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HIGH-CONTAINMENT BIOSAFETY LABORATORIES

DHS Lacks Evidence to Conclude That Foot-and-Mouth-Disease Research Can Be Done Safely on the U.S. Mainland

Statement of Nancy Kingsbury, Managing Director
Applied Research and Methods

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Highlights

Highlights of GAO-08-821T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

DHS is proposing to move foot-and mouth disease (FMD) research from its current location at the Plum Island Animal Disease Center—located on a federally owned island off the northern tip of Long Island, New York—and potentially onto the United States mainland.

FMD is the most highly infectious animal disease that is known. Nearly 100 percent of exposed animals become infected. A single outbreak of FMD on the U.S. mainland could have significant economic consequences. Concerns have been raised about moving FMD research off its island location and onto the U.S. mainland—where it would be in closer proximity to susceptible animal populations—as opposed to building a new facility on the island.

GAO was asked to evaluate the evidence DHS used to support its decision that FMD work can be done safely on the U.S. mainland, whether an island location provides any additional protection over and above that provided by modern high containment laboratories on the mainland, and the economic consequences of an FMD outbreak on the U.S. mainland.

In preparing this testimony, GAO interviewed officials from DHS and USDA, talked with experts in FMD and high-containment laboratories worldwide, and reviewed studies on FMD, high-containment laboratories, and the economic consequences of FMD outbreaks. GAO also visited the Plum Island Animal Disease Center and other animal biocontainment laboratories in other countries.

To view the full product, including the scope and methodology, click on GAO-08-821T. For more information, contact Nancy Kingsbury at (202) 512-2700 or kingsburyn@gao.gov.

What GAO Found

GAO found that the Department of Homeland Security (DHS) has neither conducted nor commissioned any study to determine whether work on foot-and-mouth disease (FMD) can be done safely on the U.S. mainland. Instead, in deciding that work with FMD can be done safely on the mainland, DHS relied on a 2002 U.S. Department of Agriculture (USDA) study that addressed a different question. The study did not assess the past history of releases of FMD virus or other dangerous pathogens in the United States or elsewhere. It did not address in detail the issues of containment related to large animal work in BSL-3 Ag facilities. It was inaccurate in comparing other countries' FMD work experience with that of the United States. Therefore, GAO believes DHS does not have evidence to conclude that FMD work can be done safely on the U.S. mainland.

While location, in general, confers no advantage in preventing a release, location can help prevent the spread of pathogens and, thus, a resulting disease outbreak if there is a release. Given that there is always some risk of a release from any biocontainment facility, most experts GAO spoke with said that an island location can provide additional protection. An island location can help prevent the spread of FMD virus along terrestrial routes, such as from vehicles splashed with contaminated mud, and may also reduce airborne transmission. Some other countries besides the United States have historically seen the benefit of an island location, with its remoteness from susceptible species and permanent water barriers. A recent release from the Pirbright facility—located in a farming community on the mainland of the United Kingdom—highlights the risks of a release from a laboratory that is in close proximity to the susceptible animals and provides the best evidence in favor of an island location.

Figure 1: The Plum Island Animal Disease Center

Source: DHS.

FMD has no health implications for humans, but it can have significant economic consequences, as recent outbreaks in the United Kingdom have demonstrated. The economic effects of an FMD outbreak in the United States, however, would depend on the characteristics of the outbreak and how producers, consumers, and the government responded to it. Although estimates vary, experts agree that the economic consequences of an FMD outbreak on the U.S. mainland could be significant, especially for red meat producers whose animals would be at risk for diseases, depending on how and where such an outbreak occurred.

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here to discuss our findings on the evidence the Department of Homeland Security (DHS) has used to support its decision that foot-and-mouth disease (FMD) work can be conducted as safely on the U.S. mainland as on Plum Island.

By law, live FMD virus may be used only at a coastal island, such as Plum Island, unless the Secretary of Agriculture specifically determines that it is necessary and in the public interest to conduct such research and study on the U.S. mainland.[1] The only facility that studies high-consequence foreign livestock diseases, such as FMD, in the United States is the Plum Island Animal Disease Center (PIADC), located on a federally owned island off the northern tip of Long Island, New York.

The U.S. Department of Agriculture (USDA) was responsible for Plum Island from the 1950s until June 1, 2003. The Homeland Security Act of 2002 transferred Plum Island to DHS, shifting overall responsibility for Plum Island to DHS, including all costs associated with PIADC's maintenance, operations, and security.[2] The Act specified that USDA would continue to have access to Plum Island to conduct diagnostic and research work on foreign animal diseases, and it authorized the President to transfer funds from USDA to DHS to operate Plum Island.[3]

DHS has identified PIADC as "reaching the end of its life cycle" and as lacking critical capabilities to continue as the primary facility for such work. DHS has announced that to meet the obligation of Homeland Security Presidential Directive/HSPD-9, it will

[1]21 U.S. Code §113a.

[2]Public Law 107-296, §310, 116 Stat. 2135, 2174 (2002), codified at 6 U.S. Code §190.

[3]6 U.S. Code §542(b)(3).

establish a new facility, the National Bio and Agro-Defense Facility (NBAF).[4] This facility, according to DHS, would have high-containment laboratories able to safely contain the pathogens currently under investigation at PIADC—including the FMD virus.[5]

FMD is the most highly infectious animal disease that is known. Nearly 100 percent of exposed animals become infected. The virus can spread from infected animals in various ways, including by contaminated animal feed or water, contaminated shoes or clothing, and contaminated vehicles or farm equipment. In some circumstances, the wind can spread the virus from farm to farm. The traditional approach, once infection is confirmed, is to depopulate infected and potentially infected herds.

The United States has been free of FMD since 1929. A single outbreak of FMD on the U.S. mainland could have significant consequences. The value of U.S. livestock sales was $140 billion in 2007; about 10 percent of this figure, or approximately $13 billion, is accounted for by export markets. Concerns have been raised about moving FMD research off its island location and onto the U.S. mainland, where it would be in closer proximity to susceptible animal populations, as opposed to building a new facility on the island.

You asked us to evaluate

1. the evidence DHS used to support its decision that FMD work can be done safely on the U.S. mainland,

[4]HSPD-9 tasked the Secretary of Agriculture and the Secretary of Homeland Security with developing a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases. HSPD-9 also tasks the Secretaries of Homeland Security, Agriculture, and Health and Human Services, the Administrator of the Environmental Protection Agency, and the heads of other appropriate Federal departments and agencies, in consultation with the Director of the Office of Science and Technology Policy, with the acceleration and expanded development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases". "Defense of United States Agriculture and Food," Homeland Security Presidential Directive/HSPD-9, The White House, Washington, D.C., Jan. 30, 2004, secs. 23 and 24.http://www.whitehouse.gov/news/releases/2004/02/20040203-2.html.

[5]Since by law, research on FMD virus is not permitted on the U.S. mainland, except by permit, USDA would have to issue DHS a permit if NBAF is constructed on the mainland, or the Congress would have to waive the statutory provision.

2. whether an island location provides any additional protection over and above that provided by modern high containment laboratories on the mainland, and

3. the economic consequences of an FMD outbreak on the mainland.

To address the first question, we interviewed officials from DHS and USDA. We visited PIADC and talked with DHS and USDA officials who oversee and operate the facility, toured the animal containment areas, and examined the unique aspects of the island location. We obtained and reviewed relevant legislation and regulations governing USDA and DHS; literature on FMD as well as on high-containment laboratories; and agencies' documents, including the study DHS used to support its decision. In addition, we talked to the contractor who conducted the study for USDA in 2002 and many of the members of the expert panel used in the study. We also talked to experts on animal diseases and high-containment laboratories dealing with animal, zoonotic, and human pathogens, as well as representatives from the American Society for Microbiology, National Grange of the Order of Patrons of Husbandry, National Cattlemen's Beef Association, and National Pork Producers Council.[6]

For the second question, we interviewed officials from DHS and USDA and experts in animal diseases. We visited and talked with officials of some of the other facilities that are conducting FMD work, including the Australian Animal Health Laboratory in Geelong, Canada's National Centre for Foreign Animal Disease in Winnipeg, the Danish National Veterinary Institute on Lindholm Island, the German Federal Research Institute for Animal Health (Friedrich-Loeffler-Institut) on the Island of Riems, and the United Kingdom's (UK) Institute for Animal Health Pirbright facility. In addition, we talked to officials of the World Organisation for Animal Health (OIE) in France.

For the third question, we obtained and reviewed studies conducted on the economic consequences of the FMD outbreak in the United Kingdom in 2002 and the potential consequences of outbreaks in the United States.

[6]A zoonotic disease is one that can be transmitted from animals to people or, more specifically, that normally exists in animals but that can infect humans.

We conducted our work from March 2008 through May 2008 in accordance with generally accepted government auditing standards.

Results in Brief

We found that DHS has not conducted or commissioned any study to determine whether FMD work can be done safely on the U.S. mainland. Instead, DHS based its decision that work with FMD virus can be done safely on the mainland on a 2002 USDA study that addressed a different question: whether it is technically feasible to conduct exotic disease research and diagnostics, including foot-and-mouth disease and rinderpest, on the U.S. mainland with adequate biosafety and biosecurity to protect U.S. agriculture.[7] This approach fails to recognize the distinction between what is technically feasible and what is possible, given the potential for human error. We found that the study was selective in what it considered. It did not assess the history of releases of FMD virus or other dangerous pathogens, either in the United States or elsewhere. It did not address in detail the issues of containment related to large animal work in BSL-3 Ag facilities.[8] Also, the study was inaccurate in comparing other countries' FMD work experience with the situation in the United States. Consequently, the study does not clearly support the conclusion that FMD work can be done safely on the mainland.

While location, in general, confers no advantage in preventing an initial release, location can help prevent the spread of pathogens and, thus, a resulting disease outbreak if there is a release. Given that there will always be some risk of a release from any biocontainment facility, most of the experts we spoke with told us that an island location can provide additional protection. An island location can help prevent the spread of FMD virus along terrestrial routes, such as from vehicles splashed with contaminated mud, and may also reduce airborne transmission.

[7]The study, prepared for USDA by Science Applications International Corporation (SAIC), was entitled *United States Department of Agriculture Biocontainment Feasibility Studies, Study Report: Plum Island Animal Disease Center* (Washington, D.C.: Aug. 15, 2002), (p. 1).

[8]A BSL-3 Ag facility is a special type of biosafety laboratory that is used with large animals. It employs policies and practices such as (1) shower upon exit, (2) blow nose and expectorate to clear nasal and throat passages, (3) clean underneath fingernails with nail files, (4) scrub hands and arms with soap using a brush, and (5) soak eyeglasses in a decontamination solution.

Historically, not just the United States but also other countries have seen the benefit of an island location, with its combination of remoteness from susceptible species and permanent water barriers. For example, Denmark, Germany, and the United States decided to conduct FMD and related animal disease work on islands when modern containment technology did not yet exist. Islands were considered to be an extra layer of protection. However, faced with the decision today of whether to replace aging infrastructure on the island versus building a new facility on the mainland, Denmark and Germany have both decided to keep FMD work on their islands, given the non-zero risk of a release and the serious economic consequences of an outbreak on the mainland.[9]

Australia has built a state-of-the-art BSL-4 laboratory at Geelong, south of Melbourne.[10] However, Australia's approach is to avoid the risk of any release by contracting out live FMD virus work to foreign countries, despite the fact that it has the most sophisticated high-containment laboratories for such work.[11] Canada has decided to conduct FMD work on the mainland. However, the location is downtown, where susceptible animals are not likely to be found in the immediate neighborhood. In addition, Canada's scope of work on FMD is smaller than the present FMD work at the PIADC facility or the facility DHS proposes. Some of the proposed U.S. sites are potentially more likely to pose a risk, given their closer proximity to susceptible animal populations. A recent release from the Pirbright facility in the United Kingdom highlights the risks of a release from a laboratory that is in close proximity to susceptible animals and provides the best evidence in favor of an island location.

FMD has no health implications for humans, but it can have significant economic consequences, as recent outbreaks in the United Kingdom have demonstrated. The economic effects of an FMD outbreak in the United States would depend on the characteristics of the outbreak and how

[9] In the case of Germany, since 1971 the island has been connected to the mainland by a causeway. For ecological reasons this has been interrupted in late 2007 by construction of a roadbridge so that access to the island is still possible.

[10] Biosafety laboratories are classified by the type of agents used in them and the risk those agents pose to personnel, the environment, and the community. The Department of Health and Human Services' Biosafety in Microbiological and Biomedical Laboratories has four biosafety levels, with BSL-4 the highest. The levels include combinations of laboratory practices and techniques, safety equipment, and facilities that are recommended for laboratories that conduct research on potentially dangerous agents and toxins.

[11] Australia only allows work with inactivated FMD viruses at Geelong.

producers, consumers, and the government responded to it. Although estimates vary, experts agree that the economic consequences of an FMD outbreak on the U.S. mainland could be significant, especially for red meat producers, whose animals would be at risk for diseases, depending on how and where such an outbreak occurred.

We discussed our findings with both DHS and USDA. DHS officials told us that in addition to the SAIC study, the results of the EIS would be used to determine the safety of FMD work on the mainland. Previously, DHS had stated categorically that the SAIC study allowed them to conclude that FMD work can be done safely on the mainland. In light of this, the recent DHS statement about the results of EIS clearly conflict with the earlier position. Without detail information, it is impossible to determine whether or not the EIS would contribute significantly to addressing this issue. We asked but DHS would not provide any information on what analysis they would do as part of the EIS concerning biosafety. For example, it is not known to us whether or not EIS will include an analysis of the factors that may lead to a release of FMD virus from containment laboratories, for example, a laboratory air pressure system going positive.

USDA officials stated that the German facility no longer meets the actual definition of an island since it is now connected to the mainland by road. We noted this in our testimony.

USDA officials also cited the Centers for Disease Control and Prevention BSL-4 laboratory in Atlanta as an example of the safe operation of high-containment laboratory in the middle of a densely populated area. We believe that this example is not an appropriate comparison to the FMD work involving large animals in BSL-3 Ag laboratories. In a BSL-4 laboratory, work is done within a biological safety cabinet, which provides the primary level of containment. Accordingly, there is no contact between the human operator and the infective material. The laboratory provides the secondary containment and the laboratory staff is required to wear special protective equipment to prevent any exposure to the pathogens. Furthermore, according to experts we spoke with, the most dangerous human pathogens have, fortunately, a much lower level of infectivity and transmissibility than FMD. That is why we believe that this comparison is not valid.

Unique risks are associated with BSL-3 Ag facilities, in contrast, where the facility itself is considered the primary containment area. Because large animals cannot be handled within a biological safety cabinet, they are free to move around in a BSL-3 Ag laboratory, where the laboratory walls

provide the primary containment. Another important distinction in a BSL-3 Ag laboratory is that there is extensive direct contact between the human operator and the infected animal. It is also worth noting that the infectious dose of FMD for cattle is about 10 virus particles. Because the virus can be carried in a person's lungs, nostrils, or other body parts, the human becomes a potential avenue by which the virus can escape the facility. This potential avenue for escape of the virus outside the containment does not exist in BSL-4 laboratory.

Background

FMD Is a Highly Contagious Animal Disease

FMD is a highly contagious animal disease. [12] It affects cloven-hoofed animals such as cattle, sheep, goats, and pigs, and has occurred in most countries of the world at some point during the past century. [13] It has 7 types and over 80 subtypes. Immunity to, or vaccination for, one type of the virus does not protect animals against infection from the other types. FMD-infected animals usually develop blister-like lesions in the mouth, on the tongue and lips, on the teats, or between the hooves. They salivate excessively or become lame. Other symptoms include fever, reduced feed consumption, and miscarriages. Cattle and pigs, which are very sensitive to the virus, show disease symptoms after a short incubation period of 3 to 5 days. The incubation period in sheep is considerably longer, about 10 to 14 days, and the clinical signs of the disease are usually mild and may be masked by other diseases, thereby allowing FMD to go unnoticed.[14]

[12]FMD virus is the prototypic member of the Aphthovirus genus in the Picornaviridae family. This picornavirus is the etiologic agent of the acute systemic vesicular disease that affects cattle and other animals worldwide.

[13]Horses, dogs, and cats are not susceptible but could spread the virus by carrying it on their hair.

[14]GAO, *Foot and Mouth Disease: To Protect U.S. Livestock, USDA Must Remain Vigilant and Resolve Outstanding Issues*, GAO-02-808 (Washington, D.C.: July 26, 2002), p. 12.

The mortality rate for young animals infected with FMD varies and depends on the species and strain of the virus; in contrast, adult animals usually recover once the disease has run its course. However, because the disease leaves them severely debilitated, meat-producing animals do not normally regain their lost weight for many months, and dairy cows seldom produce milk at their former rate. Therefore, the disease can cause severe losses in the production of meat and milk.

The FMD virus is easily transmitted and spreads rapidly. Before and during the appearance of clinical signs, infected animals release the virus into the environment through respiration, milk, semen, blood, saliva, and feces. The virus may become airborne and spread quickly if pigs become infected because pigs prolifically produce and excrete large amounts of the virus into the air. Animals, people, or materials that are exposed to the virus can also spread FMD by bringing it into contact with susceptible animals. For example, the virus can spread when susceptible animals come in contact with contaminated

- animals;
- animal products, such as meat, milk, hides, skins, and manure;
- transport vehicles and equipment;
- clothes or shoes worn by people; and
- hay, feedstuffs, or veterinary biologics.[15]

FMD virus is the most infectious animal disease-causing virus. It has been determined that for certain strains, the dose required to infect cattle or sheep through inhalation is about 10 organisms (10 1 TCID50). Infected pigs produce immense amounts of airborne virus. An infected pig exhales 400 million organisms per day (10 8.6 TCID50). The sensitivity of cattle to infection and the high levels of airborne virus produced by infected pigs illustrate that the airborne spread of infection is another important factor in FMD outbreaks.

FMD occurs throughout much of the world, and although some countries have been free of FMD for some time, its wide host range and rapid spread represent cause for international concern. After World War II, the disease was widely distributed across the globe. In 1996, endemic areas included

[15]A veterinary biologic is a product used for diagnosing, preventing, and treating an animal disease. Such products include vaccines and kits for diagnosing specific animal diseases.

Asia, Africa, and parts of South America. In North America, the last outbreaks of FMD for the United States, Canada, and Mexico occurred in 1929, 1952, and 1953, respectively.

North America, Australia, and Japan have been free of FMD for many years. New Zealand has never had a case of FMD. Most European countries have been recognized as disease free, and countries belonging to the European Union have stopped FMD vaccination.

Plum Island Animal Disease Center

Plum Island is a federally owned 840-acre island off the northeastern tip of Long Island, New York. Scientists working at the facility are responsible for protecting U.S. livestock against foreign animal diseases that could be accidentally or deliberately introduced into the United States. Plum Island's research and diagnostic activities stem from its mission

to protect U.S. animal industries and exports from accidental or deliberate introduction of foreign animal diseases.[16] Plum Island's scientists identify the pathogens that cause foreign animal diseases and work to develop vaccines to protect U.S. livestock.[17] The primary research and diagnostic focus at Plum Island is foreign or exotic diseases that could affect livestock, including cattle, pigs, and sheep. In addition to FMD and classical swine fever, other types of livestock diseases that have been studied at Plum Island include African swine fever, rinderpest, and various pox viruses, such as sheep and goat pox.

Some of the pathogens maintained at Plum Island are highly contagious; therefore, research on these pathogens is conducted in a biocontainment area that has special safety features designed to contain them. If accidentally released, these pathogens could cause catastrophic economic losses in the agricultural sector. The biocontainment area includes 40

[16]GAO, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132 (Washington, D.C.: Dec. 19, 2005).

[17]USDA conducts research on high-priority diseases affecting animals besides livestock, such as poultry, at other locations. For example, diseases like Newcastle disease and avian influenza, which affect poultry, are studied at USDA's Southeast Poultry Research Laboratory in Athens, Georgia. USDA's National Animal Disease Center in Ames, Iowa, studies indigenous diseases of livestock and poultry, including brucellosis. USDA performs diagnostics on these diseases at the National Veterinary Services Laboratories in Ames, Iowa.

rooms for livestock and is the only place in the United States that is equipped to permit the study of certain contagious foreign animal diseases in large animals. USDA uses this biocontainment area for basic research, for diagnostic work, and for the clinical training of veterinarians in the recognition of foreign animal diseases. DHS now shares bench space with USDA in the biocontainment area for its applied research. The North American Foot-and-Mouth Disease Vaccine Bank is also located on Plum Island.[18]

USDA was responsible for Plum Island until June 1, 2003, when provisions of the Homeland Security Act of 2002 were implemented that transferred Plum Island, including all its assets and liabilities, to DHS.[19] This action shifted overall responsibility for Plum Island to DHS, including all the costs associated with the facility's maintenance, operations, and security. The Act specified that USDA would continue to have access to Plum Island to conduct diagnostic and research work on foreign animal diseases, and it authorized the President to transfer funds from USDA to DHS to operate Plum Island.[20]

Plum Island is now operated as part of a broader joint strategy developed by DHS and USDA to protect against the intentional or accidental introduction of foreign animal diseases. Under the direction of DHS's Science and Technology Directorate, the strategy for protecting livestock also includes work at DHS's National Center for Food Protection and Defense and at its National Center for Foreign Animal and Zoonotic Disease Defense, as well as at other centers within the DHS homeland security biodefense complex. These include the National Biodefense Analysis and Countermeasures Center and the Lawrence Livermore National Laboratory. The strategy calls for building on the strengths of each agency's assets to develop comprehensive preparedness and response capabilities.

[18]There is no universal FMD vaccine that is effective for all subtypes of FMD. The United States stockpiles some FMD vaccines at the North American Foot-and-Mouth Disease Vaccine Bank on Plum Island. However, these vaccines are not stored in a "ready-to-use" state. That is, they are stored as a vaccine antigen concentrate that requires finishing in order to be used.

[19]Pub. L. 107-296, §310, 116 Stat. 2135, 2174 (2002), codified at 6 U.S. Code §190.

[20]6 U.S. Code §542(b)(3).

National Bio and Agro-Defense Facility

Homeland Security Presidential Directive 9 tasks the Secretary of Agriculture and the Secretary of Homeland Security to develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories for the research and development of diagnostic capabilities for foreign animal and zoonotic diseases. To partially meet these obligations, DHS has asked the Congress to appropriate funds to construct NBAF, a new facility. This facility would house high-containment laboratories able to handle the pathogens currently under investigation at PIADC, as well as other pathogens of interest.

DHS selected five potential sites for NBAF in July 2007 and must prepare an environmental impact statement (EIS) for each site.[21] According to DHS, although not included in the competitive selection process, the DHS-owned PIADC will now be considered as a potential NBAF site, and DHS will also prepare an EIS for Plum Island. (See table 1.)

Table 1: Final Candidate Sites for the Proposed National Bio and Agro–Defense Facility

Candidate	Site
Department of Homeland Security	Plum Island, N.Y.
Georgia Consortium for Health and Agro-Security	University of Georgia, Athens, Ga.
Gulf States Bio and Agro-Defense Consortium	Flora Industrial Park, Madison County, Miss.
Heartland Bio Agro Consortium	Kansas State University, Manhattan, Kans.
North Carolina Consortium for the NBAF	Umstead Research Farm, Granville County, N.C.
Texas Biological and Agro-Defense Consortium	Texas Research Park, San Antonio, Tex.

Source: DHS, http://www.dhs.gov/xres/labs/gc_1184180641312.shtm, and 72 Federal Register (July 31, 2007): 41764.

DHS has asked for public comment on the selection process. Following completion of the environmental impact statements and public hearings, DHS expects to choose a site by October 2008 and to open NBAF in 2014. According to DHS officials, the final construction cost will depend on the site's location and may exceed the currently projected $451 million. Additional expenses, such as equipping the new facility and relocating existing personnel and programs, may reach $100 million. DHS has not yet

[21]All federal agencies are required to comply with the National Environmental Policy Act, 1142 U.S. Code §§ 4321–4347. Under the act, agencies evaluate the likely environmental effects of projects that could significantly affect the environment.

determined what action to take with respect to PIADC when construction of NBAF has been completed.[22]

Evidence That FMD Work Can Be Conducted Safely on the U.S. Mainland Is Lacking

We found that DHS has neither conducted nor commissioned any study to determine whether FMD work can be done safely on the U.S. mainland. Instead, DHS relied on a study that USDA commissioned and a contractor conducted in May 2002 that examined a different question: whether it is technically feasible to conduct exotic disease research and diagnostics, including FMD and rinderpest, on the U.S. mainland with adequate biosafety and biosecurity to protect U.S. agriculture. [23] This approach fails to recognize the distinction between what is technically feasible and what is possible, given the potential for human error. DHS told us that this study has allowed it to conclude that it is safe to conduct FMD work on the U.S. mainland.

In addition to a number of other methodological problems with the study, we found that it was selective in what it considered in order to reach its findings.[24] In particular, the study

1. did not assess the history of releases of FMD virus or other dangerous pathogens,
2. did not address in detail the issues related to large animal work in BSL-3 Ag facilities, and
3. was inaccurate in comparing other countries' FMD work experience with that of the United States.

[22]The final disposition of the existing PIADC facilities and infrastructure, regardless of whether Plum Island is the selected site, is not known to us.

[23]SAIC, *United States Department of Agriculture Biocontainment Feasibility Studies, Study Report.* The study examined a number of other questions concerning a possible move of PIADC to the mainland, in addition to the questions on technical feasibility regarding biosafety and biosecurity.

[24]Among other things, (1) the study used an ad hoc method to select its expert panel that was not necessarily free from bias; (2) the study report was written by a single third-party person under contract for that purpose who was not present during the panel discussions; and (3) no concern was taken to ensure that the expert panel members reviewed either the draft or the final version of the report. At least one expert panel member expressed disappointment with the slant of the report.

A comprehensive analysis to determine if FMD work could be conducted safely on the U.S. mainland would have considered these points, at a minimum. DHS did not identify or remedy these deficiencies before using the USDA study to support its conclusions. Consequently, we believe DHS does not have evidence to conclude that FMD work can be done safely on the U.S. mainland.[25]

The Study Did Not Examine the Evidence from Past Releases of FMD or Other Dangerous Pathogens

We found no evidence that the study examined data from past releases of FMD—particularly the release of FMD on Plum Island in 1978—or the history of internal releases at PIADC. The study did not assess the general history of accidents within biocontainment laboratories, and it did not consider the lessons that can be learned from a survey of the causes of such accidents. Such a survey would show that technology and operating procedures alone cannot ensure against a release, since human error can never be completely eliminated and since a lack of commitment to the proper maintenance of biocontainment facilities and their associated technology—as the Pirbright facility showed—can cause releases.

The study panel members we interviewed said that no data on past accidents with or releases of either FMD or other pathogens was systematically presented or discussed. Rather, the panel members recalled that they relied on their own knowledge of and experience with the history of releases in a general discussion.

The release of FMD virus from facilities is very rare. In fact, the incidence of the release of any dangerous pathogen from modern containment facilities is quite low. During the vast majority of the time, such facilities have been operating safely. Some releases have occurred, however. Table 2 lists known and attributed releases of FMD virus from laboratories worldwide, including those that produce vaccines.

[25]As required by the National Environmental Policy Act, DHS must prepare an EIS for each of the six potential NBAF sites. DHS told us that each EIS will contain an analysis of site-specific environmental consequences, given, among other things, an accidental release of FMD at the site. However, DHS would not give us specifics on what this analysis will contain or which accident scenarios are being considered. DHS told us that the draft EIS for each site is due at the end of May 2008.

Table 2: Years Foot-and-Mouth Virus Is Known or Believed to Have Been Released from Laboratories

Year	Country
1960, Jan.	United Kingdom
1968	Denmark
1969	Czechoslovakia
1972	Hungary
1974	Germany
1975	Czechoslovakia
1976	Germany
1977	Germany
1978, Sept.	United States
1979	Spain
1987	Germany
1988	Germany
1993	Russia
2007, July	United Kingdom

Source: GAO analysis of UK's Department of Environment, Food, and Rural Affairs.

A particular deficiency in the 2002 USDA study was the omission of any explicit analysis of the release of FMD virus from Plum Island itself in 1978. In September of that year, FMD virus was found to have infected clean animals being held outside the laboratory compound in the quarantined animal supply area of PIADC. The exact route by which the virus escaped from containment and subsequently infected the animal supply was never definitely ascertained. An internal investigation concluded that the most probable routes of escape of the virus from containment were (1) faulty air balance of the incinerator area, (2) leakage through inadequately maintained air filter and vent systems, and (3) seepage of water under or through a construction barrier near the incinerator area. Animal care workers then most likely carried the disease back to the animal supply area on the island, where it infected clean animals being held for future work. (See table 3.)

Table 3: Deficiencies Noted as Contributing to a 1978 Release of FMD Virus at Plum Island

Issue	Deficiency
Air balance	Deficient recordkeeping
	Exhaust air filters in poor state of repair
	Improperly wired exhaust air handling units
	Failure to follow normal procedures
Exhaust air filters	Failure to inspect and test new filters after changing
	Failure to maintain filter gaskets
	Insufficient personnel
Movement of personnel	Change in procedures
New construction	Containment barrier removed before building replacement barrier
	Improperly built temporary construction barrier

Source: GAO analysis of USDA data.

An analysis of the deficiencies underlying these probable routes of escape noted during the investigation show that all were related to human error and that none were related to insufficient containment technology. Any one of these deficiencies could happen in a modern facility, since they were not a function of the technology or its sophistication, procedures or their completeness, or even, primarily, the age of the facility. The deficiencies were errors in human judgment or execution and, as such, could occur today as easily as they did in 1978.

In addition, a number of incidents at PIADC have resulted in internal releases such that animals within the laboratory compound inadvertently became infected, although no FMD virus was released outside the facility. These incidents show that technology sometimes fails, facilities age, and humans make mistakes. Table 4 lists known internal releases of FMD virus at PIADC since 1971.

Table 4: Internal Releases of Foot-and-Mouth Virus at Plum Island, 1971–2004

Date	Incident	Probable cause
Sept. 1971	A scientific publication in the proceedings of the 75th Annual Meeting of the U.S. Animal Health Association in 1971 identified the accidental infection of two steers. The infection was believed to have been caused by an air leak found in a door gasket. This resulted in an infectious aerosol being drawn into the room because of lower air pressure. Two steers in the acute clinical stage of infection with FMD had been moved through an adjacent corridor; 5 days later, the two steers maintained in the room had clinical signs and lesions of FMD of the same virus type as the animals in the adjacent corridor. The door seals in use at that time were not self-inflating. This problem is addressed today with inflatable seals that close the gap around doors and prevent aerosol entry.	An air leak in a door gasket
Apr.12, 1974	Two steers in the West Animal Wing developed symptoms of FMD. The animals had never been inoculated with intentionally exposed to any infectious agents, but both exhibited signs of disease and both were determined to be infected with FMD. An investigation determined that FMD probably came into the animal room through leaks in the walls. A power failure may also have resulted in a difference in pressure between two rooms, causing virus to flow from an infected room into the one housing the steer. Preventative maintenance of the rooms was conducted to prevent re-occurrence.	Leaks in the walls combined with a power failure
Aug. 21, 1980	Eighteen steers being used in a vaccine trial had been vaccinated with a Type C PIADC-produced FMD vaccine. Before challenge, approximately half the animals were found to have fever and lesions indicative of FMD. Further study identified that the animals had Type O and Type C antibodies. Because they had not been vaccinated for the Type O strain, these antibodies were related to an unknown exposure. The actual cause of this outbreak was not identified, but it could have been a mechanical transfer in which a laboratory worker carried the virus into the facility and transmitted it to the animals.	Mechanical transfer by a laboratory worker
Feb. 24, 1981	Four steers vaccinated 60 days earlier with FMD Type O were found to be infected with Type A. The actual cause of this incident was not identified; it was determined that cross-contamination from other areas in the laboratory was the most likely cause.	Cross-contamination from an unknown source
May 26, 1987	One of two Heifers housed in the East Animal Wing was found to be infected with FMD without previous inoculation or known exposure to the virus. On testing, the animal was found to be infected with FMD virus Type O. Investigation determined that Type O virus had been used in research experiments in two nearby rooms. The infected animals in these other rooms had been euthanized and the carcasses transported down the outside corridor. It was determined that the potential cause of the incident was fluids leaking during transport or an aerosol created from the bags used for transport. Negative air pressure in the animal room could then have resulted in cross-contamination from the hallway. Actions were taken to replace equipment used in transport and to decontaminate corridors more thoroughly.	Fluids leaking during transport of carcasses

Date	Incident	Probable cause
June 24, 2004	Two cattle in the East Wing, Room 1178, not involved in live virus research were observed with clinical signs of FMD. Testing identified them as being infected with Type O FMD. In addition, on July 19, 2004, four pigs in a separate, Orient Wing room not involved in live virus research were observed with clinical FMD. Subsequent testing revealed a different strain Type O. Although no specific cause was found for either incident, the most likely cause was cross-contamination from other areas in the laboratory. New animal care protocols were instituted to restrict direct access from the laboratories to the animal wings. The new protocols included a single point of entrance to animal wings for authorized personnel who had undergone extensive training in biosafety measures, laboratory clothing exchanged before entering the animal wing, mandatory showering on exiting from animal rooms (even if they contained uninfected animals), and decontamination of all laboratory samples coming in or being removed from the animal rooms. Since this new control was initiated, there have been no other instances of cross-contamination inside the animal wing.	Cross-contamination from an unknown source

Source: GAO analysis of DHS and USDA data.

These incidents involved human error, lack of proper maintenance, equipment failure, and deviation from standard operating procedures. Many were not a function of the age of the facility or the lack of technology and could happen in any facility today. While these incidents did not directly result in any external release, they could have been useful in the 2002 study in illustrating the variety of ways in which internal controls—especially in large animal biocontainment facilities—can be compromised.

Given the rarity of the release of FMD virus from laboratories, and how relevant its release is to the question of moving FMD work off its present island location, we believe that the 2002 study was remiss in not more explicitly considering this matter. In fact, members of the panel we spoke with could recall little, if any, discussion of incidents of release at Plum Island.

Beyond the history of incidents at Plum Island, we found no evidence that the study considered the history of accidents in or releases from biocontainment facilities generally. Had the study considered this history, it would have shown that no facility for handling dangerous pathogens can ever be completely safe and that no technology can be totally relied on to ensure safety.

The study found that "today's technology is adequate to contain any biosafety risks at any site."[26] While we agree that technology—biocontainment facilities, filtration technologies, and the like—has come a long way and is a critical component of biosafety, we believe that it is inadequate by itself in containing biosafety risks. A comprehensive biosafety program involves a combination of biocontainment technology, proper procedures, and properly trained people. The study also concurred that "biosafety is only as effective as the individual who practices it."[27]

Even with a proper biosafety program, human error can never be completely eliminated. Many experts told us that the human component accounts for the majority of accidents in high-containment laboratories. This risk persists, even in the most modern facilities and with the latest technology. The 2002 study, in fact, acknowledged this, although it did not elaborate on the critical role that people play in keeping biocontainment laboratories safe when it stated that "biosafety is only as effective as the individual who practices it." The study's summary conclusion that "biocontainment technology allows safe research" is, therefore, disingenuous.[28]

Finally, as we have reported previously, the maintenance of any biocontainment facility or technology plays a critical role in biosafety. [29] For example, the lack of proper maintenance was one of the probable routes of escape in the 1978 release at Plum Island. High-containment laboratories are highly sophisticated facilities that require specialized expertise to design, construct, operate, and maintain. Because they are intended to contain dangerous microorganisms, usually in liquid or aerosol form, even minor structural defects—such as cracks in the wall, leaky pipes, or improper sealing around doors—can often have severe consequences. For example, leaking drainage pipes was determined to be the likely cause of the FMD outbreak at Pirbright in 2007.

[26]SAIC, *United States Department of Agriculture Biocontainment Feasibility Studies, Study Report*, p. 16.

[27]SAIC, *United States Department of Agriculture Biocontainment Feasibility Studies, Study Report*, p. 16.

[28]SAIC, *United States Department of Agriculture Biocontainment Feasibility Studies, Study Report*, p. ii.

[29]GAO, *High Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T (Washington, D.C.: Oct. 4, 2007), pp. 22–23.

According to the experts we talked with, failure to budget for and conduct regular inspections and maintenance of biocontainment facilities is a risk to which even the most modern facilities are susceptible. All the experts we talked with, including the panel members who contributed to the 2002 study, emphasized the importance of effective maintenance and the need to protect maintenance budgets from being used for other purposes. One official told us, for example, that as his containment facility ages, he is spending more and more of his operating budget on maintenance and that, in fact, he is having to offset the rise in maintenance costs from other categories of funding within his overall budget.

The Study Did Not Address in Detail the Issues of Containment Related to Large Animals Infected with FMD

The 2002 study did not address in detail the issues of containment related to large animals like cattle and pigs, which present problems very different from those of laboratory animals like rats, mice, and guinea pigs. It did not address the unique risks associated with the special containment spaces required for large animals or the impact of highly concentrated virus loads on such things as the air filtration systems.

Large animals cannot be kept in containers. They must be allowed sufficient space to move around in. Handling large animals within confined spaces—a full size cow can weigh up to 1,430 pounds—can present special dangers for the scientists as well as the animal handlers. Moving carcasses from contained areas to necropsy or incineration poses additional risks. For example, one of the internal releases of FMD virus at PIADC happened in transporting large animal carcasses from contained rooms through to incineration.

Although it could not have been known to the study group in 2002, transferring FMD work to NBAF is to be accompanied by an increase in both scope and complexity over the current activities at PIADC. These increases in scope and complexity would mean an increase in the risk associated with work at the new facility. For example, the proposed BSL-3 Ag space at the new NBAF is projected to be almost twice the size of the space currently at PIADC and is to accommodate many more large animals. USDA's Agricultural Research Service animal holding area requirements at PIADC specify space for 90 cattle, 154 swine, or 176 sheep (or combinations thereof). Translational studies will involve clinical trials with aerosolized FMD virus challenging groups of 30 to 45 animals and

lasting 3 to 6 months. This is contrasted with about 16 large animals that PIADC can process today.[30]

Moreover, unique risks are associated with BSL-3 Ag facilities, where the facility itself is considered the primary containment area. In a standard BSL-3 laboratory, in contrast, work is done within a biological safety cabinet, which provides the primary level of containment, eliminating direct contact between the human operator and infected material. The outer parts of the facility walls thus provide a secondary barrier. Because large animals cannot be handled within a biological safety cabinet, they are free to move around in a BSL-3 Ag laboratory, where the laboratory walls provide the primary containment.[31]

An important difference between a standard BSL-3 laboratory, such as those used with human pathogens, and a BSL-3 Ag laboratory therefore is that in the latter there is extensive direct contact between the human operator and the infected animal and, consequently, the virus. Because the virus can be carried in a person's lungs, nostrils, or other body parts, the human becomes a potential avenue by which the virus can escape the facility. Special biosafety procedures are needed—for example, a full shower upon exiting containment, accompanied by expectorating to clear the throat and blowing through the nose to clear the nasal passages. Additionally, a 5-to-7-day quarantine period is usually imposed on any person who has been within containment where FMD virus is present, a tacit acknowledgment that humans can carry the disease out with them even after these additional procedures. Although the study mentioned these matters, it gave no indication that these unique risks associated with working in large animal biocontainment facilities informed the study's eventual findings.

We also found that the study did not consider other safety issues specific to FMD. For example, the study did not look at the likely loads that air filtration systems have to deal with, especially in the case of pigs infected with FMD virus—which, through normal expiration, excrete very large amounts of virus-laden aerosols. Properly fitted and maintained high-

[30]In addition to an increase in the number of large animals being processed, the new facility is to house a vaccine production plant with a capacity of up to 30 liters—a significant increase in volume of FMD virus than is handled at PIADC.

[31]In some cases, a BSL-3 Ag facility can be placed within another containment area for additional protection.

efficiency particulate air (HEPA) filters are a key factor in all modern biocontainment facilities and have a record of being highly effective in keeping aerosolized pathogens, including viruses, contained. Nevertheless, they do not represent an absolute barrier. The typical standard for such filters is that they must operate with an efficiency of at least 99.97 percent.[32] Often the highest level-containment laboratories use two HEPA filters in series, in addition to prefiltration systems, to gain increased efficiency. However, we found no indication that the study examined specific filtration issues with the FMD virus or that it questioned the efficiency of such systems specifically in relation to a high-volume challenge of virus, a concern that, while remote, should not have been dismissed, given the very low dose of FMD virus required for animals to become infected.[33]

The Study Was Inaccurate in Comparing Other Countries' FMD Work Experience with the Situation in the United States

The study cited the experience of three countries around the world in working with FMD—Australia, Canada, and the United Kingdom. While the study cited Australia as a foreign precedent, it noted that Australia has not conducted any FMD work on the mainland. In fact, Australia—by law—does not allow any FMD work on the mainland. In this respect, it is even more restrictive than the United States. Australia maintains a ban on live virus FMD work at all its laboratories, whether on mainland, island, or peninsula, including the laboratory at Geelong—considered by many to be the premier laboratory in the world in terms of state-of-the-art animal containment technology. Australia mitigates the risk FMD poses to its livestock by outsourcing its FMD work to other countries.[34]

The Canadian laboratory at Winnipeg was not in operation at the time of the 2002 study and is not appropriately compared to the U.S. situation. Canada has decided to conduct FMD work on the mainland. However, it is in a downtown location where there is little likelihood that susceptible

[32]Institute of Environmental Sciences and Technology, IEST-RP-CC001.3 and MIL-STD-282 Method 102.9.1, are typical standards applied for HEPA filtration. It has been shown that because of the unique design of HEPA filters, they are least efficient around the 0.3 micron particle size and the efficiency benchmark of 99.97 is applied at that particle size.

[33]Few, if any, empirical studies examin the true efficiency of HEPA filtration against a specific challenge of FMD virus. One expert in airborne transmission of FMD virus told us that while it is theoretically possible for transmission through HEPA filters to occur, to his knowledge there has never been a documented case.

[34]Australia contracts, for example, with laboratories in Thailand for its live FMD research and challenge work.

animals will be in the immediate neighborhood. In addition, its scope of work for FMD is smaller than the present FMD work at the PIADC facility or the proposed facility. The proposed U.S. sites are potentially more likely to pose a risk, given their closer proximity to susceptible animal populations.

The 2002 study used the U.K. Pirbright facility as an example of a precedent for allowing FMD work on the mainland. The study participants could not have known in 2002, however, that an accidental release of FMD virus at the Pirbright facility in 2007 led directly to eight separate outbreaks of FMD on farms surrounding the Pirbright laboratory. This fact highlights the risks of release from a laboratory that is in close proximity to susceptible animals and provides the best evidence in favor of an island location.

Finally, the study did not consider the German and Danish situations. For example, all FMD work with large animals in Germany is restricted to Riems, an island just off the northeastern coast of Germany in the Baltic Sea.[35] FMD work in Germany was originally restricted to the island in the1910s. During the post-World War II period, when Riems was controlled by East Germany, West Germany maintained a separate mainland facility for its FMD research, but after re-unification, Germany again decided to restrict all FMD research to Riems and disestablished the mainland facility. Construction is currently under way to expand the facility on the island at Riems.

Similarly, Denmark restricts all FMD work to the National Veterinary Institute Department of Virology, on the island of Lindholm. The Danish government has recently made a further commitment to Lindholm and has rebuilt a new BSL-3 Ag laboratory exclusively for FMD work on the island.

[35] The character of the island has changed over time. Whereas in the past, it could only be reached by boat or suspended cablecar, since 1971 it is connected to the mainland by a causeway. For ecological reasons this has been interrupted in late 2007 by construction of a roadbridge so that access to the island is still possible.

Given That Releases Can Occur from Any Biocontainment Facility, an Island Location Can Provide Additional Protection

While location confers no advantage in preventing a release, location can help prevent the spread of FMD virus and a resulting disease outbreak, if there is a release. An island location can help prevent the spread of FMD virus along terrestrial routes, such as by vehicles splashed with contaminated mud or other material. An examination of the empirical evidence of past FMD releases from research facilities shows that an island location can help keep a release from becoming a more general outbreak. Another benefit of an island location is that it provides a permanent geographical barrier that may not be impregnable but that can more easily allow the Office International des Epizooties (OIE) to declare the rest of the U.S. mainland disease-free from FMD if there happened to be a release on the island.[36]

Experts we spoke with—including a number of the expert panel members from the 2002 study—agreed that an island location provides additional protection. They agreed that all other factors being equal, FMD research can be conducted more safely on an island than in a mainland location.[37]

A comparison of the releases at Plum Island in 1978 and Pirbright in 2007 provides evidence that an island location can help keep a release from becoming a more general outbreak. In September 1978, FMD virus was found to have been released from containment at PIADC. The exact route of escape was never definitely ascertained, but clean animals held on the island in the animal supply area outside the laboratory compound became infected with FMD.

However, no virus was ever found off the island. In fact, when the subsequent investigation by USDA's Animal and Plant Health Inspection Service on the mainland of Long Island found that no spread of FMD,

[36]OIE is the intergovernmental organization responsible for improving animal health worldwide. The need to fight animal diseases at the global level led to the creation of the Office International des Epizooties through an international agreement signed on January 25, 1924. In May 2003, OIE became the World Organisation for Animal Health but kept its identity as OIE.

[37]The members of the expert panel involved in the 2002 study we talked with told us that the advantages of an island location had not been extensively considered. Rather, the discussion focused on the availability of modern facilities and technology and the fact that they can be built anywhere. One expert summarized the discussion by saying that the safety risk had been "put to rest" by the availability of modern biocontainment facilities. However, we found that the consensus that FMD work could be moved safely to the mainland was not unanimous among the panel members and that there was at least one member in dissension, a fact that was missing from the written report.

OIE—in consideration of PIADC's island location—continued to officially consider the United States as a whole free from FMD. This was a significant declaration that allowed the continued unrestricted export of U.S. animal products from the mainland.

In summarizing the 1978 FMD virus release, the PIADC Safety Investigation Committee identified three main PIADC lines of defense that stood as barriers against the escape of disease agents: (1) the design, construction, and operation of its laboratory buildings; (2) its restrictions on the movement of personnel, materials, supplies, and equipment; and (3) the island location.[38] This internal investigation concluded that although the first two barriers had been breached, probably by human error, the final line of defense—the island location—succeeded in containing the release from becoming a wider outbreak beyond PIADC itself.

The 1978 release at Plum Island can be compared to the release at Pirbright in the summer of 2007. Pirbright is located on the mainland of Great Britain in Surrey, a semi-agricultural area just southwest of London. The U.K. Institute for Animal Health and Merial, a commercial vaccine production plant, are collocated there, and both work with FMD virus. The site is surrounded by a number of "hobby farms," on some of which 40 to 50 cattle are bred and raised. In summer 2007, cattle on farms near the Pirbright facility became infected with FMD. Subsequent investigations concluded that the likely source of the release was a leaking drainage pipe at the facility that carried waste from the contained areas to an effluent treatment plant. The virus was then spread onto local farms by the splashing of contaminated mud onto vehicles that had unrestricted access to the contaminated area and could easily drive onto and off the site. The investigations determined that there had been a failure to properly maintain the site's infrastructure. In all, eight separate outbreaks occurred over a 2-month period.

A key difference, of course, between the Pirbright incident in 2007 and the incident at Plum Island in 1978 is that virus did not spread off the Plum Island.

[38]"Final Committee Report: Exploratory Analysis—FMD Outbreak in Animal Supply, Memorandum from PIADC Safety Investigation Committee to Director J. J. Callis, January 9, 1979.

Similarly, escapes in 1968 in Denmark from the Lindholm facility and in the 1970s in Germany from the Riems facility, when compared to Pirbright in 2007, also demonstrate the benefit of an island location in containing a release.

An Island Facility Could More Easily Allow the United States to Maintain Disease-Free Status If a Release Were to Occur

Since 1996, OIE has provided a procedure for officially recognizing the sanitary status of countries with regard to particular animal diseases, including FMD. A country can apply for and be granted disease-free status if it can prove that a disease is not present in the country. Ad hoc groups of international experts examine countries' applications for official recognition of sanitary status. An elected Specialist Commission reviews the recommendations of these groups and either accepts or rejects them.

If an outbreak does occur, procedures exist for countries to regain their disease-free status. This offers significant economic benefit, because export bans can exist for countries not considered disease-free. In 2002, GAO reported that an export ban on U.S. livestock products because of an FMD outbreak in the United States, similar to the 2001 outbreak in the United Kingdom, could result in losses of $6 billion to $10 billion a year while the nation eradicated the disease and regained disease-free status.[39]

Instead of revoking the U.S. disease-free status in response to the 1978 release at Plum Island, OIE continued to consider the United States as a whole free from FMD. This was because of the facility's island location. This status from OIE allowed the United States to continue exporting animal products from the mainland after the release was identified. However, these OIE officials said that if a similar release were to occur from a facility on the U.S. mainland, OIE would most likely not be able to declare the United States disease-free.[40] In their view, the island location provides a natural "zoning" ability that, under OIE's rules, more easily allows the country to prove the compartmentalization that is necessary for retaining "disease-free" status.

[39]GAO-02-808, p. 20.

[40]The specific geographic features surrounding the release site would have to be considered, but speaking generally about the U.S. Central Plains, these officials said it would be difficult for the United States to retain a disease-free status given a release from a facility in such a location.

The Economic Consequences of an FMD Outbreak in the United States Could Be Significant

While humans cannot become infected with FMD through contact with infected animals or through eating products of diseased animals, still, FMD can have economic consequences, as recent outbreaks in the United Kingdom have demonstrated. Although estimates vary, experts agree that the economic consequences of an FMD outbreak on the U.S. mainland could be significant, especially for red meat producers whose animals would be at risk for diseases, depending on how and where such an outbreak occurred.

The Economic Impact of the 2001 FMD Outbreak in the United Kingdom

According to a study by the U.K. National Audit Office, the direct cost of the 2001 FMD outbreak to the public sector was estimated at over $5.71 billion and the cost to the private sector was estimated at over $9.51 billion.[41] By the time the disease was eradicated, in September 2001, more than six million animals had been slaughtered: over four million for disease control purposes and two million for welfare reasons.[42]

Compensation and other payments to farmers were expected to total nearly $2.66 billion. Direct costs of measures to deal with the epidemic, including the purchase of goods and services to eradicate the disease, were expected to amount to nearly $2.47 billion. Other public sector costs were estimated at $0.57 billion.[43]

In the private sector, agriculture and the food chain and supporting services incurred net costs of $1.14 billion. Tourism and supporting industries lost revenues eight times that level—$8.56 billion to $10.27 billion, when the movement of people in the countryside was restricted. The Treasury had estimated that the net economic effect of the outbreak was less than 0.2 percent of gross domestic product, equivalent to less than $3.8 billion.[44]

[41]Comptroller and Auditor General, *The 2001 Outbreak of Foot and Mouth Disease* (London: National Audit Office, June 21, 2002).

[42]The 2001 outbreak of FMD spread to France, the Republic of Ireland, the Netherlands and Northern Ireland. However, the NAO study did not include the cost incurred by these countries.

[43]We have converted the British pound to 2001 U.S. dollars and then we adjusted to current value.

[44]The total cost to the country was estimated at $30.4 billion at current values.

The Potential Impact of an FMD Outbreak in the United States

The possibility of the introduction of FMD into the United States is of concern because this country has the largest fed-cattle industry in the world, and it is the world largest producer of beef, primarily high-quality, grain-fed beef for export and domestic use.

Although estimates of the losses vary, experts agree that the economic consequences of an FMD outbreak on the U.S. mainland could mean significant losses, especially for red meat producers, whose animals would be at risk for disease, depending on how and where an outbreak occurred. Current estimates of U.S. livestock inventories are 97 million cattle and calves, 7 million sheep, and 59 million hogs and pigs, all susceptible to an FMD outbreak. The total value of the cash receipts for U.S. livestock in 2007 was $141.4 billion. The total export value of red meat in 2007 was $6.4 billion. These values represent the upper bound of estimated losses.

Direct costs to the government would include the costs of disease control and eradication, such as the maintenance of animal movement controls, control areas, and intensified border inspections; the destruction and disposal of infected animals; vaccines; and compensation to producers for the costs of disease containment. However, government compensation programs might not cover 100 percent of producers' costs. As a result, direct costs would also occur for disinfection and for the value of any slaughtered animals not subject to government compensation.

According to the available studies, the direct costs of controlling and eradicating a U.S. outbreak of FMD could vary significantly, depending on many factors including the extent of the outbreak and the control strategy employed.

Indirect costs of an FMD outbreak would include costs affecting consumers, ancillary agricultural industries, and other sectors of the economy. For example, if large numbers of animals were destroyed as part of a control and eradication effort, then ancillary industries such as meat processing facilities and feed suppliers would be likely to lose revenue.

Furthermore, an FMD outbreak could have adverse effects such as unemployment, loss of income (to the extent that government compensation would not fully reimburse producers), and decreased economic activity, which could ripple through other sectors of the economy as well. However, our analyses show that these effects would likely be local or regional and limited in scope.

The economic effects of an FMD outbreak would depend on the characteristics of the outbreak and how producers, consumers, and the government responded to it. The scale of the outbreak would depend on the time elapsed before detection and the number of animals exposed, among other factors. Costs to producers of addressing the disease outbreak and taking steps to recover would similarly vary. The responses of consumers in the domestic market would depend on their perceptions of safety, as well as changes in the relative prices of substitutes for the affected meat products, as supply adjusted to the FMD disruption. In overseas markets, consumers, responses would be mediated by the actions their governments would take or not take to restrict imports from the United States. Because an overall estimate of effects depends heavily on the assumptions made about these variables, it is not possible to settle on a single economic assessment of the cost to the United States of an FMD outbreak. We have reviewed literature that considers but a few of the many possible scenarios in order to illustrate cost components and to consider the possible market reaction rather than to predict any particular outcome.

Conclusions

DHS believes that modern technology, combined with biosafety practices, would provide for a facility's safe operation on the U.S. mainland. Most experts we talked with believe that technology has made laboratory operations safer over the years. However, accidents, while rare, still occur because of human or technical errors. Given the non-zero risk of a release from any biocontainment facility, most of the experts we spoke with told us that an island location can provide additional protection.

DHS has not conducted any studies to determine whether FMD work can be done as safely on the mainland as on Plum Island. Instead, in deciding to move FMD virus to the mainland, DHS relied on a 2002 USDA study that addressed a different question. Consequently, that study does not clearly support the conclusion that FMD work can be done safely on the mainland.

Given the non-zero risk of a release from any biocontainment facility, most of the experts we spoke with told us that an island location can provide additional protection. An island location can help prevent the spread of FMD virus along terrestrial routes of escape, such as by vehicles splashed with contaminated mud, and may also reduce airborne transmission. Historically, the United States and other countries as well have seen the benefit of an island location, with its combination of remoteness from susceptible species and a permanent water barrier.

Although FMD has no human-health implications, it can have enormous economic consequences, as recent outbreaks in the United Kingdom have demonstrated. Although estimates vary, experts agree that the economic consequences of an FMD outbreak on the U.S. mainland could be significant, with losses in the tens of billions of dollars, depending on how and where such an outbreak occurred.

Contacts and Acknowledgements

For further information regarding this statement, please contact Nancy Kingsbury, Ph.D. at (202) 512-2700 or kingsburyn@gao.gov, or Sushil K. Sharma, Ph.D., Dr.PH, at (202) 512-3460 or sharmas@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. William Carrigg, Jack Melling, Penny Pickett, and Elaine Vaurio made key contributions to this statement.

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