

**Animal Disease Risk Assessment,
Prevention, and Control Act of 2001
(PL 107-9)**

Final Report

Prepared by the PL 107-9 Federal Inter-agency Working Group

January 2003

Executive Summary

As required by Congress in the Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9), this report provides the people of the United States and Congress with information concerning:

- the economic impacts associated with the potential introduction of foot-and-mouth disease (FMD), bovine spongiform encephalopathy (BSE), and related diseases into the United States;
- the risks to public health from possible links of BSE and other spongiform encephalopathies to human illnesses;
- actions by Federal agencies to prevent FMD, BSE, and related diseases; and
- the sufficiency of legislative authority to prevent or control FMD, BSE, and related diseases in the United States.

The Secretary of Agriculture formed a Federal Inter-Agency Working Group to write the report. The PL107-9 Working Group gathered public and stakeholder input, and considered many sources of information, as required by the Act.

FMD

Foot-and-mouth disease is a severe, highly communicable viral disease of cattle, swine, and a variety of other ruminants. It is not a direct threat to human health. The disease has occurred in most countries of the world. Besides the United States, only 48 countries or geographical regions were free of the disease as of January 2002. The United States has not had an outbreak of FMD since 1929.

In today's highly mobile environment and globalized agricultural economy, there is a risk of an introduction of FMD into the United States. Unless the virus is eradicated very quickly after introduction, such an event would be devastating for animal industries, as well as for many other sectors of the economy.

The U.S. Government's strategy for protecting the country from the risk of FMD and other highly contagious foreign animal diseases includes four main components:

- *Outside U.S. borders*, monitor for the occurrence of FMD and other foreign animal diseases worldwide, evaluate the potential exposure of the United States to foreign outbreaks, and reduce the threat of significant foreign animal diseases spreading to the United States.
- *At U.S. borders and other domestic ports of entry*, regulate, inspect, and intercept or quarantine products and animals potentially carrying foreign animal diseases.
- *Inside the United States*, maintain a strong animal health infrastructure that includes surveillance and monitoring systems and research capacity to quickly detect the

presence of a highly contagious foreign animal disease such as FMD, before it spreads.

- Also inside the United States, establish and maintain a strong *emergency response capacity* to quickly control and/or eradicate a foreign animal disease or pest.

Although this strategy has been effective—the United States remains free of FMD—the PL107-9 Federal Inter-agency Working Group identifies a number of risk management areas that need attention and describes what the U.S. Government is planning to do to address some of those needs.

BSE and Related Diseases

Bovine spongiform encephalopathy, widely referred to as “mad cow disease,” causes a progressive degeneration of the central nervous system in cattle. The disease, which is believed to be caused by an agent smaller than most viruses, has an incubation period of two to eight years and is invariably fatal. There is neither any treatment nor a vaccine to prevent the disease, and there is no test to detect the disease in a live animal. There is no evidence that BSE spreads by contact between adult cattle or, in nature, from cattle to other species. In the United Kingdom (UK), where the disease was first identified in 1986, over 175,000 head of cattle have been diagnosed, post-mortem, with the disease. It has spread to native cattle in 19 other countries, mostly in Europe, probably mainly through the practice of mixing BSE-contaminated ruminant products into animal feed as an added source of protein. BSE has never been detected in the United States, despite active surveillance since 1990.

BSE is classified as a transmissible spongiform encephalopathy (TSE). The TSE family of diseases affects a number of animals, both domesticated and wild. Some TSEs affect humans also. One of those, variant Creutzfeldt-Jakob disease (vCJD) has been linked to BSE. The Centers for Disease Control and Prevention (CDC) conducts an on-going surveillance program to detect vCJD in the United States. The disease has not been detected to date in the United States, other than in one ill UK resident who sought medical care in the United States. (This case was already known to the UK health authorities.)

The U.S. Department of Agriculture (USDA) has conducted several risk assessments examining the possibility of BSE emerging in the United States. All the assessments have concluded that the potential risk of BSE emerging in the United States is substantially less than in the United Kingdom. A three-year study of the risk of BSE in the United States, completed by the Harvard Center for Risk Analysis in November 2001, concluded that the U.S. Government’s actions have successfully minimized the risk of BSE in the United States, to the point that even if a few infected animals were detected here, the disease

would not become established. Nevertheless, the adverse economic impact of a BSE case in the United States would likely be similar in many respects to that experienced in the United Kingdom.

To date, there is no evidence of BSE in the United States, and the U.S. Government has worked proactively to keep BSE out of this country. The U.S. approach to managing the risk of BSE is focused on three primary goals:

- Prevent the agent of BSE from entering the United States and infecting U.S. cattle;
- Prevent the amplification of the agent of BSE throughout the U.S. cattle herd, were it to penetrate the primary firewall at the borders and infect U.S. cattle; and
- Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.

According to the Harvard risk assessment, several key actions have been particularly effective in achieving these goals:

- The Animal and Plant Health Inspection Service's (APHIS) ban on the import of live ruminants and ruminant meat and bone meal from the United Kingdom (since 1989) and all of Europe (since 1997),
- The Food and Drug Administration's (FDA) feed ban instituted in 1997 to prevent recycling of potentially infectious cattle tissues to ruminants, and
- Measures instituted in meat packing plants by the industry and the Food Safety and Inspection Service (FSIS) to reduce the opportunity for infectious tissues (brain and spinal cord) to contaminate human food.

Recommendations

The PL107-9 Working Group makes three main recommendations.

1. Legislative authorities:

Congress, Federal and State agencies, and industry stakeholders should work together to implement the recently enacted Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), which updates and consolidates USDA's animal health safeguarding authorities. In addition, the working group makes the following specific recommendations:

- Review the Virus-Serum-Toxin Act and its implementing regulations. Such a review will determine whether civil or criminal penalties are needed to enhance enforcement of the Act and regulations on imports of animal biologics. It will also determine the need for additional authorities to take action against products produced by unlicensed

veterinary biologics producers that may present a risk to the U.S. livestock industry.

- Review the Swine Health Protection Act and its implementing regulations, to determine whether adequate authorities are in place to ensure biosecurity and sanitation safeguards.
- Develop and enact legislation to strengthen FDA's ability to enforce its animal feed regulation (21 CFR 589.2000). This would include clarification of "prohibited acts" under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) and the authority to impose civil penalties or embargo products for violations of the feed rule.
- Develop and enact legislation to update and strengthen FDA's authorities at the borders, to control the entry of certain products that carry a risk of bringing TSEs into the United States.
- Develop and enact legislation to strengthen FDA's ability to help address the problem of chronic wasting disease in captive deer and elk.
- Review and update the Public Health Service Act to clarify that TSEs are "communicable" diseases. (This clarifying legislation would remove any question about the meaning of the "communicable" diseases in Section 361 of the Act.)

2. Resources:

This past year's international outbreak of FMD, combined with recent U.S. biosecurity incidents, creates an unprecedented demand on the U.S. animal health infrastructure. The existing system is being challenged in a radically changing environment that has transcended annual appropriations cycles and strained discretionary spending caps. A number of the needs identified in this report require long-term investments. For example, a key component of the infrastructure must be a comprehensive and coordinated surveillance system that integrates existing and new information systems for animal health, public health, food safety, and environmental health. Such a system can only be built with an extended commitment of resources and focus. Several provisions of the Farm Security and Rural Investment Act of 2002 address these concerns, and Federal agencies need to follow up in implementing the Act.

The President's FY2003 budget request includes a total of \$92.7 million to meet current USDA agency resource needs identified in this report. In the USDA request, \$79.5 million is for increased inspections, monitoring, surveillance and emergency management for APHIS; \$10 million is for BSE and FMD research for the Agricultural Research Service (ARS) and the Cooperative State Research, Education, and

Extension Service (CSREES); \$1.2 million is for FSIS surveys; and \$2 million is for Economic Research Service (ERS) studies relative to invasive pests and diseases.

3. Federal Inter-Agency Panel:

A Federal inter-agency panel should be established to coordinate animal disease issues that have significant links to economic or public health concerns. Given the potential deliberate introduction of an animal or human health threat into the environment, a policy group is needed to work closely with the Office of Homeland Security to coordinate the management of such a threat. Although the mechanism of transmission and the impact on human health for FMD and BSE are very different, similar multiple-firewall preventive strategies, infrastructure and resources can be shared government-wide to protect public health and well-being, the national herd, and the economy.

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Introduction

The purpose of the Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9) is to provide the people of the United States and Congress with information concerning:

- the economic impacts associated with the potential introduction of foot-and-mouth disease (FMD), bovine spongiform encephalopathy (BSE), and related diseases into the United States;
- the risks to public health from possible links of BSE and other spongiform encephalopathies to human illnesses;
- actions by Federal agencies to prevent FMD, BSE, and related diseases; and
- the sufficiency of legislative authority to prevent or control FMD, BSE, and related diseases in the United States.

The Act requires the Secretary of Agriculture to submit a report containing this information, after consultation with a wide range of Federal agencies, State and local government officials, private and non-profit sector experts, and other stakeholders and interested members of the public. To meet this requirement, the Department of Agriculture (USDA) formed a Federal Inter-Agency Working Group, including representatives from 13 Federal Executive Departments and Agencies. (See Appendix 2 for a list of the Agency representatives who participated on the Working Group.)

PL107-9 Inter-Agency Working Group

Agriculture
Commerce
Defense
Environmental Protection Agency
Executive Office of the President
Federal Emergency Mgmt. Agcy.
Health and Human Services
Interior
Justice
State
Transportation
Treasury
U.S. Trade Representative

For input from non-Federal stakeholders, the PL 107-9 Inter-Agency Working Group held a public hearing on September 28, 2001, solicited comments through Federal Register Notices (August 7 and August 21, 2001), and sent letters about the Act to key stakeholders. Over 40 organizations and private individuals provided written comments, and representatives of eight organizations spoke at the public hearing. (To view a transcript of the hearing and the comments submitted electronically, see the following website: <http://www.aphis.usda.gov/ppd/rad/webrepor.html>. For a complete list of those who provided written or oral comments for the public record of PL107-9, as well as a list of members of the expert panels, see Appendix 3.)

The Working Group also used the input of three other expert panels that recently have written reports related to the risk of FMD, BSE, and other foreign animal diseases: the Animal Health Safeguarding Review, completed in October 2001 by a panel of experts selected by the National Association of State Departments of Agriculture Research Foundation; recommendations from the August 2000 meeting of the Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases; and a comprehensive BSE risk assessment completed in November 2001 by the Harvard University Center for Risk Analysis. Many of the comments the PL107-9 Working Group received from stakeholders and the general public suggested that these reports be primary sources for the PL107-9 report. (The executive summary of the Harvard risk

assessment is in Appendix 4. The complete Harvard study and the Safeguarding Review can be accessed on the internet at www.aphis.usda.gov. A list of useful internet sites related to FMD and BSE is in Appendix 5.)

This report is organized into three principal sections. First, it discusses the risk—the likelihood and consequences of introduction of these diseases—to the economic and public health of the United States. Then the report describes how the United States currently manages these risks, and what other actions are being planned to further reduce the risks. For ease of reading, the report first addresses FMD and animal diseases in general, then covers activities specifically centered on BSE. The final section includes the Working Group’s recommendations.

FMD

Risk Assessment

Description of FMD

Foot-and-mouth disease is a severe, highly communicable viral disease of cattle and swine. It also affects sheep, goats, deer, and other ruminants (cloven-hoofed, cud chewing quadrupeds). FMD is not a threat to human health.

Vesicles (blisters) in the mouth, on the tongue and lips, on the teats, or between the toes—and the resulting excessive salivation or lameness—are the best-known signs of the disease. Blisters may not be observed until they have ruptured. Other signs, including fever, reduced feed consumption, and abortions, also may appear in affected animals during an FMD outbreak. Prior to and during the occurrence of such clinical signs, the virus can be shed through exhaled air, lesions, milk, semen, and blood, making its transmission difficult to control. Direct contact between animals can transmit the disease, as can most animal products, and even inanimate objects. The virus has a remarkable capacity for remaining viable in carcasses, in animal byproducts, in water, in such materials as straw and bedding, and even in pastures.

FMD rarely kills animals; however, affected animals do not normally regain lost flesh for many months. Indeed, the same infectious virus can cause varying signs, depending on the species infected. In the recent UK outbreak cattle showed vesicular signs, pigs generated high amounts of the virus, and sheep appeared to be carriers, exhibiting limited vesicular signs. Recovered cows seldom produce milk at their former rates. Death from FMD occurs most often in new-born animals.

There are at least seven separate types and over 60 subtypes of the FMD virus. Recovered animals may suffer repeated attacks of the disease because immunity to one type does not protect an animal against the others. Vaccines are available, but they must match the type and subtype of virus present in the area. Because there are so many virus subtypes, it is difficult to rely on having the correct vaccine in sufficient volume to address a significant FMD outbreak. Countries that resort to vaccination to control an outbreak take longer to recover their disease-free status, which is crucial for meat and livestock exports. Also, vaccinated animals can become carriers without showing signs of the disease.

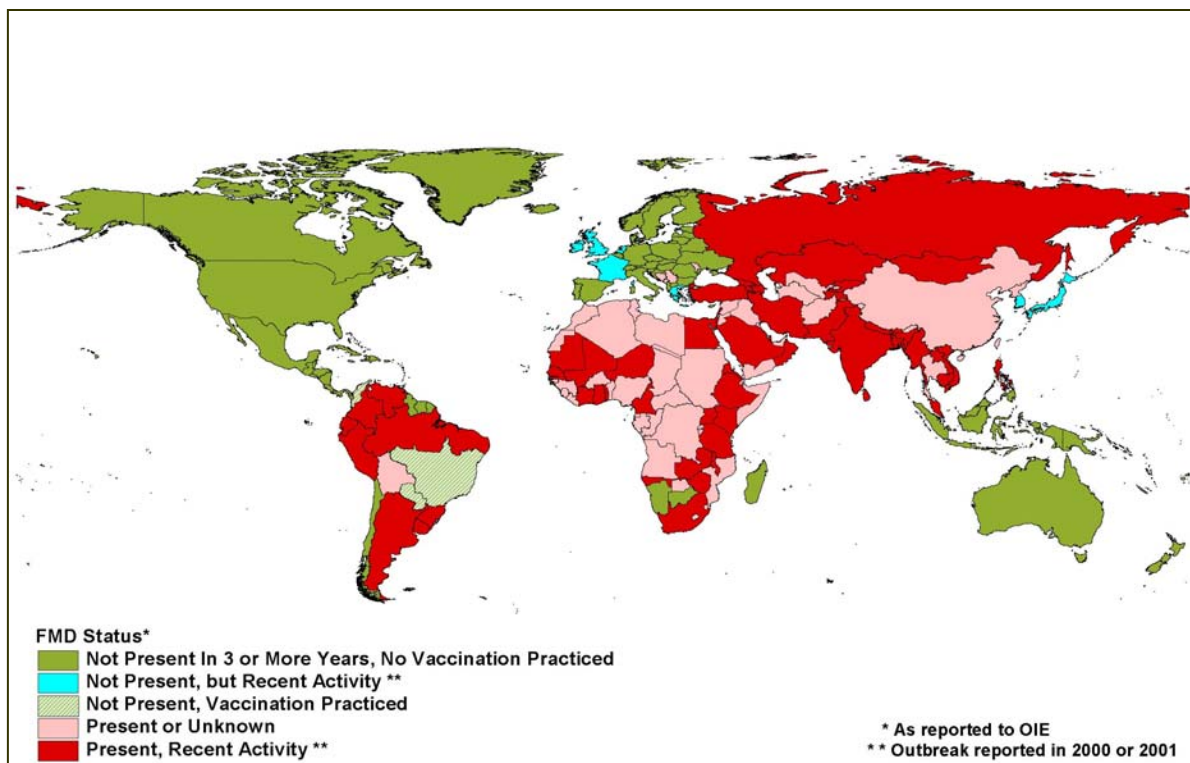
FMD can be confused with several similar—but less harmful—domestic diseases, such as vesicular stomatitis, bovine virus diarrhea, and foot rot. There are two other foreign animal diseases that are clinically identical to FMD in swine – swine vesicular disease and vesicular exanthema of swine. Whenever blisters or other typical signs are observed and reported, tests must be conducted to determine whether the disease causing them is FMD.

FMD Distribution Around the World

The disease has occurred in most countries of the world at some point in the last century. Only a handful of countries have never had FMD. The United States has not had FMD since 1929.

The International Office of Epizootics (OIE), an organization designated by the World Trade Organization (WTO) as the standard-setting body for animal health issues, maintains a database to monitor animal disease status in 199 countries around the world (http://www.oie.int/eng/OIE/en_oie.htm). Of those countries listed in the OIE database, 86 (43 percent) reported the occurrence of FMD in one or more years during 1999, 2000, or 2001. Map 1, below, summarizes worldwide FMD status, as reported to OIE. (For updated information on FMD status worldwide, visit the OIE website: http://www.oie.int/eng/info/en_fmd.htm)

Map 1. Worldwide distribution of FMD, January 2002*



How Other Countries Manage FMD

Based on the information reported to the OIE, most countries of sub-Saharan Africa have endemic FMD, defined as a constant presence of the disease. Most of the North African countries report only sporadic disease outbreaks and do not have an endemic situation. Of the Sub-Saharan countries with endemic FMD most use vaccination as a major control measure and many employ surveillance and movement controls within the country as well. Only a few of the sub-Saharan African countries are able to control movement across national borders. Several countries in the southern part of Africa (Botswana, Namibia, South

Africa, Swaziland, and Zimbabwe) have zones within the country where tighter controls are in place. These zones are usually free of FMD with only occasional sporadic outbreaks occurring. However, in all of Africa, only Botswana and Namibia have zones that are recognized by the OIE as free of FMD.

The seven countries in the Americas that reported FMD outbreaks to the OIE in 2000 or 2001 were all in South America: Argentina, Brazil, Colombia, Ecuador, Peru, Uruguay, and Venezuela. Most of these countries have an endemic situation and practice vaccination, surveillance, and movement controls at national borders and within the country. However, Uruguay and Argentina had been free of FMD until 2001, and therefore had prohibited vaccination. Both countries began vaccinating to control a large outbreak that affected them in early 2001. Brazil, Colombia, and Peru have established FMD-free zones within each country, with increased preventative measures. Only the zones in Brazil and Colombia are recognized by the OIE as free of FMD with vaccination. Colombia also has one small zone on the Panama border that is recognized as free without vaccination. All countries in North America, Central America, and the Caribbean islands have been free of FMD for many years.

Most countries in Asia, including the Middle East, report an endemic FMD situation. The exceptions are several island countries, including Japan, Indonesia, and Singapore, which the OIE considers free of FMD. Peninsular Malaysia has sporadic FMD outbreaks, but Sabah and Sarawak (provinces on the island of Borneo) have never reported FMD. The Philippines has some zoned areas that are recognized by the OIE as free of FMD. The control measures that the endemic countries reportedly practice include vaccination and animal movement controls across national borders and within the country. A few of the endemic countries also practice surveillance, monitoring, or screening. Many Asian countries have difficulty controlling animal movement across national borders.

Four of the European countries (United Kingdom, Republic of Ireland, France, and Netherlands) reporting the occurrence of FMD in 2001 were previously FMD-free countries. They experienced a common outbreak, which began in the United Kingdom in February 2001. By January 2002 all these countries had regained FMD-free status, as recognized by the OIE. Three of the other European countries reporting FMD outbreaks in 2000 or 2001 (Armenia, Georgia, and Turkey) have endemic FMD, at least in certain areas of their countries. All three endemic countries share common borders, and use vaccination, and movement controls across national borders and inside the country. Turkey and Armenia also report establishing zoning as a control measure. Greece shares a common border with Turkey and has reported occasional outbreaks of FMD. The most recent FMD outbreak in Greece occurred in July 2000, near its border with Turkey. The source of the outbreak was considered to be Turkey. Azerbaijan shares common borders with Armenia and Georgia and reports occasional FMD outbreaks, the most recent in August 2001.

Likelihood of Introduction into the United States

In today's highly mobile environment and globalized agricultural economy, the possibility exists for an accidental or intentional introduction of FMD into the United States. A single infected animal or one contaminated sausage could carry the virus to American livestock.

Due to the serious FMD outbreaks occurring throughout the world in 2001, USDA reviewed potential pathways of entry of the FMD virus into the United States. APHIS veterinarians ranked these pathways according to the perceived risk of entry. (See Table 1, below.)

Table 1. FMD Entry Pathways Reviewed by USDA (ranked from highest perceived risk to lowest perceived risk*)

1. Contraband (prohibited meat products carried by passengers/in cargo containers/sent by mail/courier, black market)
2. Illegal transshipments (products from other than stated point of origin)
3. Garbage (small boats/private planes)
4. Edible animal products (fresh, frozen, chilled meat/dairy products)
5. Garbage (commercial ships/planes)
6. Illegal human movements from foreign countries (illegal immigrants)
7. Other animal-related products (straw, hay, packing material, crop movements, feed, farm equipment, shipping containers)
8. Legal human movements (civilian) from foreign countries
9. Live animals (zoo, breeding livestock)
10. Animal germplasm
11. Inedible animal products (fertilizer, vaccines and other biologics, cosmetics, pet food, casein, hides, taxidermy)
12. Military movements

*Source: Opinion survey of USDA/APHIS Area Veterinarians in Charge, from an "Evaluation in Response to International FMD Outbreaks in 2001", by USDA/APHIS, 10/2001

Several aspects must be considered in estimating entry pathway risk, including the volume of potentially contaminated products entering the United States, as well as the likelihood that a contaminated product would come into contact with a susceptible animal population. Imports of live animals, germplasm, animal feed, and vaccines are more likely to come into direct contact with susceptible animal populations than are prohibited meat products carried by airline passengers or garbage from planes or ships. However, shipments of live animals, feed, and biologics are closely regulated and therefore highly unlikely to be contaminated with FMD virus. On the other hand, contraband carried by air passengers, illegal meat shipments, and garbage are not very likely to come into direct contact with susceptible animals but are more likely to be contaminated with FMD virus.¹

¹ It is important to note that this survey took place before the terrorism events of September 11, 2001. The veterinarians who took part in the survey were not asked to consider the possibility of the deliberate introduction of a foreign animal disease virus into the United States for the purpose of disrupting animal health and the country's agricultural economy.

Because many in USDA perceive the contraband pathway as being the highest risk to U.S. animal industries, APHIS has recently investigated this pathway in greater detail. International passengers, cargo, mail, and vehicles could bring contraband materials into the United States at over 300 ports of entry. On average, 30 to 40 percent of all agricultural contraband found at the ports of entry are animal products. In FY 2000, APHIS seized a total of 314,641 prohibited animal products at U.S. ports of entry (Table 2, below). The number of prohibited animal products arriving in the United States is not distributed uniformly. Ten airports with international air travelers accounted for over half of all of APHIS' interceptions of prohibited animal products.

Table 2.
Interceptions of Prohibited Animal Products, FY 2000

Ports of Entry (International Airports)	Number of Animal Products Seized	% of Total Animal Product Seizures Nationwide
JFK, New York	55,900	18%
Miami Airport, Florida	22,449	7%
San Francisco, California	18,944	6%
Los Angeles, California	18,156	6%
Chicago, Illinois	12,690	4%
San Juan, Puerto Rico	9,737	3%
Dulles Airport, Virginia	8,349	3%
Dallas-Ft. Worth, Texas	6,185	2%
Detroit, Michigan	5,823	2%
Atlanta, Georgia	4,739	1%
<u>All Other Ports of Entry (and conveyances)</u>	<u>151,699</u>	<u>48%</u>
Total Animal Product Seizures	314, 641	

Source: USDA/APHIS

To pose a risk to U.S. animals, contraband entering the country must come into contact with a susceptible livestock host. This could happen if a contraband meat product, for example, were disposed of directly on a farm or in waste products that were subsequently fed to a susceptible livestock host. This may have been the means by which the FMD virus entered the United Kingdom and caused the recent outbreak there.

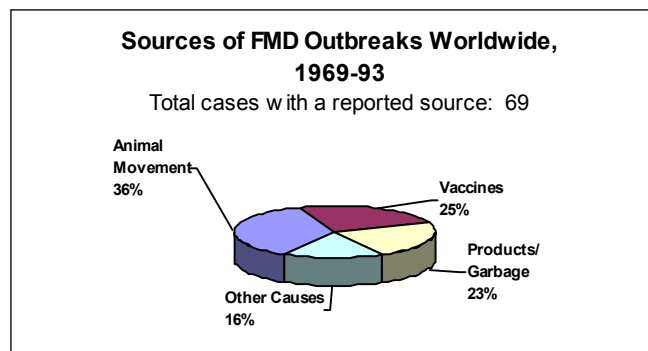
The vast majority of contraband meat and other products entering the United States are unlikely to come into contact with susceptible livestock. A 1995 risk assessment examining the feeding of untreated waste to swine in the United States estimated the median risk of FMD virus exposure to waste-fed swine by contraband meat to be 4.1 incidents of exposure in 100 years. USDA is currently updating this risk assessment. Preliminary information suggests that the risk associated with this pathway may be decreasing due to the declining numbers of premises feeding waste to swine, the decreased amount of plate waste fed to swine, and new regulations in some states outlawing the feeding of animal waste products to animals. Contaminated garbage from maritime and air vessels also poses a potential risk of FMD virus

transmission, if the garbage is not properly disposed of and subsequently comes into contact with susceptible animal hosts, such as feral swine.

Apart from their role in carrying contraband into the United States, it is possible (although unlikely) for international travelers (civilian and military) to transmit the FMD virus by harboring the virus in their upper respiratory system or on their clothing, luggage, or other belongings. A 1998 USDA study found that passengers harboring virus in their upper respiratory system present a negligible risk of FMD virus transmission to U.S. livestock. Extremely close contact with infected animals is required for humans to acquire the virus in their upper respiratory system, and close contact with susceptible animals is subsequently required for them to transmit the virus. Further, the amount of time that FMD virus will remain viable in human nasal passages is generally insufficient to allow for the movement of the person from an FMD-affected area to the United States and to a susceptible livestock host. FMD virus on passenger clothing, luggage, or other belongings was found in the same study to pose a moderate risk of FMD virus transmission to U.S. livestock. Mechanical transmission could occur, for example, if (1) FMD virus "hitchhiked" in contaminated dirt on the passenger's shoes, (2) the passenger wore the same shoes to a farm in the United States, (3) the dirt from the shoes was left in the vicinity of the livestock, and (4) susceptible livestock came in direct contact with the virus infected dirt.

In 1994 USDA examined the source of all primary FMD outbreaks worldwide from 1870 through 1993. The study found that of the 558 outbreaks with a reported source, contaminated meat, meat products, or garbage caused 66 percent of the outbreaks. As shown in Chart 1, for the latter 25 years under study—1969 through 1993—the sources of most of the 69 primary FMD outbreaks were livestock importations, animal vaccines (including both contaminated vaccines and escapes of virus from vaccine production facilities), and contaminated meat, meat products, or garbage. Outbreaks from live animal movements have often been due to animals crossing into neighboring countries. The United States, bordered by countries free of FMD, has a distinct advantage in this regard.

Chart 1. Main Sources of FMD Outbreaks Worldwide, by Percent of Total Cases, 1969-93



Economic Impacts

If an FMD outbreak were to occur in the United States, the disease could spread rapidly to all sectors of the country by routine livestock movements, unless it was detected early and eradicated immediately. The economic impacts of such an outbreak would include not only the immediate losses to livestock production, but also the upstream and downstream costs of an outbreak and its control in the United States. The Nation's deer, feral swine, and other wildlife populations could also rapidly become infected and potentially remain a reservoir of infection, possibly requiring that some animals be depopulated.

The 2001 outbreak of FMD in the United Kingdom has had a substantial impact on many segments of European economies. The firm Price Waterhouse Coopers estimates that economic impacts of the current FMD outbreak there will total between 0.3 percent and 0.8 percent of the United Kingdom's gross domestic product, or approximately \$3.6 to \$11.6 billion. Because recent U.S. experience with FMD is limited, it is instructive to examine the UK case and compare it with expert opinions on possible economic effects in the United States.

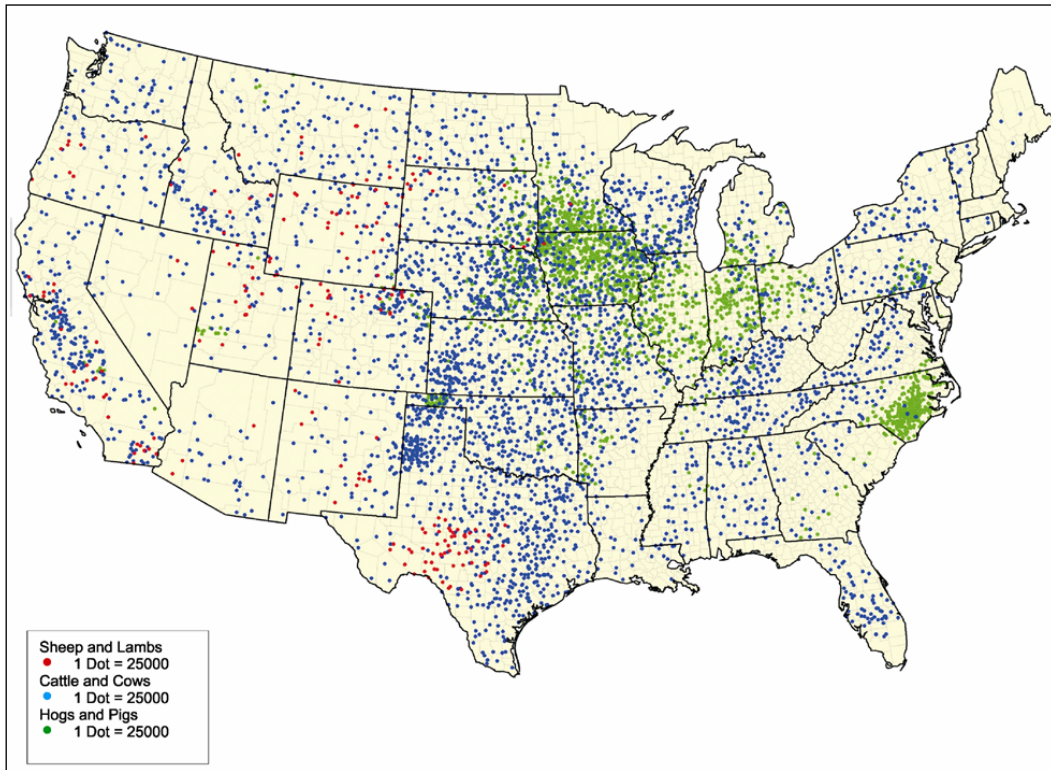
Generally, productivity losses of 10 to 20 percent are reported if FMD is allowed to run its course. For an industry with the narrow profit margins of U.S. livestock agriculture, losses of this magnitude could significantly reduce receipts and increase costs, putting some producers out of business. Outbreaks of FMD in the United States would be most severe and cause the most extensive economic losses in those areas densely populated with livestock (Map 2, next page). The most significant direct economic effects to livestock owners, however, would come from the necessity to depopulate any infected herds. Meat, milk, and other products from infected animals would not be allowed into the food chain. For all infected animals and any marked for preventive culling, the production would effectively drop to zero.

Costs to producers go well beyond the immediate loss of livestock slaughtered to control the disease. Premises would have to be cleaned and disinfected, and there would be a waiting period of at least 30 days before restocking could begin. There would be no production income during that period and only a reduced income while rebuilding herds. In an area seriously affected by an outbreak, it may be prohibitively difficult to purchase replacement stock, and prices would increase as supplies of replacement livestock were depleted. There would be restrictions on movement of livestock from infected to uninfected areas, which could also prevent immediate rebuilding. Inability to absorb additional fixed costs of rebuilding and a reduced cash flow could force some producers out of business. Many producers would not be able to replace the many years of work that went into building their breeding herds. Within a quarantine area, poultry producers (whose flocks would not contract FMD) could incur costs of destroying birds and eggs that could not be moved to market or additional feed costs for maintaining more permanent flocks.

The rate of spread of an FMD outbreak in the United States would be

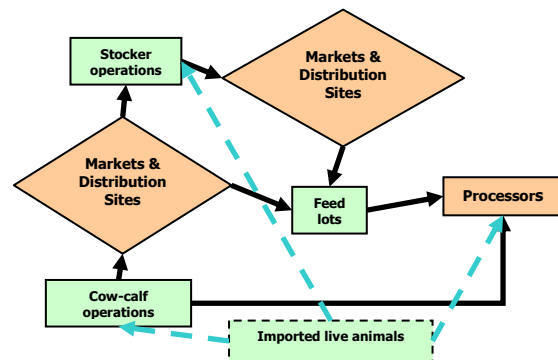
most rapid in areas that have dense populations of susceptible livestock (Map 2), where there is considerable livestock movement between operations, or areas with extensive agri-tourism. Current estimates of U.S. livestock inventories are 97 million cattle and calves, 7 million sheep, and 60 million hogs and pigs, with dense livestock population in certain areas.

Map 2. Distribution of Cloven-Hoofed Livestock in the United States
Source: 1997 Agricultural Census



Cattle generally move from dispersed farms throughout the country – 80 percent of cattle move more than 200 miles – to primary feeder markets and cattle feeding areas in the central and southern plains (Chart 2). Experts estimate that, if the United States failed to stamp out FMD within a reasonable time, the disease could affect 30-

Chart 2. Flow chart of Market Movement of Cattle



70 percent of the livestock in the United States.

The United Kingdom slaughtered or marked for slaughter over four million animals to contain the FMD outbreak, accounting for roughly 8 percent of the total cattle, swine, and sheep inventories. Most of the animals affected in the UK outbreak were sheep. A similar percentage in the United States would represent over 13 million animals, but most of those animals would likely be cattle and hogs. (Hog, cattle, and calf inventories in the United Kingdom are about 12 percent of U.S. hog, cattle, and calf inventories, while the United Kingdom has over 4 times the U.S. sheep population.)

The recent FMD outbreak in the United Kingdom and its European Union (EU) neighbors had significant, but not long-lasting, effects on food consumption, trade, and tourism, as well as agriculture. EU authorities managed to contain the FMD epidemic, minimizing its spread to continental Europe. An early drop in beef consumption, possibly resulting from confusion with BSE, recovered to its earlier down trend.

An FMD outbreak in the United States would have effects on trade that would cause significant losses to livestock and other sectors. In the United States, exports of cattle, sheep, hogs, poultry, and many of their products varies annually from six to ten billion dollars. This accounts for roughly 10 percent of the cash receipts for those livestock species at the farm level. In 2000, U.S. exports consisted of \$608 million in live animals and \$5.4 billion in meat products, many of which would face restrictions during an FMD outbreak. Because meat, even though safe to eat, could not be exported under these restrictions, supplies of beef, pork, and lamb would increase domestically and prices would decline. The prices (and therefore farmers' returns) of some products not popularly consumed in the United States (for example, variety meats, pigs feet, and chicken "paws") would decline significantly if exports were under restriction. Sectors that provide inputs for the livestock production and meat processing sectors would also see declining prices and business. Despite its large size, the United States is still considered by OIE to be one region. Thus, if there were an FMD outbreak in one small area of one state, trade restrictions would still be enforced on the nation as a whole, at least during the initial days of the outbreak.

An outbreak might lead to changes in processing or packaging to retain export markets. While fresh meat would be restricted, some types of meat could be processed to adhere to any restrictions trading partners impose.

The animal products rendering and meat by-product processing industries would also weaken following an outbreak of FMD. U.S. renderers employ 10,000 workers, have a payroll of \$270 million, and are heavily concentrated in certain areas, especially in Texas and California. After an FMD outbreak, communities in those areas could face problems with unemployment.

If there were an FMD outbreak in the United States, many activities not directly related to agriculture would be disrupted by restrictions on

movement of both animals and humans, to limit the mechanical spread of the virus. Some of these activities, such as tourism, recreation, and hunting, constitute large sectors of the national and regional economies. For example, Amish farms in Pennsylvania and dude ranches in the West and Southwest could face significant losses if an outbreak of FMD restricted movement in those areas. If hunting and tourism were restricted in such areas, spending on those activities would likely shift to other areas of the country or to different types of recreation. In some cases, losses to these industries could exceed losses to livestock sectors. In the recent UK outbreak, losses to tourism were high and exceeded losses to the livestock sector.

Department of the Interior (DOI) lands are managed for a variety of purposes, including resource protection, recreation, grazing, mining, and energy production. Should an FMD outbreak occur in the United States, the social and economic costs of quarantining DOI lands or of eradicating infected animals could be enormous for all of these sectors. Furthermore, because certain tribes and individual Native Americans derive income from hunting and grazing permits, raise their own animals, and have introduced bison herds on their reservations for cultural, religious and ceremonial purposes, an outbreak of FMD could have significant financial, cultural and religious impacts.

The Federal Government, along with States and producers, would bear the brunt of costs associated with containing an outbreak of FMD. The U.S. Government would incur costs for increased surveillance, tests and confirmation, livestock depopulation and disposal, and any type of vaccination intervention. The Government would also pay producers an indemnity for their condemned livestock. Current indemnity processes are set up to pay producers a fair market value for their livestock based on an assessment by an appraiser.

(See Appendix 6 for more details on the economic impacts of FMD.)

Risk Management

The U.S. Government's strategy for protecting the country from the risk of FMD and other highly contagious foreign animal diseases includes four main components:

- *Outside U.S. borders*, monitor for the occurrence of FMD and other foreign animal diseases worldwide, evaluate the potential exposure of the United States to foreign outbreaks, and reduce the threat of significant foreign animal diseases spreading to the United States.
- *At U.S. borders and other domestic ports of entry*, regulate, inspect, and intercept or quarantine products and animals potentially carrying foreign animal diseases.
- *Inside the United States*, maintain a strong animal health infrastructure that includes surveillance and monitoring systems and research capacity to quickly detect the presence of a highly contagious foreign animal disease such as FMD before it spreads.
- Also inside the United States, establish and maintain a strong *emergency response capacity* to quickly control and/or eradicate a foreign animal disease or pest.

International Activities

Several U.S. Government agencies participate in international activities that help reduce the threat of FMD and many other foreign animal diseases.

Collaboration with OIE and Other Organizations

The United States participates fully in the OIE, the World Trade Organization, and other international bodies that track FMD and negotiate issues related to the disease. The Chief Veterinary Officer of the United States, normally a high ranking veterinarian in APHIS, is a voting member on all issues that come before the OIE. FSIS has a Chief Veterinary Public Health Officer and DHHS has a Chief Public Health Veterinarian, and they work with the Chief Veterinary Officer to strengthen collaboration between food safety and animal health issues nationally and internationally. USDA also has several representatives working on key OIE committees that decide on issues related to FMD and other foreign animal diseases.

Three USDA facilities act as "collaborating centers," as part of OIE's worldwide animal health structure. The National Veterinary Services Laboratories (NVSL), the Center for Veterinary Biologics (CVB) and the Centers for Epidemiology and Animal Health (CEAH) provide technical expertise to scientists and laboratories in other countries. NVSL, located in Ames, Iowa and Plum Island, New York, and CVB, also in Ames, Iowa, are jointly recognized as specialists in the diagnosis of animal diseases and vaccine evaluation. CEAH, located in Ft. Collins, Colorado, is recognized for its expertise with animal disease surveillance systems and risk analysis. As an OIE reference laboratory for selected animal diseases, NVSL provides expertise and technique standardization in animal disease diagnostics, stores and distributes biological reference products and reagents, and develops new diagnostic procedures for use around the world. Several State animal health diagnostic laboratories in the United States are also recognized as OIE reference centers for a variety of animal diseases.

The Department of State and the U.S. Trade Representative (USTR) also participate in these multilateral international organizations. Because of its broad responsibility to provide policy leadership in matters involving international relations and security, the State Department devotes diplomatic resources to advocate U.S. policy and to garner international support for U.S. government positions concerning FMD and other foreign animal diseases. The State Department also engages scientific and technical agencies to foster maximum cooperation and to coordinate, as appropriate, relevant informational materials, advisories, and public affairs products that will assist American citizens living or traveling abroad. International trade in agricultural products, along with the actions taken by governments regarding food safety or plant and animal health, are disciplined by the trade rules of the World Trade Organization (WTO). The USTR represents the U.S. government at the WTO. USTR coordinates an interagency process to develop U.S. positions that ensure that safety concerns and trade rights and obligations are respected by the United States and our trading partners.

USDA (APHIS and the Foreign Agricultural Service—FAS) maintains a presence in many countries around the world, to collaborate with animal health officials and international organizations such as the United Nations Food and Agriculture Organization (FAO), the Inter-American Institute for Cooperation on Agriculture (IICA), the Pan American Health Organization (PAHO), the International Regional Plant and Animal Health Organization (OIRSA), and the Hemispheric Committee for the Eradication of Foot-and-Mouth Disease. Researchers at USDA's Agricultural Research Service (ARS) actively work with international scientists, in their home countries or as guest workers in ARS facilities, to investigate emerging FMD viral isolates from different regions of the world. Efforts include sequencing new isolates, pathogenesis studies and vaccine trials to determine differences from current isolates and to assess whether current vaccine stocks are effective against new isolates of the virus. These efforts improve the surveillance of FMD, increase the knowledge of local animal health officials in export and import requirements, help develop animal health and quarantine infrastructures, and improve communication between scientific experts.

Coordination with Close Neighbors

For over 30 years, the United States has held regular meetings on animal health issues with the governments of Canada and Mexico. The three neighbors continue to work together to harmonize North America's import requirements and have coordinated recent preventive actions and emergency response activities. They also carried out joint exercises to test FMD communication and response plans. Last year, the three parties signed a Tripartite Memorandum of Understanding to formally establish the North American Animal Health Committee. This committee represents animal health issues to the North American Free Trade Agreement (NAFTA) and has goals to harmonize North America's animal and animal product import requirements, plan emergency response activities, and jointly carry out test exercises.

Canada, Mexico, and the United States created a North American FMD Vaccine Bank in 1982. The Bank is housed at APHIS' Foreign Animal Disease Diagnostic Laboratory at USDA's Plum Island Animal Disease Center (see Text Box).

Mexico and the United States coordinate on the bilateral U.S./Mexico Commission for the Prevention of FMD and Other Exotic Animal Diseases, and have successfully prevented outbreaks of the disease since the last case of FMD occurred in Mexico in 1954. USDA veterinarians in Mexico and the United States are dedicated to surveillance, diagnostic capabilities, and training. This is increasingly important, as NAFTA has tripled Mexican beef exports to the United States since 1990. Mexico is working to maintain the same exclusion standards as the United States and Canada.

North American FMD Vaccine Bank

The bank stores different types of concentrated, inactivated FMD virus antigen which can be formulated into vaccine rapidly should an FMD outbreak occur. The bank also maintains master seeds for production of larger amounts of finished products. Stocks at the bank are monitored in light of outbreaks occurring around the world, to ensure that the bank is stocked with master seeds for the most active strains of the virus. In addition, APHIS scientists constantly monitor the quality of the vaccine concentrates available. This testing helps ensure that FMD vaccines are not contaminated with other microorganisms and that they do not produce adverse local or systemic reactions following administration. APHIS also sets standards for the Bank and inspects potential vaccine production facilities. The Chief Veterinary Officers of Canada, Mexico, and the United States act as commissioners of the bank. They have the authority to activate the bank in the event of an outbreak of FMD in any of the three countries. An evaluation of an outbreak simulation exercise in 2001 resulted in a decision matrix for use of vaccine.

There is an ongoing, coordinated effort in Mexico, Panama, and all of the countries of Central America to maintain their FMD-free status, with the United States providing assistance. The countries all take part in the Cooperative Agreements for the Prevention of Foot-and-Mouth Disease and Rinderpest. OIRSA also provides a forum for cooperation among Central American countries and with the United States. Animal health authorities in the Central American countries collect samples from livestock with vesicular diseases and send them for laboratory analysis in Panama. They also have regulations in place to ban products that represent a high animal disease risk, and they all carry out inspections to enforce those policies. USDA also works through bilateral commissions in Honduras, Nicaragua, and Costa Rica, to improve disease prevention, surveillance, diagnosis, and emergency preparedness.

USDA and Panama jointly operate a commission to maintain an FMD-free area along the Colombia-Panama border. This barrier serves as the "first line of defense" for preventing the spread of FMD northward into Panama, Central America, Mexico, and the United States. Until FMD is eradicated from South America, USDA plans to maintain this barrier to prevent the disease's northward spread. The commission also supports the Vesicular Diseases Diagnostic Laboratory to provide all of Central America and Panama with reliable capacity to diagnose FMD. This is crucial because some less severe vesicular diseases, such as vesicular stomatitis, have

clinical signs similar to FMD, and misdiagnosing animals could lead to enormous costs.

Panama has particular concern because of the existence of FMD in Colombia, right across the border, in an area where FMD is difficult to control and monitor. Therefore, the United States also maintains a program of cooperation with Colombia for the control and eradication of FMD in its border area with Panama and in interior areas of the country. This program was initiated in 1973 and has resulted in the creation of FMD-free buffer zones that help to prevent the spread of FMD into Panama and Central America.

*Surveillance and
Monitoring Disease
Status*

The U.S. Government is actively involved in monitoring changes in animal disease status worldwide.

USDA analyzes information gathered from the OIE, as well as from APHIS and FAS personnel stationed overseas, news reports, and other U.S. Government agencies. APHIS officials have also participated directly in surveillance activities in Korea, Japan, and Taiwan during recent FMD outbreaks. FSIS inspects foreign meat processing plants and reports abnormal animal health findings when appropriate. Other aspects of FSIS' monitoring include assisting APHIS in inspecting perishable cooked ruminant and swine meat from restricted countries and assisting in traceback and biosecurity activities, by ensuring that all animal identification records remain associated with carcasses until completion of post-mortem examinations.

The Armed Forces Medical Intelligence Center of the Department of Defense (DOD) gathers information on the status of human and zoonotic diseases throughout the world. DOD is also available for support of specific animal disease investigations, for example by providing transport of needed disease surveillance equipment. The Department of State also provides information to help prevent deliberate acts that would breach biosecurity.

*Technical Assistance and
Training*

The U.S. Government also supports reducing the FMD threats around the world by providing technical assistance and other resources. Historically, the major focus for these efforts has been in South America, where USDA is working with PAHO to eradicate FMD from the continent. The Department of State and the U.S. Agency for International Development also support this activity by providing logistical help and resources to projects in several countries in South America.

Similar technical assistance efforts have begun recently in other parts of the world. To increase awareness and begin to improve the animal health infrastructure in Asia, USDA has initiated seminars on animal import risks in such countries as Vietnam, Thailand, and Bangladesh. In Africa, technical assistance has focused on workshops and infrastructure building. APHIS and FAS also collaborate to train foreign veterinarians at the Foreign Animal Disease Diagnostic Laboratory on Plum Island. The course provides instruction in the clinical signs associated with FMD and other important animal diseases, appropriate sampling methods, and diagnostic techniques. This form of outreach helps these veterinarians

quickly identify any emerging FMD infections in their own countries well before they present a more proximate danger to the United States. Additionally, the ARS laboratories on Plum Island actively train foreign scientists in developing novel FMD diagnostics, vaccines, and techniques for determining disease pathogenesis and resistance mechanisms.

During the recent FMD outbreak in the United Kingdom, the United States responded to the United Kingdom's request for assistance on disease diagnosis and carcass removal. More than 200 veterinarians from state agencies, private practice, universities, and other organizations from the United States took part in the control efforts. Another 125 Federal veterinarians from several agencies also participated, and the U.S. Environmental Protection Agency provided support for carcass disposal and burial. ARS scientists visited the main UK reference laboratory at Pirbright and assessed sampling protocols and diagnostic tools utilized throughout the outbreak. This experience, as well as the practice USDA gained in coordinating such a diverse group, will be beneficial in the event of future emergencies.

**International Activities:
Additional Needs and Future Plans**

Although these international activities have been effective in helping safeguard the United States from FMD, the PL107-9 Inter-agency Working Group believes the United States needs to:

- Strengthen on-site capacity to analyze and verify reports of FMD outbreaks in other countries.
- Continue and broaden efforts to harmonize its risk management activities with Mexico and Canada.
- Develop additional mechanisms to better access the foreign intelligence capabilities of other agencies in the U.S.

Government that deal with biological threats that are deliberate attempts to breach U.S. biosecurity safeguards.

Congress designated \$328 million of the Defense Appropriations Act, signed by the President in January 2002, to bolster USDA's Homeland Security efforts in FY2002. USDA plans to use \$853,000 of these funds overseas for increased surveillance of foreign animal diseases and improved security at high-risk USDA facilities. USDA has prepared plans to increase the number of animal scientists and veterinarians working overseas to gather and analyze animal disease data. More exchange visits of U.S. and international scientists will:

- *enhance information exchange and understanding of new emerging infectious diseases, particularly new FMD variants;*
- *enable researchers to develop serotype specific diagnostics and to prove their utility in natural disease outbreaks;*
- *allow testing of new vaccine and drug formulations to determine efficacy in preventing disease and in eliminating carrier animals;*
- *enable scientists to evaluate new disinfectant and disposal technologies and determine survivability of new serotypes in the environment.*

<p>International Activities: Additional Needs and Future Plans (continued)</p>	<p><i>The Department of State can assist USDA in gathering this information and in other related activities. For example, State Department personnel can help identify and coordinate diplomatic, informational, and security enhancement measures to be pursued in the event of a confirmed outbreak of these diseases in the United States, as well as periodically monitor the response of other countries to these diseases. Furthermore, the Department of State and other agencies will assist Federal departments and agencies as necessary regarding the assessment of alleged terrorism risks related to these diseases.</i></p>
	<p><i>For FY 2003, USDA is proposing a \$4.9 million increase for increasing foreign animal disease information gathering and providing technical assistance for emergency management outside the United States.</i></p>

Exclusion Activities Another important part of the U.S. FMD safeguarding strategy is to exclude from entry those animals and animal products that pose a risk of FMD, while, at the same time, meeting trade obligations established by the World Trade Organization (WTO).

Import Regulations Strict, science-based import regulations have played a major role in safeguarding the United States, not only from known disease threats like FMD, but also from new or emerging animal disease threats. APHIS has authority to enforce these regulations through a series of Federal laws, some of which date back to the nineteenth century. These laws have been consolidated and updated into the Animal Health Protection Act (7 USC 8301 *et seq.*).

APHIS has regulations in place to restrict imports of livestock, germplasm, livestock products (including edible and inedible products), and other animal-related products coming from countries the United States does not recognize as free of FMD, or has identified as FMD-free but in a special category (Table 3). As part of its import risk assessment process, APHIS independently validates countries' disease status reports sent to the OIE. As of January 2002, USDA recognizes only 48 countries or geographical regions as free of FMD.

APHIS also regulates biological products such as animal vaccines and diagnostic test kits. APHIS has the authority under the Virus-Serum-Toxin Act to test the purity, safety, and potency of these products prior to issuing a permit or releasing them from quarantine. However, this authority does not extend to being able to issue civil penalties to individuals and companies that illegally import unlicensed veterinary biological products that pose a threat of introduction of foreign animal diseases.

**Table 3. Countries/Areas Free of FMD – USDA Assessment
(as of January 9, 2002)**

*Austria	*Germany	*Norway
Australia	Greenland	Panama
*Bahamas	Guatemala	*Papua New Guinea
Barbados	Haiti	*Poland
*Belgium	Honduras	*Portugal
Bermuda	*Hungary	*Spain
Belize	Iceland	*Sweden
Canada	*Northern Ireland	*Switzerland
*Channel Islands	*Republic of Ireland	Territory of St. Pierre and Miquelon
*Chile	*Italy	Tobago
Costa Rica	Jamaica	Trinidad
*Czech Republic	Japan	Trust Territories of the Pacific Islands
*Denmark	*Luxembourg	
Dominican Republic	Mexico	
El Salvador	*Netherlands	
Fiji	*New Caledonia	
*Finland	New Zealand	
*France	Nicaragua	

*SPECIAL CATEGORY REGARDING FMD. Even though the country/area has been determined by USDA to be free of FMD, one or more of the following conditions occur:

- (1) They supplement their national meat supply through the importation of fresh, chilled, or frozen meat of ruminants or swine from countries/areas that are NOT designated in Title 9, CFR, Part 94.1(a) (hereafter known as The Regulations) as free of FMD; or
- (2) They have a common land border with countries/areas that are NOT designated in The Regulations as free of FMD; or
- (3) They import ruminants or swine from countries/areas that are NOT designated in The Regulations as free of FMD under conditions less restrictive than would be acceptable for importation into the United States.

Meat and animal products from countries in this restricted category are required to have additional certification verifying the origin of the product and attesting to the fact that it hasn't been commingled with product from countries not considered free of FMD.

Reference: Title 9, Code of Federal Regulations (CFR) Part 94.1

For an up-to-date list, see <http://www.aphis.usda.gov/NCIE/country.html>

To ensure that its import regulations are not unjustified trade barriers, APHIS has established guidelines that are consistent with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The agreement obligates members to base animal and plant health safeguarding measures on science, which is consistent with APHIS' approach to decision-making. USTR, Department of State and USDA work closely to ensure that the trade effects of regulatory decisions respond to domestic health and safety concerns and are consistent with international obligations under the WTO. In the event of an animal disease outbreak in the United States, USTR would work to ensure that U.S. domestic regulatory actions are consistent with WTO obligations and would defend any challenge of these regulations by another WTO member.

To meet one of the key SPS Agreement requirements – transparent, science-based risk assessments – APHIS in 1997 finalized its “regionalization” rule, which provides guidelines for APHIS’ risk assessments on animal health issues. Table 4 summarizes the guidelines included in this regulation.

Table 4. Risk Factors for Evaluating Import Requests

APHIS regulations require that the following information about a country or a region accompany a request for recognition of the animal health status in that region:

- Authority, organization, and infrastructure of the veterinary services organization
- Disease status
- Status of adjacent regions with respect to the agent
- Extent of an active disease control program
- Vaccination status
- Degree of separation from adjacent regions of higher risk
- Extent to which movement of animal and animal products from regions of higher risk is controlled
- Livestock demographics and marketing practices
- Type and extent of disease surveillance
- Diagnostic laboratory capabilities
- Policies and infrastructure for animal disease control

USDA evaluates the information provided, conducts a site visit for verification, and carries out a risk assessment. On the basis of the risk assessment, USDA makes a decision about whether imports from the country or region are safe.

FSIS also plays an important regulatory role to exclude FMD and other foreign animal diseases. When a country applies to export meat products to the United States, FSIS has the authority to evaluate the country’s laws, policies, and inspection system. Once FSIS deems a country’s food safety inspection system as equivalent to ours, approved meat processing plants may apply for APHIS approval for FMD-specific treatments that make the meat products safe for import into the United States.

Inspections and Quarantines

The volume of cargo and travelers entering the United States—over 30 million commercial shipments and 60-80 million international travelers per year—creates a tremendous challenge to the Federal inspection service agencies. Ongoing monitoring at ports of entry indicates that on average about 95 percent of passengers and about 98 percent of cargo shipments comply with regulations designed to keep agricultural pests and diseases such as FMD out of this country. APHIS, U.S. Customs Service, and the Immigration and Naturalization Service (INS) are the primary Federal inspection agencies working at the ports of entry. Other agencies also play important roles to ensure compliance with Federal regulations.

U.S. Customs Service At over three hundred ports in the United States, the U.S. Customs Service (<http://www.customs.gov>) enforces not only the laws related to its own authorities, but also the laws for over 40 Federal agencies. These enforcement efforts include commercial shipments, personal shipments, passenger, and pedestrian processing. There are several modes of transportation used for international trade and travel. They include ocean vessels, airplanes, trucks, rail, automobiles, mail, and express consignments. Each mode of transportation has its own unique requirement for clearance. U.S. Customs Service electronically processes an average of over 25 million commercial shipments every year. Another five to eight million shipments are processed via non-electronic means. These include personal shipments. The numbers of shipments have been increasing at a rate of two to five percent per year. An estimated 60 to 80 million passengers are processed through U.S. Customs Service each year. The majority of the passengers are processed at international airport facilities.

APHIS APHIS' Agricultural Quarantine Inspection (AQI) program is USDA's core activity to implement import regulations designed to prevent animal diseases such as FMD and BSE from entering the United States. In FY 2001, APHIS spent over \$222 million and deployed over 3,000 staff-years in this program. This represents nearly a tripling of spending since FY 1993. AQI officers, with the help of detector dogs and x-ray technology, inspect over 75 million international air, maritime, and land border passengers arriving in the United States at 186 domestic ports of entry and 8 foreign ports of departure. (At other ports where APHIS is not staffed full-time, U.S. Customs Service officials collaborate to carry out the inspections of baggage and vehicles and seize prohibited agricultural items.) Each year the AQI program intercepts several tons of meat products in passenger baggage arriving from countries affected by foreign animal diseases. For cargo shipments, APHIS also collaborates with Customs officials to ensure inspection of agricultural products subject to APHIS regulations. In addition, regulations of transportation companies require incineration and cooking of all international garbage collected from aircraft and maritime vessels. APHIS inspectors monitor agreements with companies and carry out inspections to ensure compliance with these regulations.

Some materials and passengers clear inspection overseas. APHIS oversees a number of preclearance programs around the world, to facilitate trade of a variety of plant products, such as flower bulbs, mangos and citrus. In cooperation with the Department of Defense and U.S. Customs Service, APHIS also inspects military cargo, vehicles, household goods, and personal effects of military personnel before their return to the United States. APHIS, INS, and U.S. Customs Service operate several Federal inspection service preclearance operations for air passengers coming from some airports in Canada and the Caribbean islands.

INS INS conducts immigration inspections of travelers entering (or seeking entry) to the United States as they arrive at officially designated ports of entry. U.S. Customs Service, APHIS, and INS share access to several

database systems that enable inspectors to focus inspection efforts on the highest risks while expediting the clearance process.

FSIS and FDA FSIS ensures that imported meat, poultry and egg products are safe, wholesome and accurately labeled. FDA is responsible for the safety of all other food products arriving at U.S. ports of entry. When a shipment of cargo regulated by FDA or FSIS arrives at a port of entry, U.S. Customs Service notifies the appropriate agency for a determination of whether to hold the product for inspection before entry into the U.S. market. FSIS employs and is updating a computerized database that centralizes re-inspection and shipping information. The database also provides a method for rapid communication with inspectors at ports of entry when they must intercept products from an individual country. For example, USDA used the system in February 2001 to stop shipments from Brazil, when the United States temporarily suspended them. FSIS currently also performs cooked beef testing for every shipment from countries where there is a presence of certain diseases (such as rinderpest, FMD, swine vesicular disease, hog cholera and African swine fever). In addition, APHIS and FSIS work closely with FDA to assure that other products under FDA's jurisdiction are identified, inspected, and denied entry if the products represent a threat to the animal or public health of the United States. When U.S. Customs Service notifies FDA that a shipment is being held for FDA inspection, a computerized FDA database then screens these entries for products that require additional manual review. By loading appropriate screening criteria into the database, FDA can also identify imported products subject to joint inspection by FSIS or APHIS and refer the entries to those agencies.

Actions to Prevent the Possibility of Deliberate Introductions While inspection activities stop most inadvertent or minor violations of the import laws, there is growing concern about the potential for deliberate efforts to illegally move large quantities of prohibited products around the port of entry inspection systems. USDA, U.S. Customs Service, the U.S. Fish and Wildlife Service, FDA, and agricultural officials in various States coordinate their activities to identify and investigate the illegal importation of uninspected and prohibited animal products and by-products. USDA has an active internet search working group that detects illegal sales of banned products. APHIS has recently initiated an anti-smuggling program to deal with these deliberate violations. USDA may assess administrative and civil penalties for import violations, and the Justice Department has the authority to prosecute criminal violations and to bring certain civil actions.

As part of an ongoing attempt to ensure that USDA safeguards are operating effectively, the USDA-Office of Inspector General (OIG) conducts audits and criminal investigations. USDA is taking action on recent audits concerning port of entry regulations. Current OIG audits include an assessment of USDA activities to prevent the entry of FMD into the United States and one on the FSIS re-inspection program's efficacy.

Heightened Alert Due to 2001 FMD Outbreak in the United Kingdom The inspection agencies at ports of entry activated many enhanced exclusion activities in response to the 2001 FMD outbreak in the United Kingdom and other European countries. USDA imposed immediate

import restrictions and approved spending an additional \$32 million of AQI user fee revenue to hire approximately 350 additional inspectors in FY 2001 and 2002. As of the end of FY 2001, APHIS had hired 114 additional inspectors, was preparing to place 18 new animal health officials at the borders, and had begun training new dog teams to help carry out the inspections.

U.S. Customs Service instituted more rigid inspection protocols on travelers from Europe and other FMD-affected countries to provide greater assurance that they were not carrying animal products that could spread FMD. APHIS also worked closely with U.S. Customs Service to develop an FMD at-risk product list for both commercial cargo and passenger processing.

Inspectors continue with extra efforts to ensure that passengers identify any visits to farms or rural areas to U.S. Customs Service and USDA officials. If passengers visited a farm in a country with a risk of transmitting FMD, USDA port of entry policy calls for inspectors to inspect those passengers' clothing and footwear and to clean items that may have been contaminated with the FMD virus. To carry out some of these safeguards, USDA consulted with the EPA on the increased use of disinfectants. (EPA must, under the Federal Insecticide, Fungicide, and Rodenticide Act, license and regulate disinfectants used on inanimate objects or hard surfaces to control the spread of exotic animal diseases. Section 18 of this Act authorizes exemptions to Federal and State agencies for use of an unregistered product under emergency conditions, including quarantine, to control the spread or introduction of any pest or disease. EPA has been expediting USDA's requests for products to control FMD, using this exemption authority.)

**Exclusion Activities:
Additional Needs and
Future Plans**

Although the Federal inspection agencies already provide an important "line of defense" at ports of entry, there is need to:

- Close a current loophole in the Virus-Serum-Toxin Act, to enable APHIS to assess civil penalties and/or seek criminal penalties against individuals and companies that illegally import unlicensed veterinary biological products that pose the threat of introduction of foreign animal diseases such as FMD.
- Strengthen efforts to share information and cooperate at ports of entry, where each Federal agency employs its unique expertise to fulfill its specialized mission.
- Strengthen the capacity to assess animal health risks and to develop regulations that safeguard U.S. animal health while meeting requirements of the SPS Agreement.
- Strengthen essential programs and services related to biosecurity issues at ports of entry.

Exclusion Activities:
Additional Needs *and Future Plans* (continued)

- Develop guidance and plans at ports of entry to fully implement the consolidated provisions in the Animal Health Protection Act (7 USC 8301 *et seq.*), especially new civil penalty authorities.

U.S. Customs Service is developing a new information system, called Automated Commercial Environment, to replace the current system and to better share trade data with other Federal agencies. APHIS is also developing a port information database that will enable AQI officers to have enhanced access to passenger and cargo information. Of the \$328 million USDA received as part of the Defense Appropriations Act (January 2002), \$35 million is going toward improved border inspections, including \$15.2 million for technology to rapidly detect pests and diseases and to better coordinate with U.S. Customs Service. This amount will offset declines in collections following the September 11, 2001 events. By the end of FY 2002, APHIS will have increased its inspection personnel by nearly 40 percent over FY2000 and will double its inspection dog teams from levels of two years ago.

USDA is also proposing for FY2003 a \$12 million increase in the APHIS agricultural quarantine inspection program, to provide additional inspectors and canine teams, improve port-of-entry inspections, and improve database coordination with U.S. Customs. (See Appendix 8 for a complete list of all the USDA FY2003 budget proposals related to animal diseases such as FMD and BSE.)

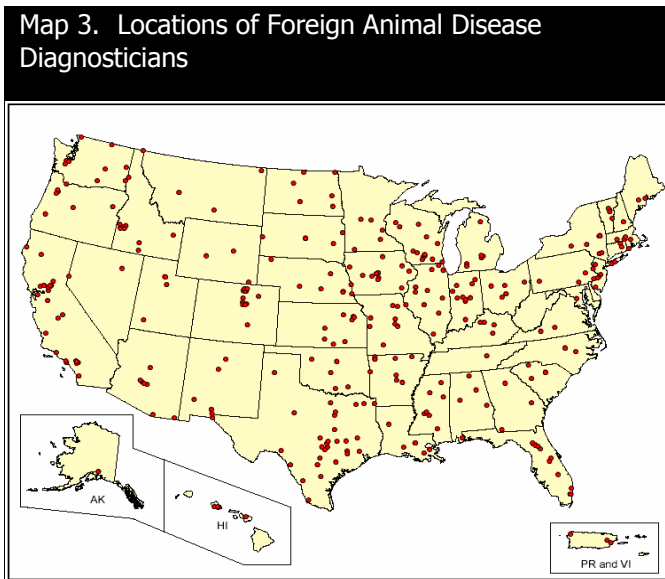
Based on the experience at ports of entry during the height of the FMD outbreak in the United Kingdom, U.S. Customs Service has proposed an "Interagency Enforcement Strategy" to enhance the Federal inspection agencies' capacity to coordinate and communicate effectively during an emergency. (See Appendix 7 for details of Customs' proposal.)

Domestic Activities

Despite the best efforts to contain FMD overseas and to prevent its entry, the tremendous flow of people and commodities into the United States makes it vital to maintain a strong animal health infrastructure in this country. Key components of that infrastructure include disease surveillance and monitoring and emergency preparedness.

Surveillance and Monitoring

Because the FMD virus can spread so quickly, rapid detection capacity is an absolute necessity. The United States' domestic surveillance activities include several components. Private veterinarians, accredited by USDA to perform work in Federal programs, are working every day on farms and feedlots around the United States. These accredited veterinarians are required to report unusual or suspicious signs suggestive of foreign or emerging animal diseases. If an unusual disease is reported to APHIS, over 520 veterinarians have been specially trained to investigate as foreign animal disease diagnosticians. Of these diagnosticians, 239 have done at least one field investigation since 1999. (See Map 3, below, for locations of these diagnosticians.) A goal of this surveillance program is to have a foreign animal disease diagnostic expert within four hours of any farm in the United States.



In recent years, foreign animal disease investigations have steadily increased. In FY 2001, the foreign animal disease diagnostician conducted 802 investigations (Table 5). This is a significant increase from FY 2000, when there were 386 investigations.

Table 5.
Number of Foreign Animal Disease Investigations in the United States, 1999 - 2001

	FY1999	FY2000	FY2001
Vesicular conditions	230	148	444
Other conditions	106	238	358
TOTAL INVESTIGATIONS	336	386	802

In addition, FSIS conducts continuous inspection at slaughter facilities and daily inspection of processing facilities, with approximately 1,000 veterinarians and 7,600 inspectors. There is a heightened awareness for foreign animal diseases, and FSIS collaborates with other Federal and State inspection agencies to monitor and survey animals. In FY 2000 approximately 39 million cattle were inspected by FSIS.

USDA maintains diagnostic testing capacity for FMD at the Plum Island Animal Disease Center, located 1.5 miles east of Long Island, New York. Plum Island is the only place in the United States where scientists can test samples for highly contagious exotic animal diseases such as FMD. At the center, APHIS carries out diagnostic tests on submitted samples and ARS conducts research on new diagnostic methods, including new rapid detection techniques for use in outbreak control. Veterinary scientists at State and private laboratories around the country are also trained to send samples to Plum Island, if they suspect a vesicular disease such as FMD.

Another important part of the domestic surveillance infrastructure is maintained at APHIS' Centers for Epidemiology and Animal Health

(CEAH) in Fort Collins, Colorado. The multi-disciplinary staff there support several surveillance systems and develop new methodologies to improve surveillance capacity. In cooperation with the National Agricultural Statistics Service, CEAH's National Animal Health Monitoring System conducts animal health management studies of the nation's livestock populations.

In addition to animal disease surveillance activities, APHIS has the authority under the Swine Health Protection Act to monitor swine producers who are licensed to feed waste to pigs. Inspectors ensure that these farmers follow rules requiring that waste is cooked at a high enough temperature to kill any virus that could affect swine.

Emergency Planning

Because specific outbreak situations vary, and each State's emergency response capabilities differ, the U.S. Government's FMD response plan is designed to be flexible and to foster partnerships that will allow for an expanded pool of resources to be readily available.

Response Coordination

USDA is working with the Federal Emergency Management Agency (FEMA) so that in the event of a significant animal health emergency, like an FMD outbreak, all relevant Federal agencies would respond to an outbreak in accordance with guidelines established by the Federal Response Plan (FRP). The FRP, a signed agreement between 26 Federal departments and agencies and the American Red Cross, provides for the coordination of Federal assistance to augment State and local response and recovery efforts in an emergency. FEMA is the lead agency for implementation of the FRP, under the Robert T. Stafford Disaster Relief and Emergency Assistance Act. FEMA has technical advisory expertise in several areas, such as emergency communications, command and control, logistics, and public affairs.

A plan for FMD or other highly contagious animal diseases supplements the FRP with specific information about capabilities and roles of Federal, State, and local agencies. FEMA and USDA will coordinate the support of the other Federal agencies. In a serious and widespread emergency outbreak situation, USDA's Office of Crisis Planning and Management (OCPM) would help coordinate response activities within USDA and among other Federal agencies. The U.S. Customs Service would, if necessary, do a "lock-down" to prevent the movement of cargo into or out of specified ports. The Department of Defense could provide skilled personnel, equipment, and transport for equipment needed to investigate animal diseases. EPA could provide technical support in the disposal of carcasses without harming the soil or water and respond directly to any USDA or State needs for support of this type. (The primary environmental concerns from burial of carcasses are ground and surface water contamination and gas management at the burial site. If incineration was selected as a disposal method, EPA would review fuel sources and monitor and sample for pollutants. EPA could also work with States on compliance with the Clean Air Act, including providing exemptions of certain portions of the Act's requirements in an emergency.) The Coast Guard, under the Department of Transportation, would aid in preventing vessels with

suspected FMD cargoes from entering U.S. waters, to allow for further investigations and testing. In the event of an FMD outbreak in the United States, DOI, including all of its land management agencies, will convene a pre-identified committee to address appropriate issues and to oversee its role in response activities. The DOI's National Park Service has drafted detailed plans and set up linkages with APHIS and State veterinarians to guide the response of park managers, should an FMD outbreak affect wildlife in national parks. DHHS, in conjunction with local and State health authorities, including collaboration with Land Grant University extension programs, would be responsible for addressing public health (mental and physical) issues arising from actions taken to address the FMD outbreak. USTR, State Department and USDA would communicate actions to trading partners and minimize the impact on U.S. exports to the extent possible.

The National Animal Health Emergency Management System (NAHEMS) Steering Committee (<http://www.usaha.org/NAHEMS/>), a consortium of Federal, State, and non-governmental groups, has developed a strategic plan for dealing with all animal health emergencies. The Steering Committee has sponsored several workshops on emergency management, assisted in the production of emergency management standards, and developed a "call to action" video, outlining the health challenges facing U.S. animal agriculture. As a result of this effort most States have developed animal disease emergency response plans, with substantial local input.

Emergency Outbreak Strategy

The proven strategy for controlling an FMD outbreak includes several key actions:

- Quarantine and stop movement of animals and products
- Disinfect vehicles and personnel
- Slaughter infected and contact animals
- Destroy infected carcasses
- Assess the need for strategic vaccination of animals and implement this action as appropriate

Excerpts from USDA/APHIS "Red Books"

As part of this preparedness effort, APHIS is updating its disease management guidelines (called "Red Books") into comprehensive emergency response manuals. These manuals will provide detailed and easily understood nation-wide plans and procedures, focusing on:

- Disease eradication strategies (see text box, left) for various types of diseases;
- Principles for conducting field investigations;
- Operating procedures in areas such as quarantine management, biosecurity, disposal alternatives, and cleaning and disinfection;
- Site-specific strategies for various types of facilities and operations including slaughterhouses and zoos;
- Resource management; and
- Educational resources, including a catalog of teaching materials.

Another group providing input into emergency response and recovery planning efforts is the Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases. This group meets annually to discuss a wide variety of topics to help USDA safeguard against foreign animal diseases. The PL107-9 Interagency Working Group studied the 2000 report of the Advisory Committee. Appendix 2 has a list of the people on the Advisory Committee in 2000.

USDA's Office of Inspector General (OIG) emergency response

activities center on investigations, in coordination with Federal, State, and local entities, when there are suspected illegal acts that would jeopardize the agriculture infrastructure. For example, OIG has conducted several investigations involving animal disease threats to American cattle, dairy, and stockyard owners, in cooperation with the FBI, U.S. Postal Service, APHIS, and local law enforcement. Although the threats turned out to be hoaxes, USDA responds to all threats as real and potentially intentional. OIG also continues to participate in multi-agency exercises simulating agricultural, biological and terrorist attacks.

Test Exercises

Federal emergency planners regularly carry out test exercises for emergency response to foreign animal disease outbreaks. Since 1998 APHIS has implemented two international and two regional exercises. APHIS and other Federal agencies have also participated in numerous State and local exercises. Participants in the exercises simulate a disease outbreak and challenge existing response plans, policies, and procedures. These exercises reveal opportunities for improving the response system. One of the two international exercises conducted in 2000 was a joint Canada, Mexico, and U.S. program focusing specifically on FMD. Specific goals were to examine communication protocols among the three countries during an FMD outbreak and the process for making decisions regarding the use of vaccine as a control measure during an outbreak. As a result of that exercise, the three countries developed a decision matrix for use of vaccine.

Recovery Planning

Planning for recovery from an emergency is another important aspect of the work of FEMA and other agencies. USDA continues to refine and plan for an indemnity program to limit the losses to livestock producers. If there were ever an animal disease outbreak within the United States, USTR would work for fair treatment to limit the loss of U.S. export markets. The Department of State and USTR will assist in managing the health, environmental, and trade implications of such an outbreak through diplomatic engagement with affected states, key allies and U.S. trading partners, as a complement to the technical exchanges of information in which U.S. regulatory agencies may be engaged. As required, the Department of State will also assist with collection of technical data from other countries, support efforts to explain and clarify the U.S. disease situation, and provide information directly to foreign public audiences.

The impact of an FMD outbreak on human and environmental health as well as the psychological stress to farmers, ranchers, and those living in rural America cannot be overlooked. DHHS studied the UK example to determine the public health issues of an FMD outbreak. Their findings included stress and trauma for rural families (especially children) and veterinary staff. Other risks include those to environmental and public health from pollutants generated from the disposal of carcasses and water contamination by biologic agents and chemicals, and a disruption of health services. The U.S. Government would clearly need to factor in these human health issues, in the event of an FMD outbreak.

Public Awareness and Participation

The Federal Government recognizes the necessity of keeping the public aware of the existence of these diseases and the need to aid in any exclusion, emergency response, or surveillance activity. As part of an FMD public education campaign, USDA continues to disseminate information about the disease to industry partners, State and local officials, and interested individuals and organizations. Agencies have posted advisory signs in airports, prepared public service announcements, updated website information, and contacted members of the air transportation and travel industries to help raise awareness among travelers and airline crews about the risk of inadvertently spreading FMD. Agriculture officials who helped with the UK outbreak have been invited speakers at meetings of local animal production associations, farm groups, and emergency responders. These presentations have increased local awareness of potential FMD consequences.

USDA's Cooperative State Research, Education, and Extension Service (CSREES) provides information about FMD and TSE issues to a variety of constituents and stakeholders. This has included extension personnel at the county level as well as international youth exchange program participants. Extension faculty specialists in veterinary medicine and animal science have taken the lead in preparing and disseminating education materials related to FMD. In a number of instances, this has included advising the leaders or managers of county and State fairs about biosecurity issues. Public affairs offices of the various involved Federal agencies endeavor to coordinate efforts, keeping web sites updated and providing timely and accurate press releases.

To deal with issues of wildlife and FMD, the Department of the Interior has developed informational materials to inform the public about how an FMD outbreak could affect wildlife and the activities of people within national parks and other Federal lands. While management of wildlife is primarily a State issue, DOI bureaus are actively involved in FMD prevention and mitigation planning, because of the movement of people and animals through DOI lands and the potential for them to contract FMD or to act as carriers.

**Domestic Activities:
Additional Needs
and Future Plans**

Although the domestic infrastructure is in place to manage the risk of FMD, there is need to:

- Strengthen disease surveillance activities in several areas, including:
 - + Training of FSIS and extension veterinarians and local livestock extension agents in the recognition, diagnosis, and control of foreign animal diseases and other biosecurity risks.
 - + Modernization of laboratory facilities at Plum Island and major upgrades at the USDA laboratories in Ames, Iowa.
 - + A more coordinated approach to surveillance, to integrate the efforts of State governments, universities, and commercial diagnostic laboratories. *This national surveillance system would be similar to that envisioned by the Animal Health Safeguarding Review, available at the following internet website: <http://www.aphis.usda.gov/vs/safeguarding.pdf>. CSREES proposes the integration of existing diagnostic facilities across the United States into a coordinated Rapid Response and Detection Network that would maintain a state of readiness for diagnosis of new or re-emerging diseases affecting either plants or animals. NVSL would serve as the central reference laboratory for animal diseases and work with a selected group of State laboratories that would be distributed geographically to provide local diagnostic support. This network would establish and implement national test methods and standards, develop new or improved diagnostic test methods, and establish early detection and reporting systems.*
 - + Improved diagnostic methods to enable scientists to more rapidly and specifically determine whether a vesicular disease is FMD. Methods are needed to differentiate vaccinated from infected animals and to assess fresh and processed animal products for FMD contamination.

- Develop vaccines and adjuvants that quickly and fully protect livestock against FMD, that prevent the “carrier state,” and that can be produced in the 48 contiguous states of the United States. This would include novel formulations, not the traditional killed viral vaccines.

- Put more focus on monitoring the feeding of waste to swine. Current monitoring of this practice – including maintaining improved animal identification systems throughout production and processing — reduces the risk of transmitting FMD to swine. However, industry stakeholders believe that more attention should be focused on compliance with biosecurity and sanitation regulations, and that the Swine Health Protection Act should be

Domestic Activities:
Additional Needs *and*
Future Plans (Continued)

reviewed and updated.

- Continue to integrate Federal, State, and local planning efforts and support specific activities to strengthen the NAHEMS. For example, APHIS needs to complete the revisions of the comprehensive USDA emergency response manuals. Support is needed for a national effort to sensitize rural extension agents and land grant specialists to the types of problems farm families will face during an FMD emergency and to provide counseling services. Revisions to current indemnification procedures need to be finalized. Comprehensive FMD test exercises are needed to update decision support matrices to reflect today's highly integrated animal industries and to expose potential biosecurity loopholes. These exercises should also address the impact of restrictions imposed by an FMD outbreak on interstate commerce and on unaffected animal industries, e.g., poultry and aquaculture operations.

USDA plans to use a significant part of the \$328 million received under the Defense Appropriations Act, (January 2002) to strengthen emergency preparedness activities and to help meet several of the other critical needs listed above. This includes about \$80 million for upgrading USDA facilities and operational security; \$73 million for construction of improved biocontainment facilities at ARS laboratories in Ames, Iowa and Plum Island, New York; \$20.6 million for CSREES to establish a unified rapid detection and diagnostics network of public agricultural institutions such as universities and State Department of Agriculture diagnostic laboratories; \$15 million for security upgrades and bioterrorism protection for FSIS; \$14 million for increased security measures at the APHIS National Veterinary Services Laboratories in Ames, Iowa; \$3 million for animal health monitoring and surveillance; and \$18.5 million for direct assistance to States for emergency preparedness.

For FY2003, USDA is proposing a \$21.3 million increase for APHIS' animal disease surveillance and monitoring activities (\$9 million for foreign animal disease surveillance in livestock, \$8.2 million for FMD surveillance in wildlife, and \$4 million for monitoring swine feeding facilities); a \$1.2 million increase to strengthen FSIS' monitoring and surveillance activities, including an improved information technology infrastructure and risk management systems and more slaughter epidemiological surveys; and a \$6.3 million increase for additional emergency response capacity (35 APHIS emergency managers in selected States) and for programs to expand diagnostic response management and other technical services within APHIS. (See Appendix 8 for a complete list of USDA's FY2003 budget proposals related to animal diseases such as FMD and BSE.)

FMD Research
Activities and Methods
Development

Research and methods development projects help increase understanding of FMD and find ways to fight it. USDA mainly conducts research through ARS and CSREES. Both agencies conduct or fund research to find ways to improve the level of protection and methods to control any outbreaks. USDA also contracts with academic institutions to collaborate on research projects. CSREES provides extramural funding to universities and other research and education organizations to support

research and extension programs on FMD. Research and diagnostic work on live FMD virus is currently limited to the Plum Island Animal Disease Center. ARS devotes over half of the research funds at the center to FMD.

USDA's Economic Research Service (ERS) provides research support on the economics of FMD and other animal diseases. In general, analysts study policy and program alternatives, and conduct special studies on domestic and international markets. Their work results in short-term and long-term commodity and trade forecasts and projections in a global context.

The Department of Interior is actively involved in research on the susceptibility of wildlife to FMD, as well as serving as a source of information to stakeholders about the disease. The U.S. Geological Survey (USGS) is working closely with other Federal and State agencies to provide research and information about animal health and related issues. If FMD occurs in the United States, USGS may need to dedicate resources, or even entire science centers, to FMD prevention, investigation, and elimination in wildlife and livestock. The USGS National Wildlife Health Center is a biomedical laboratory dedicated to assessing the impact of disease on wildlife and to identifying the role of various pathogens in contributing to wildlife losses.

FMD Research Projects

Vaccines

ARS is testing several promising vaccine candidates that have potential to actually protect animals from FMD infection (and not just from developing clinical signs of the disease). Research will compare each vaccine for efficacy, particularly under outbreak conditions. Moreover each vaccine must be proven to clearly induce protection against infection and not lead to development of the carrier state. ARS is also collaborating with several nations that have enzootic FMD to develop new vaccines. APHIS and ARS are working together to ensure that research on FMD vaccines and diagnostics meets existing regulatory standards for commercially available biologics.

Diagnostics

Genetic sequencing of every new FMD variant has been included in current ARS diagnostic approaches. This data adds to the catalogue of genes that are potential candidates for new diagnostics and new vaccine targets. Future use of molecular diagnostics is being supported by ARS research. ARS has developed, and is currently validating, a highly specific nucleic acid on-site detection technology that allows trained personnel using a briefcase-sized device to detect FMD viruses on the farm within hours.

Disease Modeling

Understanding disease transmission is important for planning emergency response activities. CSREES has provided a grant to a researcher at the University of California-Davis to quantify and visually display the potential size and spread of outbreaks in California. The research will simulate and evaluate alternative eradication strategies to identify the most economically effective response. The same researcher has nearly completed a system to simulate and evaluate airborne pathogen movement and direct animal contact. The system will be useful in quantifying levels and costs associated with alternate epidemic control

strategies. APHIS has developed a model that simulates the spread of FMD infection via direct and indirect contact as well as airborne spread. USDA has also modeled disease eradication and control strategies such as ring vaccination and various slaughter policies.

Consequence Management

ARS scientists are working to determine the most effective methods for decontaminating facilities, vehicles and personnel in an environmentally safe manner. CSREES has provided a grant to a researcher in California to examine the potential economic effects of disease outbreaks such as FMD and BSE on the U.S. economy and on international markets. ERS analyzes policy and program alternatives, and conducts special studies on domestic and international markets.

Basic Molecular Biology

CSREES also provided funding to an ARS researcher to conduct a basic molecular biology study of FMD. The research focuses on the recent FMD outbreak in Taiwan, which had significantly different characteristics from recent outbreaks in Europe and South America.

**FMD Research:
Additional Needs
and Future Plans**

Although USDA and the Department of Interior have ongoing FMD research programs, there is a need for:

- New research initiatives to strengthen emergency response management capacity. For example, consequence management research is needed to determine how infected milk and carcasses can be safely disposed of and new disinfectant materials and procedures need to be developed. Also, there is need to assess the persistence of FMD in animal facilities, stockyards, transport, and processing equipment after decontamination. Early detection and reporting systems, supported by new educational and extension tools and database software, need to be established for strategic monitoring of FMD during an outbreak.
- Improved diagnostic techniques and vaccines, which are critical to implementing an FMD control program. Research is needed to develop a secure communication system both within the network and with the NVSL and to identify new or improved FMD diagnostic test methods/procedures to ensure rapid, sensitive and specific test results.
- Effective methods for distinguishing each FMD serotype and for predicting pathogenesis in each livestock species.
- A better understanding of FMD in wildlife and effective control measures. The critical actions of detection and control of FMD in wildlife can only effectively occur through a partnership between Interior, USDA, States, and others. The control of FMD in wildlife is a formidable task. With appropriate resources, agencies can develop a better understanding of this disease in affected wildlife species, through research on detection technologies, understanding of FMD pathogenesis in each

FMD Research: Additional
Needs and Future Plans
(continued)

species, and evaluation of vaccines and plans for their implementation.

- Complex econometric analyses, which need to be performed to fully assess the economic impact of an FMD outbreak. These updated decision support matrices and econometric analyses will aid State and Federal regulators and emergency response coordinators in evaluating outbreak response capabilities and their impacts. *In addition to ongoing programs, ERS plans in 2002-2003 to carry out a high priority study on the globalization of plant and animal diseases and their effects on domestic and international markets.*
- Fundamental research on disease pathogenesis and transmission as well vaccination and eradication strategies.

These needs are consistent with PL107-9 stakeholder comments and the Animal Health Safeguarding Review Panel's recommendations to provide additional funding to "reverse the serious erosion of animal health applied research funding that has occurred in past years." (For the entire Safeguarding Review report, see: <http://www.nasda.org/ASGRwebsite/FullBook.pdf>).

As part of the President's FY2002 Homeland Security funding (Defense Appropriations Act, January 2002), USDA is providing additional funding to bolster research related to preparing for and responding to a deliberate introduction of a biological threat such as a foreign animal disease. For example, \$113 million is for the Agricultural Research Service, for additional research and security enhancements and upgrading facilities at Plum Island, New York and Ames, Iowa; and \$1.7 million is for the Economic Research Service to develop a geographic information system to assist in the analysis of the effects of possible and actual attacks or disasters and of options to limit or contain devastation..

USDA has proposed a \$10 million increase for FY2003 to support research aimed at protecting the nation's agriculture and food system from attack by animal and plant diseases, along with a \$2 million increase for research on the effects of invasive pests and diseases on the competitiveness of U.S. agriculture. This proposal reflects USDA's commitment to protecting U.S. agriculture food systems.

Bovine Spongiform Encephalopathy (BSE)

Risk Assessment

Description of BSE

Bovine spongiform encephalopathy, widely referred to as "mad cow disease", causes a progressive degeneration of the central nervous system in cattle. The disease has an incubation period of two to eight years (the time from when an animal becomes infected until it first shows disease signs) and is invariably fatal. Currently, there is no treatment, no vaccine, and no test to detect the disease in a live animal. In the United Kingdom, where the disease was first identified in 1986, over 175,000 head of cattle have been diagnosed (post-mortem) with the disease. There is no evidence that BSE spreads by contact either between unrelated adult cattle or from cattle to other species. It has spread to 19 other countries, mostly in Europe, primarily through the practice of mixing ruminant products contaminated with the agent of BSE into cattle feed as a source of protein. BSE has never been detected in the United States, despite eleven years of active surveillance. The cause of BSE is not completely understood, but researchers believe that the disease agent responsible is smaller than most known viruses. Scientists have found that it is extremely resistant to heat and to normal sterilization processes, and it does not evoke any detectable immune response or inflammatory reaction in host animals.

BSE is classified as a transmissible spongiform encephalopathy (TSE), so named because of the sponge-like appearance of the brain tissue of infected animals. Veterinary pathologists confirm BSE by postmortem microscopic examination of brain tissue or by the detection of an abnormal form of prion protein in tissues. Infectivity is determined by inoculating animals, usually mice, with material believed to be infected with the agent of BSE. These mouse inoculation studies take a long time—up to 700 days—to detect the agent.

There are different scientific hypotheses concerning the origins of BSE. In the United Kingdom the disease may have been caused by feeding to cattle rendered protein that was produced from the carcasses of cattle with a previously unidentified TSE or from scrapie-infected sheep. The practice of using products such as meat-and-bone meal as a source of protein in cattle rations has been common for several decades. Changes in rendering operations in the United Kingdom in the early 1980's may have played a part in the appearance of the disease. Limited research suggests that vertical (maternal) transmission may occur at a very low level. This low level most likely would not perpetuate the epidemic under British farming conditions. Research continues in this area. There is no evidence that BSE spreads horizontally (by contact between unrelated adult cattle or from cattle to other species).

The TSE family of diseases includes BSE, scrapie (which affects sheep and goats), transmissible mink encephalopathy, chronic wasting disease

(CWD—affecting deer, elk, and other cervids), feline spongiform encephalopathy, and TSEs of exotic ruminants. TSEs affecting humans include kuru, both classic and what has been termed variant Creutzfeldt–Jakob disease (CJD and vCJD), Gerstmann–Straussler–Scheinker syndrome, and fatal familial insomnia.

It is important to clarify the difference between classic CJD and vCJD, because epidemiological and laboratory evidence provides strong support for the hypothesis of a causal link between the agent of BSE and vCJD. Classic CJD occurs each year at a rate of 1 to 2 cases per 1 million people throughout the world, including in the United States and other countries where BSE has never been detected and among vegetarians and meat eaters alike. In 1996, the United Kingdom’s Spongiform Encephalopathy Advisory Committee announced the identification of the first 10 cases of vCJD, with characteristics that differed from other routinely diagnosed cases of classic CJD. The ten individuals experienced the onset of symptoms at a younger age, exhibited behavioral changes, were sick for longer than patients with classic CJD, displayed a normal electroencephalogram, and experienced brain lesions that were different from lesions seen in brain tissue from patients with classic CJD. Based on available data and in the absence of any credible alternative, the UK advisory committee concluded that the cases were a novel condition that resulted from exposure to the agent of BSE before the UK’s 1989 ban that excluded from human consumption brain, spinal cord, and other organs with potential BSE infectivity. As of January 2002, 113 cases of vCJD had been identified in the United Kingdom, one in Ireland, five in France, and one in Hong Kong (of UK origin). According to the DHHS’ Centers for Disease Control and Prevention (CDC), no cases of vCJD have been identified in the United States. (There has been one UK resident who, after contracting vCJD outside the United States, sought medical care here.)

Two other TSEs—scrapie and chronic wasting disease (CWD)—are present in the United States and are therefore the focus of Federal and State animal health programs and research. CWD, first recognized as a clinical “wasting” syndrome in 1967 in mule deer in a wildlife research facility in northern Colorado, is typified by chronic weight loss leading to death. The first case of scrapie in the United States was diagnosed in 1947 in a Michigan sheep flock. The flock owner had imported sheep of British origin through Canada for several years. From this first case through August 2001, approximately 1,600 cases in sheep and 7 cases in goats have been reported.

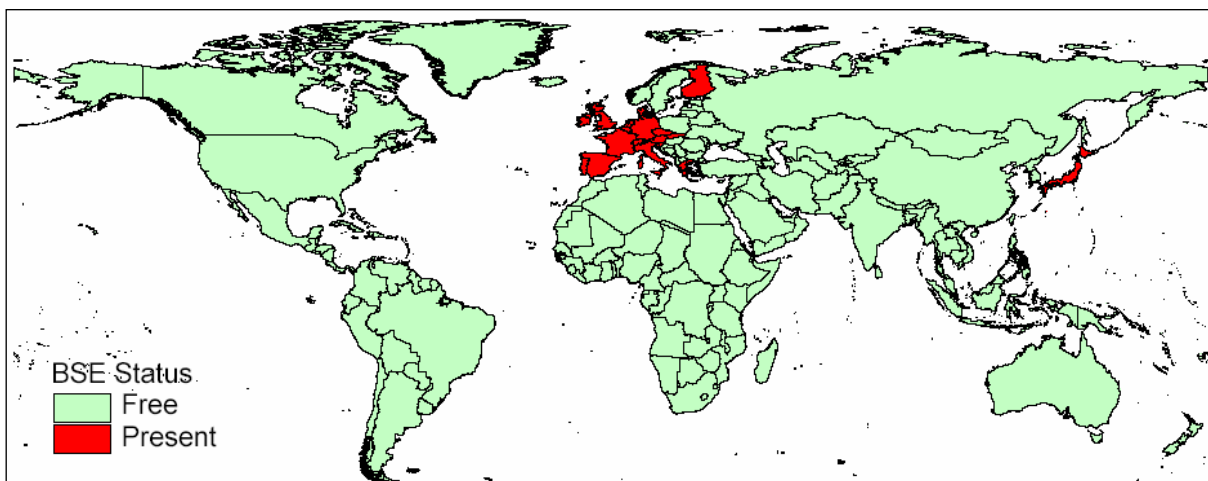
BSE Distribution Around the World

Worldwide, there have been more than 180,000 cases of BSE, over 95 percent of which have been in the United Kingdom. From 1986 (when BSE was first identified as a separate disease entity) through August 2001, a total of 178,164 head of cattle in 35,209 herds have been diagnosed with BSE in the United Kingdom. The epidemic peaked in January 1993 at approximately 1,000 new cases reported per week. Officials in the United Kingdom have taken a series of actions to address and, hopefully, eradicate BSE and protect humans from vCJD. There is compelling epidemiological evidence that these actions have reversed the course of the BSE epidemic within the United Kingdom.

Since the original discovery of BSE, various measures have been taken at different levels within the European Union to control the spread of the disease. These measures ranged from initial actions taken by individual member states to more recent harmonized legislation. In 1994, an EU regulation prohibited the feeding of mammalian protein to ruminants throughout all member states, although there were problems noted with the implementation and enforcement of this feed ban. Due to the cross contamination of livestock feeds and new BSE cases in Germany and other member states, in January 2001 the European Union expanded this prohibition to a ban on feeding of processed animal protein to any farmed animal. Requirements on the removal of specified risk material were initially imposed only in the United Kingdom, but have been required throughout the EU countries since October 2001. (For a full explanation of the EU rules on specified risk material, see the website <http://www.defra.gov.uk/animalh/bse/index.html> and click on “Public Health”). The European Union has also recently instituted mandatory BSE testing of animals over a certain age that are sold into the food chain.

Unfortunately, these measures were insufficient, or not instituted in time, to prevent the spread of BSE to other countries. As of December 2001, the disease has been confirmed in native-born cattle in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Liechtenstein, Luxembourg, the Netherlands, Portugal, Slovakia, Slovenia, Spain, and Switzerland. (See Map 4, below. Disease status updates are available at <http://www.aphis.usda.gov/oa/bse/#otherbse>) Although the number of BSE cases in the United Kingdom is on the decline, confirmed cases have risen substantially in many of these other countries. For example BSE cases in France increased from 31 in 1999 to 258 in 2001, according to OIE reports. (See http://www.oie.int/eng/info/en_esbmonde.htm for updated reports.) In addition, based on EU export data, eastern European countries and many Asian countries are at-risk for developing BSE, primarily because of their past practices of importing meat-and-bone meal from European Union countries. BSE has never been detected in the United States, despite 11 years of active surveillance.

Map 4. World-wide Distribution of BSE in Native-Born Cattle, December 2001



Likelihood of Introduction into the United States

The U.S. Government for the past decade has actively instituted policies and practices to mitigate against the entry of the agent of BSE into the United States and to minimize the chance for disease amplification in the U.S. cattle herd, were it to be found here. BSE poses a particular challenge because of the lack of a live-animal (ante-mortem) diagnostic test, the long incubation period before the agent is detected, the lack of any preventative or therapeutic medications, and also because it is extremely resistant to heat and normal sterilization processes. As a non-contagious disease, potential entry pathways for the BSE agent into the United States differ considerably from those for FMD. For example, based on current scientific understanding, direct physical contact between live animals incubating the disease and U.S. animals would not lead to the transmission of the BSE agent to the U.S. herd. Also, mechanical transmission of the disease agent (for example, via passenger or equipment movements) is not a significant factor in BSE transmission. Therefore, the most likely routes of introduction of BSE into the U.S. national herd would be through the importation (either legal or illegal) of:

- Meat and bone meal contaminated with the agent of BSE, or
- Live cattle that are already incubating the disease and then are slaughtered, rendered, and incorporated into domestic meat and bone meal that is mistakenly fed to cattle.

In the early 1990s, APHIS conducted several risk assessments examining the possibility of BSE emerging in the United States. These risk assessments led to a model to track the spread of BSE, an assessment of risk in the United States at the State and county levels based on scrapie contamination of rendered products, and a comparison of U.S. risk factors for BSE against those in the United Kingdom. These assessments all concluded that the potential risk of BSE emerging in the United States was substantially less than in the United Kingdom.

Given the enormous impacts of BSE in Great Britain, USDA in 1998 entered into a cooperative agreement with Harvard University's Center for Risk Analysis, to further analyze and evaluate the U.S. Government's measures to prevent BSE. The risk analysis reviewed current scientific information, assessed the ways that BSE could enter the United States, and evaluated existing regulations and policies to prevent the spread of BSE within the United States, if the disease were to occur. The Harvard risk assessment, released in November 2001, concluded that:

“... the United States is highly resistant to any introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the United States... Similarly there appears to be no potential for an epidemic of BSE resulting from scrapie, chronic wasting disease, or other cross-species transmission of similar diseases found in the U.S.... If the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in one to two cases per year with little spread. Only a small amount of potentially dangerous tissues would reach the human food supply and be available for possible human consumption.”

(The executive summary of the report is in Appendix 4. The complete Harvard study is available online at <http://www.aphis.usda.gov/oa/bse/mainreporttext.pdf>)

Economic Impact

The analysis of the economic impact of BSE draws chiefly on the UK experience. Although the Harvard University risk assessment concluded that BSE in the United States is extremely unlikely either to occur or to follow the extensive pattern of spread experienced in the United Kingdom, the UK experience is the only example of a major occurrence of BSE--an epidemiological "worst case" scenario. Even if the U.S. experience is not likely to be at all like that in the United Kingdom, the economic consequences from even one confirmed case of BSE in the United States could easily exceed the costs incurred thus far in the United Kingdom, for a number of reasons:

- U.S. beef exports are much greater than pre-BSE beef exports from the United Kingdom (where current exports are virtually zero).
- The U.S. population is five times the U.K. population, and
- The U.S. dairy and beef sector is ten times the size of that in the United Kingdom.

Beef consumption would likely decline. In Japan, which recently experienced its first case of BSE in native-born cattle, meat consumption dropped an estimated 70 percent immediately after announcement of the case. Dairy producers with infected or quarantined herds would not be able to sell milk, thus losing considerable income and incurring disposition costs. If vCJD were discovered here, it could also initiate similar adverse responses in domestic beef consumption and associated drops in market prices.

Production losses would likely occur in infected cattle. In the United Kingdom production efficiency decreased as signs of BSE increased in infected cattle. This increased the losses associated with BSE, because of its long incubation period. Producers forced to destroy their livestock would face additional long-term costs associated with rebuilding. Even though U.S. farmers could be compensated for the market value of the animals, as were farmers in the United Kingdom, producers would lose the time and funds they had spent in building their breeding stock. There would be reduced income while rebuilding the stock. Prices may be higher for purchasing additional stock, while the market price for animal products could decline.

The reactions of U.S. trading partners would likely have an enormous effect on the economic losses associated with an occurrence of BSE. Past experience has shown that importing countries will stop imports of beef and most ruminant products from BSE-infected countries. These are long-term bans, unlike the restrictions imposed in the case of a quickly eradicated FMD outbreak. Trade restrictions would increase domestic supplies, if the amount of infected meat removed from the market did not exceed the quantities of meat banned for export, and this would lead to reduced retail beef prices. Prices of other non-ruminant meat, poultry, and fish products might increase as the public's taste shifted away from beef

and possibly other meats following an outbreak of BSE.

Because BSE is not considered to be a disease that is infectious through normal animal to animal contact or airborne routes, restrictions on animal movement, which are essential to disease control for FMD, would not be required for BSE. Thus collateral industry costs would be minimized. Some collateral economic impacts could occur in the deer and elk hunting sector as TSE-related fears about the consumption of venison reduced activities in this and associated sectors.

The animal rendering, processing, and meat by-product industries would experience a significant economic impact in the event of a BSE outbreak. Because meat and bone meal would likely be further restricted or even totally banned to reduce the spread of the disease, the industries might face significant restructuring. For example, with rendered products being restricted from animal feed, the industry would need to find ways to dispose of large amounts of meat and bone meal and animal carcasses. One non-agricultural possibility is the use of some by-products for the production of bio-fuel, but this or any other significant industry-wide change would inevitably be quite costly.

Other sectors of the U.S. economy, such as cosmetics, pharmaceuticals, medical supplies, and related industries, currently depend to some degree on livestock by-products or rendered products. For example, gelatin and collagen are animal by-products used in the cosmetic industry and as products used in medical treatment. They would also be affected if such products were no longer available or their use more severely restricted.

In the event of a BSE incident, USDA's BSE Response Plan requires a complete trace-out of all herd-mates and progeny of the original case animal and herd-mates. The U.S. Government would face increased costs for surveillance, testing, depopulation, and disposal of infected livestock, herd-mates and progeny. States and producer groups may share in some of those costs. The Federal government would also face some costs for compensating producers whose livestock are slaughtered to prevent and control the spread of BSE.

(See Appendix 6 for more details on the economic impacts of BSE.)

Risk Management

To date, there is no evidence of BSE in the United States, and the U.S. Government has worked proactively to keep BSE out of this country. The U.S. approach to managing the risk of BSE is focused on three primary goals:

- Prevent the agent of BSE from entering the United States and infecting U.S. cattle;
- Prevent the amplification of the agent of BSE throughout the U.S. cattle herd, were it to penetrate the primary safeguards at the U.S. borders and infect U.S. cattle; and

- Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.

According to the Harvard risk assessment, several key actions have been particularly effective in achieving these goals:

- APHIS' ban on the import of live ruminants and ruminant meat and bone meal from the United Kingdom (since 1989) and all of Europe (since 1997),
- FDA's feed ban instituted in 1997 to prevent recycling of potentially infectious cattle tissues to ruminants, and
- Measures instituted in meat packing plants by the industry and FSIS to reduce the opportunity for infectious tissues (brain and spinal cord) to contaminate human food.

This section discusses these and other actions to manage animal and human health risks of BSE and related TSEs. The activities are in addition to the animal health safeguarding activities addressed in the preceding section on FMD and other highly contagious foreign animal diseases.

International Activities

The U.S. Government participates on international working groups set up to prevent the spread of BSE to new areas of the world and to standardize approaches for addressing BSE surveillance and response. USDA and DHHS participate in OIE meetings as members and as consultants on several work groups. Due to the human health risk that BSE poses, the World Health Organization (WHO) and the Pan American Health Organization (PAHO) are also involved in BSE-related issues. U.S. representatives offer technical advice and uphold U.S. interests in these organizations as well.

Since 1986, when BSE was first found in the United Kingdom, the United States has exchanged scientists with several European countries. USDA assigned an epidemiologist to a long-term detail in the United Kingdom early in the BSE outbreak, and its field veterinarians have visited there to learn techniques in diagnosis and epidemiology. Interactions have continued, especially at the laboratory and research levels. Pathologists from the National Veterinary Services Laboratory recently went to Europe to learn about newly developed tests. APHIS and the American Association of Veterinary Laboratory Diagnosticians collaborated to bring a pathologist from the United Kingdom to the United States to train laboratory diagnosticians.

APHIS and FDA coordinated with Canadian government veterinary health representatives on a trip to Germany, Austria, and Switzerland to look at those countries' latest developments in BSE, including their control and surveillance measures. USDA has also participated in a shared program with the Department of Defense in the Azores that provided technical advice to establish different surveillance activities and assist with laboratory diagnostics work.

Outside Europe, U.S. officials and technical experts coordinate on BSE with counterparts in many countries and international organizations. FDA scientists have participated in PAHO meetings in 2001 involving BSE

policy decisions for the Americas. USDA laboratories are helping Central American countries with surveillance and laboratory work. Canada, Mexico, and the United States share technology and work towards ensuring that all three countries have coordinated and harmonized their approaches and policy regarding BSE, and they also share BSE risk assessments for countries outside of North America. With the recent case of BSE in Japan, USDA has also engaged in meetings there to share information concerning the BSE threat. In addition, FDA scientists have been collaborators with their Asian and European counterparts in various meetings regarding policy decisions on blood safety. ARS scientists have shared expertise and reagents developed for scrapie and CWD with scientists worldwide.

International

Activities:

Additional Needs and Future Plans

International interactions have been vital elements of the effort to manage the risk of BSE. The Inter-agency Working Group identified some additional needs in this area of activity:

- Development of international standards for protocols for BSE risk assessments now planned or underway in many countries. *The United States plans to continue working closely with OIE and other international standard-setting organizations to develop these protocols and to gain a more comprehensive understanding of TSE diseases.*

Federal agencies, in coordination with their counterpart agencies overseas, are planning to evaluate 'best practices' associated with key aspects of the various international BSE safeguard systems and to recommend procedural and policy changes where appropriate.

- Continued visits and more research collaboration between scientists from the United States and countries with BSE. *To this end APHIS, ARS, CSREES and FSIS plan to use new FY2002 funds to expand these activities. ARS scientists plan extended research activities with several of the European Union laboratories investigating BSE. Expanded research into the animal TSEs, scrapie and CWD, will provide a broader knowledge of TSE development in large animals and of the design of effective control and eradication programs.*

Exclusion Activities

Import Restrictions

The U.S. Government's actions to restrict imports from Europe have played an important role in excluding BSE from this country. Since 1989 APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle. Other products derived from ruminants (for example, meat and meat products, fetal bovine serum, meat-and-bone meal, blood meal, offal, fats, and glands) are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes. These restrictions were initially

applied to the United Kingdom in 1989, and then were applied to each country that subsequently identified native cases of BSE. In 1997 APHIS extended these restrictions to include most of the countries in Europe, due to concerns about widespread risk factors and inadequate surveillance for BSE. As of December 2000, USDA prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries. This decision followed the recent determination by the European Union that feed of non-ruminant origin was potentially cross-contaminated with the BSE agent. The restriction applies to products originating, rendered, processed or otherwise associated with products from BSE-restricted countries. When BSE was recently identified outside Europe, in native-born cattle in Japan, APHIS restricted imports of ruminants and ruminant-origin products from there also. FDA has issued various import alerts and import bulletins identifying products of concern under its jurisdiction that contain materials of bovine origin. In addition, FDA placed entry screening criteria in its computerized import system database to automatically flag any product from a BSE-affected country that could potentially contain a bovine ingredient. The database will automatically alert FDA entry reviewers to perform a more intensive check and to refer the entry to USDA for further action if necessary.

FDA has taken several steps to help ensure the safety of medical products, such as human and animal drugs, dietary supplements, human blood, human vaccines, and human medical devices. In 1990 the agency began recommending that manufacturers of products derived from bovine sources document that the animal tissues did not come from a country with cattle that had tested positive for BSE. Beginning in 1992 and most recently in May 1996, FDA also issued a series of letters advising all manufacturers of FDA-regulated products derived from bovine tissue materials that source materials should not come from cattle that ever resided in a country with BSE. Any product that requires pre-market approval and that uses such materials is reviewed to determine whether the medical benefit of the product outweighs any potential BSE-related risks. FDA also has conducted inspections of nine bovine gelatin manufacturers in Europe to verify that they are following the FDA's sourcing guidance.

In January 2002, FDA issued new, more cautious guidance to prevent potential spread of vCJD by blood, although it is not presently known whether human blood transmits vCJD. Because there is no test to screen blood for the agents of CJD or vCJD, FDA evaluated potential TSE-related risk factors for donors. The agency now recommends deferring potential blood donors who have lived or traveled in the United Kingdom for three months or more (cumulatively) from 1980-1996. Also, because a limited number of cases of vCJD have been diagnosed outside the United Kingdom, FDA recommends deferral of donors who lived in France for five years or more (cumulatively) from 1980 to the present, and this recommendation applies also to donors of whole blood and its components in most of the rest of continental Europe. Deferrals will also affect some U.S. military personnel stationed in Europe through the end of 1996 and anyone who has had a blood transfusion in the United Kingdom since 1980. (Complete specifics of the FDA recommendations are available at the FDA web site: www.fda.gov/cber/guidelines.htm.) The

FDA, recognizing the need to reduce the theoretical risk of CJD and vCJD while maintaining an adequate supply of safe blood and blood products, intends to reevaluate frequently its policy concerning deferral of blood donors.

Inspection Activities

The U.S. Government's port of entry inspection activities, described in the FMD section of this report, are designed to ensure that BSE import regulations are adequately enforced also.

When APHIS instituted the December 2000 prohibition on all rendered animal protein products, U.S. Customs Service immediately issued instructions to all Customs field offices. The instructions identified all BSE at-risk countries and products. In addition, U.S. Customs Service created cargo selectivity criteria in its electronic Automated Commercial System to identify BSE at-risk shipments. The cargo selectivity criterion is an "automated alert" to Customs inspectors, which provides instructions on the handling of the BSE at-risk shipment. Under this system, all BSE at-risk shipments are detained and the local APHIS office is contacted for release disposition.

In addition, FDA has issued various import alerts and bulletins and entered screening criteria into its automated import database, to identify products under FDA jurisdiction that contain materials of bovine origin of concern. The electronic screening system and the import alerts and bulletins allow FDA inspectors the opportunity to work with their APHIS and Customs counterparts in assessing these products for their potential to introduce BSE into the United States. For example, in March 2001, FDA alerted its field offices to the potential importation of human food products and dietary supplements containing ruminant materials from BSE-affected or high-risk countries. This action was a follow-up to a January 2001 FDA import alert regarding bulk shipments of high-risk bovine tissues for animal feed from these same countries. In October 2001, FDA implemented a sampling program to use feed microscopy techniques to help assure that animal feed ingredients from BSE and other high risk countries contain no prohibited material.

**Exclusion Activities:
Additional Needs
and Future Plans**

As BSE cases are confirmed in other countries, USDA and DHHS need to update risk assessments, import regulations, and guidance on enforcing regulations at ports-of-entry.

As discussed in the FMD exclusion activities section of this report, the newly enacted Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) will help USDA inspection agencies enforce BSE import regulations. Agencies need to develop guidance and plans at ports of entry to fully implement the Act, especially new civil penalty authorities. Revisions in the Virus-Serum-Toxin Act are also needed to help APHIS in enforcing import regulations related to imports of animal biological products.

FDA needs additional authority to strengthen its activity at ports of entry, specifically with respect to issues regarding TSEs. *FDA is considering a number of activities that it would carry out at ports of entry, if it had the*

**Exclusion Activities:
Additional Needs and Future
Plans (continued)**

additional authority. These measures would bolster control over imports of FDA-regulated products containing bovine materials, bovine-derived materials, and, in some cases, imported products with mammalian or mammalian-sourced ingredients. The measures being considered include:

- *In conjunction with the U.S. Customs Service, to designate ports of entry for certain products and to direct importers to use specified ports of entry for these products;*
- *To establish an import broker certification program and to require brokers be certified in specified product areas in order for the brokers to import those products into the United States;*
- *To destroy products FDA has detained at US ports of entry because those products do not meet FDA standards for marketing in the USA (thus preventing the possibility of importers trying to get the product in the United States via another port or at another time at the same port);*
- *To require that all imported products containing either mammalian or mammalian-sourced ingredients be declared, with country-of-origin documentation of all such ingredients on import manifests;*
- *To prohibit the importation of any FDA-regulated product that (1) contains bovine materials or bovine-derived material from any country listed in USDA regulations as a BSE-positive or BSE-high-risk country or (2) was manufactured in a plant in which bovine material from any such country has been processed. (Note: This measure would contain provisions to exempt or waive certain products from the prohibition because of documented proof of minimal BSE agent risk in the specific product or because of the necessity to have the product available to protect public health. The prohibition would apply for both entry-for-import and entry-for-export, i.e., transshipment.)*

Through the Defense Appropriations Act (January 2002), funding was provided to allow for integrating computer technologies among Federal agencies. This funding will be used to strengthen coordination of databases among the agencies involved with inspecting products entering ports of entry.

Domestic Activities

Coordination and Planning

The U.S. Government coordinates and plans ongoing activities and policies regarding BSE and other TSEs through technical working groups and an inter-agency policy planning committee.

For policy-level coordination, a strategic planning group, the Inter-agency BSE Steering Committee, has several responsibilities, including:

- Planning ways to minimize the spread of BSE and identify potential vulnerabilities in present policies,
- Clarifying jurisdictional issues,
- Improving communication between Federal agencies on TSE – related matters,

- Developing contingency plans and communication strategies for the public if a case of BSE or vCJD or BSE-contaminated animal feed were found in the United States.

Policy-level representatives participate from USDA, DHHS, U.S. Customs Service, USTR, DOD, the State Department, the Office of Management and Budget, the White House Office of Science and Technology, the American Association of Feed Officials, the National Association of State Departments of Agriculture, and the National Assembly of Chief Livestock Health Officials.

A great deal of coordination and planning also takes place at the technical level among scientists working on BSE issues. APHIS, ARS, CDC, U.S. Customs Service, DOD, FAS, FDA, FSIS, and NIH participate together on the Inter-agency BSE Working Group. Technical representatives from each participating agency discuss prevention activities, new science, and changing world events and coordinate efforts across agencies. In addition, the group holds annual meetings with Canadian and Mexican technical experts from counterpart agencies that cover animal health, public health, diagnostics, and research in those countries. These meetings have contributed to greater understanding and harmonization of TSE control and prevention policies among the three countries, which is crucial given the amount of trade taking place among the North American countries.

USDA established an internal TSE Working Group in the late 1980s to study the issues surrounding these degenerative neurological diseases. The group includes representatives from FSIS and several APHIS units, including headquarters staffs, field personnel, laboratory experts at NVSL, and staff from the Centers for Epidemiology and Animal Health, the Center for Veterinary Biologics, Legislative and Public Affairs, and International Services. They provide technical analyses of the risk of BSE to the United States, recommendations regarding actions that should be taken in response to these risks, assistance with the implementation of policy, and dissemination of information about TSEs. Specific recommendations from the group have included the decision in 1997 to extend import restrictions to all countries in Europe, increasing surveillance in “downer” animals, and placing restrictions on the import of sheep. The group also serves as a liaison for USDA to Federal and State agencies, as well as to Canada and Mexico.

A DHHS BSE/TSE Action Plan helps agencies coordinate their TSE activities. The Action Plan has four major risk management components: surveillance, protection, research, and oversight. FDA, along with USDA, conducts surveillance and regulation of animal feeds and foods for human consumption. Surveillance for human TSEs is primarily the responsibility of the CDC. Human health research is primarily the responsibility of the National Institutes of Health, although CDC and FDA also have specific research initiatives underway related to their respective activities and missions. The Office of the Secretary of DHHS oversees the activities of the three agencies.

FDA established an internal TSE Coordinating Committee to coordinate BSE and other TSE-related activities among the various program units (Center for Drug Evaluation and Research, Center for Biologic Evaluation

and Research, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Devices and Radiological Health, the Office of the Commissioner) and enforcement centers (the Office of Regulatory Affairs). This group of technical experts evaluates TSE issues relative to FDA's missions, makes recommendations to the Commissioner regarding action FDA should undertake with respect to TSEs, and helps formulate FDA responses to various queries from outside the Agency regarding TSEs. In addition, FDA's TSE Advisory Committee continues to meet publicly to address various TSE-related issues regarding FDA-regulated products. USDA and other agency officials, along with those from DHHS, academia, and the private sector, often make presentations at meetings of this committee.

In April 2001, FDA published its own agency-specific TSE Action Plan. This plan details actions FDA is undertaking (several in concert with USDA, U.S. Customs Service, and other Federal and State agencies) to fulfill the "protection" role assigned it by the Secretary of DHHS. FDA's activities primarily fall into five major initiatives to enhance, sustain, and communicate safeguards for which it is responsible. These initiatives include:

- In partnership with USDA and with other federal, state, and private sector entities, FDA seeks to prevent exposure of the public to TSE agents through human and animal food products.
- FDA will continue and, as necessary, expand its policies designed to minimize potential exposure to TSE agents through blood transfusions or tissue transplantation.
- FDA will continue and, as necessary, expand its policies to minimize potential exposure of the public to TSE agents through drugs, medical devices, vaccines, other biological products, cosmetics, and dietary supplements that use bovine-derived materials during their production.
- FDA will continue and expand its TSE-related public education and outreach programs to consumers, patients, practitioners, industry, academia, and other Federal and State agencies.
- FDA will continue and expand as much as possible, its regulatory research related to TSEs, especially with respect to new ante-mortem diagnostic tools and decontamination protocols.

(The FDA action plan is available online at http://www.fda.gov/oc/oca/roundtable/bse/FDA_actionplan.html.)

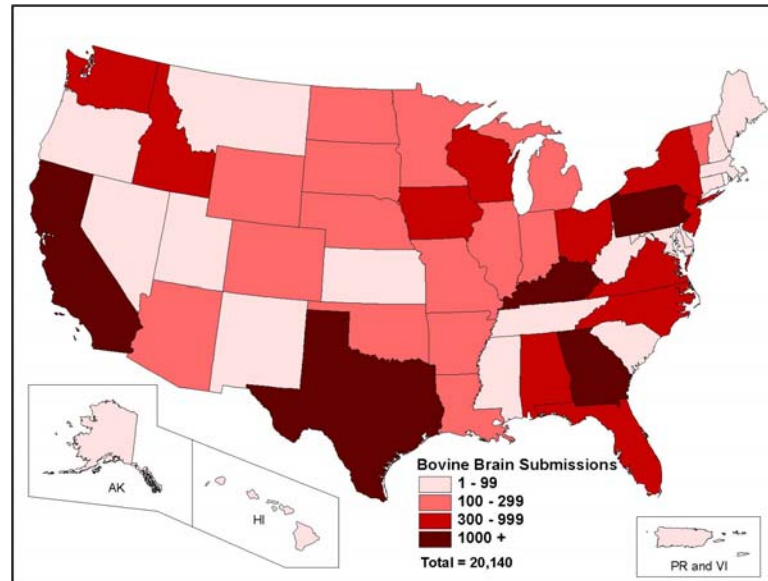
Surveillance and Monitoring for BSE in Cattle

The results of the Harvard risk assessment on BSE confirmed that disease surveillance is an important component of the U.S. Government's risk management strategy. APHIS and FSIS implement BSE surveillance by targeting sectors of the cattle population where the disease would most likely be detected:

- Field cases of cattle exhibiting signs of neurological disease
- Cattle condemned at slaughter for neurological reasons
- Rabies-negative cattle submitted to public health laboratories
- Neurological cases presented to veterinary diagnostic laboratories
- Aged cattle that are non-ambulatory (downer cattle/fallen stock).

APHIS' National Veterinary Services Laboratories in Ames, Iowa and other veterinary diagnostic laboratories examine brain samples sent in from all areas of the country. As of January 1, 2002, over 20,000 cattle brains have been examined in the U.S, with no evidence of BSE detected. (See Map 5, below; updated information may be found online at: <http://www.aphis.usda.gov/oa/bse/bseurvey.html#charts>)

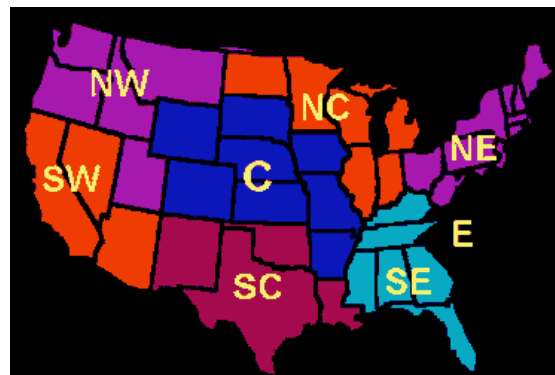
Map 5. BSE Surveillance: Cattle Brain Submissions by State, From 1990 Through 2001



APHIS has continued to adjust the sampling rate as dictated by science and to reassure the public and trading partners. The rate of surveillance for BSE in the United States has been approximately double the OIE recommendation. In 2000, the number of samples nationwide was more than five times the OIE standard, and in 2001 it was more than 10 times the OIE recommendation.

APHIS officials recently established a regional sampling model after they determined that a State-based approach was not the most effective method. (Adult cattle are often not slaughtered in the state in which they are born and raised, and therefore a State-based approach is not the most accurate.) Based on animal movement patterns, APHIS divided the United States into eight regions (Map 6) where adult cattle would be raised and exit the production system.

Map 6. BSE Regional Surveillance Plan



Using the adult cattle population in each region, surveillance goals were calculated based on the OIE standards as if each region were an individual country. In 2001, these goals were doubled in order to be able to detect an even lower level of BSE. These goals have been increased even further for 2002, with a national annual goal of at least 12,500 samples. (For up-to-date information about surveillance goals see:

<http://www.aphis.usda.gov/oa/bse/bseurvey.html#charts> .)

Another part of the surveillance program is to locate and monitor all cattle imported from the United Kingdom during the 1980s, before the USDA ban. Any of these cattle found to be still alive were monitored, and APHIS offered to purchase them. Upon purchase, they were destroyed and tested for BSE. No evidence of BSE has been found in any of these imported animals. Currently, three of these UK imports are still alive and are regularly monitored by a Federal veterinarian for clinical signs compatible with BSE. In addition, APHIS traced all 46 cattle imported from continental Europe in 1996 and 1997. As with the United Kingdom imports, APHIS has offered to purchase these animals. As purchases occur, the cattle are destroyed and tested for BSE. No evidence of BSE has been found. Five of the 46 European imports are still alive as of October 2001, and Federal veterinarians are monitoring them. APHIS is also tracing cattle imported from Japan during the last decade.

As part of its increased surveillance activities, APHIS is continuing an education effort to inform U.S. cattle producers and veterinarians about this disease and to make all stakeholders aware of reasons that testing should continue.

Surveillance and Monitoring for vCJD

To monitor BSE linkages to human health concerns, CDC collects, reviews, and, when indicated, actively investigates reports by health care personnel or institutions of possible CJD or vCJD cases. CDC also monitors overall mortality data and carefully scrutinizes mortality data in populations of concern. In addition, after the report of vCJD in the United Kingdom in 1996, CDC augmented its domestic CJD surveillance. Because of the striking age differences between vCJD and CJD patients, CDC, in partnership with state and local health departments, initiated post-mortem follow-up investigations of patients diagnosed with CJD who were less than 55 years of age at death. In 1996-1997, CDC, in collaboration with the American Association of Neuropathologists, established the National Prion Disease Pathology Surveillance Center at Case Western Reserve University, which performs special post-mortem tests for vCJD. CDC also has cooperated with the Council of State and Territorial Epidemiologists on an ongoing review of clinical and neuropathologic records of CJD decedents aged younger than 55 years.

Thus far, through the examination of death certificate data for U.S. residents, CDC has determined that the incidence of CJD has remained steady. No cases of vCJD have been identified to date in the United States except for one UK resident who sought medical care in the United States. With increased awareness of vCJD and increased surveillance, it is possible that a case of vCJD will be identified in the future in the United States. However, given the amount of travel to and from Europe, exposure to the agent may be more likely to have occurred in Europe, not in the United States. The travel

history of any U.S. patient with vCJD will obviously be a critical part of the epidemiologic work-up of the case.

A foundation of CDC disease surveillance and outbreak investigation activities is its relationship with – and support of – State, local, and, to a smaller degree, counterpart international health agencies and officials. State and local health officials are likely to be the first to encounter newly emerging human diseases or changes in the epidemiology of recognized human diseases. CDC relationships with State and local health officials complement those that CDC maintains with health care providers and are designed to maximize the likelihood that a sentinel event will be detected as soon as it occurs, whether in an expected or an unexpected location. CDC provides financial and technical support for the State and local health department surveillance.

The National Academy of Sciences' Institute of Medicine issued a report in 1995 recommending that the Secretary of DHHS establish a Public Health Service Blood Safety Committee. This internal government committee and its external counterpart, the Advisory Committee on Blood Safety and Availability have responded to concerns about the possible role of blood in the transmission of human TSEs and are prepared to continue in that role in the future.

Regulating and Inspecting

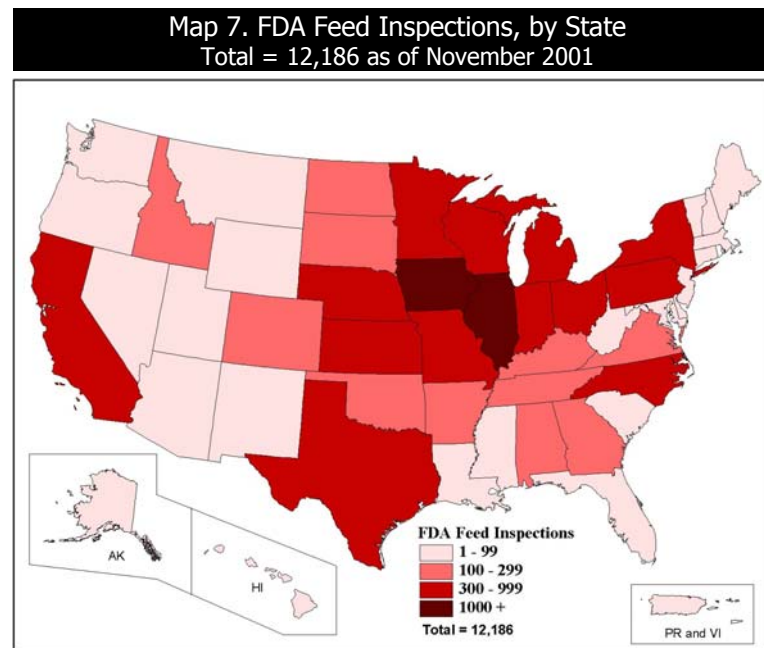
In 1997, the U.S. Government prohibited the use of most mammalian protein in the manufacture of animal feeds given to ruminants. The Harvard risk assessment concluded that this measure was crucial for reducing the risk of a BSE epidemic in U.S. cattle.

The regulation, established and implemented by FDA, requires manufacturers to use appropriate process and control systems to ensure that feed for ruminants does not contain the prohibited mammalian tissue. FDA uses its own inspectors and contracts with State regulators to inspect feed mills, ruminant feeders, dairy farms, renderers, protein blenders, feed haulers, and distributors. To help assure compliance, FDA has sponsored many educational workshops and other training initiatives on the feed rule. FDA also has an education and outreach program to inform consumers, patients, practitioners, and industry of the risks of TSEs and of their potential transmission through the products that FDA regulates.

As a complement to this activity, FSIS registers rendering facilities that accept dead, diseased, dying and disabled ("4D") cattle, and USDA officials work cooperatively with State authorities and the industry to assure compliance with regulations. (4D cattle are of particular concern because if they were dying from BSE or had clinical signs of the disease, the animals would be at peak levels of infectivity. If their carcasses were rendered and incorporated into animal feed that was then, in spite of the 1997 feed ban, fed to ruminants, there would be a higher risk of BSE spread.) FSIS has 150 Compliance Officers who are available to quickly respond to the need for enhanced surveillance of animals with central nervous system disorders at uninspected locations or after normal business hours in inspected plants.

FDA and its state partners have performed over 10,000 inspections of firms involved in the production and use of animal feed that might have materials

prohibited under the feed rule (Map 7).



These inspections included all renderers and licensed feed mills in the United States and all known unlicensed feed mills in the United States. On initial inspection, approximately 75 percent of firms handling prohibited materials were found to be in compliance with the various provisions of the rule. On re-inspection of those initially found to be out of compliance, approximately 90 percent were found to have corrected their deficiencies adequately and to be in compliance with the rule. Further educational, inspection, and enforcement efforts are under way to help achieve as close as possible to 100 percent compliance with the feed rule.

FDA is also responsible for the safety of all domestic and imported foods that are marketed in interstate commerce (except for meat, poultry, and eggs), as well as game meat, dietary supplements, food additives and animal feed and feed additives. Other FDA regulated products that include bovine-derived materials, and thus are pertinent to a discussion of BSE and related diseases include some human and animal drugs, some human biologic products, some human medical devices, and some cosmetics. FDA regulates these products under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

In FY 2001, FDA spent about \$3.8 million primarily for BSE-related activities, including inspections and monitoring of the U.S. human blood supply, biologics, and animal renderers, protein blenders, and feed mills. Given the events related to BSE in Europe, FDA re-adjusted its activities in order to complete inspections of all known renderers, protein blenders, and feed mills in FY2001. FDA also used one-time contingency funding to augment base resources to contract with the states to finish all the inspections and provide training and equipment to adequately perform these inspections.

Emergency Planning

Although the Harvard risk assessment concluded that BSE is not a highly contagious disease that could quickly become an epidemic in the United States, the U.S. Government has emergency plans in place to be used if BSE is identified in the United States.

USDA's plan, which was initially developed in 1990 and updated most recently in April 2001, outlines the steps involved in a control operation following the identification of a suspect animal. Once USDA has confirmed the presence of BSE, it will conduct an epidemiologic investigation and, after tracing the disease to its origin, begin disposing of animals and herds. The plan also includes specific communication steps to keep the public, stakeholders, and foreign governments informed about the U.S. Government's activities related to BSE. In addition, APHIS' TSE Working Group monitors and assesses all ongoing events and research findings regarding TSE's. Prevention and diagnostic measures are revised and updated as new information and knowledge becomes available. (The USDA plan is available online at: <http://www.aphis.usda.gov/oa/bse/bsesum.pdf>.)

FDA and other Federal agencies have developed contingency plans that would operate in association with the USDA plan. Likewise, FDA has contingency plans, should there be a confirmed presence of BSE-contaminated animal feed or human food or medical products in the United States. CDC has the lead in terms of contingency planning should there be a person in the United States diagnosed with vCJD.

USDA and DHHS have undertaken and are undertaking various outreach and table top exercises to "test" various components of their contingency plans. In November 2001, FDA produced a three-hour educational program on BSE contingency plans that was available publicly via satellite downlink.

In July 2000, APHIS demonstrated its readiness to deal with an undifferentiated TSE of foreign origin. Tests on four imported sheep in Vermont detected an abnormal prion protein, which is the only marker, or evidence, for TSEs currently available. The Secretary of Agriculture declared an extraordinary emergency and transferred funds from the Commodity Credit Corporation to purchase and dispose of the flocks. While APHIS was able to quickly remove and dispose of the smallest of the flocks, the other two owners challenged the Secretary's orders and delayed the disposal of the two remaining flocks. APHIS, with the help of the USDA OIG, seized the sheep in March 2001, and humanely euthanized, tested, and disposed of them. (Test results are not expected for at least another year, since TSE testing using laboratory animals takes two to three years to complete.)

CWD and Scrapie

For the other two animal TSEs of current concern in the United States—chronic wasting disease and scrapie—the U.S. Government, States, and industry have initiated a number of risk management activities.

CWD is currently known to affect free-ranging deer and elk in several western and mid-western States. Over 15,000 harvested free-ranging deer and elk had been tested as of February 2002. CWD has also been found in

captive elk herds in several western and mid-western States. All positive herds are under State quarantines. Surveillance for CWD in farmed elk began in 1997 and has been a cooperative effort involving State agencies and APHIS. As of the end of February 2002, over 6,000 farmed cervids have been tested. (For a map showing CWD incidence to date, see the website:

<http://www.aphis.usda.gov/vs/naahps/cwd/cwd-incidence.html>.)

All of the involved States, along with Federal agencies and other stakeholders, are committed to limiting the distribution of CWD in free-ranging deer and elk to the current localized areas and decreasing its occurrence in both the free-ranging and farm-raised deer and elk populations. For example, the Colorado Division of Wildlife is currently developing and implementing a management plan for CWD in free-ranging cervids. The Department of Interior also has a role in the detection and control of this disease in susceptible wildlife species on Federal lands.

In May 2002, USDA, Department of Interior, and State wildlife management and agriculture agencies formed a CWD task force to ensure that Federal and State agencies cooperate in the development and implementation of an effective national CWD program. The task force has developed an action plan and formed six working groups to handle communications, scientific and technical information dissemination, diagnostics, disease management, research, and surveillance.

USDA has provided assistance to State officials in diagnosing CWD and in monitoring international and interstate movements of animals to help prevent further spread of CWD. In September 2001, APHIS began a program to eradicate CWD in affected farmed elk populations. To date, a total of \$14.8 million has been transferred to APHIS from the Commodity Credit Corporation for depopulation, indemnity payments, cleaning and disinfections and information dissemination. These funds are also being used to support surveillance and diagnostics in wild elk and deer.

Colorado and Wyoming wildlife management agencies and USDA are continuing to invest resources in CWD research efforts. ARS has performed disease transmission studies to determine whether CWD can be transmitted by contact between species, and whether genetically resistant elk and deer can be identified.

USDA has worked to control scrapie since 1952. In recent years, the control program has emphasized two main strategies: flock certification and restrictions on the interstate movement of high-risk and affected animals. Since 1992 APHIS' Scrapie Flock Certification Program (SFCP) has monitored participating flocks and certifies those flocks as free of scrapie once they have been in continuous compliance with the program standards for five years. As of October 2001, there were 861 flocks enrolled in the program. Of those enrolled, 67 were scrapie infected and source flocks, and 51 were newly infected flocks. In addition, 98 other scrapie cases were confirmed and reported by APHIS' National Veterinary Services Laboratories.

USDA has also initiated an accelerated scrapie eradication program. The

program is based on the following strategies:

- Identification of preclinical infected sheep through slaughter surveillance and live animal testing
- Effective tracing of infected animals to their flock/herd of origin, made possible as a result of new identification requirements, and
- Providing effective cleanup strategies that will allow producers to stay in business, preserve breeding stock, and remain economically viable.

(Additional information on scrapie and CWD can be found at <http://www.aphis.usda.gov/vs> .)

**Domestic Activities:
Additional Needs
and Future Plans**

The Inter-agency Working Group identified a number of areas that need to be strengthened to continue to effectively manage the risk of BSE:

Coordination and Planning

TSE diseases uniformly have lethal outcomes, and the level of scientific knowledge about them is quite nascent. The U.S. Government must communicate effectively with all stakeholders as openly and frankly as possible regarding TSE issues. Agencies should continue to utilize public advisory committees and other public forums, along with internal and external experts, domestic and foreign, to provide advice concerning development of scientific, regulatory, and communications policies. Science-driven facts and transparent discourse are the best tools to build public trust and understanding.

BSE Surveillance and Monitoring

USDA will significantly increase its BSE surveillance in 2002. Already as of the end of March 2002, over 15,000 samples have been tested, well over twice the number of BSE tests done in 2001. To be able to accommodate this level of sampling, APHIS is expanding and enhancing laboratory facilities at the National Veterinary Services Laboratories in Ames, Iowa.

In addition, the Harvard risk assessment confirmed that cattle that die on the farm and downer cattle present a potential pathway for the spread of BSE (via the recycling of feed). *A focus of increased surveillance will be to obtain more samples from animals that die on farms. As of the end of March 2002, there have been over 1,200 samples taken from this population. In addition, USDA will be considering disposal options for this part of the cattle population. Regulations need to be developed to clarify USDA's authorities for testing of animals at slaughter plants, rendering facilities, market points, and farms.*

Domestic Activities:
Additional Needs *and Future
Plans* (continued)

Monitoring and Enforcing Domestic Regulations

There is a need to work together to assure a consistent, comprehensive Federal government approach to respond to the findings and recommendations of the Harvard risk assessment on BSE. FDA, Congress, and stakeholders should examine the need for FDA to have additional enforcement options for the feed ban, 21 CFR 589.2000. FDA and USDA need to develop consistent regulations or measures regarding the use of certain bovine materials (e.g., brain, spinal cord, intestines) as human food. This should include deciding which parts of cattle (that are fed materials under 21 CFR 589.2000) may present the highest risk of exposing humans and animals to the BSE agent.

USDA is considering additional plans and actions in response to the results of the Harvard risk assessment:

- *USDA published on January 15, 2002 an options paper describing “current thinking” on measures that could be implemented to minimize human exposure to materials that could potentially contain the BSE agent (http://www.fsis.usda.gov/oa/topics/bse_thinking.htm). The options include:*
 - *prohibiting the use of brain and spinal cord from specified cattle in human food;*
 - *prohibiting the incorporation of central nervous system tissue in boneless beef products, including meat from advanced meat recovery systems;*
 - *prohibiting the use of the vertebral column from certain categories of cattle in the production of meat from advanced meat recovery systems;*
 - *prohibiting the use of cheek meat from certain categories of cattle and downer cattle regardless of age unless meat is removed before the skull is split;*
 - *implementing measures that will be consistent with any policy that FDA adopts concerning the disposition of cattle that have been fed prohibited materials; and*
 - *increasing enforcement of recordkeeping and registration requirements for renderers and persons who engage in the business of buying, selling, and transporting “4-D” livestock.*
- *USDA plans to propose to prohibit the use of certain stunning devices at slaughter.*
- *USDA plans to publish an advanced notice of proposed rulemaking to consider disposal options for dead and downer animals, as these are considered an important potential pathway for the spread of BSE.*
- *FSIS is increasing emphasis on investigations of breaches in the feed ban, import restrictions, and other regulatory control systems.*

DHHS is also considering additional plans and actions in response

Domestic Activities:
Additional Needs and *Future Plans (continued)*

to the results of the Harvard study and comments received at various public meetings on BSE issues:

- *FDA plans to publish an Advance Notice of Proposed Rulemaking to consider options to revise the present regulations at 21 CFR 589.2000. Specific areas to be examined in the proposal will include, but not be limited to:*
 - *Licensing firms that handle materials prohibited under the regulation,*
 - *Banning certain ruminant materials (e.g., CNS materials and intestines) from all animal feeds,*
 - *Eliminating certain exemptions from the present rule (e.g. plate waste),*
 - *Prohibiting the use of poultry litter in the production of feed for ruminants,*
 - *Setting stricter manufacturing and transportation standards to prevent co-mingling (including either dedicated facilities or dedicated manufacturing lines),*
 - *Banning the "import-for-export" (transshipment) of any feed that would not be allowed to be marketed legally in the United states under this regulation,*
 - *Removing or otherwise altering the present exemption regarding labeling of pet foods, and*
 - *Extending the recordkeeping provision of the regulation for a longer period of time.*

- *FDA also has proposed expanding its authority to enforce 21 CFR 589.2000. Options being considered include expanding the authority to:*
 - *Impose civil money penalties,*
 - *Order an immediate embargo of a product or facility reasonably thought to be in violation of the regulation, and*
 - *Revoke quickly and administratively any required FDA license to handle materials prohibited under the regulation.*

Other TSEs

USDA and DHHS are developing plans on how best to ensure that the public is protected from exposure to CWD. FSIS is considering options for potential additional sanitation requirements to prevent cross-contamination of slaughter plants in which deer or elk are slaughtered in the same facility as cattle and other livestock subject to mandatory inspection. (The additional sanitation may be required in USDA-inspected facilities to prevent potential human exposure to the agent that causes CWD.) FDA is also considering options for additional requirements for FDA-regulated products and the use of materials from animals or herds confirmed positive for CWD. (This could include a prohibition on the use in FDA-regulated products of materials from any animal in a herd from which at least one animal has been confirmed positive for CWD, unless FDA deems inclusion of such materials necessary to protect public health, for example if the benefits of including the materials outweigh the known or theoretical risks of the material.)

Domestic Activities:
Additional Needs and *Future
Plans (continued)*

USDA and Department of Interior plan to work closely with States to support surveillance and diagnostics in wild elk and deer, to develop management and control plans for CWD on Federal lands, and to control CWD in farmed elk and deer herds.

For scrapie, USDA is planning a significant expansion of its ongoing eradication program.

Emergency Preparedness

Further tabletop exercises will continue throughout 2002 under contract with a private sector organization specializing in emergency planning and preparedness. Lessons learned in these exercises will be incorporated into the emergency preparedness plans.

As mentioned in the FMD section of this report, USDA plans to use a significant part of the \$328 million received under the Defense Appropriations Act, (January 2002) to strengthen emergency preparedness activities and to help meet several of the other critical needs listed above. This includes \$80 million for upgrading USDA facilities and operational security; \$73 million for construction of improved biocontainment facilities at ARS laboratories in Ames, Iowa and Plum Island, New York; \$20.6 million for CSREES to establish a unified rapid detection and diagnostics network of public agricultural institutions such as universities and State Department of Agriculture diagnostic laboratories; \$15 million for security upgrades and bioterrorism protection for FSIS; \$14 million for increased security measures at the APHIS National Veterinary Services Laboratories in Ames, Iowa; \$3 million for animal health monitoring and surveillance; and \$18.5 million for direct assistance to States for emergency preparedness.

To maintain its efforts to monitor and enforce regulations of FDA-related products in FY2002, Congress provided FDA \$15 million in additional funding that had been requested in the FY2002 President's budget. This represents a component of FDA's continuing multi-year effort to prevent exposure of American citizens and food-producing animals to the agent of BSE. FDA currently plans to spend approximately \$22 million in FY 2002 for BSE/TSE related activities and expects to seek additional increases in future years to support this effort.

For FY2003, USDA is proposing a \$34.8 million increase for animal TSE monitoring and control programs (\$8.4 million for BSE, \$7.2 million for CWD, and 19.2 million for scrapie); a \$1.2 million increase to strengthen FSIS' monitoring and surveillance activities, including an improved information technology infrastructure and risk management systems and more slaughter epidemiological surveys; and a \$6.3 million increase for programs to expand diagnostic response management and other technical services within APHIS. (See Appendix 8 for a complete list of USDA's FY2003 budget proposals related to animal diseases such as FMD and BSE.)

**BSE Research
Activities and Methods
Development**

DHHS, USDA, and DOD conduct or support TSE research projects. Key areas of research include: basic research on the disease agent, transmission and pathogenesis of the TSEs, developmental work on diagnostic tests, examinations of potential drugs or treatments for BSE and other TSEs, and economic impact analyses. In addition, the Department of Interior is interested in pursuing research related to TSEs in wildlife.

USDA Research

ARS conducts TSE research at the National Animal Disease Center in Ames, Iowa, and the Animal Disease Research Unit in Pullman, Washington. The research program focuses on developing control measures for scrapie and CWD through improved diagnostic tests, defining genetic susceptibility, and defining the routes of transmission. The ARS scientists in Pullman have developed the only practical live (ante-mortem) animal test for a TSE (scrapie).

ARS researchers are also working to determine if TSEs are transmissible among species. Some of this research is being done in conjunction with cooperators at Colorado State University and the University of Wyoming. ARS researchers have identified animals (sheep and elk) which are genetically resistant to certain TSEs. These studies are being extended to prove their utility in restocking programs, to determine their resistance to other TSEs, and to assess mule deer for similar genetic resistance.

ARS also has several ongoing projects for CWD diagnosis, including a live animal test for elk, techniques for the detection of the CWD agent in soil and water, and the development of a test that can be used at check stations during hunting season.

ARS has also initiated a research program at the Western Regional Research Center in Albany, California, to develop methods to detect the presence of ruminant proteins and central nervous system tissue in food for animals.

CSREES provides grants for several projects that could improve TSE control. Colorado State University is doing research to determine the molecular epidemiology of several important livestock pathogens, including CWD. Creighton University is attempting to develop a new diagnostic technique for rapid identification of TSE's in livestock. Another grant to Creighton scientists funded an investigation into transmissible mink encephalopathy. North Carolina State University is studying the efficacy of an enzymatic degradation process for inactivation of prions for production of safe animal products. A new project at Washington State University is focused on resistance of sheep to scrapie. A new CSREES project specifically addresses the possible transmission of CWD to young calves through oral exposure.

APHIS' National Wildlife Research Center (NWRC) has also been involved with research on CWD. NWRC is researching ways to identify barriers, repellents, and other methods to keep deer and cattle separated. This research is being conducted to control bovine tuberculosis, but much of the information will apply to CWD.

In conjunction with the current biological research on TSEs, USDA's Economic Research Service (ERS) provides analyses of the economic issues affecting the safety of the U.S. food supply. International food safety incidents, such as the connection of BSE with vCJD, may change consumer perceptions about food safety and consumers' food purchasing patterns. Consumer perceptions about the implicated food product and about the ability of exporting countries to produce safe food may be slow to change, which may have a lasting influence on food demand and global trade. ERS programs evaluate the effectiveness and equity of alternative policies and programs designed to protect consumers from unsafe food, including:

- Estimates of the costs of food-borne disease to identify the magnitude of the societal impact.
- Benefit/cost analyses of programs for improving food safety to provide insight into least-cost interventions throughout the food continuum. Coupling economics with risk assessment is an integral part of benefit/cost analyses.

DHHS Research

FDA is involved in research aimed at developing new methods to detect prohibited protein in animal feed, to aid in its assessment of compliance with the mammalian-to-ruminant feed ban regulation. Collaborative research is underway in conjunction with Auburn University and at the research office of FDA's Center for Veterinary Medicine.

The National Institutes of Health (NIH) conduct research on human TSE cases. NIH research (including that funded at other institutions) on TSE is currently focused on understanding the prions associated with TSEs, defining how TSEs are transmitted among animal species and across species, developing diagnostic tests using tissues and blood, and designing drug therapy.

The National Institute of Neurological Disorders and Stroke supports basic and applied research on TSEs. Prior accomplishments have been recognized by the award of Nobel Prizes, to Dr. Carleton Gajusek for demonstrating that both kuru and classic CJD were transmissible, and to Dr. Stanley Prusiner for his discovery and characterization of prions.

The National Institute of Allergy and Infectious Diseases also supports research on TSEs, with a particular focus on CWD of deer and elk. The program, which is conducted at the Rocky Mountain Laboratories in Hamilton, Montana, has developed genetically engineered mouse models of scrapie and CWD to study the effects of particular genes and of species barriers on the natural history of these diseases.

The National Heart, Lung, and Blood Institute is the lead institute within NIH for the development of tests suitable for screening the blood supply for TSEs. The research currently funded is targeted at developing and validating test strategies for various human and animal TSEs in samples of known infectivity.

DOD Research

The DOD National Prion Research Program (NPRP) was established in FY2002 by Joint Appropriations Conference Committee Report No. 107-350, which provided \$42.5M for research on prion disease. The Senate

Appropriations Committee Report No. 107-109 also specified that "The priority goal of the Project's first phase is to rapidly develop a diagnostic test to detect the presence of prion disease." As part of the NPRP, the National Academy of Sciences Institute of Medicine will release a report in September 2003 assessing the current status of prion detection and disease diagnosis. Research grants for phase one will be awarded in FY2003.

**BSE Research:
Additional Needs
and Future Plans**

Although USDA, DHHS, and the Department of Interior have ongoing TSE research programs, there is a need for:

- More collaboration between USDA and Department of Interior researchers to develop better methods for CWD detection in wildlife species.
- Additional research and analysis of the economic impacts of TSEs. *ERS is planning a research report for 2002-3 that draws together the market analysis work and food safety issues in a global economy.*
- Practical methods for sanitizing equipment used to slaughter and/or process an animal that has been found to have, or to have been exposed to, a TSE (BSE or CWD).
- Additional funding to:
 - Develop a live animal test for TSEs.
 - Develop and validate tests for central nervous system tissues, including comparative evaluation of existing tests.
 - Develop improved methods to differentiate TSE types.
 - Obtain more basic information on animal TSE pathogenesis and genetic resistance.
 - Develop and validate tests for ruminant protein in feeds and other products.
 - Perform research on alternative uses of rendered animal products.
 - Address the critical shortage of laboratory investigators and laboratories capable of handling the extremely hazardous materials needed to perform research on TSEs and TSE agents. *NIH plans to establish a repository of reagents by the end of FY2002 and double the laboratory facilities available for TSE-related research over the next two years. Tripling the number of researchers involved in TSE-related research over the next five years and doubling or tripling the present \$16 million/year on TSE-related research are fundamental components of NIH's short-term research agenda for TSEs.*

As noted previously in the FMD research section of this report, these needs are in keeping with PL107-9 stakeholder comments and the Animal Health Safeguarding Review Panel's recommendations to provide additional funding to "reverse the serious erosion of animal health applied research funding that has occurred in past years." (The Safeguarding Review report is available at <http://www.nasda.org/ASGRwebsite/FullBook.pdf>)

BSE Research: Additional
Needs and Future Plans
(continued)

USDA has proposed a \$10 million increase for FY2003 to support research aimed at protecting the nation's agriculture and food system from attack by animal and plant diseases, along with a \$2 million increase for research on the effects of invasive pests and diseases on the competitiveness of U.S. agriculture. This proposal reflects USDA's commitment to protecting U.S. agriculture food systems.

Recommendations

The PL107-9 Working Group makes three main recommendations.

1. Legislative authorities:

Congress, Federal and State agencies, and industry stakeholders should work together to implement the recently enacted Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), which updates and consolidates USDA's animal health safeguarding authorities. In addition, the working group makes the following specific recommendations:

- Review the Virus-Serum-Toxin Act and its implementing regulations. Such a review will determine whether civil or criminal penalties are needed to enhance enforcement of the Act and regulations on imports of animal biologics. It will also determine the need for additional authorities to take action against products produced by unlicensed veterinary biologics producers that may present a risk to the U.S. livestock industry.
- Review the Swine Health Protection Act and its implementing regulations, to determine whether adequate authorities are in place to ensure biosecurity and sanitation safeguards.
- Develop and enact legislation to strengthen FDA's ability to enforce its animal feed regulation (21 CFR 589.2000). This would include clarification of "prohibited acts" under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) and the authority to impose civil penalties or embargo products for violations of the feed rule.
- Develop and enact legislation to update and strengthen FDA's authorities at the borders, to control the entry of certain products that carry a risk of bringing TSEs into the United States.
- Develop and enact legislation to strengthen FDA's ability to help address the problem of chronic wasting disease in captive deer and elk.
- Review and update the Public Health Service Act to clarify that TSEs are "communicable" diseases. (This clarifying legislation would remove any question about the meaning of the "communicable" diseases in Section 361 of the Act.)

2. Resources:

This past year's international outbreak of FMD, combined with recent U.S. biosecurity incidents, creates an unprecedented demand on the U.S. animal health infrastructure. The existing system is being challenged in a radically changing environment that has transcended annual appropriations cycles and strained discretionary spending caps. A number of the needs identified in this report require long-term investments. For example, a key component of the infrastructure must be a comprehensive and coordinated surveillance system that integrates existing and

new information systems for animal health, public health, food safety, and environmental health. Such a system can only be built with an extended commitment of resources and focus. Several provisions of the Farm Security and Rural Investment Act of 2002 address these concerns, and Federal agencies need to follow up in implementing the Act.

The President's FY2003 budget request includes a total of \$92.7 million to meet current USDA agency resource needs identified in this report. In the USDA request, \$79.5 million is for increased inspections, monitoring, surveillance and emergency management for APHIS; \$10 million is for BSE and FMD research for ARS and the CSREES; \$1.2 million is for FSIS surveys; and \$2 million is for ERS studies relative to invasive pests and diseases. Details of this request are listed in Appendix 8.

3. Federal Inter-Agency Panel:

A Federal inter-agency panel should be established to coordinate animal disease issues that have significant links to economic or public health concerns. Given the potential deliberate introduction of an animal or human health threat into the environment, a policy group is needed to work closely with the Office of Homeland Security to coordinate the management of such a threat. Although the mechanism of transmission and the impact on human health for FMD and BSE are very different, similar multiple-firewall preventive strategies, infrastructure and resources can be shared government-wide to protect public health and well-being, the national herd, and the economy.