United States Government Accountability Office

GAO

Report to Congressional Committees

July 2009

BIOLOGICAL RESEARCH

Observations on DHS's Analyses Concerning Whether FMD Research Can Be Done as Safely on the Mainland as on Plum Island

The electronic version of this report was reposted July 30, 2009, to correct errors in table 6.

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GAO-09-747

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Abbreviations

BKC	Biodefense Knowledge Center
BSL	biosafety level
BSL-3-Ag	biosafety level 3 agricultural
DHS	U.S. Department of Homeland Security
EIS	environmental impact statement
EPA	Environmental Protection Agency
FMD	foot-and-mouth disease
HCL	high-containment laboratory
HPAC	Hazard Prediction and Assessment Capability
HSPD-9	Homeland Security Presidential Directive 9
LLNL	Lawrence Livermore National Laboratory
MIT	Massachusetts Institute of Technology
MM5	Mesoscale Model version 5
NASS	National Agricultural Statistics Service
NBAF	National Bio- and Agro-Defense Facility
NCAR	National Center for Atmospheric Research
NOAA	National Oceanic and Atmospheric Administration
OIE	World Organisation for Animal Health
PIADC	Plum Island Animal Disease Center
USDA	U.S. Department of Agriculture

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United States Government Accountability Office
Washington, DC 20548

July 30, 2009

Congressional Committees

Foot-and-mouth disease (FMD) is the most highly infectious animal disease known: nearly 100 percent of exposed animals become infected with it.[1] Although the United States has not had an outbreak of FMD since 1929, a single outbreak of FMD virus as a result of an accidental or intentional release from a laboratory on the U.S. mainland could have significant consequences for U.S. agriculture. The traditional approach to the disease, once infection is confirmed, is to depopulate infected and potentially infected livestock herds to eradicate the disease. The value of U.S. livestock sales was $140 billion in 2007; about 10 percent of this figure, or approximately $13 billion, was accounted for by export markets.

The Plum Island Animal Disease Center (PIADC), on a federally owned island off the northern tip of Long Island, New York, is the only facility in the United States that studies the live FMD virus. The U.S. Department of Agriculture (USDA) was responsible for the PIADC from its opening in the 1950s until June 2003, when USDA transferred responsibility for it to the U.S. Department of Homeland Security (DHS), as required by the Homeland Security Act of 2002.[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 the PIADC.[3] Also, under Homeland Security Presidential Directive 9 (HSPD-9), the secretary of Agriculture and the secretary of Homeland Security are to develop a plan to provide safe, secure, and state-of-the-art agricultural biocontainment

[1]FMD is a highly contagious and easily transmissible animal disease that affects cattle, sheep, goats, pigs, and other cloven-hoofed animals. It occurred in most countries of the world at some point during the past century and continues to occur throughout much of the world; although some countries have been free of FMD for some time, its wide host range and rapid spread constitute cause for international concern.

[2]Public Law 107-296, § 310, 116 Stat. 2135, 2174 (Nov. 25, 2002), *codified at* 6 U.S.C. § 190.

[3]See 6 U.S.C. § 542(b)(3).

laboratories for researching and developing diagnostic capabilities for foreign animal and zoonotic diseases.[4]

On January 19, 2006, DHS announced that to meet its obligations under HSPD-9, it would construct and operate a new facility—the National Bio- and Agro-Defense Facility (NBAF)—containing several biosafety level 3 (BSL-3) laboratories, BSL-3 agricultural (BSL-3-Ag) laboratories, and biosafety level 4 (BSL-4) laboratories. FMD research is to be performed in a BSL-3-Ag laboratory.[5] When fully operational, the NBAF is meant to replace the PIADC.[6] The primary research and diagnostic focus at the PIADC is foreign or exotic diseases, including FMD virus, that could affect livestock, including cattle, pigs, and sheep. DHS stated that the PIADC was "nearing the end of its life cycle" and was lacking critical capabilities to continue as the primary facility for such work. Another reason DHS cited was the need to be close to research facilities. According to DHS, although the PIADC coordinates with many academic institutes throughout the northeast, its isolated island location means that few academic institutes are within a reasonable commuting distance; DHS believes that these are needed to provide research support and collaboration required for the anticipated NBAF program.

We testified in May 2008 that (1) studies that DHS cited in support of its conclusion that FMD work can be done as safely on the mainland did not specifically examine a possible FMD virus release and (2) DHS had not conducted or commissioned studies to show that FMD virus work can be

[4]HSPD-9 also mandates that 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, "accelerate and expand the development of countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases." Homeland Security Presidential Directive (HSPD) 9, "Defense of United States Agriculture and Food," The White House, Washington, D.C., Jan. 30, 2004, secs. 23 and 24. www.dhs.gov/xabout/laws/gc_1217449547663.shtm

[5]BSL-3-Ag is unique to agriculture, whose studies employ large agricultural animals where the facilities' barriers serve as the primary containment.

[6]The NBAF's mission is to allow for basic research, diagnostic testing and validation, countermeasure development (i.e., vaccines and antiviral therapies), and diagnostic training for high-consequence livestock diseases with potentially devastating impacts to U.S. agriculture and threats to public health.

done safely on the mainland.[7] In response, DHS stated that the results of its forthcoming draft environmental impact statement (EIS) on the site proposed for the NBAF would provide the evidence needed to assess whether FMD research can be conducted safely on the U.S. mainland.

On June 27, 2008, DHS published the notice of availability for the NBAF draft EIS in the *Federal Register*, soliciting public comments. On December 12, 2008, DHS published a notice of availability for the NBAF final EIS in the *Federal Register*, and on January 16, 2009, it published its decision to construct the new NBAF at a site in Manhattan, Kansas, to replace the PIADC, based on the information and analysis in the final EIS and other factors.

We are doing this work to respond to the statutory mandate in the fiscal year 2009 appropriations act for DHS (Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (Public Law 110-329)). The act restricted DHS's obligation of funds for constructing the NBAF on the mainland until DHS completed a risk assessment on whether FMD work can be done safely on the U.S. mainland and we reviewed DHS's risk assessment. In our review, we specifically assessed the evidence DHS used to conclude that work with FMD can be conducted as safely on the U.S. mainland as on Plum Island, New York.

To accomplish this task, we reviewed agencies' documents, including the draft and final EIS, threat and risk assessment, and studies conducted by DHS's Biodefense Knowledge Center (BKC) at Lawrence Livermore National Laboratory (LLNL).[8] We also reviewed relevant legislation and regulations governing USDA and DHS and literature on FMD and high-containment laboratories (HCL). We interviewed officials from the DHS Office of Science and Technology and USDA Agriculture Research Service. We visited the PIADC, where we examined animal containment areas and unique aspects of the island location, and we talked with DHS and USDA officials who oversee and operate the facility. We also talked with the

[7]GAO, *High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland*, GAO-08-821T (Washington, D.C.: May 22, 2008).

[8]The BKC was established in 2004 at LLNL to develop a new distributed knowledge management infrastructure for anticipating, preventing, and responding to biological terrorism. It serves as a national clearinghouse for biological threat agent knowledge to ensure that timely, authoritative, and actionable biodefense information is available to persons with a need to know.

contractors who performed the dispersion modeling and with officials of BKC who analyzed the potential impact of an accidental release of FMD virus from each proposed facility. We also talked with experts on animal diseases and HCLs dealing with animal, zoonotic, and human pathogens.

We consulted with large-animal veterinarians and agriculture economists. We talked with officials of the Interagency Modeling and Atmospheric Assessment Center at LLNL, the Defense Threat Reduction Agency, the National Ground Intelligence Center of the U.S. Army, the Risø National Laboratory for Sustainable Energy at the Technical University of Denmark, and the Division of Meteorological Model Systems of the Danish Meteorological Institute, as well as other experts on plume modeling.

We also visited other facilities that conduct FMD work, including Denmark's National Veterinary Institute on Lindholm Island, Germany's Federal Research Institute for Animal Health (Friedrich-Loeffler-Institut) on the Island of Riems, and the United Kingdom's Institute for Animal Health Pirbright Laboratory. We also talked with officials at the Australian Animal Health Laboratory in Geelong and Canada's National Centre for Foreign Animal Disease in Winnipeg. In addition, we talked with officials of the World Organisation for Animal Health (OIE) in France.

We conducted our work from October 2008 through May 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform an audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. We believe that the evidence we obtained provides a reasonable basis for our findings and conclusions, based on our audit objectives.

Background

The Foot-and-Mouth Disease Virus

FMD is a highly infectious disease that affects cloven-hoofed animals, including livestock such as cattle, sheep, goats, and pigs. FMD virus has seven serotypes and many subtypes.[9] Immunity to or vaccination for one

[9]The seven FMD serotypes—or closely related microorganisms distinguished by a characteristic set of antigens—are O, A, C, SAT-1, SAT-2, SAT-3, and Asia-1. They show some regionality, O being the most common.

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 abortion. Cattle and pigs, which are very sensitive to the virus, show disease symptoms after a short incubation period of 3 to 5 days. In sheep, the incubation period is considerably longer, about 3 to 12 days, and the clinical signs of the disease are usually mild and may be masked by other diseases, allowing FMD to go unnoticed.

The mortality rate for young animals infected with FMD depends on the species and strain of the virus. Adult animals usually recover once the disease has run its course, but because FMD 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. Thus, the disease can cause severe losses in the production of meat and milk.

FMD virus is easily transmitted and spreads rapidly. Before and during the appearance of clinical signs, infected animals release it into the environment through respiration, milk, semen, blood, saliva, and feces. The virus may become airborne and spread quickly when animals become infected. The virus replicates prolifically in pigs, so that they release large amounts of the virus into the air. Animals, people, or materials 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 animal products (meat, milk, hides, skins, manure); transport vehicles and equipment; clothes or shoes; and hay, feed, or veterinary biologics.

FMD Outbreaks

FMD outbreaks occurred in most countries of the world during the twentieth century. Although some countries have been free of FMD for some time, its wide host range and rapid spread constitute cause for international concern. After World War II, the disease was widely distributed around the world. In 1996, endemic areas included Africa, Asia, and parts of South America. In North America, the last outbreaks of FMD for the United States, Mexico, and Canada were in 1929, 1946, and 1952, 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.

However, in the United Kingdom, a major outbreak in 2001 resulted in more than 6 million animals being slaughtered. Another outbreak in the United Kingdom in 2007 resulted from an accidental release of FMD virus at the Institute of Animal Health's Pirbright Laboratory, leading directly to eight separate outbreaks of FMD on surrounding farms that summer (Pirbright Laboratory is near the village of Pirbright, near Guildford, Surrey, just southwest of London). Both Pirbright Laboratory and Merial Animal Health Ltd., a commercial vaccine production plant, are at Pirbright and work with FMD virus. They are surrounded by a number of "hobby farms," where 40 to 50 cattle are bred and raised.[10] In all, eight separate outbreaks occurred over 2 months.

The Economic Consequences of an Outbreak

While FMD has no health implications for humans, it can have significant economic consequences, as the recent outbreaks in the United Kingdom demonstrated. The economic effects of an FMD outbreak in the United States would depend on its characteristics and on how producers, consumers, and the government responded. 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 and pork producers whose animals would be at risk for diseases, depending on how and where such an outbreak occurred.

Agriculture Biosafety Levels: Animals of Agricultural Significance

Risk assessment and management guidelines for agriculture differ from human public health standards. Risk management for agricultural research is based on the potential economic impact of animal and plant morbidity and mortality and the trade implications of disease. Worker protection is important, but great emphasis is placed on reducing the risk of an agent's escape into the environment. BSL-3-Ag is unique to agriculture because of the need to protect the environment from economic, high-risk pathogens where facilities study large agricultural animals or a facility's barriers serve as the primary containment.

BSL-3-Ag facilities are specially designed, constructed, and operated with unique containment features for research involving certain biological

[10]Investigations concluded that the likely source of the 2007 release was a leaking drain pipe at Pirbright that carried waste from contained areas to an effluent treatment plant. The virus then spread to local farms by contaminated mud splashing onto vehicles that, having unrestricted access to the contaminated area, easily drove on and off the site. The investigations found a failure to properly maintain the site's infrastructure.

agents in large animal species. Specifically designed to protect the environment, they include almost all features ordinarily used for BSL-4 facilities as enhancements. All BSL-3-Ag containment spaces must be designed, constructed, and certified as primary containment barriers. There may be enhancements beyond the BSL-3 and Animal Biosafety Level-3 that USDA's Animal and Plant Health Inspection Service may require for work with certain veterinary agents of concern conducted in primary containment devices (i.e., work with cultures or small animals).

The Plum Island Animal Disease Center

The PIADC is a federally owned research facility on Plum Island—an 840-acre island off the northeastern tip of New York's Long Island. PIADC scientists are responsible for protecting U.S. livestock against foreign animal diseases that could be accidentally or deliberately introduced into the United States. The PIADC's research and diagnostic activities stem from its mission to protect U.S. animal industries and exports from the accidental or deliberate introduction of foreign animal diseases. USDA's scientists identify pathogens that cause foreign animal diseases and develop vaccines to protect livestock at the PIADC. Its primary research and diagnostic focus is foreign or exotic diseases that could affect livestock such as FMD, classical swine fever, and vesicular stomatitis.[11]

Because some pathogens maintained at the PIADC are highly contagious, research on them is conducted in a biocontainment area that has special safety features designed to contain them. Its BSL-3-Ag includes 40 rooms for livestock and is the only place in the United States used to conduct research on live FMD virus. Unique risks are associated with BSL-3-Ag facilities because large animals are not handled within a biological safety cabinet; they are free to move around within a room inside a laboratory-secured facility whose walls provide the primary containment.

Another important distinction in a BSL-3-Ag laboratory is the extensive direct contact between human operators and infected animals. Because the virus can be carried in a person's lungs or nostrils or on other body parts, humans are a potential avenue for the virus to escape the facility.[12]

[11]Classical swine fever, also known as hog cholera and swine fever, is a highly contagious viral disease of swine. Vesicular stomatitis is a viral disease characterized by fever, vesicles, and subsequent erosions in the mouth and epithelium and on the teats and feet. Horses, cattle, and pigs are naturally susceptible; sheep and goats are rarely affected.

[12]Special biosafety procedures are needed—for example, a full shower on leaving the containment area, accompanied by expectorating to clear the throat and blowing through the nose to clear the nasal passages. Additionally, a 5-to-7-day quarantine is usually imposed on any person who has been within a containment where FMD virus is present.

An additional key feature of FMD virus research is that because the virus rarely causes infection in humans, FMD virus containment practices are designed to protect susceptible domestic animals and wildlife rather than humans from exposure to the virus. 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 at the PIADC.

DHS's Reasons for Considering Relocation

DHS has stated that the PIADC is nearing the end of its life cycle and lacks critical capabilities to continue as the primary facility for such work. According to DHS, the nation's national biodefense and agrodefense capabilities are inadequate to meet future research requirements supporting both agricultural and public health national security. Foreign animal disease studies; public health threats from emerging, high-consequence zoonotic pathogens; and the need to develop and license medical countermeasures have generated additional demands for biocontainment laboratory space.

Legislation Allowing FMD Work on the Mainland

Until 2008, live FMD virus could by law be used only on a coastal island, such as Plum Island, unless the secretary of Agriculture specifically determined it necessary and in the public interest to conduct such research and study on the U.S. mainland.[13] Section 7524 of the Food, Conservation, and Energy Act of 2008 directed the secretary of Agriculture to issue a permit to the secretary of Homeland Security for work on live FMD virus at any facility that is a successor to the PIADC and charged with researching high-consequence biological threats involving zoonotic and foreign animal diseases.[14] The permit is limited to one facility.

DHS's Site Selection Process for the NBAF

DHS began its site selection process for the NBAF with a solicitation of expressions of interest for potential sites in Federal Business Opportunities on January 17, 2006, and the *Federal Register* on January 19, 2006.[15] Having received 29 submissions by the March 31, 2006, deadline, DHS used four evaluation criteria to reduce the number of sites to 18: (1) proximity of the suggested site to research capabilities; (2) proximity to

[13] 21 U.S.C. § 113a.

[14] Public Law 110-246, 122 Stat. 1651 (June 18, 2008).

[15] Federal Business Opportunities, or FBO.gov, is a virtual marketplace in which "commercial vendors and government buyers may post, search, monitor, and retrieve opportunities solicited by the entire federal contracting community." See FedBizOpps.gov at www.fbo.gov.

work force; (3) acquisition, construction, and operations requirements; and (4) community acceptance. In the 2006 *Federal Register* notice, the four evaluation criteria are described as follows.[16]

Research capabilities include proximity to (1) existing research programs (medical, veterinary, or agricultural) that can be linked to NBAF mission requirements, (2) strength and breadth of the scientific community and infrastructure, (3) ability of the proposed site and surrounding community to absorb additional research programs and infrastructure, (4) experience of existing research programs with BSL-3 or BSL-4 agents, (5) proximity to other related scientific programs and research infrastructure, and (6) proximity to vaccine industry capability.

Workforce includes proximity to (1) a critical mass of intellectual research capacity, (2) recruiting opportunities for research staff, (3) local labor force for operations staff with expertise in operating a biocontainment facility, and (4) capability to meet mutual aid (police, fire services, or hospital) requirements to operate the facility and meet physical security requirements for a BSL3/4 facility.

Acquisition, construction, and operations include (1) land acquisition and development potential to locate the facility, (2) access to the site by highways and proximity to international airports, (3) environmental compatibility with the intended use of the site, (4) adequate utility infrastructure to support the operations of the facility, and (5) availability of local labor force for construction.

Community acceptance includes letters of support for locating NBAF at the site (i.e., local and state governments, national and local agricultural producer and commodity stakeholders, industry, academia).

DHS conducted a further evaluation in the second round of the site selection process, determining that five sites met the four evaluation criteria, later adding the PIADC to the selections for a total of six sites for consideration. The five other sites are in Athens, Georgia; Butner, North Carolina; Flora, Mississippi; Manhattan, Kansas; and San Antonio, Texas.

[16]Notice, *National Bio- and Agro-Defense Facility (NBAF); Notice of Request for Expression of Interest for Potential Sites for the NBAF*, 71 *Fed. Reg.* 3107 (Jan. 19, 2006).

DHS published a notice of intent to prepare an EIS and hold public scoping meetings in the *Federal Register* on July 31, 2007. When it published the draft NBAF EIS on June 27, 2008, a 60-day public comment period began that ended on August 25, 2008; in that interval, 13 public comment meetings were held. DHS's analysis of the oral and written comments yielded more than 5,000 delineated comments. Comments on the NBAF draft EIS included the following concerns:

- the ability of DHS and the federal government in general to safely operate a biosafety facility such as the proposed NBAF;
- the potential for a pathogenic release through accidents, natural phenomena, and terrorist actions;
- our May 2008 testimony that concluded that DHS had not conducted or commissioned a study to determine whether FMD research could be conducted safely on the U.S. mainland;[17]
- natural phenomena such as tornadoes, earthquakes, and hurricanes that could cause catastrophic damage to the NBAF and result in the release of a pathogen;
- the possibility that an infected mosquito vector could escape, allowing a pathogen such as Rift Valley Fever virus to become permanently established in the United States;[18]
- the economic effects of a release or a perceived release on the local, state, and national livestock industry.[19]

In the notice of availability for the final EIS, published in the *Federal Register* on December 12, 2008, DHS identified the preferred alternative as the site at the university campus in Manhattan, Kansas. The record of decision, published in the *Federal Register* on January 16, 2009, provided DHS's rationale for selecting this site for the NBAF.

[17]GAO-08-821T.

[18]Rift Valley Fever is a viral disease affecting sheep, goats, and cattle that mosquitoes transmit between animals. There is also a human form of the disease.

[19]Department of Homeland Security, *National Bio- and Agro-Defense Facility: Final Environmental Impact Statement* (Washington, D.C.: December 2008). www.dhs.gov/xres/labs/gc_1187734676776.shtm#2

Plume Modeling

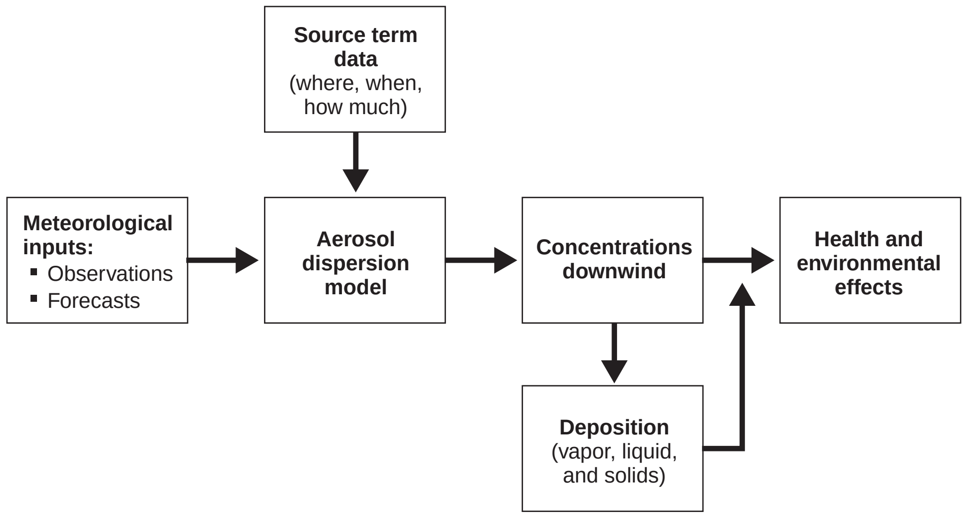
The consequences of a release of an infectious agent from an HCL depend on, among other things, the characteristics of the agent, the pathway on which it is spread, and the size and characteristics of the population exposed to it. Modeling is one way of assessing the extent of dispersion of a virus and how the disease it causes may spread.

From analyses of models' mathematical equations, plume modeling provides information on the extent of dispersion from a release of a pathogen or virus from the point of release. In emergency response, plume models provide early estimates of potentially contaminated areas and are used in combination with data gathered from the field. Several important pieces of data are required for modeling. A comprehensive model takes into account the material released, local topography, and meteorological data, such as temperature, humidity, wind velocity, and other weather conditions. Plume modeling requires the following:

- meteorological data (temperature, humidity, barometric pressure, dew point, wind velocity and direction at varying altitudes, and other related measures of weather conditions);
- data from global weather models to simulate large-scale weather patterns and from regional and local weather models to simulate the weather in the area of the agent release and throughout the area of dispersion;
- the source term, or the characteristics or properties of the material that was released and its rate of release (for example, its quantity, vapor pressure, the temperature at which the material burns, particle size distribution, its persistence and toxicity, and the height of release); and
- information on the potentially exposed populations, such as dose response (conversion of exposures into health effects), animals, crops, and other assets that the agent's release may affect.

Figure 1 shows the flow of data inputs and outputs from plume modeling.

Figure 1: The Plume Modeling Process



Source: GAO.

DHS Used Evidence from Four Types of Analysis

DHS used evidence from several analyses it conducted to compare differences across sites. The primary analyses and conclusions were as follows:

- From a hazard and accident analysis, DHS identified seven accident scenarios—representative of NBAF operations—of an FMD virus release; from the results, DHS concluded that the risk of each accident's occurring was low and primarily independent of the site, with the potential impact of a release slightly less at the Plum Island site than at the others.

- Its modeling of each accident scenario, using straight-line Gaussian plume modeling, led DHS to conclude that the sites differed very little in the dispersion of FMD virus and that the risk of FMD virus and other pathogenic releases from the laboratory at the sites was very low and independent of the NBAF's location.

- From the BKC's economic impact analyses of the potential impact of an outbreak associated with a release in the vicinity of each site, its literature review, and the EIS, DHS asserted that the major effect of an FMD release would be an export ban on U.S. livestock products, regardless of the site's location, with total costs of the same magnitude for all six sites.

- From a threat and risk assessment, developed separately from the EIS, DHS concluded that, when considering the incorporation of system recommendations to mitigate identified differences in risk, the sites differed little in terms of threats and vulnerabilities, such as terrorism or a compromised or disgruntled employee's releasing viruses, and that all sites had acceptable security risks, with or without mitigation.

Hazard and Accident Analysis Identified Seven Scenarios for FMD Virus Release

To determine the potential health and safety risks during the operation of the proposed NBAF, DHS conducted a hazard and accident analysis, focusing on pathogen handling, hazards related to the operation of any HCL, and the prevention or mitigation of accidents that could lead to outbreaks of disease in livestock, wildlife, and humans. The analysis was intended to assess the probability of the occurrence and consequences of adverse events involving a potential release of viral pathogens from the six proposed sites by

1. operational accidents such as spills from dropped containers and equipment failures,
2. external events such as an airplane crash into the facility,
3. natural phenomena such as an earthquake, or
4. intentional acts, such as terrorism or a compromised or disgruntled employee's purposefully releasing pathogens.

The viruses selected for assessment were FMD, Rift Valley Fever, and Nipah.[20]

DHS's hazard and accident analyses began with identifying a wide range of hazard scenarios, screening the hazards for those that presented the greatest potential consequences to workers and the public, selecting accidents from the screened hazards for detailed evaluation, and then developing credible scenarios for the chosen accidents involving the release of a virus that could result in exposure and ultimately an adverse effect. DHS selected eight accident scenarios as representing NBAF operations and producing "bounding" consequences.[21] The seven of the

[20]Nipah virus infects pigs and people, in whom it causes a sometimes fatal form of viral encephalitis (or brain inflammation).

[21]By "bounding," DHS meant that the scenarios represented situations involving the greatest impact or worst-case scenarios.

eight scenarios that could result in an accidental release of FMD virus are shown in table 1.[22]

Table 1: DHS's Accident Scenarios and Potential Consequences for an NBAF Site

Scenario	Consequence
Spill or uncontrolled release of aerosolized pathogens (including known and unknown releases)	Loss of biocontainment and area contamination but no environmental contamination
Loss of animal or insect control	Environmental contamination (includes the potential for loss of biocontainment of an infected animal)
Improper sterilization and disinfection of solid or liquid waste	Environmental contamination caused by release of significant viable pathogens into commercial or solid or liquid waste handling systems
Large room or facility fire	Loss of facility structure and potential environmental contamination caused by the release of one or more viral pathogens
Overpressure event from deflagration (the combustion of flammable chemicals or natural gas)	Loss of facility's biocontainment, resulting in loss of pathogens in aerosol form
Seismic or high wind event (such as earthquake or tornado)	Environmental contamination from a large, multilaboratory spill as the result of a seismic event or structural damage from high winds; potential effect on entire facility structure
Aircraft crash into NBAF's external gasoline or fuel oil storage with explosion or fire	Loss of facility's biocontainment followed by release of viral pathogens into the environment

Source: DHS, *National Bio- and Agro-Defense Facility: Final Environmental Impact Statement* (Washington, D.C.: December 2008).

DHS's Plume Modeling Determined the Extent of FMD Virus Dispersion

DHS used a simple straight-line Gaussian plume model to determine the extent of FMD virus dispersion, based on meteorological and source term data, and the potential downwind exposures from the accidental release scenarios for each of the six sites. The Gaussian plume model has been widely used to support probabilistic risk assessments for the nuclear power industry in modeling the dispersion of radiological aerosols for distances up to 10 kilometers. The model evaluates concentration levels from the accidental atmospheric releases of radio nuclides. DHS used a Gaussian plume model to determine the dispersion of FMD and other viruses from a hypothetical release.[23]

Several important pieces of data are required for modeling, including local meteorological data (wind direction and speed, humidity), source term

[22]One scenario involved an infection acquired in a laboratory, which was not relevant to an FMD virus release because the virus does not generally infect humans.

[23]This model, sponsored by the U.S. Department of Energy and the Nuclear Regulatory Commission, is called MELCOR Accidental Consequence Code System, Version 2.

(the quantity and particle size of FMD virus released), time of release (day or night), and the decay rate of the virus (measure of time in which the virus would remain viable).

Meteorological and source term data are particularly critical inputs for modeling the dispersion of any pathogen. For meteorological data, DHS modelers used a year's worth of hourly averaged meteorological data to determine the probability that areas away from the release site would be affected by the plume. Different calendar years were used for the sites. For four of the sites, 1991 meteorological data were used; 1990 data were used for New York and 1992 data for Mississippi. According to DHS contractors who conducted the modeling, they used National Oceanic and Atmospheric Administration (NOAA) weather data and they were the best and most complete weather data available.

DHS developed a different source term for each scenario. DHS's modelers calculated the amount of respirable aerosol released to the environment from a given accident, using a five-factor formula. For the accident scenario of a release of viruses from a spill, the EIS estimated that a particular package of biological material could contain approximately 100 milliliters of culture containing viable viruses and that 1×10^{8} viable virions, or virus particles, could be present in a single ml of culture media. The amount of aerosol release for a spill accident for the NBAF was estimated to be 1×10^{-4}, while the respirable fraction was conservatively taken to be 1.0.

With these inputs, the Gaussian plume model performed the calculations to produce estimates of the downwind dispersion of FMD virus from a hypothetical release up to the limit of the model—that is, 10 km from the point of release for each of the seven accident scenarios. Potential dispersion was characterized as the estimated time-integrated, downwind air and ground concentrations of virus particles at various distances from the point of release for a site. According to DHS, conservative estimates of viral pathogen quantities were modeled and based on the 95th percentile of the distribution of concentrations at a specified downwind location. In the case of FMD, an infection is considered to result from a very small number of virions—10 infectious particles constitute the minimum infectious dose. The results of the modeling are shown in table 2.

Table 2: Average Estimated Air Concentration for a Spill Scenario at Six Sites

Meters from spill	Georgia	North Carolina	Kansas	Mississippi	Texas	New York–Plum Island
50	93,400	81,100	161,000	161,000	161,000	161,000
200	9,000	7,800	15,700	15,700	15,700	15,700
600	1,660	1,440	2,910	2,910	2,910	2,910
1,000	769	666	1,350	1,350	1,350	1,350
6,000	14	15	25	91	40	91
10,000	7	5	12	16	14	30

Source: GAO conversion of data in table E.4.4.3 "Unmitigated Site-Specific Air Concentration Estimates from a Spill Release of Aerosol Pathogen," in DHS, *National Bio- and Agro-Defense Facility: Final Environmental Impact Statement* (Washington, D.C.: December 2008), vol. II, p. E-156.

Note: Concentration in a cubic meter of air without any attempt to mitigate. Calculation of the normalized concentration is independent of the parameter being modeled—in this case, a virion. It is only a function of the atmospheric parameters (wind speed, stability, rain) and the surrounding location (topography, buildings).

DHS's modeling results for the spill scenario showed estimated air concentrations that did not differ significantly from site to site. For example, as shown in table 2, at 50 meters from the spill the Georgia and North Carolina sites had estimated air concentrations of 93,400 virions and 81,100 virions, respectively, whereas Kansas, Mississippi, Texas, and New York–Plum Island all had estimated air concentrations of 161,000 virions. DHS concluded that because modeling results showed the Kansas, Mississippi, Texas, and New York–Plum Island sites as having the same air concentration levels, there would be little differentiation among the sites.

The BKC Conducted Economic Analyses to Determine the Impact of a Release

The BKC conducted a quick and limited analysis of the potential economic consequences of an accidental FMD outbreak at the six sites. DHS also reviewed the literature on simulated outbreaks in the United States and previous outbreaks of FMD virus in other countries to determine the upper and lower bounds of potential economic losses from an outbreak. From the results, DHS concluded that an export ban would be the primary economic impact, with total costs of the same magnitude for all six sites.

The May 29, 2008, economic analysis that the BKC performed was unrelated to the accident scenarios and associated plume modeling analysis presented in the EIS.[24] In its analysis, the BKC used an epidemiologic and economic simulation model to evaluate the potential impacts of seven accidental release scenarios—or outbreaks (see table 3). It also performed an assessment of an aerosol release in the vicinity of the six sites.[25] The epidemiological analysis of the outbreak scenarios showed that simulated outbreak durations for an initial, single random release in county livestock premises were comparable across all proposed sites. The potential impact by number of infected animals was largest for simulated outbreaks beginning in Kansas and North Carolina and smallest for those beginning in New York—the Plum Island site. For numbers of herds infected, Kansas had larger outbreaks and New York and Texas had smaller outbreaks.[26] The qualitative assessment of the aerosol release showed that a release from the Kansas site would have the greatest impact and a release from the Plum Island site would have the least impact.

[24]LLNL performed the analyses in its role as part of Homeland Security, Biodefense Knowledge Center, Rapid Response, which conducts work for DHS. The BKC first did a quick, preliminary study in about a day that did not include an aerosol release scenario. In the May 29, 2008, rapid tasker (1 week from inquiry to response), the BKC conducted a qualitative analysis of an aerosol release and analyzed seven scenarios.

[25]This model is called the Multiscale Epidemiological/Economic Simulation and Analysis Decision Support system. It is one of several tools used in epidemiologic simulation modeling. Spread methods accounted for in the epidemiologic model include direct contact animal movement, high-risk and low-risk indirect contact, and interstate transportation of live animals. Interherd aerosol transmission is not a spread method accounted for in the epidemiologic model, according to the May 29, 2008, LLNL study.

[26]According to the analyses, for scenarios that began with a single index case, outbreaks initiated in swine and sheep were larger, based on the number of animals infected. Also, outbreaks initiated in sheep premises resulted in the largest outbreaks, based on number of herds infected, except in Mississippi. The larger outbreaks (based on the number of animals) in Kansas and North Carolina were mainly from swine being infected. Simulated outbreaks in New York were small because of the small number of animals and herds in Suffolk and surrounding counties. Further, although Texas has the largest number of animals and herds in the county of the proposed NBAF site, the premises are primarily for small stocker cattle and cow/calf operations, and disease spread is limited in such facilities. The overall size (based on numbers of herds) of the outbreaks was comparable for Texas and New York–Plum Island.

Table 3: Outbreak Scenarios in the BKC Analysis

No. of scenarios	Category	Description
1	Single, random release in NBAF county livestock premises	Outbreak from single, random introduction of FMD virus into randomly selected livestock premises in county proposing to host NBAF (sales yards excluded but allowed to spread FMD)
4	Potential impact by type of animal species infected	FMD virus randomly occurring in cattle, swine, sheep, and goat premises; after introduction, FMD virus allowed to spread to all other types of premises (possibly represents fomite release[a])
2	Potential impact of aerosol release in county of NBAF site and surrounding counties	1. FMD virus introduction limited to one farm 2. Five farms initially infected (may correspond to larger aerosol release); relative susceptibility of various animal species at risk or animals housed indoors not considered 3. Weighting factor used to ensure that farm where initial infection occurs is proportional to number of animals on each farm because farms with higher animal density would be more likely to become infected; analysis assumed that aerosol release would infect all species equally

Source: GAO analysis of BKC study.

Note: The national dataset available for this analysis was the 2002 National Agricultural Statistical Survey, which does not include exact herd locations in a given county. For each of the six locations, seven scenarios were evaluated (42 total scenarios) and 400 epidemic realizations were simulated per scenario (16,800 epidemics).

[a]A fomite is an inanimate object or substance that has been in contact with an infected animal, retains some of the infectious agent, and can serve as a source of infection. Fomites include contaminated materials, equipment, soil, and vegetation.

The overall economic impact in the BKC analysis included estimates of (1) foreign trade lost because of the duration of export bans; (2) disruption to industry, or indirect costs; and (3) costs to government, or direct costs. Given the outbreak scenarios, the economic impact analysis showed that Plum Island would produce the least overall economic impact, at $2.8 billion, compared to the mainland sites, with the Kansas site having the greatest impact, at $4.2 billion. Because the simulated outbreaks were short and relatively small, the loss of foreign trade from an export ban was identified as the main economic impact for the six sites.

According to DHS, it concluded from the final EIS, the BKC's economic analysis, and its literature review that the primary economic effect of an accidental release would be from a ban on exporting U.S. livestock product, regardless of the location of the accidental release. DHS concluded that losses could reach as high as $4.2 billion—the potential total costs of an outbreak for the Kansas site—until foreign trade could resume.

DHS Conducted a Threat and Risk Assessment to Determine Security Risks

DHS developed a threat and risk analysis independent of the EIS that identified and evaluated potential security risks—threats, vulnerabilities, and consequences—that might be encountered in operating the NBAF.[27] They included crimes against people and property and threats from compromised or disgruntled employees.[28] The objectives of this analysis were to present the risks and effective mitigation strategies for ensuring the NBAF's secure operation and to help DHS select the site with the fewest unique security threats.

DHS concluded that the EIS and threat and risk analysis showed very little differentiation across the six sites and considered that the safety and security risks that had been identified at all sites were acceptable, with or without mitigation. Specifically, for all sites the risk was zero to low for all accident scenarios, except for an overpressure fire—an explosion from the buildup of a large amount of gas or flammable chemical in an enclosed area. The risk of an overpressure fire accident was moderate for all sites.

For all sites—except Plum Island—the overall risk rank was moderate, based on the potential for infection and opportunity for disease to spread through livestock or wildlife. The Plum Island site's overall risk rank was low, because the likelihood of any disease spreading beyond the island was small, since animals do not live in the vicinity and the potential for infection is less.

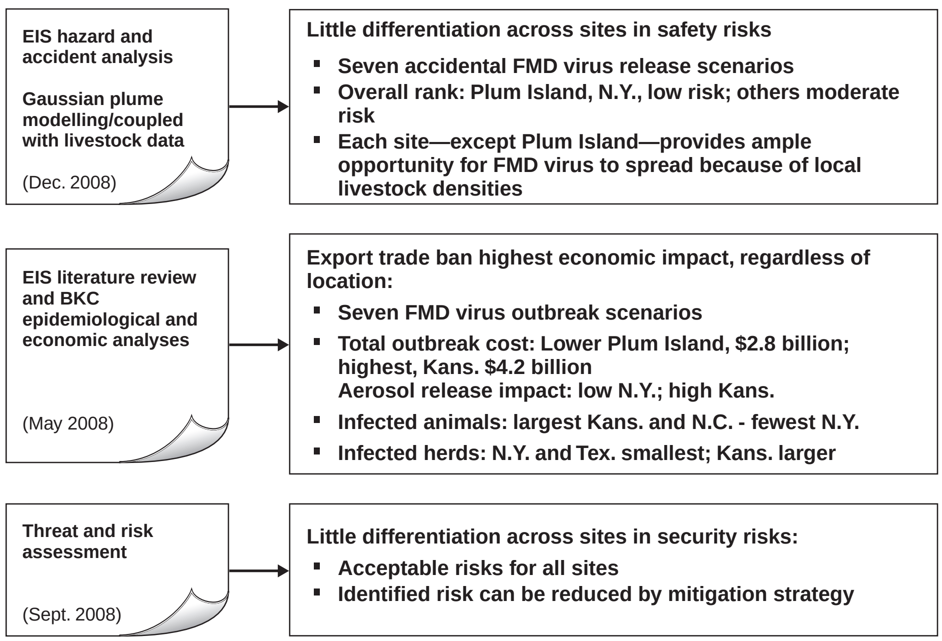
The threat and risk assessment concluded that the insider threat would be the biggest threat to the NBAF and would be independent of the site. However, DHS asserted that this and other vulnerabilities it identified would be mitigated by implementing security measures described in the EIS as well as operational protocols and by adhering rigidly to standards for safe operational practices, including those in *Biosafety in Microbiological and Biomedical Laboratories*, issued by the Centers for

[27]According to the EIS, the purpose of the threat and risk assessment was to identify potential vulnerabilities and weaknesses associated with the NBAF and to recommend the most prudent measures for establishing a reasonable level of risk for the security and operations of the NBAF and public safety.

[28]In addition, they included criminal activity by animal and environmental rights activists, intellectual property compromise by competitive intelligence agents, and bioterrorist or criminal attempts to obtain biological pathogens for inappropriate use.

Disease Control and Prevention and National Institutes of Health.[29] Figure 2 summarizes DHS's conclusions from its analyses.

Figure 2: Results from DHS's Analyses of NBAF Safety, Economic Impact, and Security



Source: GAO analysis of DHS data.

Note: The EIS accident and BKC outbreak scenarios are described in greater detail in this report.

Our Assessment of DHS's Analyses of Plume Modeling, Economic Impact, and Security Issues

We identified several limitations in the analyses from which DHS reached its conclusion that FMD work can be done as safely on the mainland as on Plum Island. We identified several limitations in the plume modeling and the economic analysis, and we found that DHS did not integrate the modeling and economic analysis. In addition, DHS's analyses showed little differentiation of risks across sites.

[29] Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: U.S. Government Printing Office, 2007).

Limitations in Plume Modeling

We found at least two limitations in the plume modeling. (1) The simple straight-line Gaussian plume model DHS used for accident analyses was not appropriate for determining the extent of the dispersion of an FMD virus release. The model has significant limitations for tracking the dispersion of biological materials from an accidental release. While this model has been widely used to support probabilistic risk assessments for the nuclear power industry in modeling the dispersion of radiological aerosols, it has not been validated for modeling FMD virus. Despite the lack of validation, this model was used to study FMD virus dispersion, as noted in the EIS. Using other available models would have been more appropriate, such as the RIMPUFF, a local-scale puff diffusion model developed by Risø National Laboratory for Sustainable Energy in Denmark. (2) Assumptions about the meteorological data and source term introduced errors that may have influenced the final results. In addition, DHS did not model the spread of FMD after infection.

The Gaussian Plume Model Is Not Appropriate for Determining FMD Virus Dispersion

According to DHS, the U.S. Department of Energy, the Environmental Protection Agency (EPA), and the Nuclear Regulatory Commission, various handbooks, guides, and standards are available on the use of Gaussian plume models for downwind concentrations of hazardous constituents resulting from an accidental release.[30] While the Gaussian plume model has been widely used in supporting probabilistic risk assessments for the nuclear power industry to model the dispersion of radiological aerosols, it has not been validated for modeling FMD virus and it has significant limitations for determining FMD virus dispersion. Gaussian plume models typically use only a single constant wind velocity and stability class to characterize turbulence diffusion. It is recognized that they treat horizontal dispersion satisfactorily but do not provide good predictions for vertical movement.

Gaussian plume models have been applied to estimate downwind concentrations of physical particles, but they have rarely been used for the dispersion of biological materials because the models, including the

[30]In the EIS, DHS noted that similar evaluations of the transportation of viral pathogens have used the Gaussian plume model: M. G. Garner, *Potential for Wind-borne Spread of Foot-and-Mouth Disease Virus in Australia* (Canberra: Australia Bureau of Resource Sciences, 1995); J. H. Sorensen, "An Integrated Model to Predict the Atmospheric Spread of Foot-and-Mouth Disease Virus," *Epidemiology and Infection* 124 (2000):577–90; T. Mikkelsen, European Geosciences Union, "Investigation of Airborne Foot-and-Mouth Disease Virus Transmission during Low-Wind Conditions in the Early Phase of the U.K. 2001 Epidemic," *Atmos Chem Phys Discuss* 3 (2003):677–703.

MACCS2, lack a mechanism to input biological decay rates. They are usually used to predict the dispersion of continuous buoyant air pollution originating from ground level or elevated sources, primarily single puff source releases. Gaussian plume models also assume that particle dispersion follows a Gaussian distribution, meaning that particles at the source have a normal distribution. The most appropriate use for straight-line Gaussian plume models is continuous releases of a constant source strength and uniform wind field. They can be reasonably reliable over short ranges (up to 10 km) in situations involving homogeneous conditions and simple flows, such as unidirectional steady state flow over relatively flat terrain. They do not model dispersion less than 100 meters from the source or long-range dispersion. The models start to break down in predictive capability when meteorology and source strength change over long time periods.

DHS's experts who reviewed the NBAF EIS methodology questioned the use of Gaussian plume models and identified limitations in their use for FMD virus release. We describe three. First, in an analysis conducted for DHS on the potential impact of an accidental release of FMD virus from each of the proposed sites, LLNL modeling experts stated that "given the location of the proposed sites, the likely range of release scenarios, and the distances to be considered, a simple straight-line Gaussian model may be insufficient to characterize the downwind impacts of an FMD virus aerosol release." LLNL modeling experts also said that no established models had been validated for tracking FMD virus releases.

Second, the Johns Hopkins University Applied Physics Laboratory's review of aerosol calculations from the draft EIS noted that while a Gaussian model is appropriate for a risk assessment of this type, it does not provide suitable information for modeling the effects of a specific release event. In the event of an actual release, mapping the plume effects effectively would require more sophisticated models and high-resolution meteorological data to determine the dispersion. It also noted the significant skepticism in the aerosol modeling community at the ability of Gaussian plume models to adequately represent the effects of turbulent transport on the dispersion of the plume. Gaussian plume calculations should be interpreted as representing estimates of areas affected by a hypothetical release, not an absolute or definitive result.

Third, Massachusetts Institute of Technology's (MIT) Lincoln Laboratory's review of the NBAF methodology stated that models such as the U.S. Department of Defense's Hazard Prediction Assessment Capability (HPAC) model, rather than the MACCS2 model, is typically used to model the dispersion of biological material.[31] Lincoln Laboratory stated that it is unclear how the MACCS2 model compared to these standard models. The Hazard Prediction and Assessment Science and Technology Manager at the Department of Defense's Defense Threat Reduction Agency also informed us that for long-range dispersion, a model such as HPAC would be more appropriate. While HPAC has not been validated for modeling FMD, long-range transport, which would include terrain effects and variable wind fields, could provide a good reality check. More advanced models could track the virus environmental decay and deposition. More important would be the spread of FMD through the livestock population after the initial infection.

Modeling experts in Denmark told us that a few models have been validated for FMD dispersion. An example is the RIMPUFF, a local-scale puff diffusion model developed by the Risø National Laboratory for Sustainable Energy in Denmark. RIMPUFF is an emergency response model to help emergency management organizations deal with chemical, nuclear, biological, and radiological releases to the atmosphere. It is being used in several European national emergency centers for preparedness and in the prediction of nuclear accidental releases (RODOS, EURANOS), chemical gas releases (ARGOS), and airborne FMD virus spread.

RIMPUFF builds from parameterized formulas for puff diffusion, wet and dry deposition, and gamma dose radiation.[32] Its range of application is about 1,000 km from the point of release. RIMPUFF calculates instantaneous atmospheric dispersion, taking into account local wind variability and local turbulence levels. The puff sizes represent instantaneous relative diffusion (no averaging) and are calculated from similarity scaling theory. Puff diffusion is parameterized for travel times from a few seconds up to about a day. Wet and dry deposition is also calculated as a function of local rain intensity and turbulence. Models like RIMPUFF are superior to Gaussian models because they apply local wind, precipitation, and turbulence data and sophisticated scaling theory and because puff diffusion can be calculated on many time scales. RIMPUFF also applies biological decay rates for FMD.

[31]The HPAC model is an automated software system that provides the means to accurately predict the effects of hazardous material released into the atmosphere and its impact on civilian and military populations.

[32]Parameterization is a technique modelers use to replace highly complex climatic processes or processes that occur on scales too small to be fully represented.

Assumptions about Meteorological and Source Term Data May Have Introduced Errors That Influenced the Modeling Results

DHS's assumptions about model input parameters, including the meteorological data and the source term, may have introduced errors that influenced its final results. These include the local meteorological data (wind direction and speed, humidity), source term (the quantity and particle size of FMD virus released), and the decay rate of the virus (time in which the virus would remain viable).

Meteorological Data

Meteorological phenomena drive the direction and potential dispersion range of aerosolized FMD virus. DHS concluded that because its modeling results showed Kansas, Mississippi, Texas, and New York–Plum Island with the same air concentrations, they differed little on meteorology. However, the Gaussian plume model used a year's worth of hourly averaged meteorological data rather than actual data for each site to determine the probability that the plume would affect areas away from the release site. As a result, any differences between the sites with regard to meteorological conditions were minimized.

Factors influencing the downwind concentration of FMD virus include wind speed, atmospheric stability, topography where the release occurred, and wet and dry deposition. For atmospheric stability, the Gaussian plume model uses Pasquill stability categories to determine vertical and horizontal plume dispersion.[33] The more stable the atmosphere is, the less vertical and horizontal dispersion there will be and, therefore, the higher the concentration of particulates will be. However, according to experts we consulted, most advanced models do not use Pasquill stability parameters because they are based on simple meteorological parameters and do not provide the detail observed with other tools.[34] When using the Gaussian dispersion model, the availability of meteorological data is crucial in determining the Pasquill stability category. If the meteorological

[33]Pasquill stability categories define atmospheric turbulence or movement and are used to estimate horizontal and vertical turbulence in the atmosphere. The six classes of stability (A through F) depend on temperature profile and wind velocity. Category A is highly unstable and represents day situations with high solar input and higher wind speeds. Category F represents night scenarios with low wind speeds and temperature inversions.

[34]Many of the more advanced air pollution dispersion models do not categorize atmospheric turbulence by the simple meteorological parameters commonly used in defining the six Pasquill classes. The more advanced models use some form of Monin-Obukhov similarity theory to estimate turbulence. For example, EPA's most advanced model, AERMOD, no longer uses the Pasquill stability classes to categorize atmospheric turbulence. Instead, it uses the surface roughness length and the Monin-Obukhov length.

data are collected from a station at a significant distance from the area being modeled, then significant errors may arise.

Meteorological data were collected not necessarily from the sites' nearest meteorological measurement location. For example, for Plum Island, the meteorological data were from what the EIS stated was the closest available location—a mainland site in Islip, New York (about 58 miles from Plum Island). However, according to the NOAA, two weather stations in West Hampton and Shirley/Brookhaven, New York, are closer. Winds and temperature data from Islip were used as input for dispersion modeling at Plum Island. The same Islip data were used to calculate Pasquill stability classes at Plum Island, even though Islip is inland on Long Island. DHS acknowledged that the Brookhaven and West Hampton stations are closer but noted that they are also on Long Island. DHS determined that without a station on Plum Island, the Islip, New York, station is sufficient when compared to the two other Long Island weather stations. Nevertheless, when sites surrounded by water are modeled, every effort should be made to collect the appropriate meteorological data and not assume that conditions are similar at sites separated by significant distances with different geographic characteristics. Crucial errors for downwind particle (virus) concentrations may result from models in which inappropriate stability classifications are applied.

The wind rose—a graphic representation of the direction and velocity of the wind—is an important meteorological tool because it can help determine wind direction and speed at a given site. According to NOAA, official wind rose data were not used for Plum Island. The hourly averaged meteorological data used in the model give long-term averages for wind direction but cannot account for variations in velocity. Therefore, the data were not representative of the prevailing wind directions at the sites and did not take into account the season or time of day.

Wind rose data as meteorological input to transport and dispersion models are, however, sensitive to the proximity of the release (and evolving cloud) to the observational sites and, hence, ultimately limited by the density of the observational network. Moreover, analyses (for example, wind fields) based on such statistical quantities do not exhibit dynamic consistency and, because of the coarseness of the data, cannot be expected to resolve small-scale processes, which may be very important for highly variable environments.

Recent developments in mesoscale climatology have significantly enhanced analysts' ability to produce statistically distributed weather data characteristics for any location in any season at any time of day. The National Ground Intelligence Center of the U.S. Army, in collaboration with the National Center for Atmospheric Research (NCAR), has developed the Global Climatological Analysis Tool for generating fine-scale (about 1 km) climatological analyses anywhere around the globe. It applies

1. Penn State University's NCAR Mesoscale Model version 5 (MM5)–based, Real-Time Four-Dimensional Data Assimilation system;
2. the National Centers for Environmental Prediction–NCAR Reanalysis Project 2.5 degree, 40-year gridded model dataset for initial and boundary conditions; and
3. observations from the National Centers for Environmental Prediction's Automatic Data Processing historical repository.

In a typical application—as in defining meteorological characteristics associated with a typical day in June in the Plum Island area—Climate-Four Dimensional Data Assimilation mesoscale downscaling is performed for each of the past 40 years. Each model run resolves fine-scale meteorological processes over a month-long period for the year being studied. These reanalyses are combined statistically to produce a "typical day" (that is, 24-hour output fields that describe the diurnal variation of weather) by using an ensemble mean. If the mean is not representative of typical climatological conditions, then clustering methods are used to identify several "typical" conditions characterizing the predominant regimes.

To determine the potential risk associated with the release of hazardous material into the atmosphere, HPAC, a probabilistic dispersion model, is used with the ensemble mean fields from the individual atmospheric dynamic runs, including the variability in the individual wind fields, to generate dosage probabilities. Additionally, HPAC-explicit dosage probabilities may be derived from individual runs over a month's time with an MM5–HPAC modeling system. In this way, the modeled transport and dispersion of hazardous material reflect both the frequency distributions of atmospheric states and the fine-scale processes known to drive local hazard levels.

In addition, as we previously noted, Gaussian plume models typically use only a single constant wind velocity and stability class to characterize turbulence diffusion. Gryphon Scientific's review of the EIS pointed out that the tendency of the wind to push aerosol releases (and light insects, such as mosquitoes) in a particular direction should influence the impact from each event at each site. If the wind generally blew away from the counties with large livestock concentrations, it would reduce the probability-weighted impact from an aerosol release of these viruses. Gryphon noted that if the wind tends to blow out to sea from Plum Island, the probability-weighted impact from an aerosol release at this facility would be greatly reduced, whereas if it generally blew into the dairy land on Long Island, the risk would be amplified. If the weather is unpredictable or highly variable, the increase or decrease in risk would be less a factor.

Source Term Data

DHS modelers calculated the source term Q—amount of respirable aerosol released to the environment from a given accidental incident—using the following five-factor formula:

$$Q = MAR \times DR \times ARF \times RF \times LPF$$

where

1. MAR (or material at risk) is the amount of biological material available from an accidental release,
2. DR (or damage ratio) is the fraction of material that is affected by the accident,
3. ARF (or aerosol release factor) is the fraction of MAR × DR that is aerosolized,
4. RF (or respirable fraction) is the fraction of the airborne material that is in the respirable range or less than 10 micrometers, and
5. LPF (or leak path factor) is the fraction of aerosolized material released into the environment.

Together, the product of MAR and these factors would determine the amount of material released to the atmosphere at an NBAF site. This quantity is used in conjunction with the breathing rate of potentially exposed humans or livestock to determine the level of exposure at a distance from the release site.

DHS's assumptions about the source term for the spill scenario illustrate the limitations of its analyses. This scenario considers the release of viruses from a small to medium spill. This accident is considered to have been caused by a storage-container handling accident—specifically, a dropped container or equipment failure that results in the contents having been spilled or sprayed, released, and aerosolized. For the spill accident scenario, the EIS made assumptions that “based on mission objectives and regulatory requirements,” a package of biological material could contain approximately 100 ml of culture containing viable viruses and that 1×10^8 (100,000,000) viable virions could be present in a single ml of culture media.

The EIS, however, did not provide evidence for how DHS reached its assumptions on the quantity of biological material and the number of viable virions in a singe ml of culture media. According to the Danish experts, the value of 1×10^8 virions per ml is a conservative value for production concentrations of viruses in stock solutions. Initial concentrations of viruses grown in laboratories typically range from 10^6 to 10^{10} viruses per ml. Viruses, after production but before being used or stored, are typically concentrated at values as high as 10^{12} ml or 10^{13} ml, depending on the virus size and other factors. Danish scientists who work with FMD virus told us that their production concentrations are typically 10^9 to 10^{10} virion per ml. Using the value of 10^8 viruses per ml and a quantity whose maximum is 100 ml raises questions concerning original assumptions. Order of magnitude underestimations of downwind hazards could arise by applying concentrations that do not represent actual values. Research has found that FMD virus can spread to greater distances downwind from the release.[35]

DHS modelers also stated in the EIS that one of the critical assumptions for estimates of the amount of material available from an accidental release was that the material form is of a solution with the assumed density and viscosity of water. The EIS noted that this is a highly conservative assumption, since most viruses are stored, grown, and handled in gelatin or agar whose densities are often greater than that of water, with a viscosity much greater than that of water. However,

[35]Most windborne spread over land is thought to be over distances shorter than 10 km, although spread over 60 km over land and 250 km over the sea are also believed to have occurred. See M. G. Garner, *Potential for Wind-borne Spread of Foot-and-Mouth Disease Virus in Australia* (Canberra: Australia Bureau of Resource Sciences, 1995). J. Gloster, R. F. Sellers, and A. I. Donaldson, “Long Distance Transport of Foot-and-Mouth Disease over the Sea,” *Veterinary Record* (London) 110 (1982):47–52, suggested that in 90 percent of outbreaks, a windborne spread over land covers distances of up to 10 km. The remaining 10 percent includes spreads over 60 km or more. In a 1967 epidemic in Hampshire in the United Kingdom, windborne spread up to 10 km was considered possible (see R. F. Sellers and A. J. Forman, “The Hampshire Epidemic of Foot-and-Mouth Disease, 1967,” *Journal of Hygiene* (London) 71:1(1973):15–34.)

according to experts we consulted, in practice only a few viruses are grown in agar or gelatin, and essentially no viruses are stored or handled in agar or gelatin, and hence the appropriate density to apply to calculations is the density of water (not a highly conservative assumption). Gryphon Scientific's review of the EIS also stated that animal viruses are not stored, grown, and handled in gelatins or agars, since these substances are used for applications other than stock production or maintenance.

The EIS stated that the aerosol release factor is one of the most important model inputs in analyzing a potential release and subsequent exposure to biological viruses. Determining it depends on the type of material, the physical form, and specific characteristics such as density and viscosity; according to the EIS, it was based on "conservative estimates" for these physical and chemical characteristics. The aerosol release factor value for a spill accident for the NBAF was estimated to be 1×10^{-4}. However, this estimate referred to values that were calculated from data collected after the anthrax letter attacks on the U.S. government and others in 2001. This raises four issues.

First, the generation of dry aerosols from a letter has little in common with aerosols generated by laboratory accident. Gryphon Scientific's review of the EIS questioned the calculation of an aerosolization factor from the amount of material retained in envelopes compared to the amount that escaped during the anthrax incidents in 2001. Gryphon pointed out that the relatively small fraction of powder that was converted into an aerosol was partly powder trapped in the envelopes. Dropping the same material from a height of 1 meter would be likely to result in an aerosol fraction much greater than 10^{-4}.

Second, the *Bacillus anthracis* spores were sampled days after the 2001 attack, when the particles originated primarily from follow-on reaerosolization. The result was an underestimation of the initial cloud concentration.

Third, the *Bacillus anthracis* spores were not used as weapons (no additives were found) but were washed, so that they tended not to stick together.

Fourth, when Department of Energy equations were used to support the value of 1×10^{-4}, the bulk density of gelatin was used, which was inappropriate for viral study cultures. If a sample of 100 ml of 1×10^{8} viruses is dropped, and an aerosol release factor of 1×10^{-4} is used, only

1×10^6 viruses could potentially be aerosolized. This value is too low, indicating that 1×10^{-4} may be an underestimation.

Particle Size

Particle size is a very important model input, dictating the extent of dispersion and biological aerosol stability. DHS's modelers determined particle size from a literature search for a representative pathogen other than FMD. Since the viruses were found to exist in the sizes that could be modeled for atmospheric transport, a representative size of 1 micron was assumed to simulate the downwind transport.

Particles can be removed from the plume and deposited on the ground (called dry deposition) or in rain (in wet deposition). The values for particle settling in the model were estimated to be in the range of 0.1 to 1 centimeters per second. However, for outdoor dispersion modeling, the rate of settling would be essentially 0 because of the horizontal and vertical components of the wind. Particles of 1 micron to 5 microns are essentially vapors and their settling rates are negligible. In addition, in its review of aerosol calculations from the draft EIS, the Johns Hopkins University's Applied Physics Laboratory found that the calculations of removal by dry deposition may have been overestimates. It found that the settling velocities of 0.1 to 1 cm/sec correspond to particles with diameters larger than 1 micron. Because of the fundamental sizes of the viruses considered in these calculations, there may be respirable, virus-containing particles that settle at significantly slower rates than those assumed. Since this would lead to the suspension of particles for longer times, the distance of plume dispersion away from the source may have been underestimated. The Applied Physics Laboratory also noted that biological particles may be incorporated into cloud droplets and transported with the cloud. It cited studies that suggest that biological aerosol would be suitable cloud condensation nuclei.[36]

Decay Rate

Decay rate can be an important model input. Lincoln Laboratory's review of the EIS questioned how the Gaussian plume model accounts for biological decay, modeled in HPAC but not in the Gaussian model. The EIS stated that the Gaussian model can account for decay of viruses over time

[36]See, for example, O. Möhler and others, "Microbiology and Atmospheric Processes: The Role of Biological Particles in Cloud Physics," *Biogeosciences* 4 (2007):1059–71, who introduced and summarized the potential role of biological particles in atmospheric clouds. Biological particles, like bacteria or pollen, may be active as both cloud condensation nuclei and heterogeneous ice nuclei and can thereby contribute to initial cloud formation stages and the development of precipitation in giant nucleic processes.

but that this was “conservatively not used.” DHS assumed a zero decay rate, meaning that all viral particles released would be viable at whatever distance they were dispersed—up to the limit of the model.

DHS’s modelers assumed that any pathogen that is released will be transported downwind and available to a potential host. However, the aerosol survival of FMD virus has been found to depend greatly on temperature and relative humidity. Generally, relative humidity levels above 55 percent, cool temperatures, and neutral or slightly alkaline conditions favor prolonged survival of FMD virus in infective aerosols and on fomites. DHS’s modeling applied very conservative values, not accounting for biological decay presumably because the model was not equipped for this treatment. Had DHS applied appropriate decay rates, it would have observed fewer viable viruses at increasing distances from the source.

DHS Did Not Model the Spread of FMD after Infection

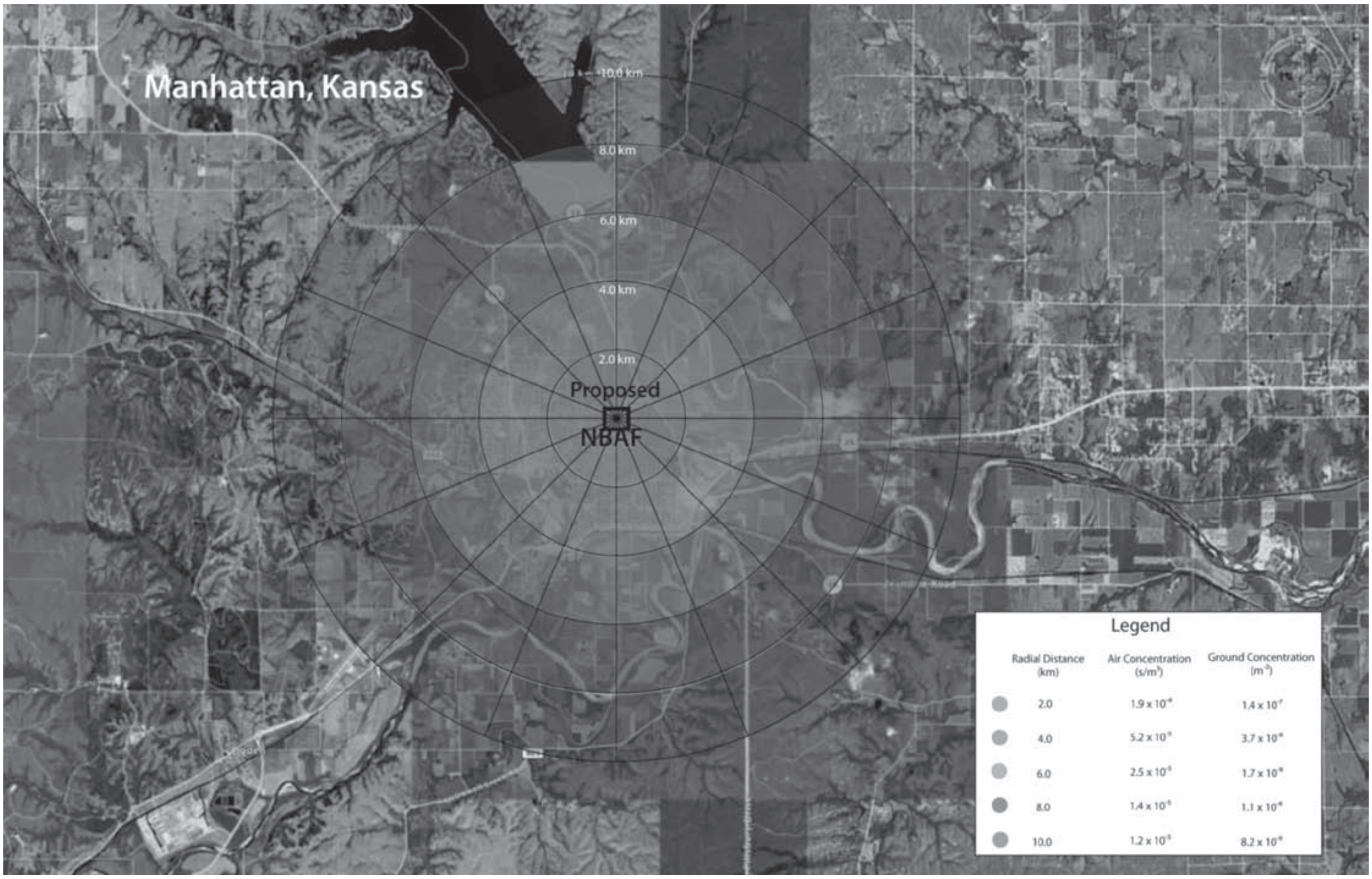
DHS did not capture site-specific differences in its modeling analysis. Gryphon Laboratory’s review of the EIS pointed out that sites can differ significantly in, among other things, availability of suitable vector species, density of susceptible wildlife, density of population, and significance of local agricultural activity. Gryphon noted further that the EIS did not analyze what would happen after an outside animal or person became infected from a release (as from an aerosol, infected work, or escaped animal). LLNL and USDA experts similarly noted that the critical, unaccounted for, component needed for the risk assessment is an estimate of the likelihood that an actual FMD virus release would lead to the infection of at least one animal at one facility. The local availability of suitable vector species, density of local livestock, and interconnectedness of local agricultural facilities would all significantly change the impact from a release that infected the same number of animals at every site.

However, in evaluating the site-specific consequences of an FMD virus release, DHS did not use additional data such as the number and type of susceptible livestock in the vicinity of the release, the decay rate of the organism, and certain types of meteorological data, along with the postulated release scenarios to conduct epidemiologic and economic analyses. These data inputs would have provided information for modeling the extent of potential exposure and likely disease and could have helped determine the economic consequences of an outbreak under the various scenarios. According to the EIS, the release of a minimum of 10,000 virions is needed before the possibility of multiple infections downwind of the release becomes credible.

As DHS acknowledged in its EIS, information on the presence of grazing livestock and crops to support them is critical to understanding potential infections from an FMD virus release. DHS stated that its site-specific evaluations factored in the details of nearby terrestrial wildlife and livestock as a prime candidate for acquiring or transmitting FMD virus. The proposed NBAF sites, with the exception of Plum Island, provide significant opportunity for its spread by infected wildlife or livestock.

To determine whether a release of FMD virus could spread and become established in the area of an NBAF site, DHS coupled the Gaussian plume modeling results on the dispersion of air and ground concentrations of virus particles with data on the distribution of livestock in counties in the vicinity of all NBAF sites except Plum Island, which contains no livestock. Using the air and ground concentrations of virions determined by the Gaussian plume modeling, DHS depicted the distribution of virus particles by “radial symmetry,” or concentric circles drawn around a site from distances of 50 meters up to 10 km—the limit of the plume model. This depiction, however, does not reflect an actual downwind plume model result. Figure 3 shows DHS’s depiction of the far field effects of a potential release of a virus and downwind transport surrounding the Manhattan, Kansas, site in terms of normalized time-integrated air and ground concentrations.

Figure 3: Far Field Manhattan, Kansas, Distribution of Virions



Source: Figure 3.14.4.2-2 Far Field Distribution of Viral Pathogens Based on Time-Integrated Atmospheric Transport from the December 2008 National Bio- and Agro-Defense Facility Final Environmental Impact Statement (Vol. I, ch. 3.14 Health and Safety, page 3-460); reprinted with permission from the U.S. Department of Homeland Security.

Note: The figure shows that at the indicated radical distances (km), the air concentration (s/m^3) and ground concentration (m^{-2}), respectively, are as follows: 2.0 km: 1.9×10^{-4}, 1.4×10^{-7}; 4.0 km: 5.2×10^{5}, 3.7×10^{-8}; 6.0 km: $2.5 \times {}^{10-5}$, 1.7×10^{-8}; 8.0 km: 1.4×10^{-5}, 1.1×10^{-8}; 10.0 km: 1.2×10^{-5}, 8.2×10^{-9}.

DHS concluded that except for Plum Island, each site is in an area where the wildlife, vegetation, agriculture, and human population would provide ample opportunity for the three pathogens to become established and spread, once released from an NBAF. The EIS stated that Plum Island provides a barrier against the spread of viruses, as well as protective features against the spread of pathogens: the island is 2 km from the mainland. At this distance, the normalized air concentrations fall, so that the quantity of material released has to be much greater than 10,000 virions before there is significant potential for infection. Table 4 lists livestock populations within 10 km of each proposed NBAF site. Plum Island has no livestock and limited wildlife. The five other sites have livestock densities that range from 0 to 30 livestock (mostly cattle) per square km for the North Carolina site up to 20 to 50 livestock per square km for the Kansas site.

Table 4: Livestock within 10 km of the Six Sites

Site	No. of livestock per sq km	Type
New York–Plum Island	0	Very limited wildlife
North Carolina	0–30	Mostly cattle
Mississippi	10–20	Mostly cattle
Texas	10–30	Mostly cattle
Georgia	20–30	Mostly cattle
Kansas	20–50	Mostly cattle

Source: DHS, *National Bio- and Agro-Defense Facility: Final Environmental Impact Statement* (Washington, D.C.: December 2008).

DHS's Estimate of Economic Impact Was Based on Limited Analysis

DHS asked the BKC to conduct quick and limited economic analyses of the potential consequences of an accidental FMD virus outbreak at each site, which it did on May 21 and May 23, 2008. In addition, DHS conducted a literature review of simulated or previous outbreaks of FMD virus in other countries. From the BKC analyses, DHS's literature review, and the final EIS, DHS concluded that the primary economic effect of an FMD virus release would be an export ban on U.S. livestock products, regardless of the NBAF's location. However, we found several weaknesses in the economic analyses. For example, they (1) did not incorporate market response to an FMD outbreak or consider the effect of establishing a containment zone to moderate the costs of the export ban and (2) were constrained by the limited outbreak scenarios used and the lack of detail. Recognizing the limitations of its analyses, the BKC recommended additional analyses. Also, the literature review did not provide information related to a release from the planned NBAF at any of the six sites.[37]

[37]DHS's literature review included a 2007 study of an FMD outbreak in southwest Kansas. According to DHS, the purpose of its literature search was to identify upper and lower bounds of potential economic losses, not to develop detailed estimates for specific sites. See D. Pendell and others, "The Economic Impacts of Foot-and-Mouth Disease Outbreak: A Regional Analysis." selected paper prepared for presentation at the Western Agricultural Economics Association Annual Meeting, Portland, Oregon, July 29 to August 1, 2007.

The BKC analyses accounted for expected economic losses, based on prerelease market conditions for affected species. However, both supply and demand for livestock products would be likely to change after FMD was detected for the expected species and other types of food animals. Considering market responses to the detection of FMD and the subsequent imposition of an export ban would affect the estimate of the overall costs of an outbreak. Since losses from export sales would be offset by domestic purchases (at lower prices) and by consumers' substituting unaffected animal products (say, chicken for pork), prices and revenues to producers of the substitutes could rise. In comparison to those of BKC, in an analysis in which market responses were incorporated, the relative rankings of the total costs of releases across mainland sites could vary.

Containment zones are used to control the impact of export restrictions. If and when country animal health officials can demonstrate an effective FMD containment zone, exporting livestock products from the rest of the country may resume.[38] OIE, an international organization that confirms the situation of a country with respect to FMD, states that the extent of a zone and its geographic limits should be established on the basis of natural, artificial, or legal boundaries and should be made public through official channels.[39] In this regard, the BKC's analyses recognized that establishing a containment zone is likely to be more straightforward for an island but did not consider the possibilities for the other sites in its preliminary studies. As a result, DHS did not consider differences across sites with regard to establishing containment zones and the potential economic effects of a release.

If national exports were to be banned, the effects on the domestic livestock industry would vary little by site. No matter where a release occurred, all export sales would be lost. The impact on exports would not permit discrimination across sites. If a containment zone was established, however, fewer exports would be affected than under a national ban. Imposing a containment zone restricts animals within it, and exported

[38]OIE is an intergovernmental organization responsible for improving animal health worldwide. It classifies countries in one or another of three disease states: FMD is present with or without vaccination, FMD is absent with vaccination, and FMD is absent without vaccination.

[39]OIE defines zone as a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control, and biosecurity measures have been applied for the purpose of international trade.

products must be shown to come from animals outside the zone. The fewer animals within the containment zone, the smaller the potential impact on exports. To the extent that a release on an island might permit defining a smaller containment zone and involve fewer animals (or not affect animals at all) than a release at a mainland site, the losses from an island release could be smaller. Estimates of the potential impact of establishing containment zones with less comprehensive export bans could help differentiate NBAF sites.

DHS cited a November 2008 letter from OIE's director general that stated that differences in the national impact of an outbreak relate more to how a country's authorities respond than to where the outbreak occurs. While we agree that the effectiveness of a country's response is paramount, we believe that where an outbreak occurs is also significant. Building FMD scenarios that take into account geographic and animal demographic factors could reveal whether there is an advantage to sites where developing a containment zone may be facilitated by unique characteristics, such as its being an island.

The BKC analyses were constrained by the limited outbreak scenarios, lack of detail, and use of a more detailed dispersion model. They did not incorporate the accident scenarios in the EIS—considered worst-case scenarios—or the results of the plume modeling of those scenarios. Also, for the outbreak scenarios used in the analyses, the relative susceptibility of the various animal species or animals kept indoors was not considered. An outbreak could be more or less costly depending on the type of animal infected. For example, since it is more difficult to detect the disease in sheep than in cows, FMD could spread farther in sheep, creating an outbreak of greater magnitude. The analyses also lacked information on the FMD virus source term (numbers and species shedding virus at the time of the outbreak by serotype), meteorological conditions, and virus decay rate in the environment. The BKC study noted that a more advanced meteorological and dispersion model would be needed to quantify the relative rankings of potential impacts for the sites.

Scenarios also lacked large-scale outbreaks of longer duration. The FMD virus outbreak scenarios in the BKC analyses were short, averaging 44 to 51 days, and relatively small in scale. However, the domestic impact could be greater than loss from an export ban if a large number of animals were infected over a large geographic area for a longer period. Analyses of scenarios involving larger outbreaks, in addition to incorporating worst-case scenarios in the EIS, would have provided additional information on the domestic impact of an FMD virus release and, thus, the relative differences across the sites.

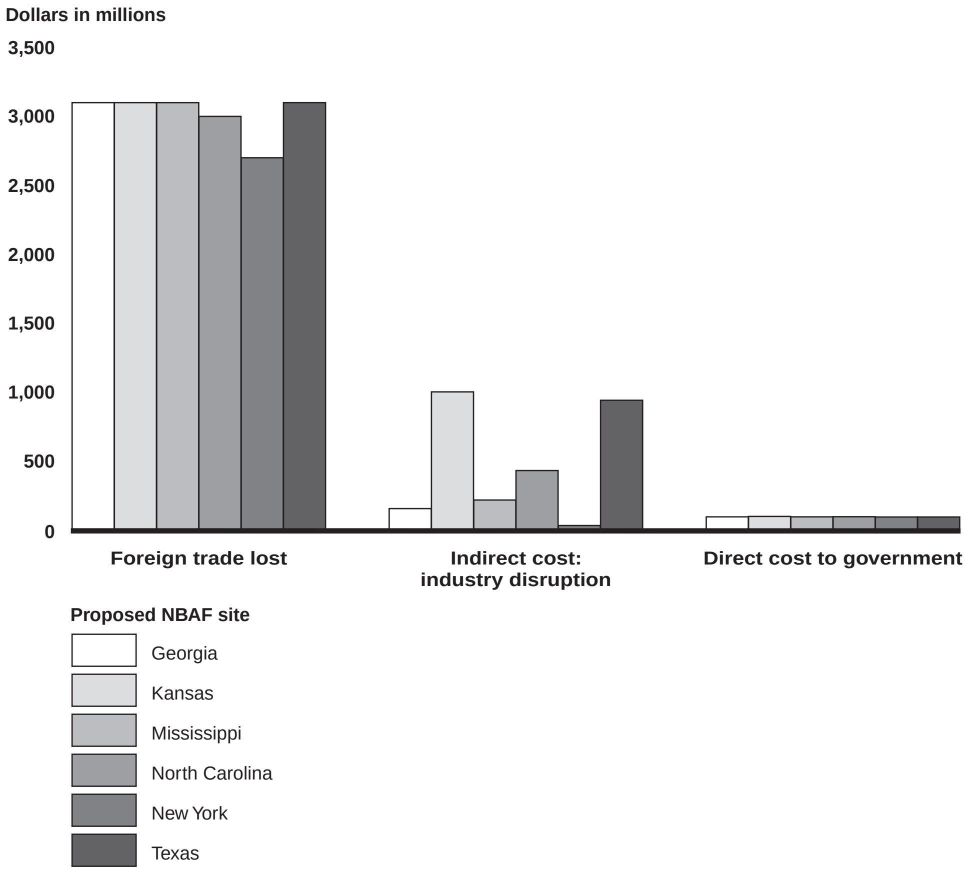
The BKC analyses showed that an off-site impact of an aerosol release would be highest for Kansas and lowest for Plum Island, but the analyses were unable to distinguish between the impacts of the four other proposed sites.[40] Livestock density within the area affected the overall economic impact for all scenarios in the BKC analyses, with Plum Island possessing an advantage over the mainland sites because of the lack of livestock in the vicinity. For example, for the aerosol release of FMD virus, the BKC used two measures: the total number of susceptible animals and the number of cattle facilities larger than 500 head. For the Kansas site, the high impact stemmed from the high numbers and densities of susceptible animals and the largest numbers of markets and large swine facilities surrounding the site; in contrast, the low impact for Plum Island stemmed from the small numbers and densities of animals surrounding the site.[41]

As shown in figure 4, for the average estimated economic impact of a single random introduction of FMD virus in the counties surrounding the proposed NBAF sites, indirect costs in the form of industry disruption showed the greatest variance across sites, ranging from a little over $1 billion for the Kansas site to as little as $31 million for the Plum Island site. The overall impact in the economic analyses included estimates of (1) foreign trade lost during an export ban; (2) disruption to industry, or indirect costs; and (3) costs to government, or direct costs. Plum Island also had the least overall economic impact, at $2.8 billion, compared to the mainland sites, with the Kansas site having the greatest overall impact, at $4.2 billion.

[40]This analysis assumed the likelihood that (1) an infection would appear in proximal livestock premises and (2) a major outbreak could result from this introduction.

[41]Criteria for assessment included total number of susceptible animals and large facilities, as well as total number of markets and number of large swine herds.

Figure 4: Average Estimated Economic Impact of FMD Virus Randomly Introduced in Counties around the Six Sites



Source: Homeland Security Biodefense Knowledge Center, Rapid Response, May 29, 2008.

The analyses were also constrained by the lack of precise information on the locations of animals in the counties surrounding the sites. As we have reported, data limitations make it difficult for any computer modeling effort to accurately predict the spread of disease.[42] Modelers must estimate the number and location of animals, as well as their interaction with other segments of industry, because the United States does not have

[42]See GAO, *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, GAO-09-178 (Washington, D.C.: Feb. 4, 2009), and *National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback*, GAO-07-592 (Washington, D.C.: July 6, 2007).

a national mandatory system that identifies the location and tracks the movement of livestock. Modelers currently use county-level agriculture census data from USDA's National Agricultural Statistics Service (NASS) (conducted every 5 years), possibly reducing the accuracy of predictions about FMD's spread if animal presence changes markedly. Without knowing the exact location of livestock, it is difficult to understand its interaction with wildlife.

We have also reported that limited information on the number and movement of wildlife and its susceptibility to the virus further complicates matters. This is an important gap, since FMD is known to have spread from livestock to wildlife in past outbreaks. The last time the United States had an outbreak, in California in the 1920s, the virus spread from pigs to cattle and black-tailed deer. It took 2 years and the slaughter of 22,000 deer to eradicate the disease from a local deer population in one national park. Interaction may be possible with susceptible species, such as deer and wild pigs, where livestock graze extensively.

The BKC recognized that its May 2008 epidemiological and economic analyses had significant limitations. Thus, several months before DHS announced the site selection, according to LLNL officials, the BKC recommended that DHS conduct additional analyses—with a better aerosol dispersion model, better input data (source term, livestock data), and more scenarios. The BKC approached DHS in July 2008, proposing a more comprehensive analysis, including (1) additional time to evaluate the consequences of the accidental release scenarios, including those identified in the EIS, to perform a more accurate risk assessment; (2) better information such as source term and regional meteorological data related to the scenarios; (3) information on the location and clustering of susceptible animals in the vicinity of the sites; and (4) the use of a more advanced aerosol dispersion model for quantitative modeling. According to the BKC, consequence modeling for each site that was tailored to the eight EIS scenarios would provide additional useful information but could not be accomplished without an estimate of the likelihood that an actual FMD virus release would lead to the infection of at least one animal at one location—which it stated would require an assessment by a qualified risk analysis team.

In May 2009, DHS stated that conducting such additional work would have little value because of the limitations in the livestock data that we previously noted. According to DHS, it held extensive discussions with the BKC on the potential scope of additional FMD release analyses, including evaluating the economic consequences of additional scenarios and additional aerosol dispersion modeling. It determined that for this analysis to have value, precise locations and numbers of livestock at the locations for each of the six NBAF sites were needed. DHS stated that these data were not available from the NASS and that data from local USDA field offices were not sufficient to support further analysis. However, in July 2009, DHS also stated that it determined that the BKC analysis using the 2002 data from the NASS on a county-level basis was sufficient because the agricultural statistics provided an accurate representation of the agricultural information at each of the six sites.

Finally, DHS's literature reviews included a hypothetical outbreak for the United States as well as previous outbreaks in other countries; none were related to the impact of an outbreak from any of the six sites. In the EIS, DHS cited some independent studies of simulated or previous outbreaks in other countries, including the 2001 Pirbright outbreak in the United Kingdom, to provide estimates of the economic costs of possible U.S. outbreaks. None of these studies were related to the EIS accident analyses, the LLNL analyses, or the six sites. DHS stated that its literature review was to identify upper and lower bounds of potential economic losses, not to develop detailed estimates for specific sites.

DHS Did Not Effectively Characterize the Differences in Risk between Mainland and Island Sites

According to DHS, risk characterization should bring together all the critical information from its analyses on hazard and accident scenarios, plume modeling, and economic impact to present a comprehensive picture of the risks an NBAF's operation would pose. However, DHS did not effectively integrate all the critical information from its analyses to characterize the differences in risks between the mainland and island sites.

The lack of integrated analyses raises questions as to whether the evidence DHS used to support its conclusions adequately characterized and differentiated the relative risks associated with the release of FMD virus from the sites. In addition, the EIS and threat and risk analyses provided little differentiation of the risks across the sites. Finally, DHS's analyses did not address issues of containment for large animals infected with FMD.

DHS Did Not Effectively Integrate the Components of Its Risk Assessment

According to the National Academy of Sciences, an effective risk assessment would integrate (1) scenario building for accidental and intentional releases of infectious diseases such as FMD, (2) appropriate methodologies for determining the extent of FMD virus dispersion and the spread of the disease, and (3) an evaluation of site-specific relative risks and potential impacts.

While DHS developed a set of accidental FMD virus release scenarios that it considered representative of those likely to have the greatest impact, and used plume modeling to determine the dispersion of FMD virus releases under those scenarios, it did not conduct epidemiologic analyses with the same scenarios and assumptions to predict the potential economic impact for each site. Because DHS did not integrate its analyses, a connection between aerosol dispersion and epidemiologic modeling could not be established; a connection would have allowed for a more comprehensive assessment, including economic consequences, of the impact of an FMD virus release on the proposed sites.

At the same time, the BKC's economic and epidemiologic analysis did not use DHS's accident scenarios or the results of Gaussian plume modeling analysis. Costs associated with disease control need to be clearly linked to the most appropriate epidemiologic models available. Using the same scenarios—with appropriate assumptions, source term, and meteorological data—to generate epidemiologic data and associated economic impacts would better inform DHS about the relative merits of the mainland and island sites with respect to the consequences of an FMD virus outbreak, despite the assumption of its low risk. An integrated set of analyses—scenarios, dispersion modeling, epidemiologic and economic impact modeling—would have allowed for a more comprehensive risk characterization and would have helped bring to light unique differences between the mainland and Plum Island.

DHS's Analyses Provided Little Differentiation in Risks across Sites

DHS's EIS and threat and risk analyses showed very little differentiation in the risks across the six sites. Although the EIS hazard and accident analyses identified several factors that differed, such as the sites' proximity to livestock, in the final rankings they were not considered significant. DHS also concluded that security vulnerabilities that the threat and risk analyses identified would be the same for all sites, regardless of location. However, DHS asserted that both the site-independent and site-specific vulnerabilities could be mitigated by incorporating improvements. DHS therefore considered the identified security risks at all sites to be acceptable.

The EIS ranked the sites by site-specific information, such as the likelihood of exposure, and site-independent information, such as accident frequency and severity. The EIS stated that the latter would be the same for all sites because they are considered characteristic of the operations of an NBAF at any site. Site-independent factors therefore did not differentiate between island or mainland sites.

For the site-specific information, the EIS showed that Plum Island had several advantages over the mainland. For example, it ranked Plum Island low in risk with respect to the likelihood of infection, calculated with the plume modeling results, and the likelihood of any disease spreading from the island (see table 5). The EIS showed that Plum Island's lack of animals placed it at an advantage with respect to the likelihood that FMD virus would become established after being released and spread from the site. In contrast, all the other sites are in areas where the virus would have ample opportunity to spread rapidly after release because of the presence of susceptible livestock and wildlife.[43] Further, the EIS showed that for all sites except Plum Island, the wind could potentially transport viral pathogens significant distances and that this pathway is not limited for them, as it is on Plum Island.

Table 5: DHS's Risk Rankings for Mitigated Accident Analyses for Potential Exposure at the Six Sites

Risk	Likelihood of receptor infection	Georgia	Kansas	Mississippi	North Carolina	Texas	New York–Plum Island
Low	Increases with concentration—i.e., the dose is equal to or greater than the minimum infection dose for FMD virus (= 10 virions)						x
Moderate	Approaches zero—i.e., the dose is less than the minimum infection dose	x	x	x	x	x	
High	Approaches certainty—i.e., the dose is more than 10 times the minimum infection dose						

Source: DHS, *National Bio- and Agro-Defense Facility: Final Environmental Impact Statement* (Washington, D.C.: December 2008).

Note: This ranking was based on calculations using plume modeling results relative to the minimum infectious dose and a cow's breathing rate. The interpretation of the site-specific risk ranks includes mitigated and unmitigated site-independent accident frequencies, which according to the EIS do not differ from one site to another

[43]For example, the EIS stated that it was considered likely that deer, elk, wild boar, and other wildlife or livestock could spread disease over long distances.

The threat and risk analyses also identified differences in risks across sites, but DHS concluded that they would be mitigated by security upgrades to facility design, operational protocols, and guidelines so that the risks would be equal across sites.

Because the different safety and security risks—no matter how extreme—that the EIS and threat and risk assessment identified were all considered mitigated, DHS selected a site by using its original evaluation criteria (see table 6). DHS officials told us that the Kansas site's being near a university would give it proximity to existing research capabilities—one of the four evaluation criteria. DHS also said that a more detailed site-specific threat assessment would be developed when the NBAF is designed, to mitigate the threats identified for the Kansas location—the preferred alternative in the EIS. Overall risk rank shows that Plum Island is generally at a low level of risk in terms of safety while the other sites are at moderate levels; however, in terms of security, all sites were considered to have acceptable risks.

Table 6: DHS's Site Rankings, Risk Ratings, and Evaluation Criteria

		Risk ratings		Meets four evaluation criteria			
Site	**Rank**	**Safety**	**Security**	**Near workforce?**	**Near research?**	**Available acquisition, construction, operations?**	**Community acceptance?**
Kansas	1	Moderate	Acceptable	Partly	Yes	Yes	Yes
Texas	2	Moderate	Acceptable	Yes	Partly	Partly	Yes
Georgia	3	Moderate	Acceptable	Partly	Partly	Partly	Partly
Mississippi	4	Moderate	Acceptable	No	No	Yes	Yes
North Carolina	4	Moderate	Acceptable	Yes	Yes	No	No
New York–Plum Island	4	Low	Acceptable	Partly	Partly	Partly	No

Source: GAO analysis of DHS's final EIS and related information.

DHS's Analyses Did Not Address Containment Risks for Large Animals Infected with FMD Virus

In earlier testimony, we found that the 2002 USDA study DHS had used to support its conclusion that work could be done as safely on the U.S. mainland as on Plum Island did not address in detail 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 air filtration systems. Our review of the EIS also found that it did not address hazards associated with large animals—a unique purpose of the NBAF. Many of these risks, reported on in our testimony, were still not addressed in the EIS. While the EIS identified the loss of animal control as one of the seven accident scenarios involving an FMD virus release, it did not address in detail the risks associated with the special containment of large animals.

As we noted in our testimony, 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 the contained areas to necropsy or incineration areas poses additional risks. For example, one of the internal releases of FMD virus at the PIADC happened in transporting large animal carcasses from contained rooms through to incineration.

We also noted that transferring FMD work to an NBAF is to be accompanied by increases in both scope and complexity over those of the current activities at the PIADC. These increases would mean an increase in the risk associated with work at the new facility. For example, the BSL-3-Ag space at the new NBAF is projected to be almost twice the size of the space currently at the PIADC and is to accommodate many more large animals. According to PIADC officials and the EIS, requirements specify NBAF space for 166 large cattle (up to 1,430 pounds) for both short-term and long-term clinical trials with aerosolized FMD virus, as well as about 50 to 60 cattle for USDA's ongoing research. This is contrasted with the more than 100 cattle that the PIADC can handle today.

In addition, we noted an important difference between a standard BSL-3 laboratory, such as the laboratories used for work with human pathogens, and a BSL-3-Ag laboratory. In BSL-3-Ag, the human operator has extensive direct contact with infected animals and, consequently, the virus. Because the virus can be carried in a person's lungs or nostrils or on other body parts, humans become a potential avenue by which the virus could escape the facility. Special biosafety procedures are needed—for example, a full shower on leaving the containment area, accompanied by expectorating to clear the throat and blowing through the nose to clear the nasal passages. Additionally, a 5-to-7-day quarantine is usually imposed on any person who has been within a containment where FMD virus is present, a tacit acknowledgment that humans can carry the disease out with them, even after these additional procedures.

DHS has cited an FMD laboratory in Winnipeg, Canada, to support its assertion that FMD work can be done safely on the mainland. Canada has decided to conduct FMD work on the mainland but in a downtown location. Susceptible animals are not likely to be in the immediate neighborhood. Its scope of work for FMD is also smaller than that at the

PIADC or the proposed NBAF. In the Winnipeg laboratory, the number of animals handled is very small (two large infected animals such as cows), whereas in the proposed NBAF, DHS plans to accommodate 166 large cattle. The FMD work in Winnipeg is done in a Canadian level (CL-3) facility, which is equivalent to a BSL-3Ag facility in the United States. The proposed U.S. facility would use many more animals than the Winnipeg facility. Consequently, using the Winnipeg facility to support its assertion regarding the U.S. mainland NBAF facility is not valid. The U.S. mainland sites are potentially more likely to pose a risk, given their being closer to susceptible animal populations.

Concluding Observations

The analyses that DHS conducted on the potential relocation of FMD work to the mainland have several limitations. DHS's analyses did not effectively characterize and differentiate the risks associated with the release of FMD virus at the six sites. From its Gaussian plume modeling results, DHS concluded that the mainland and Plum Island would differ little in air concentrations from an FMD virus release. However, the simple straight-line Gaussian plume model DHS used for its accident analyses was based on unrepresentative accident scenarios, outdated dispersion modeling techniques, and inadequate meteorological data, and therefore it was not appropriate for determining the extent of dispersion of an FMD virus release. Drawing conclusions about relocating research with highly infectious exotic animal pathogens from questionable methodology could result in regrettable consequences. Site-specific dispersion analysis, using proven models with appropriate meteorological data and defensible source terms, should be conducted before scientifically defensible conclusions can be drawn.

The economic analyses did not incorporate market response to an FMD outbreak—which would be related to the number of livestock in the site's vicinity. They also did not consider the effect of establishing a containment zone to control the effects of a national export ban on the domestic livestock industry—which could have been used to differentiate across NBAF sites. The analyses were constrained by limited scope and detail. They did not incorporate worst-case outbreak scenarios.

DHS did not effectively integrate all the critical information from its analyses to characterize differences in risks between the mainland and island sites. The lack of integrated analyses raises questions as to whether the evidence DHS used to support its conclusions adequately characterizes and differentiates the relative risks associated with the release of FMD virus from site to site. Finally, our review of the EIS also found that it did not address hazards associated with large animals—a unique purpose of the NBAF. We reported on these same risks in earlier testimony.

DHS asserted throughout its analyses that the technology, methods, and safety systems associated with operating modern HCLs will mitigate any risks and will make work with FMD virus safe on the mainland. We agree that the value of modern containment technology has reduced the risk of an accidental release and that the safety of HCLs has improved. However, evidence shows that accidents continue from human error and from operational failure in facilities. Thus, as DHS has acknowledged, the risk of release of an agent from a modern HCL is not zero, and Plum Island offers a unique advantage—with its water barrier and absence of animals—over the mainland. If foreign infectious viruses are introduced into the United States, research on these viruses must be done with the utmost care and planning. For these reasons, work of this nature should be conducted only where adequate analyses have shown that the consequences of an accidental release are absolutely minimized.

Given the significant limitations in DHS's analyses that we found, the conclusion that FMD work can be done as safely on the mainland as on Plum Island is not supported.

Agency Comments and Our Evaluation

We obtained written comments on a draft of our report from the Department of Homeland Security, whose key concerns we discuss here. The agency's letter is printed in appendix II.

First, DHS noted that while we cited limitations of the DHS risk assessment methodology, we provided no analysis that would indicate that a different methodology would yield different results. Although the congressional mandate did not require GAO to conduct an alternative analysis, we went beyond the mandate to identify an alternative plume model (RIMPUFF) that has been validated for FMD virus, as well as more appropriate source term and meteorological data that should have been used. We believe that using this validated model and appropriate source term and meteorological data—and performing additional epidemiologic and economic analyses that included worst-case scenarios, market analyses, and the use of containment zones—would have provided more comprehensive information for both decision makers and the public regarding the sites' relative differences in risks when conducting FMD research.

Second, DHS stated that the draft report was unresponsive to the direction of the Congress because we chose to evaluate whether FMD research can be done as safely on the mainland as on Plum Island. In reality, we both satisfied the mandate through our analysis of the EIS and provided additional analysis as we agreed to with congressional requestors. This is consistent with the way we work with the Congress in scoping all our work. Because the PIADC has a long history of FMD work, it was agreed that we would address the relative safety of the island and mainland sites to put the safety issue in perspective.

Third, although DHS noted that it had stated in the NBAF EIS that the water barrier around Plum Island provides an additional layer of protection in the extremely unlikely event that pathogens proposed for study at the NBAF were accidentally released, DHS determined that the Plum Island site did not best meet the purpose and need to locate, construct, and operate the NBAF, based on the research; workforce; acquisition, construction, and facility operations; and community acceptance evaluation criteria that a team of federal employees (DHS and USDA subject matter experts) had developed. We agree with DHS that Plum Island can provide an additional margin of safety compared to mainland sites; however, in the DHS decision, this extra safety factor was outweighed by nonsafety factors, such as community acceptance. DHS believes that it can mitigate the risks of accidental or intentional releases from any of the sites.

Fourth and finally, DHS stated that DHS and USDA have determined that live FMD virus research can be safely studied on the mainland because modern biocontainment technology has made the likelihood of an accidental release of a pathogen extremely small. DHS noted that modern biocontainment technology has eliminated the need for locating animal-disease research on an island, as was considered necessary decades ago. DHS stated that we should not dismiss the fact that live FMD virus research is already being performed on the mainland in other countries, since this clearly demonstrates that such work can be conducted safely on the mainland (with appropriate biosafety and biosecurity protocols to minimize the risk of release). While we agree, and while we stated in our report that modern technology has made the risk of an accidental release of a pathogen extremely low, the risk is not zero. Accidents continue, primarily from human error. The fact that live FMD work in countries such as Australia and New Zealand is done mostly offshore emphasizes that even a low risk may be considered too great where agriculture is economically important. The challenges of maintaining a high-containment environment in the case of FMD research are particularly difficult, given the large number of research animals planned for the NBAF. The NBAF

EIS did not directly address those challenges. Thus, the issue is: What level of risk is acceptable? The question is especially important when, as in this case, an alternative is available that offers a lower level of risk than the one that has been chosen.

Overall, once a certain low level of risk has been identified as being acceptable for the conceptual NBAF facility, DHS appears to rank other, nonsafety factors more highly than the further risk reduction the island site could provide. Because safety is always a relative concept, this prioritization of other issues over further safety is a matter of judgment that should, for clarity, be explicitly stated and justified.

DHS and USDA also provided technical comments on and corrections to the draft report. These comments address four areas of DHS's risk assessment: (1) modeling analysis, (2) meteorological and source term data, (3) estimates of the economic impact of an FMD outbreak, and (4) issues of containment for large animals infected with FMD. We summarize DHS's major comments in these four areas and our response below and note that we have made changes to the report, as appropriate.

Modeling Analysis

DHS commissioned three independent subject matter experts—Johns Hopkins University Applied Physics Laboratory, the Massachusetts Institute of Technology Lincoln Laboratory, and Gryphon Scientific—to review DHS's plume modeling analysis in the draft EIS. Along with areas where the subject matter experts agreed with the EIS authors, they also provided some caveats based on the assumptions in the EIS and suggestions for further analysis. DHS stated that our draft report described limitations in the DHS risk analysis based on issues raised by these subject matter experts and LLNL experts with regard to the EIS aerosol modeling methodology but that we did not mention positive comments in the independent review.

DHS also asserted that numerous models can be used to evaluate aerosol transport of FMD virus and that no one model stands out as the premier model to use. It cited research that compared six different FMD atmospheric dispersion models (which did not include the MACCS2 model DHS used or the HPAC and RIMPUFF models we cited); it concluded that all the atmospheric dispersion models compared can be used to assess windborne spread of FMD virus and can yield scientific advice to those responsible for making disease control decisions in the event of an FMD outbreak. DHS also stated that there is sufficient literature to justify the use of the MACCS2 model (originally developed to model the dispersion of radiological aerosols) for biological aerosol. DHS stated that several features of Gaussian plume models make them desirable for risk assessment. They provide, according to DHS, the ability to use yearly averaged meteorological datasets to determine the probability that areas away from the release site will be affected by the plume.

In fact, we did present positive comments, as appropriate. However, it is important to note that DHS experts raised serious caveats about the use of the MACCS2 model for FMD that are not outweighed by the positive comments. Other experts besides DHS's experts have raised the same concerns about the appropriateness of using MACCS2 for biological dispersion and safety analysis. DHS dismissed these caveats, asserting that they would not dramatically change its conclusions, but DHS offered no evidence to prove its assertion.

Modeling biological dispersion of dangerous pathogens is a complex process. Using an unvalidated model for this task was inappropriate. The MACCS2 model has a "Table of Limitations" listed in a U.S. Department of Energy report (*MACCS2 Computer Code Application Guidance for Documented Safety Analysis*, final report (Washington, D.C.: June 2004)). Limitations include a release duration of 3 minutes to 10 hours, which is inappropriate for a puff release; sensible energy issues that would affect modeling when heat or other energetics are involved; and terrain sensitivity and building wake effects that DHS addressed. The MACCS2 model also uses Pasquill stability classifications that are outdated and not used in modern, more appropriate models. Moreover, by limiting the dispersion to 10 km, the MACCS2 model fails to address more real-life scenarios and worst-case scenarios that have been found important in FMD virus dispersion.

Much better, validated, models are available and should have been used. We believe that if DHS is going to analyze something as important as the downwind dispersion of FMD virus after a release, it should use the best science and validated models available. We emphasized the use of a model that has been validated for FMD virus—such as the RIMPUFF model—as well as the use of more appropriate source term and meteorological data. Some models like the HPAC and RIMPUFF apply modern theory for diffusion and turbulence factors and have been applied and validated for the airborne spread of biologicals and, specifically, FMD. RIMPUFF, available to all users, has been shown to provide more sophisticated and accurate data than other simulation models. RIMPUFF is linked to a geographic information system, so site-specific meteorological data can be generated and integrated with geographic and demographic data for display in a format that can be easily assimilated and transmitted electronically.

DHS also asserted that our observation that Gaussian plume models do not provide suitable information for modeling the effects of a specific release is irrelevant. DHS stated that it used the Gaussian plume model as a dispersion model to compare the six sites (thus, the relative magnitude of downwind normalized concentration is of primary importance, not the absolute value). We believe our statement is relevant, especially since DHS's independent subject matter experts made the same observations. Modeling the effects of a specific release is critical. Limiting the comparison of the six sites by the relative magnitude of downwind normalized concentration does not provide the true effects of a release. Measuring the effects of a specific release is important when attempting to obtain site-specific relative information.

Meterological and Source Term Data

DHS stated that our observation on its use of meteorological data is inaccurate. We stated that DHS's using hourly averaged meteorological data in the MACCS2 model, rather than wind rose meteorological data, gave long-term averages for wind direction but cannot account for variations in velocity. Therefore, the data were not representative of the prevailing wind directions at the sites and did not account for the season or time of day. DHS stated that the MACCS2 meteorological input files contain weather data at hourly intervals for the whole year. The data take into account the season and the time of day, the MACCS2 uses wind direction at each hourly interval as input, and thus a typical MACCS2 dataset represents the full spectrum of wind directions over an entire year. DHS stated that although the NBAF EIS did not provide explicit data on the wind rose, the data from which a wind rose can be constructed are in the MACCS2 input data set.

As we stated in our report, the wind rose data are a graphic representation of the direction and velocity of the wind and a very important tool in determining wind direction and, therefore, the potential dispersion of FMD virus. Although the MACCS could provide wind direction at each hourly interval as input, DHS did not in its modeling produce a wind rose to determine the predominant direction and velocity of the wind. Wind rose diagrams are straightforward to interpret. The graphic shows the primary direction the wind travels and the relative amount of time the wind travels from that direction. Wind rose diagrams should be applied in dispersion modeling because they illustrate the magnitude and direction of the predominant wind at a particular location. In addition, hourly averaged data do not describe what dispersion would look like in a worst-case scenario, because all meteorological conditions for longer-range transport are averaged.

DHS also stated that we provided no evidence that the value DHS used for the aerosol release factor was an underestimation. We stated that if a sample of 100 ml of 1×10^{8} viruses is dropped, and an aerosol release factor of 1×10^{-4} is used, only 1×10^{6} virus could potentially be aerosolized. We believe from our discussions with FMD experts that this value is too low, indicating that 1×10^{-4} may be an underestimation. DHS noted that it stated in the EIS that a spill of 1 kilogram of a liquid containing virions, with a viscosity of water (0.01 poise), from a height of 1 meter would result in an aerosol release factor (ARF) of approximately 8×10^{-6}, which is more than an order of magnitude lower than the 1×10^{-4} ARF value used for spill accidents for the NBAF. DHS therefore believed that the EIS has appropriately characterized the source term. However, we believe that the scientific experimental data that would support the source term values cited in the EIS are lacking. DHS used the data relating to the dispersal of a powder—containing *Bacillus anthracis*—used in the 2001 anthrax attack. The energy requirements for dispersing a powder differ in a major way from the requirements for dispersing from a bulk liquid. According to Danish FMD experts, in the concentration of FMD virus they produce in their laboratory, they routinely get 10^{9} and often get as high as 10^{10} during their fermentation and production phases. During the centrifuging phase, the concentration level often goes higher. Therefore, if you start with a higher concentration of viruses in a vial and there is an accidental spill, then the source term will be that much higher.

Estimates of Economic Impact on an FMD Outbreak

DHS stated that the EIS analyses used actual events and existing studies to evaluate the economic effects of a potential FMD outbreak and that it is likely that the direct, localized effects of an outbreak would not be limited by the 10 km dispersion field determined by the plume modeling. For the EIS, DHS stated, dispersion modeling was done, and there was no reason to do epidemiologic modeling on the site selection. Because USDA's NASS does not release farm locations within a county, the precision of data needed to use the plume modeling dispersion field for a localized economic evaluation was not available. However, DHS said that the BKC analysis using the 2002 NASS data on a county-level basis was sufficient, because the agricultural statistics accurately represented the agricultural information at each of the six sites. The NBAF EIS table D.2-l shows direct economic costs less than 4 percent of the total economic costs of a potential FMD virus release for all sites. However, DHS did not directly address our point concerning the need for additional economic analyses involving market response and containment zones; instead, it stated that the EIS analyses would not include a market analysis and the establishment of containment zones to lessen the impact of an export ban for all six sites. DHS stated that OIE's determination regarding a country's FMD status is based on how the country's authorities respond to the incursion rather than to where the outbreak occurs. DHS also stated that its literature review—intended to identify upper and lower bounds of potential economic losses and not to develop detailed estimates for specific sites—had included one study that demonstrated the local impact of an FMD outbreak in southwestern Kansas.

We believe that the use of worst-case scenarios and available, if limited, livestock data for additional epidemiologic and economic analyses—including outbreaks of longer durations—would further differentiate the sites, including showing unique differences between the mainland sites and Plum Island. Because the United States has not had an FMD outbreak since 1929, much is uncertain about the potential consequences of a release. For example, it is not clear in which species, or how, wildlife can spread and act as a reservoir for the virus, despite the perceived low risk of its occurring. In addition, each site has its own level of susceptible livestock and wildlife in the vicinity, but DHS did not model the spread of FMD after an initial infection. As we stated in the report, studies have shown that the virus can travel distances far greater than 10 km from a release. Furthermore, while an export ban in the event of a confirmed FMD infection would result in an immediate foreign ban on the export of animal products, the consequences of that ban—from both a foreign and a domestic standpoint—would be affected by the ease of establishing a containment zone, as well as by the market response to the outbreak. Thus, we believe it imperative that decision makers be provided with analyses sufficiently detailed to show the relative differences in risk among sites—regardless of the confidence in HCLs to reduce those risks—before a site decision is made. Lacking these additional epidemiologic and economic analyses, we think DHS's efforts to evaluate the economic impact of an FMD outbreak did not provide sufficient information on the relative differences in risks across sites, particularly with respect to potential consequences.

Finally, DHS appears to have misunderstood our meaning of the term integration, discussing its overall risk assessment methodology and conclusions rather than addressing DHS's lack of integration of the accident analyses in the EIS with the BKC epidemiologic and economic analyses—our main point. While DHS developed a set of accidental FMD virus release scenarios that it considered to represent those likely to have the greatest impact, and used plume modeling to determine the dispersion of FMD virus releases under those scenarios, it did not conduct epidemiologic analyses with the same scenarios and assumptions to predict the potential economic impact for each site; had DHS done so, it would have produced a more comprehensive picture of the relative differences in impacts of an FMD virus release across sites and, also, a better comparison of the mainland sites to Plum Island.

Issues of Containment for Large Animals Infected with FMD

DHS stated that live FMD virus research is already being performed on the mainland in other countries and that five BSL-4 facilities currently operate in the United States in populated areas. DHS noted that no public exposure has ever resulted from research at a BSL-4 laboratory in the United States. DHS asserted that modern biocontainment technology has eliminated the need for locating animal-disease research on an island, as was done decades ago. DHS also stated that state-of-the-art operating procedures and biocontainment features minimize the potential for laboratory-acquired infections and accidental releases. In addition, DHS stated that the hazards of working with large livestock are not site-specific. It has been shown, and is demonstrated daily, that at the PIADC, with proper training, scientists and animal handlers work safely with large animals.

DHS is not addressing our main point about the significant increase in potential risks because of the larger scale of work with infected animals in BSL-3 Ag facilities than that conducted in BSL-4 facilities. The BSL-4 laboratory work that DHS refers to is work with human pathogens. Our comments relate to safety issues concerning work with FMD under BSL -3 Ag, where the containment level is lower than in BSL-4 and human operators can have direct contact with infected animals.

The more direct contact between FMD-infected animals and humans is possible because FMD virus is not a human pathogen. In BSL-3 Ag laboratories, direct contact is also more extensive between human operators—a potential avenue for escape of the virus—and FMD-infected animals. In addition, the amount of virus animals excrete will be significantly higher in BSL-3 Ag laboratories because the animals are larger; thus, the potential for exposure is greater. While it is true that with proper training, scientists and animal handlers could work safely with large animals, DHS's comments do not address the issues we raised about the lack of analyses in the EIS concerning the risks associated with the containment of large animals infected with FMD.

We recognize that the PIADC's working practices have been shown to be generally effective in preventing the release of virus. Our point here, however, is that although the hazards of handling large livestock may not be site-specific, the potential consequences are—in the event of a release of the virus. We believe the importance of the island location cannot be evaluated as a separate factor, since the United States has had no comparable mainland site. Comparison with the Pirbright facility in the United Kingdom, where FMD outbreaks occurred from an accidental release of FMD virus, emphasizes the safety value of the island location.

We are sending copies of this report to the Secretary of Homeland Security and the Secretary of Agriculture. We will also make copies available to others on request. In addition, the report will be available at no charge on the GAO Web site at www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-2700 or kingsburyn@gao.gov or contact Sushil K. Sharma, DrPH, Ph.D., at (202) 512-3460 or sharmas@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs may be found on the last page of this report. GAO staff who made contributions to this report are listed in Appendix III.

Nancy R. Kingsbury

Nancy Kingsbury, Ph.D.
Managing Director, Applied Research
and Methods

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Appendix I: Objectives, Scope, and Methodology

The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009 required us to review the U.S. Department of Homeland Security's (DHS) risk assessment of whether foot-and-mouth disease (FMD) work can be done safely on the U.S. mainland. To ensure that DHS has properly considered the risks associated with a potential release of FMD virus from a high-containment laboratory (HCL) on a mainland site compared to one on an island, we assessed, as mandated, the evidence DHS used to conclude that work with FMD can be conducted as safely on the U.S. mainland as on Plum Island.

To fulfill this mandate, we reviewed agencies' documents, including the draft and final environmental impact statements (EIS), threat and risk assessment, and Lawrence Livermore National Laboratory (LLNL) and Biodefense Knowledge Center (BKC) studies; relevant legislation and regulations governing DHS and the U.S. Department of Agriculture (USDA); and literature on FMD and HCLs.

We interviewed officials from the DHS Office of Science and Technology and the USDA Agriculture Research Service. We visited the Plum Island Animal Disease Center (PIADC), where we examined animal containment areas and unique aspects of the island, and we talked with DHS and USDA officials who oversee and operate the facility. We talked with the contractors who performed the dispersion modeling and officials of DHS's Biodefense Knowledge Center at LLNL, who analyzed the potential impact of an accidental release of FMD virus from each of six proposed sites. We also talked with experts on animal diseases and HCLs dealing with animal, zoonotic, and human pathogens. We consulted with large animal veterinarians and agriculture economists.

In addition to talking with experts on plume modeling, we talked with officials of the National Atmospheric Release Advisory Center, Interagency Modeling and Atmospheric Assessment Center, at LLNL; Defense Threat Reduction Agency; National Ground Intelligence Center of the U.S. Army; Risø National Laboratory for Sustainable Energy at the Technical University of Denmark; and Meteorological Model Systems at the Danish Meteorological Institute.

We visited other facilities that conduct FMD work, including 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 Institute for Animal Health Pirbright facility. We also talked with officials of the Australian Animal Health Laboratory in Geelong and Canada's National Centre for Foreign

Animal Disease in Winnipeg. In addition, we talked with officials of the World Organisation for Animal Health in France.

We conducted our work from October 2008 through May 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform an audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. We believe that the evidence we obtained provides a reasonable basis for our findings and conclusions, based on our audit objectives.

Appendix II: Comments from the Department of Homeland Security

Deputy Under Secretary for Science and Technology
U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

July 7, 2009

Nancy Kingsbury, Ph.D.
Managing Director, Applied Research and Methods
U.S. Government Accountability Office
441 G. Street, NW
Washington, D.C. 20548

Dear Dr. Kingsbury:

Thank you for the opportunity to review and comment on the draft GAO-09-747 report, "Biological Research- Observations on DHS's Analyses Concerning Whether FMD Research Can Be Done as Safely on the Mainland as on Plum Island."

GAO prepared the draft report in response to the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009 (P.L. 110-329) which directed GAO to review the Department's "risk assessment of whether foot-and-mouth disease work can be done safely on the United States mainland." DHS conducted this risk assessment as part of the National Bio and Agro-defense Facility (NBAF) Environmental Impact Statement (EIS).

The Department of Homeland Security (DHS) notes that although the draft GAO report cites "limitations" of the DHS risk assessment methodology, it provides no analysis that would indicate that a different methodology would yield different results, nor does the draft report offer any recommendations.

DHS also notes that the draft GAO report is unresponsive to the direction of the Congress. Instead of evaluating if foot-and-mouth disease (FMD) research "*can be done safely on the mainland*" per Congressional direction in P.L. 110-329, GAO instead chose to evaluate whether FMD research can "*be done as safely on the mainland as on Plum Island*." DHS stated in the NBAF EIS that the water barrier around Plum Island would provide an additional layer of protection in the extremely unlikely event of an accidental release of any pathogen proposed for study at NBAF. DHS determined, however, that the Plum Island site did not best meet the purpose and need to site, construct, and operate the NBAF based on the Research, Workforce, Acquisition/Construction/Operations, and Community Acceptance site evaluation criteria developed by a team of Federal employees (DHS and the U.S. Department of Agriculture (USDA) subject matter experts). There is also strong political opposition at Federal, state, and local levels to having BSL–4 research performed on Plum Island.

www.dhs.gov

DHS and USDA have determined that live FMD virus research can be safely studied on the mainland, and fully support the decision to construct and operate the NBAF at the Manhattan, Kansas, site. While the study of contagious diseases anywhere is not without risk, modern biocontainment technology has made the likelihood of an accidental release of a pathogen extremely low. Modern biocontainment technology has eliminated the need for locating animal-disease research on an island as was done decades ago. The fact that live FMD virus research is already being performed on the mainland in other countries should not be dismissed by the GAO as it clearly demonstrates that such work can be conducted safely on the mainland (with appropriate biosafety and biosecurity protocols in place to minimize the risk of release). There are five BSL-4 facilities currently operating in the United States in populated areas (Centers for Disease Control and Prevention and Georgia State University in Atlanta, Georgia; U.S. Army Medical Research Institute of Infectious Diseases at Ft. Detrick, Maryland; University of Texas Medical Branch in Galveston and Southwest Foundation for Biomedical Research in San Antonio, Texas). There has never been a public exposure resulting from research at a BSL-4 laboratory in the United States. DHS is committed to minimizing both the likelihood and the consequences of the release of any pathogen.

DHS determined that there are significant benefits to constructing the NBAF on the mainland, including rapid diagnosis and response to possible foreign animal disease outbreaks, and access to more research programs and expertise which will allow greater research advancements. DHS appreciates the independent review conducted by GAO, and takes seriously the observations made in the draft report of the consequences of a pathogen release. As part of the design process, DHS will conduct a site-specific biosecurity risk mitigation assessment for the Manhattan, Kansas site to determine the required facility design and engineering controls needed to adequately protect NBAF during operations. Risk mitigation assessments will include modeling scenarios to assist in developing a detailed emergency response plan to prepare city, state, and regional officials in the extremely unlikely event of a pathogen release. In response to the observations made by GAO in the draft report, the modeling will incorporate site-specific and regional-specific data.

Numerous DHS and USDA general and specific comments and corrections to the draft report are attached. Thank you again for the opportunity to comment.

Sincerely,

BE Buswell

Bradley I. Buswell
Under Secretary for Science and Technology (Acting)

Encl: a/s

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contacts

Nancy Kingsbury, Ph.D., (202) 512-2700, or kingsburyn@gao.gov.

Staff Acknowledgments

In addition to the contact named above, Sushil Sharma, Dr.PH, Ph.D., (Assistant Director); Hazel Bailey; Amy Bowser; Timothy Carr; Jason Fong; Jack Melling, Ph.D.; Alan Jeff Mohr, Ph.D.; Susan Offutt, Ph.D.; Timothy Persons, Ph.D.; Penny Pickett, Ph.D.; Elaine Vaurio; and Neal Westgerdes, DVM, made key contributions to this report.

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