	1	$\sqrt{}$	700
	New Mexico	1	$\sqrt{}$	0
	Oklahoma	1	$\sqrt{}$	120
	South Dakota	1	$\frac{1}{2}$	850
	Texas	1	√,	100
	Washington	1	$\sqrt{}$	27
	Colorado		V	9
	Louisiana		V	24
	Subtotal			4044
	Total			8346

Specimens for routine CSF surveillance from eligible laboratory submissions should include tonsil, or tonsil scraping, and nasal swab when available. Alternative samples listed above can be used if neither is available but would require submission to FADDL since these are not validated for the PCR testing to be performed in approved NAHLN laboratories.

The other key source of tissue specimens for routine CSF surveillance is market swine condemned at slaughter. For this data stream, only those States designated high risk on the new risk assessment were included for sampling (unlike the VDL stream where previous high risk States were retained for sampling). Based on Food Safety and Inspection Service (FSIS) data, in the high risk States, there are 361 slaughter establishments that slaughtered 92,786,005 market hogs in FY2006 (94 percent of U.S. total). There were 29 establishments that slaughtered at least 500,000 market swine in FY2006, or a total of 92,075,450 market hogs (99 percent of total in high risk States). Since several of the high risk States had no establishments that slaughtered at least 500,000 market swine, the largest slaughter establishment(s) were also designated to provide

specimens for routine CSF surveillance: Arkansas(1), Florida(3), Georgia(1), Pennsylvania(2), Tennessee(1), Texas(3). Therefore, a total of 39 slaughter establishments in the high risk States have been designated for active surveillance of sick pigs.

Expected number of carcass condemnations per year by State

_	Control of the Contro								
State	Number of slaughter	Number designated	Total number of	Number of eligible					
	establishments	for surveillance	pigs slaughtered ¹	condemnations per year ¹					
AR	7	1	1420	0					
CA	16	1	1,846,716	469					
FL	15	3	48,448	20					
GA	14	1	33,249	0					
IA	20	9	28,239,129	5051					
IL	23	3	7,843,906	321					
IN	7	2	7,023,718	791					
KY	19	1	2,338,336	69					
MN	22	2	11,231,195	1010					
MO	38	2	3,347,987	210					
NC	21	2	10,606,918	745					
NE	23	3	7,119,041	242					
OH	10	1	842,951	246					
OK	5	1	4,862,038	658					
PA	75	3	2,770,616	726					
SD	5	1	4,482,399	460					
TN	14	1	3,874	0					
TX	23	2	144,064	180					
WI	4	0	0						
Total	361	39	92,786,005	11,198					

From 39 designated slaughter establishments.

Specimens from eligible swine should be collected, prepared, and shipped according to specifications in the CSF surveillance manual (currently under development). The appropriate CSF surveillance submission form should be completed and accompany specimens being sent to a CSF approved NAHLN laboratory. The CSF approved NAHLN laboratories will run real-time rRT-PCR for CSF on all submissions meeting the above selection criteria for laboratory submissions according to NVSL standard operating procedures (VALSOP0012.01 or VALSOP0013.01). Results will be entered into the NAHLN database. Confirmatory testing for inconclusive or positive results must be performed at FADDL.

Analysis and reporting:

CEAH will be responsible for the routine and ad hoc analysis of CSF surveillance data collected via NAHLN. The number of samples tested by source and State should be summarized by CEAH and reported to NCAHP and NVSL (including NAHLN coordinator) on a quarterly basis. A

^{*} Note that condemnation rates in NE and NJ is well below average.

more detailed annual report (to be drafted later) should be summarized and distributed to a wider audience, including industry.

3) Active surveillance of high risk swine in Florida, Texas, and Puerto Rico.

These three States present the highest risk for the introduction of CSF into U.S. swine and therefore warrant special attention to CSF surveillance.

Target population:

The intended coverage of this surveillance program is high risk swine in Florida, Texas, and Puerto Rico. This includes swine fed waste containing meat scraps, swine exposed illegal movement of people and / or pigs, and swine that can be considered transitional or feral.

Actual population:

For Florida, existing slaughter establishments were listed and plotted on a map. In accordance with input from Florida animal health officials, two slaughter establishments were designated for random collection of **blood**. The catchment population for these establishments includes pigs in the southern part of the State, light weight pigs, or pigs from transitional herds.

For Texas, existing slaughter establishments were listed and plotted on a map. In accordance with input from Texas animal health officials, three slaughter establishments were designated for random collection of **blood**. The catchment population for these establishments includes pigs in the southern part of the State, feral swine, or pigs from transitional herds.

For both Florida and Texas, animal health officials should collect specimens from other high risk swine as deemed appropriate, e.g. clinically ill pigs discovered during waste feeding inspections.

For Puerto Rico, essentially all swine on the island are considered high risk swine raised by small scale farmers. Those of particularly high risk are those fed waste or exposed to illegal immigrants that arrive via illegal boat landings (yolas).

Case definition:

For Florida and Texas, market swine should be randomly sampled at the five designated slaughter establishments. Other cases eligible for surveillance will be defined by the respective State animal health officials. These may include, but are not restricted to, sick pigs on waste feeding sites, small non-monitored slaughter establishments, herd located near landfills or international airports, etc.

For Puerto Rico, swine sites within 3 km of illegal boat landings are eligible for routine CSF surveillance testing on the fourth visit 28 days after notification of illegal boat landing. Also, samples from slaughter should be collected.

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Data collection:

<u>Blood</u> should be collected from randomly selected carcasses (roughly every 10th carcass). The following table provides the allocation of samples among the five slaughter establishments. A total of 1800 blood samples from Florida and 3400 blood samples from Texas should be selected. <u>Serum samples should be sent to FADDL</u>.

State	Plant	Number of samples
		to be collected
FL	Nettles Sausage	300
FL	La Casa Sierra	750
FL	Mary's Ranch	750
TX	Cabrito Market	140
TX	Border Plants	[Remainder of 3400
TX	Transition Pigs	to be collected]

In Florida, Texas, and Puerto Rico, tonsil tissue or scrapings, nasal swabs in designated media, or blood should be collected as needed from sick swine cases in high risk herds selected at the discretion of Federal/State animal health officials. Tonsil or nasal swabs can be sent to the CSF approved NAHLN labs in Florida, Texas, and North Carolina respectively. Serum samples are to be sent to FADDL.

For Puerto Rico, serum will be collected from feral swine randomly selected at the slaughter plant. Specimens collected from slaughter establishment should be either tonsil tissue or scrapings or whole blood (EDTA or heparin). All Puerto Rico specimens will be sent to FADDL.

4) VMO/AHT-based active surveillance of registered waste feeders for CSF.

The CSF virus has been shown to survive in cured pork meat for over 180 days. Not surprisingly then, swill feeding (feeding of waste / garbage to swine) has been the mechanism of first introduction into many countries that were previously considered free. Waste feeders in the United States must be licensed and are regularly inspected by State or Federal VMO's and/or AHT's.

Target population:

The intended coverage would be all sites in the continental United States feeding waste to swine. This targeted population is relatively small, easily definable based on licensure procedures, and is routinely visited.

During FY 2005, there were on average 2,557 licensed food-waste cooking and feeding premises in the United States. During the year, 9,631 routine inspections were made on licensed premises in States that permitted the treatment and feeding of food waste to swine.

Actual population:

Waste-feeding operations in high risk States are of top priority in the implementation of this population-based surveillance program by VMO's and AHT's. Approximately 95 percent of all registered waste-feeding operations are in the 8high risk States (and Puerto Rico) listed below.

High Risk	Number of waste-		
State	feeding operations		
Arkansas	84		
California	8		
Florida	102		
Hawaii	173		
North Carolina	47		

New Mexico	26
Oklahoma	36
Texas	427
Puerto Rico	1700
Total	2603

Case definition:

Registered waste-feeding operations are visited every 1-3 months. As these pigs are most likely without clinical symptoms and will not be tested on a frequent basis, antibody-based diagnostic tests will be used on serum to assess exposure of these high risk swine to CSF. Clinically ill swine discovered during inspections may be tested via NAHLN by collection and submission of nasal swabs or tonsil specimens.

Data collection:

CSF surveillance on waste-fed operations will initially be implemented in 2007 in the above eight States and Puerto Rico. To enable effective and complete surveillance, a written plan for systematically testing all licensed garbage feeders in the State over a period of 1-3 years should be developed. At each waste-fed site sampled it is recommended that five swine be blood sampled.

Surveillance programs to meet Objective I not covered in detail at this time:

5) Population-based active surveillance of high risk herds.

Population-based: Data collected directly from producers in a 1 km area surrounding disposal sites for pork meat scraps of foreign origin, e.g. airports and military bases. Also, data collected directly from producers or practitioners from those production sites importing any type of genetic material from any foreign country with in the previous 3 months.

Active surveillance: This definable population should be relatively small and therefore can be actively monitored either using private practitioners or VMO's. Samples could be collected once, twice, or more times in the surveillance period.

Serological samples: The main case definition would be diagnostic, although the symptomatic could (and should) be included on the submission form. With agreed upon assumptions of the percent of hogs likely to be infected with CSF on a site, the sample size for collection of whole blood can be calculated.

Herds importing genetic material: The definition of the targeted population is those production sites importing live swine, semen, or germplasm.

Objective II: Monitor the risk of introduction of CSF into U.S. swine.

A population that should be targeted for CSF surveillance is swine herds that either receive visitors from other countries or have employees that visit other countries. Unfortunately, this population is not easily identifiable and is actually quite large (based on estimates from the National Animal Health Monitoring System Swine 2000 study) making it a poor candidate for active surveillance on a targeted population. A better approach may be to monitor this risk, i.e. CSF Surveillance Objective II, and follow the data over time to determine if and how these proposed surveillance programs should be modified (or new programs developed).

A. Case definitions / key indicators for tracking

The various ways CSF can be introduced into U.S. swine should be monitored regularly.

The following indicators should be available for tracking:

- Number of live pigs, by pig weight/class, imported. Present by State and type of operation importing.
- Number of importations of semen and germplasm. Present by State and type of operation importing.
- Quantity of pork meat, by type, imported. Report by State.
- Movement and travel of people and pets into and out of the United States. Cf. Center for Emerging Issues (CEI) report.
- Numbers and geographic distribution of waste feeders.

Most likely, these indicators would be summarized by the NSU annually based on secondary data from various sources including the Foreign Agricultural Service (FAS) database, NCIE, Plant Protection and Quarantine, FSIS, etc.

B. Target population for surveillance

All U.S. swine producers and production sites including Puerto Rico.

C. Surveillance programs

1) Surveillance of secondary data on imports of genetic material from NCIE & FAS. *Secondary data*: Data on the indicators described in previous paragraph already exist and should only be collated on a regular basis, e.g. annually. Great benefit for little investment. Likely sources of this secondary data would be FAD data on-line and NCIE.

2) Surveillance of secondary data on imports of pork and pork products.

As with surveillance program 1, this data already exists. Only need to determine what summary information would be of greatest benefit to track over time, relative to risk of introducing CSF into U.S. swine. Possible data sources are FSIS, FAS, and the Food and Drug Administration.

3) Surveillance of secondary data on travel and commerce.

CEI did an excellent report on this data. This should be repeated on a regular basis in order to assess trends in CSF hazards, i.e. movement of mechanical vectors into the United States.

4) Surveillance of secondary data on waste feeders.

An annual summary of the number of waste feeders by State, with number of hogs on these sites, should be presented. This data is available from VS.

Objective III: Surveillance of international CSF status.

International surveillance for CSF can incorporate CSF outbreak reports identified via OIE, Pathfinder, or International Services attaché reports.

III. Implementation plans

A. Prioritization of objectives

Surveillance Objective I is the highest priority in the comprehensive CSF surveillance plan. For meeting this objective, the first three surveillance programs are the top priority. Of these, the reporting of suspicious CSF cases must always take precedence over the other CSF surveillance activities. The level of reporting is currently inadequate and this plan seeks to improve reporting through development of a CSF case definition and implementation of a CSF awareness program. Passive reporting of suspicious cases is to be augmented by active surveillance of sick pigs in high risk States and active surveillance of high risk swine in the three States deemed the highest risk.

B. Implementation activities

The first three programs are to be implemented beginning in FY05. Other items are meant for long term implementation.

For surveillance program 1:

A communication plan should be implemented in the first year to increase awareness among producers and practitioners in high risk States of the CSF case definition and reporting criteria. The objective of this plan would be to reach practitioners and producers with information about CSF in an effort to reinforce existing knowledge and build awareness of the disease. This plan would include distribution of information regarding biosecurity, clinical signs, disease detection, response, and recovery.

The awareness program for practitioners should cover the following items:

- (i) inform them about the enhanced CSF surveillance via NAHLN
- (ii) that tonsil is the preferred tissue from eligible submissions to VDL
- (iii) for those cases ultimately tested by NAHLN they will receive a \$50 reduction in their diagnostic bill.
- (iv) however, for cases where CSF is actually suspected, they should call the State Veterinarian or AVIC for a FADD investigation and submission of samples to FADDL.

The awareness program for VDL in the 25 high risk States should cover the following items:

- (i) inform them about routine CSF surveillance via NAHLN
- (ii) the selection criteria for swine submissions
- (iii) the process for submitting eligible tonsil specimens to their designated NAHLN lab
- (iv) request that they communicate with their swine practitioners that tonsils should be included in swine submissions.

Funding should be provided to NPB to implement the communication plan which would utilize existing communications tools to communicate with both veterinarians and producers, and employ new tools to effectively communicate the information when necessary.

A second task is to change what tissues are included in case submissions sent to veterinary diagnostic laboratories, especially from large integrated farms where necropsies are not performed by veterinarians, but instead by field and service managers. The best approach for accomplishing this change will be determined by the American Association of Swine Veterinarians Swine Health Committee.

Also in the first year of implementation, actual summary reports will be drafted and a distribution plan developed for both quarterly and annual summaries.

For surveillance program 2:

Tissues from eligible laboratory submissions should begin being sent to FADDL immediately. FADDL should use EMRS for data entry.

For development of data management, a change control board (CCB) will be established and used to assist with decisions regarding data collection and data management. Key decisions will be communicated with the NAHLN steering committee and IT committee to continue development of a NAHLN database. Data submission forms have been drafted and will be finalized by the end of FY05. Initial data collection forms will be hard copy only with eventual migration to web-based data entry or use of PC tablets at collection sites.

The following table provides the specific allocation of specimens collected from diagnostic labs and slaughter establishments that are to be tested at **all** CSF approved NAHLN laboratories (including high-risk and low-risk States). For 2007, laboratories in low-risk States that are approved to perform the CSF rRT-PCR test are instructed to test all appropriate swine submission samples as outlined in the manual above. In addition, this table summarizes serology sampling that will occur in each State. All serology samples will be sent to USDA, NVSL, and FADDL for testing.

2007 CSF Surveillance Sampling

AZ /	Laboratory		VDL S	amples	Classalata		Tatal - DT				
AL I AR I AZ / CA (VDL Samples Slaughter Samples		Total rRT-				TOTAL		
AZ /		City	# Samples	From State	# Samples	From State	PCR	# Samples	# Samples	# Samples	Serology
AZ /	NO LABORATORY	NA	na	na	na	na	na	na	na	10	10
CA	NO LABORATORY	NA	na	na	na	na	na	190	na	10	200
	Arizona Veterinary Diagnostic Laboratory	Tucson	14	AZ	242	NE	256	na	na	40	40
	CAHFS	Davis	250	CA	58 469	HI CA	777	40	na	240	280
	Colorado State University Veterinary Diagnostic Laboratory	Ft. Collins	9	со	1146	IA	1155	na	na	15	15
	Animal Disease Diagnostic Laboratory	Kissimmee	10	FL	20 547	FL IA	577	205	1800	240	2245
	University of Georgia	Tifton	150	GA	460	SD	610	na	na	50	50
GA /	Athens Veterinary Diagnostic Laboratory	Athens	39	GA	na	na	39	na	na	na	0
HI /	NO LABORATORY	NA	na	na	na	na	na	480	na	100	580
IA I	Iowa State University Diagnostic Laboratory	Ames	800	IA	na	na	800	na	na	10	10
IL I	Illinois Dept of Agriculture	Galesburg	1200	IL	na	na	1200	na	na	20	20
IL !	University of Illinois	Urbana	261	IL	na	na	261	na	na	na	0
	Purdue University Animal Disease Diagnostic Laboratory	West Lafayette	800	IN	na	na	800	na	na	20	20
	Kansas State Veterinary Diagnostic Laboratory	Manhattan	150	KS	907	IA	1057	na	na	30	30
	Breathitt Veterinary Center	Hopkinsville	44	KY	321	IL	365	na	na	na	0
LA I	Louisiana Veterinary Medical Diagnostic Laboratory	Baton Rouge	24	LA	1294	IA	1318	na	na	na	0
	Michigan State University Diagnostic Center for Population and Animal Health	Lansing	50	MI	na	na	50	na	na	10	10
MN I	Minnesota Veterinary Diagnostic Lab	St. Paul	1300	MN	na	na	1300	na	na	na	0
MO I	NO LABORATORY	NA	na	na	na	na	na	na	na	120	120
	MS Vet. Research & Diagnostic Laboratory	Pearl	9	MS	na	na	9	na	na	na	0
MT I	Montana Veterinary Diagnostic Laboratory	Bozeman	9	MT	na	na	9	na	na	na	0
NC I	Rollins Laboratory	Raleigh	460	NC	644	NC	1104	130	na	75	205
ND I	North Dakota Veterinary Diagnostic Laboratory	Fargo	53	ND	na	na	53	na	na	na	0
NE I	University of Nebraska VDC	Lincoln	700	NE	na	na	700	na	na	10	10
NJ I	NJ Department of Agriculture	Trenton	50	NJ	151 69 144	IA KY PA	414	na	na	na	0
	New Mexico Dept of Agriculture Veterinary Diagnostic Services	Albuquerque	0	NM	290	IA	290	40	na	50	90
NV /	Animal Disease and Food Safety Laboratory	Reno	1	N∀	na	na	1	na	na	na	0
NY (Cornell University Animal Health Diagnostic Center	Ithaca	10	NY	791	IN	801	na	na	na	0
он (Ohio Department of Agriculture	Reynoldsburg	42	OH	246 101	OH NC	389	na	na	30	30
ок (Oklahoma Animal Disease Diagnostic Laboratory	Stillwater	120	OK	658	OK	778	75	na	120	195
OR (Oregon State University	Corvallis	26	OR	na	na	26	na	na	30	30
	Pennsylvania Department of Agriculture Veterinary Laboratory	Harrisburg	174	PA	582	PA	756	na	na	30	30
	NO LABORATORY	NA	na	na	na	na	na	3062	na	30	3092
SC I	NO LABORATORY	NA	na	na	na	na	na	na	na	75	75
	South Dakota State University Molecular Diagnostics Section	Brookings	850	SD	na	na	850	na	na	na	0
	Kord Animal Disease Diagnostic Lab	Nashville	50	TN	317	IA	367	na	na	30	30
	Texas Veterinary Med Diagnostic Lab	College Station	100	TX	399 210 180	IA MO TX	889	825	3400	300	4525
UT I	Utah Veterinary Diagnostic Laboratory	Logan	5	UT	na	na	5	na	na	na	0
	Washington Animal Disease Diagnostic Laboratory	Pullman	27 1000	WA MO	na	na	1027	na	na	na	0
wı ı	UW- Wisconsin Veterinary Diagnsotic Laboratory	Madison	12	WI	1010	MN	1022	na	na	30	30
	Wyoming State Veterinary Laboratory	Laramie	10	WY	na	na	10	na	na	na	0

Sampling Summary:

Total VDL Samples for rRT-PCR	8,809
Total Slaughter Samples for rRT-PCR	11,256
Total Serology Samples	11,972

Summary:

In the first year, States should investigate slaughter establishments to determine if their catchment population is a targeted population group such as feral swine, waste feeders, light weight hogs (junk market pigs culled before normal marketing), etc. Smaller plants may be added in the future depending on their catchment population.

In addition, a description should be made of the catchment population of slaughter establishments designated for routine CSF surveillance. The primary purpose would be to describe the States from which pigs are obtained. Specific questions for the CSF team to consider after reports are received from the respective States include:

- Determine which slaughter plants most Kansas pigs are slaughtered (IA, NE, OK?). Add plants in other States to surveillance program if needed.
- Determine which slaughter plants most New Mexico pigs are slaughtered (OK, CA?). Add plants in other States to surveillance program if needed.

Other long term items to implement include identifying and validating additional testing protocols that can be used by NAHLN labs, e.g. immunohistochemistry. Also, expansion of specimen collection from diagnostic laboratories and slaughter condemnations in low risk States will need to be considered. In FY06, high risk States that do not have a CSF approved NAHLN lab should receive training and proficiency testing. Finally, with-in 3 years of implementation of this plan, a detailed list of performance metrics should be developed.

For surveillance program 5:

Design of this program has not yet occurred. In the near term, it will be accomplished on an ad hoc basis in very high risk states (Florida, Texas, and Puerto Rico). Additional surveillance activities may be designed in the future and incorporated into the CSF surveillance program at a later date.

IV. Performance metrics and program evaluation

Three years after implementation, the NSU should conduct an evaluation of the CSF surveillance program to determine the effectiveness of the program and ensure implementation in accordance with the CSF national surveillance plan as approved by the VSMT. Specific metrics for this evaluation are suggested below (by surveillance program).

A. Quantitative

Surveillance program 1:

- 1) FAD investigations should be conducted < 8 hours after report to AVIC.
- 2) FADDL should be report initial results ≤ 2 days after receiving samples.
- 3) FAD investigations should be closed in EMRS < 7 days of lab results being entered.

Surveillance program 2:

4) The number of specimens collected from slaughter plants in the first year should be at least 50 percent of eligible condemnations.

List of figures, tables, and other references

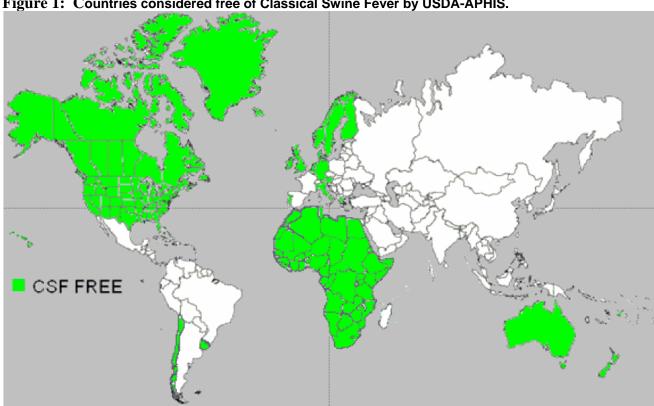


Figure 1: Countries considered free of Classical Swine Fever by USDA-APHIS.

Ref. CSF Pathways Analysis figure 2.5, 20