QUALITATIVE RISK ANALYSIS FOR THE NATIONAL BIO AND AGRO-DEFENSE FACILITY

Prepared by:

SES, Inc.
6750 Antioch Road
Suite 305
Merriam, Kansas 66204

January 6, 2012

Table of Contents

Introduction 1
Recent Foot and Mouth Disease (FMD) Outbreaks 1
2001 FMD Outbreak in the United Kingdom 1
Economic Impact 2
2010 FMD Outbreak in South Korea 2
Economic Impact 2
2010 FMD Outbreak in Japan 3
Economic Impact 3
Recent Zoonotic Disease Outbreaks 4
1999 West Nile Virus (WNV) Outbreak Summary 4
Impact on Industry (Market) 4
Impact on Human Health 4
Benefits of Research (Having a National Lab) 5
2003 Severe Acute Respiratory Syndrome (SARS) Outbreak Summary 5
Impact on Industry (Market) 6
Impact on Human Health 6
Benefits of Research (Having a National Lab) 6
Highly Pathogenic Avian Influenza H5N1 Outbreak Summary 6
Impact on Industry (Market) 7
Impact on Human Health 7
Benefits of Research (Having a National Lab) 8
2009 Novel H1NI Influenza Outbreak Summary 8
Impact on Industry (Market) 9
Impact on Human Health 9
Benefits of Research (Having a National Lab) 9
Assessment of the Risk of Foot and Mouth Disease Arriving From Outside the United States 10
Disease Source 10
Disease Pathway 11
Intentional Introduction 12
Unintentional Introduction 13
Immigration 14

International Travel 14
Personal Shipments of Goods 15
Natural Release 16
Disease Receptor 17
Conclusion 17
Large Animal Disease Laboratory Capabilities 18
NBAF Purpose and Scope 19
Domestic Laboratory Capabilities 20
International Laboratory Capabilities 22

Tables

1. International Travel 14
2. NBAF Space Requirements 20
3. NBAF Space Compared to PIADC Space 20
4. U.S. BSL- 3Ag Facility Sizes 21

Figures

1. Current Distribution of FMD 10
2. Document from a Cave in Afghanistan 12

Introduction

This report addresses the need for a state-of-the-art, large animal, contagious animal disease research facility (i.e., the National Bio and Agro-Defense Facility [NBAF]) and examines the risk to the U.S. livestock industry and to a lesser extent, the U.S. human population if this facility is not constructed. The first section of this report presents real-world case studies of contagious animal diseases and the impact that these disease emergencies had on their respective countries. The second section of this report presents a review of recent zoonotic outbreaks that have affected or threatened the U.S. population. The third section provides an assessment of the risk of foot and mouth disease (FMD) being introduced into the U.S. The last section explores the ability of existing U.S and international laboratories to perform research and their inability to fill the void in the event that NBAF is not constructed. This last section also presents findings from epidemiological models on the impact of an animal disease emergency response if there are delays in positive confirmation and vaccine deployment.

The global marketplace, increased imports of agricultural products, and growing numbers of international travelers to the United States have increased the number of pathways for the introduction of foreign and invasive agricultural pests and diseases. More than 40 contagious foreign animal diseases are currently recognized as threats to the U.S. agricultural economy.[1]

Agriculture is the largest industry and employer in the United States, generating more than $1 trillion in economic activity annually, including more than $50 billion in exports.[1] U.S. agriculture is threatened by the entry of foreign pests and pathogens that could harm the economy, the environment, plant and animal health, and public health. A key component of this economy is the livestock industry, which contributes over $100 billion annually to the gross domestic product. Diseases affecting livestock could have significant impacts on the U.S. economy and consumer confidence in the food supply. The introduction of animal and plant diseases at the farm level would cause severe economic disruption given that agriculture accounts for 13 percent of the U.S. gross domestic product and 18 percent of domestic employment.[1] The economic disruption would be magnified by the likely long-lasting trade embargoes imposed on U.S. livestock and poultry products.

Recent Foot and Mouth Disease (FMD) Outbreaks

This section of this report presents real-world case studies of FMD outbreaks and the impact it had on their respective countries.

2001 FMD Outbreak in the United Kingdom

The 2001 FMD outbreak in the United Kingdom (UK) was one of the worst economic disasters that the UK has faced in recent history. From February 20, 2001 to September 30, 2001, there were a total of 2,026 cases. The first case of the disease was believed to occur at Burnside Farm, Heddon on the Wall, Northumberland. This farm was licensed to feed waste-food under the

[1] Department of Homeland Security (DHS). National Bio and Agro-Defense Facility Final Environmental Impact Statement (NBAF FEIS)-Executive Summary. December 2008.

Animal Byproducts Order 1991. The disease was thought to have been introduced at this farm the end of January or the beginning of February 2001. It is believed that the owner of this farm fed FMD-contaminated waste food scraps obtained from a Chinese freighter to his hogs. The hogs became infected with the virus and consequently, through direct and indirect contact (originally believed to be airborne, but then possibly through contact with contract sheep herds that were being moved across the country) infected sheep herds at Prestwick Hall Farm, Ponteland, Northumberland. These sheep were sold through markets at Hexham (Northumberland), and Longtown (Cumbria), which resulted in widespread dissemination of disease throughout the rest of England and Wales and to bordering counties in southern Scotland.

There was a considerable delay in reporting the suspect disease to the authorities, which contributed to the widespread dissemination of disease and the scale of the disease. [2] From there, authorities in the UK waited three days from the confirmation of the disease to declare a stop movement order of animals, resulting in further spread of the disease. This differed from the 2007 outbreak, where a stop movement order was issued within three hours of disease confirmation; resulting in the disease being contained to four premises.

Economic Impact

It has been estimated that due to the 2001 FMD outbreak, the UK's tourism industry lost between $4.91–7.36 billion and the agriculture industry lost between $1.96–5.89 billion. The total net cost to farming, rural industry and tourism amounted to the equivalent of 0.2 percent of the UK's Gross Domestic Product (GDP).[3]

2010 FMD Outbreak in South Korea

The FMD outbreak in the Republic of Korea (South Korea) was first noted on November 29, 2010 and has been ongoing, with small outbreaks continuing into the summer of 2011. According to South Korea's National Veterinary Research and Quarantine Service, the outbreak was caused by an immigrant worker from China or Mongolia that was hired by a local farm and had received a package containing clothes and shoes contaminated with the FMD virus.[4] During its peak, from November 29, 2010 to February 26, 2011, more than 3.47 million cows, pigs and other animals were culled.[5]

Economic Impact

This has been the most severe FMD outbreak in South Korea's history. During the period from November 29, 2010 to February 26, 2011, the government culled more than 3.47 million cows, pigs and other animals, resulting in losses of 3 trillion won (US$2.77 billion).[5] Another economic aspect to the culling of pigs is that the FMD outbreak so decimated South Korea's

[2] Origin of the UK Foot and Mouth Disease epidemic in 2001
http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/documents/fmdorigins1.pdf
[3] http://www.publicsafety.gc.ca/prg/em/ccirc/2006/ia06-001-eng.aspx
[4] http://koreajoongangdaily.joinsmsn.com/news/article/article.aspx?aid=2920605
[5] http://english.yonhapnews.co.kr/business/2011/04/22/21/0501000000AEN20110422001700320F.HTML

swine breeding stock that South Korea imported 31,000 sows in 2011 from the U.S. and other nations in an attempt to rebuild the swine industry. [6]

2010 FMD Outbreak in Japan

On April 20, 2010, Japan's Ministry of Agriculture, Forestry and Food (MAFF) reported an outbreak of FMD in the Miyazaki prefecture. Over the course of 11 weeks, MAFF reported infection on a total of 292 farms within the prefecture, resulting in the depopulation and burial of 211,608 infected and susceptible animals. The last affected farm was depopulated on July 5. On October 6, MAFF requested that the International Office of Epizootics (OIE) and the USDA-APHIS reinstate Japan to the list of FMD-free regions.[7,8] The source of the virus was not definitively identified; however, MAFF suspected that it was introduced through contaminated people or personal goods from a nearby affected country.[8]

According to the Japanese Ministry of Agriculture, the first case in the time line was in water buffalo. The farm had reported non-typical clinical signs in late March. Samples were collected from the site, but were not tested for FMD until April after disease had been confirmed in the area. This first case and other farms were linked epidemiologically by a feed company.[9]

Economic Impact

The Miyazaki Prefecture estimates that recovery from the 2010 FMD outbreak will take five years and have an economic impact of around ¥235 billion (about $3.6 billion). The Prefecture estimates that its livestock industry will lose ¥82.5 billion (about $1.1 billion) and the meat processing industry will lose ¥8.9 billion (about $116 million). Aligned industries such as feed suppliers and equipment manufacturers are expected to lose around ¥47.8 billion (about $623 million). Non-aligned industries such as restaurants and tourism are expected to lose around ¥95 billion (about $1.2 billion).[10]

A total of 28 percent of all the farms in Miyazaki were affected by the disease. These totals include 262 individual farms. The Miyazaki prefecture is home to the genetics of the prized Wagyu cattle, responsible for supplying the bulk of the world's demand for this type of beef. A total of 68,266 cows were culled amounting to 22 percent of the entire prefectural population. A total of 50 out of 55 stud bulls used to sire calves with the Wagyu genetics in the Miyazaki prefecture were culled.[11] The loss of export markets for the Japanese Wagyu beef opened the door for Australian and New Zealand Wagyu beef producers to fill the international demand.[12] It was reported that it could take five years for their beef industry to recover. A total of 24 percent (or 220,034) of the pigs in the prefecture also were culled.[13]

[6] http://af.reuters.com/article/idAFL3E7HL0EG20110621
[7] http://en.mercopress.com/2010/10/06/japan-requests-oie-free-of-fmd-status-korea-de-listed-resumes-pork-exports
[8] APHIS Evaluation of the Foot and Mouth Disease Status in Japan http://www.r-calfusa.com/Animal_Health/110401APHISJapanFMDEvaluation.pdf
[9] http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/monitoring/documents/fmd-eastasia100610.pdf
[10] http://www.japantimes.co.jp/text/nn20100812a8.html
[11] Financial Times (FT).com article: "Disease takes toll on Japanese beef exports. July 18, 2010.
[12] http://www.australianwagyuforum.com.au/wagyunews.html
[13] http://www.zenoaq.jp/english/aij/1009.html

Recent Zoonotic Disease Outbreaks#

This section reviews four recent zoonotic outbreaks that affected or threatened the U.S. population.

1999 West Nile Virus (WNV) Outbreak Summary

The outbreak of West Nile Virus in 1999 began with an unknown cause of bird die-offs in June 1999.[14] These outbreaks were identified in New York City parks. In August of 1999, the first cases of human health cases of West Nile Virus infection (in retrospect) came from Flushing Hospital in Queens. It was not until mid to late September that the link between the bird die-offs and the human health cases were made. Prior to the link being made, NYC health officials asked the Centers for Disease Control and Prevention (CDC) several times if there could be a link between the two, and CDC doubted the probability (page 49 of the Government Accountability Office [GAO] report).[14] In late September, researchers determined that the virus in question was most likely West Nile Virus, three months after the outbreak in birds began. West Nile Virus is now endemic to the U.S. with approximately three million infections confirmed in humans from 1999 to 2008.[15]

Impact on Industry (Market)

While West Nile Virus affects a wide range of birds, there is no experimental or field evidence that the clinical disease can develop in chickens or turkeys. Chickens and turkeys can become infected with the disease, but do not show clinical signs and cannot directly infect other birds, animals or humans, nor can they act as a reservoir for the virus. Chickens are often used as sentinel animals to monitor for the presence of infected mosquitoes in high-risk areas. There is some evidence that waterfowl may be more susceptible to the virus than chickens or turkeys, but the susceptibility of game birds is in question.[16] There were also over 14,000 horses infected with the West Nile Virus in 2002, which led to the development of a vaccine for horses.[17]

The potential economic impact on the poultry market is non-existent as West Nile Virus is now endemic to the U.S. and many other countries.

Impact on Human Health

According to a Pennsylvania State University study, there is no evidence of animal-to-person transmission of West Nile Virus. The primary way in which people can become infected is through the bite of an infected mosquito.[16,17] However, person-to-person transmission of West Nile Virus has been documented through organ donations, blood transfusions, breastfeeding, and intrauterine infection, but in much smaller numbers than from mosquito bites.[17,18,19]

[14] West Nile Virus Outbreak, Lessons for Public Health Preparedness, http://www.gao.gov/new.items/he00180.pdf
[15] http://wwwnc.cdc.gov/eid/article/15/10/08-1668_article.htm
[16] Information Sheet: West Nile Encephalitis and Poultry, http://pubs.cas.psu.edu/freepubs/pdfs/un192.pdf
[17] http://www.cdc.gov/ncidod/dvbid/westnile/conf/pdf/Roehrig_WrapUp_04.pdf
[18] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1005a1.htm
[19] http://www.cdc.gov/ncidod/dvbid/westnile/surv&controlCaseCount11_detailed.htm

Benefits of Research (Having a National Lab)

The West Nile Virus outbreak identified several key issues surrounding the identification of new and emerging diseases in the U.S. The following bullet points identify just a few of these issues.

- There were several issues with identifying the link between human health cases and the bird die-offs in New York City. At one point, the CDC vertebrate ecologist replied that the two incidents are probably coincidental (page 49 of the GAO report).[14] Samples were being collected and submitted to a large number of different laboratories and samples from the Bronx Zoo of infected birds were sent to at least four different labs, often with different handling times and sometimes different results. Initially, the human health side of the investigation identified the virus as St. Louis Encephalitis, which derailed some of the results of the investigation.
- The GAO report cited multiple instances in which the lead state or federal agency recommended to hold off on sending samples to the laboratory in order to avoid shipping samples over the weekend.[14] This was at a time when people were sick.
- Once the human health cases began to ramp up in early September, and some animal health officials in New York State began to question whether the two events were linked, some of the satellite labs began to question whether or not they had the appropriate personal protective equipment and procedures in place to handle samples possibly infected with a zoonotic disease (page 46 and 48 of the GAO report). It took more than a week before the CDC ordered samples being tested at smaller unequipped labs cease and be sent to the New York State laboratory (page 51 of the GAO Report).[14]
- Maintaining a national laboratory in the U.S. dedicated to studying and understanding zoonotic diseases is critical.

2003 Severe Acute Respiratory Syndrome (SARS) Outbreak Summary

In March 2003, the World Health Organization (WHO) identified SARS as a new disease and a worldwide threat. The first case was reported in southern China in November 2002 by a WHO physician who had diagnosed a businessman with the disease after he had traveled from the Guangdong province of China, through Hong Kong and to Hanoi, Vietnam. Both men eventually died from the illness.[20]

SARS spread quickly through Asia, Australia, Europe, Africa and North and South America. The WHO identified SARS as a global health threat, which prompted them to issue a travel advisory. The WHO was unsure at the time if SARS would become a global pandemic. Because of the worldwide attention that SARS was given and the precautions that were put into place, the outbreak was short-lived. In late July 2003, the last cases were reported to the CDC. More than 8,000 people became sick with SARS and 774 died.[21]

[20] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004460/
[21] http://www.cdc.gov/ncidod/sars/faq.htm

Impact on Industry (Market)

The impact to the livestock industry was non-existent.

Impact on Human Health

It is believed the 2003 epidemic started in China when the virus spread from small mammals through intermediate hosts to humans.[20] Further evidence compiled in 2005 suggests that the virus was similar to that found in horseshoe bats in China. It is suggested that the virus spread to humans from intermediate hosts when the bats were captured and sent to market for sale.[22] Bats appear to be the natural reservoir for many viruses, including Ebola, Hendra and Nipah. It is believed that their tendency to roost tightly together in caves with other bat species allows opportunities for viruses to evolve and recombine. Because of this possibility, introducing human viruses into the mix can create opportunities for other viruses to evolve with genes that can create human health epidemics.[22]

Benefits of Research (Having a National Lab)

It is important to continue to study and understand paths of disease transmission in order to prevent future outbreaks of new and emerging diseases. The changes in human behavior and the fact that the human population continues to expand and encroach on the territory of wild animals creates conditions favorable for the introduction of new and emerging diseases. The study of the SARS outbreak, and the fact that it took almost three years to determine the source of the virus, reinforces the need to continue the implementation of a national laboratory dedicated to studying zoonotic diseases.

Highly Pathogenic Avian Influenza H5N1 Outbreak Summary

The first cases of Highly Pathogenic Avian Influenza (HPAI) H5N1 were discovered in Hong Kong in 1997. The virus was dormant until it resurfaced in Vietnam in October 2003. From there it spread rapidly in January 2004 to other Asian countries, including Laos, Cambodia, Hong Kong, Thailand and China. Other countries followed shortly afterwards from Asia to Africa to Europe through July 2006. In January 2007, H5N1 resurfaced again in Japan. The virus was found in the Miyazaki Prefecture, Japan's largest poultry-producing region. Another outbreak surfaced in Hungary in January 2007. In February 2007, the H5N1 virus was found in the United Kingdom at a turkey farm owned by Bernard Matthews PLC, Europe's largest turkey producer, causing the deaths and culling of 159,000 turkeys in an effort to stamp out the disease.[23] For Japan, this was the first outbreak in more than three years; for the United Kingdom, it was the first outbreak in 11 months.[24] The HPAI H5N1 virus appears to have become endemic for some parts of the world, specifically in Vietnam where the country

[22] http://evolution.berkeley.edu/evolibrary/news/060101_batsars
[23] United Kingdom Department for Environment, Food, and Rural Affairs (Defra), Avian influenza outbreak update, February 2007. http://www.defra.gov.uk/news/2007/070212a.htm
[24] http://www.ers.usda.gov/Publications/LDP/2007/10Oct/LDPM15902/LDPM15902.pdf

continues to battle outbreaks of the disease.[25] Additionally, the outbreak of HPAI H5N1 in early 2011 in Japan, coupled with the earthquake, greatly impacted Japan's poultry markets.[26]

Impact on Industry (Market)

Markets in Japan

The domestic broiler meat production in Japan dipped an estimated eight percent (as compared to the same period of time last year) during the first half of 2011. The massive outbreak of HPAI H5N1 in early 2011 in Japan's largest broiler producing region, the Miyazaki Prefecture, caused a large number of birds to be culled. This outbreak coincided with Japan's most recent FMD outbreak in the same prefecture.

Markets in Turkey

The economic effects of the 2005-06 HPAI H5N1 outbreaks in Turkey created hardships on many of the poultry producers across the nation. Poultry (turkey) producers in Turkey lost on average 38 percent of their production and their management fees were reduced by 9.3 percent in the eight months after the outbreak. As a result, production levels declined by 36 percent over that period of time.[27]

Impact in the U.S.

The U.S. is the world's largest producer of poultry meat and the second largest egg producer. Poultry production in the U.S. is valued at $29 billion annually. An outbreak of HPAI in the U.S. would greatly impact the poultry industry and would lead to import bans of a variety of poultry products from the U.S.[28]

HPAI has occurred and been eradicated three times (1924, 1983 and 2004) in the U.S. The U.S. Department of Agriculture (USDA) has experience responding to and eradicating HPAI. The outbreak of HPAI (H5N2) in 1983-84 resulted in the depopulation of approximately 17 million chickens, turkeys and guinea fowl just in Pennsylvania and Virginia in order to contain the disease. The management of this outbreak cost nearly $65 million and caused retail egg prices to increase by more than 30 percent.[28] The typical operating procedure of U.S. poultry producers is to cull flocks with H5 or H7 **low pathogenic** AI to prevent the birds from developing H5 or H7 HPAI.

Impact on Human Health

As of July 31, 2007, the number of confirmed human cases of HPAI H5N1 totaled 319, including 192 fatalities.[24] The death rate of those infected with the disease is about 60 percent. In general, HPAI H5N1 does not infect humans easily, and if a person does become infected it is very difficult for the virus to spread to other people. The biggest concern is that the HPAI H5N1

[25] http://www.oie.int/animal-health-in-the-world/update-on-avian-influenza/2011/
[26] http://themeatsite.com/articles/1456/japan-poultry-and-products-annual-report-2011
[27] http://www.bioone.org/doi/abs/10.1637/8710-031809-Reg.1?journalCode=avdi
[28] http://www.aphis.usda.gov/publications/animal_health/2011/hpai_brochure.pdf

virus will combine with a different Influenza A virus that spreads easily within the human population, resulting in a pandemic. Because these viruses do not commonly infect humans, there is little or no immune protection against them in the human population. [29]

There have been other forms of avian influenza A being transmitted to humans and causing illnesses, the most typical being H7 type viruses. On February 19, 2004, the Canadian Food Inspection Agency announced an outbreak of avian influenza A (H7N3) in poultry in the Fraser Valley region of British Columbia. In order to control the virus, culling operations and other measures were performed. Health Canada reported two cases of laboratory-confirmed H7 influenza A illnesses – one from a worker involved in the culling operations and one from a worker that had close contact with poultry. Both patients developed conjunctivitis and flu-like symptoms, but their illness was resolved after treatment with antiviral medication.[30] In November 2003, a person was admitted to a hospital in New York with respiratory symptoms. Initial tests indicated that the person had an influenza A virus (suspected to be H1N1), but further testing indicated that the virus was H7N2 influenza A. The person recovered and returned home after a few weeks.[27]

Benefits of Research (Having a National Lab)

With outbreaks of HPAI H5N1 continuing to occur across Asia, it is critical that the U.S. have a national laboratory that is able to quickly identify poultry diseases and continue to research new strains of the disease. The National Veterinary Services Laboratory (NVSL) in Ames, Iowa conducts most of the poultry disease testing. However, many of the cattle and swine vesicular diseases such as FMD and classical swine fever are studied and diagnosed at the NVSL-Plum Island Animal Disease Center (PIADC).

2009 Novel H1NI Influenza Outbreak Summary

The 2009 novel H1N1 outbreak was a human health influenza A outbreak that resulted in the World Health Organization (WHO) declaring a pandemic. At the time, experts believed that avian influenza A (H5N1) viruses posed the greatest pandemic threat. H5N1 viruses were endemic in poultry in parts of the world and were infecting people sporadically, often with deadly results. The CDC responded to the H1N1 outbreak in a multi-faceted response that lasted more than a year.

The 2009 H1N1virus outbreak was first detected in the United States in March 2009. This virus was identified as a unique combination of influenza virus genes that had never been identified before – the virus genes most closely resembled those of North American swine-lineage H1N1 and Eurasian lineage swine-origin H1N1 influenza viruses. Unfortunately, because of this close link to swine-origin viruses, early reports referred to the virus as a swine origin influenza virus (swine flu).[31]

[29] http://www.cdc.gov/flu/avian/gen-info/facts.htm
[30] http://www.avianinfluenza.org/avian-flu-outbreaks-in-north-america.php
[31] http://www.cdc.gov/h1n1flu/cdcresponse.htm

Impact on Industry (Market)

The early reports referring to the H1N1 virus as a swine origin influenza virus made consumers leery of buying pork products because of fears that the disease may be linked to pork products.[31] Tyson Foods, Inc. reported a drop in domestic pork sales, and as sales fell, retail and wholesale hog prices fell sharply, along with hog and pork-belly futures prices. Economists at Purdue University estimate that Indiana hog producers were losing about $5 a head on April 24, compared to estimated losses of about $20 immediately following reports of the initial outbreak in March.[32]

Towards the end of April, consumers were still confused by how humans can get the 2009 H1N1 flu. A phone survey conducted by the Harvard School of Public Health on April 29 that asked 1,067 consumers about the ways humans can get the 2009 H1N1 flu. The results of the survey are as follows:

- 83% of respondents said "From being in close contact with someone who has swine flu – that is, within about three feet."
- 29% of the respondents said "From being near someone who has swine flu, but not in close contact – that is, being at thirty feet away"
- 34% responded with "From coming in contact with pigs" and
- 13% responded with "From eating pork." [32]

Impact on Human Health

After the WHO declaration of a pandemic on June 11, the 2009 H1N1 virus continued to spread and the number of countries reporting cases of 2009 H1N1 nearly doubled from mid-June 2009 to early July 2009. By June 19, 2009, all 50 states in the United States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands had reported cases of 2009 H1N1 infection. The United States continued to report the largest number of 2009 H1N1 cases of any country worldwide, although most people who became ill recovered without requiring medical treatment. At the June 25, 2009 Advisory Committee on Immunization Practices Meeting, CDC estimated that at least 1 million cases of 2009 H1N1 influenza had occurred in the United States.[31]

Benefits of Research (Having a National Lab)

Since the 2009 Novel H1N1 influenza outbreak was a new strain of influenza A, closely resembling swine-origin lineage H1N1 influenza viruses, it is critical that research continue into potential influenza virus strains that can evolve and impact not only human health, but also the health of the livestock and poultry industries.

[32] http://www.fas.org/sgp/crs/misc/R40575.pdf

Assessment of the Risk of Foot and Mouth Disease Arriving From Outside the United States

This section presents a qualitative risk assessment of FMD entering the U.S. from outside our borders. Assessment of risk requires consideration of three factors. These factors include disease source; pathway of exposure; and receptors. The following subsections include an analysis of these three factors as they apply to foreign animal diseases.

Disease Source

There is a broad array of pathogens in existence that could infect either livestock or humans. Some of these pathogens are present in the United States such as anthrax, pseudorabies, rabies, bovine tuberculosis and scrapie, to name a few. Others have never occurred in the United States or have been eradicated such as FMD.

FMD is an economically devastating livestock disease that affects cloven hoofed livestock and wildlife. The disease is not fatal to livestock but greatly reduces productivity. Receiving "FMD Free" status from OIE means there would likely be no export restrictions based on FMD. A country recognized as having a current outbreak of FMD or having endemic status may be prohibited from exporting livestock products. OIE makes embargo recommendations, but it is up to individual nations to decide if they will restrict trade based on FMD status. These restrictions can apply to a region or to the entire country. Figure 1 provides the current status of FMD around the world.

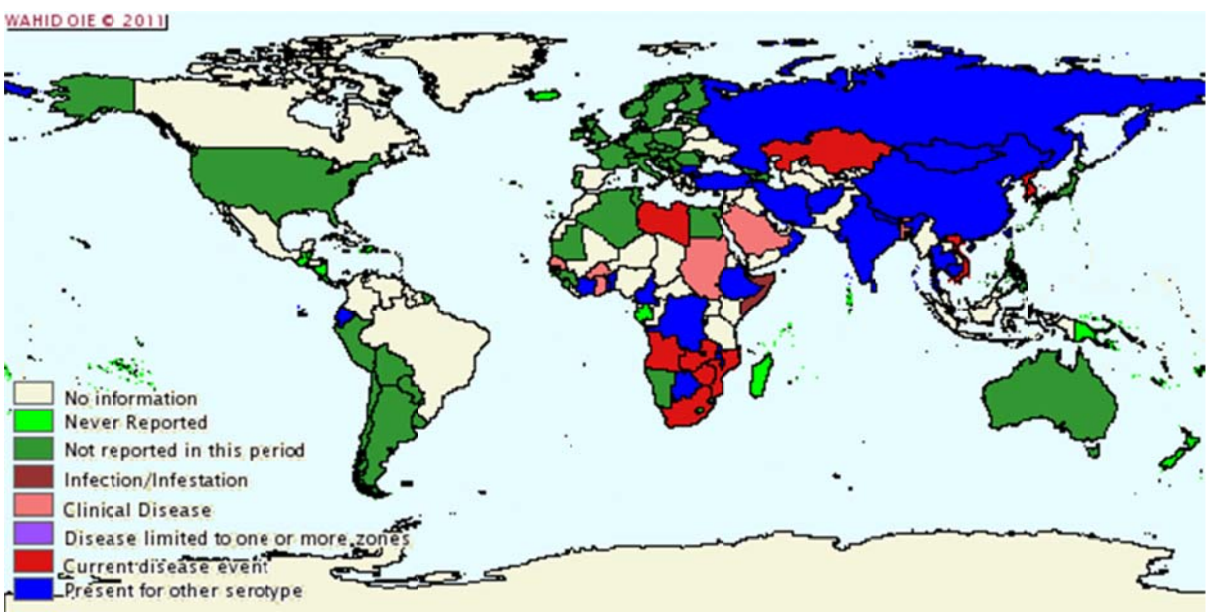

Figure 1. Current distribution of FMD.

Figure 1 demonstrates two important elements. First the USA is currently free of FMD. An FMD outbreak has not occurred in the U.S. since 1929. The second important element is FMD is present in much of the world and there are current active outbreaks in numerous countries.

Disease Pathway

FMD is transmitted by both direct contact between animals and indirect contact through contaminated fomites such as vehicles, clothing, etc. FMD can also be transmitted as an aerosol. This portion of the qualitative risk assessment addresses the introduction of FMD into a FMD free country.

Several recent outbreaks have been started through indirect contact. Researchers have attributed the cause of the 1997 FMD Taiwan outbreak to smuggling meat and live animals from China.[33] This event decimated the Taiwanese pork industry and to date it has not recovered.

The 1967-1968 FMD outbreak in Great Britain was most likely caused by meat imported from South America.[33] Pharo noted that most outbreaks in Great Britain from the period 1938 to 1953 were derived from feeding livestock food-waste.[33] A major outbreak occurred in Great Britain in 2001. This outbreak was caused by a hog producer feeding food-waste obtained from a Chinese freighter.[34] This outbreak cost nearly £10 billion and required the destruction of six million head of livestock.[35]

Several other FMD outbreaks have been attributed to feeding pigs food-waste or illegal movements of livestock. Pharo cited several authors regarding these causes for the outbreaks in Siberia and Mongolia in 2000 and South Africa in 2000.[33] A 2000 outbreak in Japan was attributed to possible FMD contamination of straw imported from China.[36]

In 2010 Korea experienced an outbreak of FMD. In January an outbreak in Pocheon, Gyeonggi was apparently caused by an immigrant farm worker from a northeast Asian country battling FMD, who received a package from home containing clothing and shoes infected with the FMD virus. In March an additional outbreak occurred in the Gangwha area caused by a farmer returning from a trip to China.[37]

An outbreak also occurred in Japan at the same time the outbreak was occurring in South Korea. The cause of the outbreak remains unknown. The strain of FMD that infected Japanese livestock was serotype O.[38] This strain is common in China and is the strain that infected Korea.

[33] Pharo, H. J. Foot and Mouth Disease: An Assessment of the Risks facing New Zealand. New Zealand Veterinary Journal 50 (2). Pages 46-55. 2002

[34] Alexandersen S., Kitching R. P., Mansley L. M. and Donaldson A. I. Clinical and Laboratory Investigations of Five Outbreaks of Foot-And-Mouth Disease During the Early Stages of the 2001 Epidemic in the United Kingdom. 2003. Vet. Rec., 152 (16), 489-496.

[35] Press Release- The 2001 Outbreak of Foot and Mouth Disease. 21 June 2002. National Audit Office. http://www.nao.org.uk/whats_new/0102/0102939.aspx

[36] K. Sugiura, H. Ogura, K. Ishikawa, K. Hoshino and K. Sakamoto. Eradication of Foot and Mouth Disease in Japan. 2001. Rev.Sci. Tech. Int. Epiz. 20 (3). 701-713.

[37] Vets Helped Spread FMD. JoongAng Daily. English Joongangilbo-IHT Partner. May 18, 2010

[38] Foot and Mouth Disease: Keeping it a Foreign Disease. http://veterinaryextension.colostate.edu/News/dzinfo/Japan%20FMD%20_2_1%20_2_.pdf

Outbreaks of FMD continue to occur in countries previously free of the disease. Therefore it must be assumed that FMD is entering these countries from outside their borders.

FMD can be introduced into a FMD free country intentionally or unintentionally by human action or potentially by natural causes.

Intentional Introduction

Precedent exists for an intentional introduction of a foreign animal disease. Glanders is a potentially fatal disease of horses and can infect humans as well. In World War I German agents introduced Glanders into the eastern front to infect Russian horses. It is also reported that Germany, at that same time, introduced the disease into the United States and Argentina to infect horses being sent to Europe. The Soviet Union may also have introduced Glanders into Afghanistan in the 1980s.[39]

Foreign animal diseases can also be used by terrorists. Although there are no known terror attacks using a foreign animal disease as a weapon, there is evidence that terrorists have considered using a FAD for this purpose. Figure 2 shows a document (one of many) obtained in 2002 in a cave in Afghanistan detailing a method for culturing a biological weapon to target people, crops, or animals.

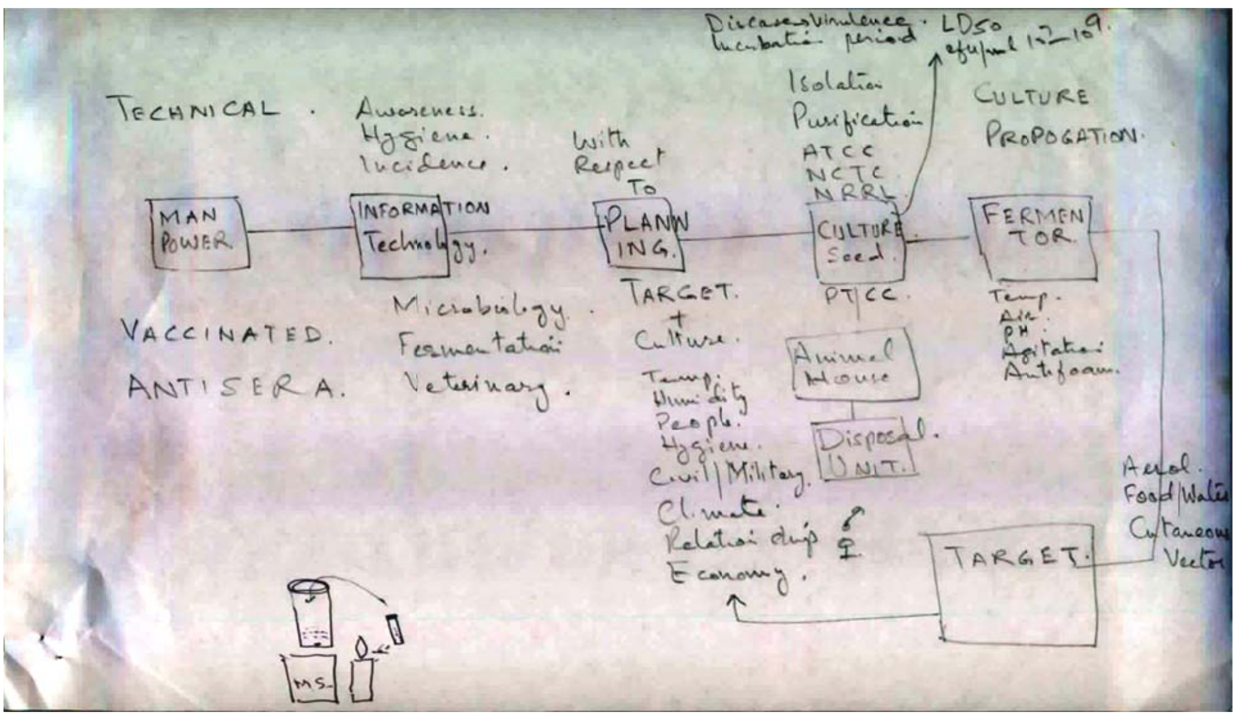

Figure 2. Document recovered during U.S. military action in Afghanistan.

Intentional introduction of FMD would be a potentially devastating economic event for any nation. However, an accidental introduction could be equally damaging.

[39] Weapons of Mass Destruction (WMD): Glanders. http//www.globalsecurity.org/wmd/intro/bio-glanders.htm

Unintentional Introduction

All of the FMD outbreaks in previously FMD free countries have resulted from unintentional actions or the causes have not been definitively determined. Exposure of livestock to FMD occurs either through direct exposure (animal to animal) or through indirect exposure (via fomite).

FMD exposure can occur through direct contact of contagious animals, arriving from outside the United States, with domestic livestock. USDA data show that 2.284 million head of cattle were imported in 2010. About half the cattle originated in Canada and half originated in Mexico. In 2001 the U.S. imported 5.7 million head of hogs, mainly from Canada. The U.S. imported about 1,500 sheep and goats in 2010. The sheep and goats originated from Canada, New Zealand and Australia.[40] All of these countries are currently FMD free. The risk of animals entering the U.S. from FMD free countries and infecting domestic livestock is minimal. However U.S. agricultural and customs officials must remain vigilant as the status of these countries could change. In addition, the possibility of trans-shipments of animals must be considered with the FMD free country acting as an intermediate.

There is precedence for undocumented, economically motivated, trans-shipments of agricultural products into the U.S. to avoid food safety restrictions. For example China exports honey to the U.S. through undocumented intermediate locations.[41] U.S. Customs and Border Protection (CBP) monitors trans-shipments by evaluating current vs. historical shipment volumes. If unusual shipments are detected CBP investigates.[42]

The risk of introduction of FMD through unintentional acts generally involves indirect exposure of a host through a fomite. Fomites can include nearly any object that could become contaminated with the FMD virus. Some recent FMD outbreaks were caused by contaminated meat (e.g., Great Britain, 2001) and contaminated boots and clothing (e.g., South Korea, 2010).

Unintentional introduction could occur by a number of mechanisms including:

- Immigration (documented or undocumented)
- International travel, including non-immigrant admissions
- International trade
- Mail

All of the documented FMD outbreaks appear to have occurred through unintentional acts.

[40] Livestock and Meat Trade Data http://www.ers.usda.gov/data/meattrade
[41] "Laundered Honey": The problem of Illegal Chinese Imports. January, 2009. The BeeKeeper. http://www.thedailygreen.com/environmental-news/blogs/bees/honey-laundering-88010606
[42] Virginia McPherson, Branch Chief Import Safety, US Customs and Border Protection. Personal Communication. November 21, 2011.

Immigration

Immigration consists of individuals establishing residence in the United States from a foreign country. In 2010 1.04 million people established permanent legal status in the U.S.[43] Of these more than 500,000 were from Africa and Asia. Figure 1 shows that large parts of both Asia and Africa either had past outbreaks or FMD is currently present. In addition, more than 73,000 refugees were admitted into the United States in 2010, nearly all from Africa or Asia.[43]

The US Department of Homeland Security estimates that 10.75 million unauthorized immigrants resided in the U.S. in 2009.[44] Of these, the majority originate from Mexico (6.65 Million). However, many of the remaining unauthorized immigrants originated from China (120,000), Brazil (150,000) and Korea (200,000). These three countries either have current or recent outbreaks of FMD or the disease is endemic. In addition 1.65 million unauthorized immigrants were classified as originating from "other countries." [45] Cultural preferences often result in these populations receiving food products and other items from their countries of origin, creating another avenue for disease entry.

International Travel

International travelers could bring the FMD virus in to the U.S. by contamination of clothing or shoes or by bringing in contaminated food or other items. The U.S. Department of Transportation reports that there were more than 160 million US-international passengers in 2010.[45] Table 1 shows the number of passengers traveling to and from areas of recent FMD outbreaks or where FMD is endemic.

Table 1
International Travel for 2010[a]

Area	Number of Passengers
Africa	1,397,840
Far East	23,393,113
Middle East	4,794,560
South America	11,250,759

[a] This is the total number of passengers traveling to and from the U.S. and other parts of the world in 2010. These passenger numbers do not differentiate the passenger's country of origin.

The number of international airline passengers is very large. However, data were not obtained regarding the nature of international visits. For example it is unknown how many international travelers are exposed to livestock or other FMD infected materials either in foreign countries or in the U.S. It is assumed that tourists and business travelers generally remain away from

[43] 2010 Yearbook of Immigration Statistics. Office of Immigration Statistics. US Department of Homeland Security. August 2011.
[44] Michael Hoefer, Nancy Rytina and Bryan C. Baker. Estimates of the Unauthorized Immigrant Population Residing in the United States: January 2009. Office of Immigration Statistics, Policy Directorate. US Department of Homeland Security.
[45] U.S. International Air Passenger and Freight Statistics. December 2010. Office of the Assistant Secretary for Aviation and International Affairs. International Aviation Development Series. US. Department of Transportation. Released November, 2011.

livestock production areas. It is also assumed that some of these travelers will be exposed to livestock or potentially infected materials such as meat products or infected soil. The U.S. CBP issues every international traveler a questionnaire that requires the passenger to report contact with livestock. These questionnaires are reviewed at customs; however, the data are not compiled to allow determination of the percentage of passengers that are exposed to livestock.[42]

In 2005 the U.S. received about 9.4 billion pounds of cargo by air.[46] Air cargo consists of a number of different items including perishable food. Cargo sent by air arrives within hours of departure. If an item were to be contaminated with the FMD virus it could result in infection if it was introduced to livestock.

The U.S. imports many items by container ship. These items include farm machinery and other materials used in livestock or poultry production. Shipping products requires more transit time; however, under the right conditions FMD virus could survive until the shipment reaches the U.S. The FMD virus can be quite persistent. The virus can survive in an exposed state up to a year when frozen and for 8-10 weeks at a temperature of 71.6° Fahrenheit. If the virus is contained in other materials it can survive for extended periods of time. For example, in moist and dry feces the virus can survive for 8 days and more than 2 weeks, respectively. On cardboard, wood, etc. infected with blood the virus can survive 5 weeks, and in soil the virus can survive up to 200 days.[47]

Personal Shipments of Goods

In 2009 the U.S. Census Bureau reported that there were 38.5 million foreign born residents of the United States. Of these residents 27.7 percent were from Asia, and 3.9 percent were from Africa. FMD is endemic in parts of both these continents. In addition, 38.8 percent of the foreign-born residents were reported to be from "other countries."[48] It is reasonable to assume that these foreign-born residents maintain family and other ties with their home countries. Therefore it is also reasonable to assume that some portion of these 38.5 million foreign-born residents receive mail and packages from their family and friends remaining in their countries of birth. If items mailed into the U.S. are infected with the FMD virus or some other foreign or emerging animal disease, then an outbreak could occur assuming the item came into contact with a susceptible species.

Here are two examples of how mailed packages have either caused an outbreak or how they could. The most recent FMD outbreak in Korea is believed to have been caused by clothing and boots sent from an area in China where FMD was endemic.[4] In the United States an unpreserved dead deer was received from the Ivory Coast, a country that OIE reports as having FMD.[49] The

[46] Aviation Security: Federal efforts to Secure U.S.-Bound Air Cargo Are in The Early Stages and Could Be Strengthened. Report to Congressional Requesters. GAO-07-660. United States Government Accountability Office. April 2007.

[47] Foot and Mouth Disease (FMD) Technical Information Reporting Guide. National Humint Requirements Tasking Center; National Center for Medical Intelligence: and National Agricultural Biosecurity Center, Kansas State University. 2009.

[48] Place of Birth of the Foreign-Born Population: 2009. American Community Survey Briefs. ACSBR/09-15. US Census Bureau. October 2010.

[49] http://web.oie.int/wahis/public.php

recipient was located in West Virginia. The deer was in an advanced state of decay when received and the recipient disposed the deer in an open dump. The open dump was frequented by feral hogs.[50]

Natural Release

A natural outbreak of FMD in the United States is possible. If either Mexico or Canada had an outbreak, wildlife or short range aerial dispersion could transmit the disease into the United States. In addition FMD could be transmitted by aerial dust. The 2001 FMD outbreak in Great Britain was officially attributed to a hog farmer feeding infected garbage to his pigs. A 2001 paper by the United States Geologic Survey (USGS) provides a potential alternative cause. The USGS authors noted that a stream of dust originated in the Sahara Desert and was observed, by satellite, over Great Britain on February 13, 2001. The outbreak was detected on February 19, 2001 which would be within reasonable incubation time for the disease.[51] In addition the authors noted that previous FMD outbreaks in Great Britain and Scandinavia have occurred in February which is when dust from Africa generally arrives. Burt notes that windborne dispersal of FMD virus to Great Britain from Africa could occur.[52]

There is precedent for wind-born dispersion of disease over long distances. In 2004 soybean rust was discovered in the southeastern United States. Soybean rust is transmitted by spores. The 2004 soybean rust infection is believed to have originated in Columbia and carried to the U.S. by Hurricane Ivan. [53] In fact the soybean rust outbreak was predicted through modeling by Xaito Pan and X. B. Yang in early 2004.[53]

Long range transport of FMD has not been thoroughly investigated. Donaldson reported survivability of the FMD virus based on relative humidity and temperature.[54] In general Donaldson reported that a relative humidity of 60 percent was required for good survival of the virus in the environment. In addition temperatures below 20° Celsius are required for good survival. With a relative humidity above 60 percent survivability was not adversely affected by sunlight or 'open air' factors.' Donaldson also reported that larger particle size may have an influence in survivability. The studies reviewed by Donaldson used particles between 0.5 and 3.0 micrometers in size. He noted that FMD would probably survive better on larger particles.[54] The OIE notes that airborne transmittal of FMD of up to 60 km (land) and 300 km (water) can occur in temperate areas.[55]

---

[50] Dr. Steve Van Wie, DVM. Personal Communication. 11-30-2011.

[51] Griffin, Kellogg and Shinn. Dust in the Wind: Long Range Transport of dust in the atmosphere and its implications for global public and ecosystem health. Global Change & Human Health, Volume 2, No. 1. US geological Survey, Center for Coastal Geology and Regional Marine Studies, St. Petersburg, Florida. 2001.

[52] Burt. Viewpoint: Airborne Foot and Mouth Virus. 2002. Weather, Volume 57. May 2002.

[53] Isard, Gage, Comtois and Ruso. Principles of the Atmospheric Pathway for Invasive Species Applied to Soybean Rust. BioScience. Volume 55, No. 1. October 2005.

[54] Donaldson. Quantitative Data on Airborne Foot-and-Mouth Disease Virus: Its Production, Carriage and Deposition. 1983. Phil. Trans. R. Soc. Lond. B 302, Pages 529-534.

[55] Foot and Mouth Disease. http://www.oie.int/fileadmin/home/eng/Animal_Health_in_the_world/docs/pdf/foot_and_mouth_disease_final.pdf. 2009.

Disease Receptor

In order for an outbreak of FMD to occur the virus must infect a susceptible species. Susceptibility varies by species. The following estimates provide susceptibilities by exposure route of major U.S. livestock species. Sheep and goats probably require 15 to 100 virus particles to become infected by inhalation. It is not known how many viruses are needed to infect sheep or goats by ingestion. Cattle require from 10 to 1,000 virus particles to become infected by inhalation, and require several million to become infected by ingestion. Pigs require less than 500 virus particles to become infected by inhalation and about 100,000 viruses by ingestion.[47] The U.S. raises millions of cattle, pigs, sheep and goats every year. In addition other species that are prevalent in the U.S. are susceptible to FMD such as deer, elk, and moose. USDA estimates that the U.S. has a feral swine population of over 5 million animals. These animals are concentrated in California, Texas, Oklahoma, and Florida, which are all large livestock producing states.[56] If FMD were to infect a susceptible species within the United States the disease could potentially spread very rapidly requiring the destruction of millions of animals.

Conclusion

In order for a disease risk to be realized three conditions must be met. First, there must be a source of the disease. Second, there must be a pathway for exposure. Third, there must be receptors. This risk assessment has clearly demonstrated that there are multiple reservoirs of FMD virus in the world, including several active outbreaks. The United States raises millions of susceptible livestock at locations throughout the country, and the U.S. is host to more than 5 million head of feral swine and more than 20 million deer. These animals make susceptible species for FMD ubiquitous in the U.S.

The risk of an FMD outbreak in the U.S. becomes a function of pathway completion. Completion of the exposure pathway is the one element of risk that the U.S. can control, at least to a certain degree. The United States has been free of FMD since 1929; therefore, the disease pathway has not been completed since that time.

The U.S. actively works to block the exposure pathway. At the production level, growers institute biosecurity to isolate their animals from disease. Customs officials monitor all international arrivals of air passengers and monitor imports. CBP officials seize an average of 4,125 illegal animal products, meat or plant items every day.[57] SES requested from CBP, but has not received, an assessment of the efficiency of their seizure efforts in terms of what percentage of illegal items are seized compared to what gets through.

New Zealand conducted a review of "slippage" in 1996.[33] "Slippage" was defined as the amount of prohibited animal, meat and plant materials that was missed by their inspections. Pharo reported that 7.7 tons are missed annually. In 2000, New Zealand received 3.5 million international passengers. The U.S receives almost 20 times that amount. The U.S.

[56] USDA APHIS Program Aid No. 2086. "Feral Swine: Damage and Disease Threats." August 2011.
[57] Fact Sheet. U.S. Customs and Border Protection. October 2008.

Reports 160 million international travelers.[45] Assuming all passengers are traveling on round trip tickets, assume 80 million international arrivals. A simple extrapolation results in 154 tons missed by U.S. CBP inspections. Of course this comparison does not take into account differing methods and level of effort between New Zealand and U.S. customs agencies. However it highlights the fact that significant amounts of prohibited materials are probably missed during passenger inspections.

Many of the 38.5 million foreign-born U.S. residents are likely to maintain contacts with friends or family in their native countries. Mailed items have been observed to have caused FMD outbreaks in other countries, most recently in Korea. It is possible that infected items could easily be mailed to a recipient in the United States, completing the exposure pathway.

The U.S. is currently involved in a war on terror. Many of the countries that are directly or indirectly involved in this action have FMD and other dangerous livestock diseases as an endemic disease. The vast majority of these diseases do not impact humans and require no advanced technology to make them infectious. A terrorist could easily obtain FMD contaminated material and introduce it into the United States at locations where the damage would be extreme.

Numeric probabilities of the FMD virus entering the country were not determined. In fact these probabilities may be impossible to determine because there is very little data available that would allow the calculations. While the probabilities were not calculated, this risk assessment demonstrates in a qualitative manner that a significant risk exists of introduction of the FMD virus into the U.S. This risk relative to all countries, prompted the United Nations to issue worldwide warning for increased FMD surveillance in April and June 2010.

It is possible that the FMD virus has entered the U.S. through accidental means, although no data was available to support this conclusion. With an annual count of 160 million international travelers, 38.5 million foreign born residents and an unknown number of undocumented immigrants it is likely that some of these individuals have come into contact with the FMD virus. If this premise is accepted, then the lack of an FMD outbreak in the U.S. can be attributed to the fact that none of these individuals came into contact with susceptible species, completing the exposure pathway.

Based on a review of existing literature regarding the causes of FMD outbreaks around the world it is apparent that the predominant causes were from importation of contaminated materials or infected animals. Garbage feeding of pigs appears to be the cause most often cited. In addition infected fomites also have caused several outbreaks.

Large Animal Disease Laboratory Capabilities

This section of the report provides an overview of the planned capabilities of the NBAF and a subsequent discussion of the capabilities of current U.S. and international large animal disease laboratories.

NBAF Purpose and Scope

The Department of Homeland Security (DHS) intends the NBAF (planned for Manhattan, Kansas) to be much more than just a replacement facility for PIADC. DHS intends it to exceed PIADC's capacity and capability. The NBAF's modern design will provide state-of-the-art biocontainment features and operating procedures. The science of biocontainment has evolved considerably since PIADC was built in 1954. The highest level of biocontainment available at PIADC is Biosafety Level 3 Agricultural (BSL-3Ag). Because DHS plans to perform experiments with some pathogens that require a higher level of biocontainment, a portion of the NBAF will include BSL-4 laboratories.[58]

According to DHS, the definition of BSL-3Ag is "Microorganisms present in the United States, and foreign and emerging agents that may cause serious consequences in livestock but are not harmful to human beings because of available protective measures." An example of a BSL-3 Ag microorganism is the FMD virus. The definition of BSL-4 is "Microorganisms that pose a high risk of life-threatening disease and for which there is no known vaccine or therapy." Examples of BSL-4 microorganisms that could possibly be studied in a BSL-4 lab include Nipah and Hendra viruses, both of which are emerging zoonotic diseases that can spread from their natural reservoir to human beings, and are often fatal.[58]

DHS plans for the facility to focus on FMD, Classical Swine Fever, African Swine Fever, Rift Valley Fever, Nipah Virus, Hendra Virus, Contagious Bovine Pleuropneumonia, and Japanese Encephalitis. The DHS plans to perform research at NBAF to study how these pathogens infect animals, what types of cells the disease affects, what effects the disease has on cells and animals, and how newly developed countermeasures, such as vaccines and anti-viral therapies, help animals develop protection against the disease.[58] In addition, NBAF will be used to continue the foreign animal disease diagnostician (FADD) training that is currently done at PIADC.

DHS projects the size of NBAF to be between 500,000 and 520,000 gross square feet. The approximate breakdown in percentage by area is provided in Table 2.[1] Approximately 55,000 gross square feet of the facility would be BSL-4 laboratory space. The NBAF would be more than twice as large as PIADC as shown in Table 3.[59] This sizeable increase in laboratory capacity may meet the requirements put forth by Homeland Security Presidential Directive (HSPD)-9, as well as establishing the expanded, modern facilities necessary to replace PIADC and perform research activities.

[58] DHS NBAF website: http://www.dhs.gov/files/labs/editorial_0762.shtm
[59] Shea, D., J. Monke., and F. Grotton. "The National Bio- and Agro-Defense Facility: Issues for Congress." Congressional Research Service Report. December 14, 2009.

Table 2
NBAF Space Requirements

Space	Percent of Total Area
Office/Administrative	6.9
BSL-2[a]	6.0
BSL-3[b]	73.8
BSL-4	10.9
Production Module	2.4

[a] BSL-2 includes laboratory and support areas.
[b] BSL-3 includes laboratory, 3Ag, and training and support areas.

Table 3
NBAF Space Compared to PIADC Space (net square footage)

Space	NBAF	PIADC
BSL-2	9,570	4,488
BSL-3E	36,080	28,311
BSL-3Ag	62,144	31,868
BSL-4	15,290	0
Vaccine Production	7,080	0
Other[a]	389,803	169,535
Total	**519,967**	**234,202**

[a] "Other" includes office and support space including space for mechanical and air handling needs.

Domestic Laboratory Capabilities

The proposed NBAF includes BSL-4 capability for large animals. PIADC does not have BSL-4 laboratory space, and the existing infrastructure is inadequate to support a BSL-4 laboratory. Refurbishing the existing facilities and obsolete infrastructure to allow PIADC to meet the new mission would be more costly than building the NBAF. In addition, for the existing facility to be refurbished, current research activities might have to be suspended for extensive periods.[1]

There is an established USDA-APHIS diagnostic laboratory network known as the National Animal Health Laboratory Network (NAHLN). There are 42 laboratories in this network including PIADC and the National Veterinary Services Laboratory (NVSL) in Ames, Iowa that are approved for FMD testing[60]. These NAHLN labs use real-time polymerase chain reaction (RT-PCR) as the diagnostic test for FMD. The RT-PCR test allows the labs to determine if there is a "presumptive positive" case of FMD. The FMD confirmation has to be done by a virus neutralization or virus isolation technique at PIADC. Formal confirmation is the primary trigger to start a disease containment response. The NAHLN labs can also be used for diagnostic surge capacity in the event of a large-scale animal disease outbreak. The NAHLN labs (except NVSL-Ames and PIADC) are not a suitable substitute for NBAF because (1) they only perform

[60] http://www.aphis.usda.gov/animal_health/nahln/

diagnostic testing, not research functions; and (2) they do not have the diagnostic capabilities to provide positive confirmation of FMD and other high-consequence animal disease agents. NVSL-Ames is not approved for confirmation testing of FMD and other high consequence hog or cattle diseases.

There are several other existing or planned BSL-3Ag facilities in the U.S. including:

- The Biosecurity Research Institute (BRI) in Manhattan, Kansas
- University of Georgia-Animal Health Research Facility (AHRF) in Athens, Georgia
- University of Wisconsin Influenza Research Institute in Madison, Wisconsin
- Plant and Animal Agrosecurity Research (PAAR) facility in Wooster, Ohio (planned construction)

Table 4 provides a summary of the size of these facilities.

Table 4
U.S. BSL-3Ag Facility Sizes

Space	BRI	AHRF	Wisconsin	PAAR
Total Gross Square Footage for Entire Facility	113,000	74,500	30,000	27,500
BSL-3Ag[a] Square Footage	31,000	16,000	NA	NA
Number of Animal Holding Rooms	5 large animal 1 small animal	2 large animal 12 small animal	NA	4

[a] Includes animal holding rooms, laboratory space, and support.
NA Not available.

The NBAF facility is planned to have about 40 large animal holding pens.[61] A comparison of Table 3 and Table 4 demonstrates that these existing or planned BSL-3Ag facilities are considerably smaller than the planned NBAF facility. In addition, these facilities do not have BSL-4 biocontainment space. Therefore, these BSL-3Ag facilities will not be able to meet the research, analytical, and training needs established by DHS and USDA.

There are two federal BSL-3Ag facilities within USDA-APHIS; the NVSL facility in Ames, Iowa and the National Wildlife Research Center (NWRC) in Fort Collins, Colorado. The NWRC facility's vision and mission do not encompass the same research needs as NBAF. The NVSL facility in Ames, Iowa and the associated USDA-APHIS Center for Veterinary Biologics and USDA-Agricultural Research Service (ARS) National Animal Disease Center were expanded and merged in 2010 to form the National Centers for Animal Health (NCAH). The NCAH does perform similar research with regard to domesticated livestock to that of NBAF; however, (1) the research is conducted on different species and diseases; (2) the NCAH facilities are not allowed to handle FMD; (3) NCAH is not a BSL-4 facility; and (4) even after an expansion of the facilities in 2010, these facilities are functioning at capacity with regard to research projects. The NCAH facilities would have to eliminate other programs in order to focus on the research, diagnostics, and training planned for NBAF.[61]

[61] Personal Communication with Mr. Scott Rusk, Director of Pat Roberts Hall at the Biosecurity Research Institute in Manhattan, Kansas. December 2011.

There a number of a number of BSL-4 facilities in the U.S. that study known and emerging infectious zoonotic diseases, such as:

- The National Center for Zoonotic, Vector-Borne, and Enteric Diseases (NCZVED) at the CDC in Atlanta, Georgia
- The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland
- DHS's National Biodefense Analysis and Countermeasures Center (NBACC) in Fort Detrick, Maryland
- National Institute of Allergy and Infectious Diseases/National Institutes of Health (NIAID/NIH), Galveston National Laboratory in Galveston, Texas and Rocky Mountain National Laboratories in Hamilton, Montana
- Boston University National Emerging Infectious Diseases Laboratories (NEIDL) in Boston, Massachusetts (under construction)

Although all of these facilities have BSL-4 biocontainment labs, only the Galveston laboratory has BSL-3Ag capabilities (i.e., large animal holding areas where research can be conducted using BSL-3 microorganisms). The Galveston laboratory space is not being used for large animals.[62] These facilities rely on research on small primates and small mammals such as mice, rats, and guinea pigs.[63]

In summary, no existing U.S. facility could meet the mission needs determined by DHS and USDA for NBAF. Although a number of BSL-3 and BSL-4 facilities are located in the U.S., they do not have the capacity to conduct the research required.

International Laboratory Capabilities

There are international laboratories that study foreign and emerging animal diseases, including FMD, such as the National Center for Foreign Animal Disease in Winnipeg, Manitoba, Canada; the Institute for Animal Health in Pirbright, Surrey, England; the Australian Animal Health Laboratory in Geelong, Victoria, Australia; and the Federal Research Center for Virus Diseases in Animals in Riems, Germany. There are multiple issues with relying on international labs for research, diagnostic, and training capabilities, especially in times of a foreign animal disease emergency response. A few of these issues include:

- It has long been known that the very first diagnosis of any foreign animal disease (FAD) in the U.S., especially FMD, must be timely, accurate the first time, and highly secure. Results would be gradually released along a need-to-know chain of command prior to public announcement. This system is in place to prevent producer, public and market panic due to misdiagnosis, as well as to allow law enforcement to prepare for and anticipate a terrorism investigation. Loss of in-country, secure, government-run diagnostic facilities would impair the diagnostic pathway in terms of speed and accuracy.

[62] Comments on draft report from Dr. Stephen Higgs, Research Director of the Biosecurity Research Institute. December 2011.
[63] Personal Communications with Scott Rusk and Dr. Jerry Jaax, Associate Vice President for research compliance and the university veterinarian at Kansas State University. December 2011.

It would also threaten close hold of information and could impair a law enforcement investigation.

- There are logistical issues related to shipping and importation/exportation of infectious samples and select agents. This could easily cause delays in response time of days to weeks and require additional levels of responder training. Delays in confirmation or response would result in catastrophic economic consequences to the U.S. livestock industry. Even if paperwork issues are worked out ahead of time, shipping times internationally could easily add 1 to 2 days to a response. As noted by Dr. Steve Henry, a practicing veterinarian in Kansas, response time to a foreign animal disease emergency is measured in terms of "million-dollar hours."[64]

- A group of researchers modeled an FMD outbreak that originated at a 2,000-head dairy in California. The epidemic model used in this simulation was the Davis Animal Disease model and was used to predict the spread and control of FMD. The modeled FMD simulation estimated direct primary costs (disease management and carcass disposal); direct secondary costs (i.e., international trade impacts); and indirect costs, which included consumer and employment effects, losses to related industries and impacts on local economies. The economic model used to estimate direct secondary and indirect losses in the U.S. agricultural sector beyond direct primary costs was the Agricultural Sector Model, which is a component of the Forest and Agriculture Sector Optimization Model. [65]

  In this modeled FMD outbreak in California, as detection delays increased from 7 to 22 days, the median number of infected premises ranged from 15 to 745; the median number of animals slaughtered increased from 8,730 to 260,370; and the median economic impact was estimated to result in national agriculture losses of $2.3 billion after 7 days to $69.0 billion after 22 days. Although the distribution of costs varied by size and duration of the epidemic, they were primarily direct costs. The economic model examined only the economic impact for the first year of the epidemic; therefore, long-term trade impacts were not estimated. **If assuming a detection delay of 21 days, it was estimated that, for every additional hour of delay, the impact would be an additional ~2,000 animals slaughtered, an additional six infected premises, and an additional economic loss of $565 million.**[65]

- The United States would lose its present ability to confirm the presence of a FAD in the country, and to conduct rapid but detailed analysis (serotyping and determination of sub groups) necessary to even begin vaccine preparation and production. It is also possible that the U.S. could lose the North American FMD Vaccine Bank if PIADC is not replaced.

---

[64] http://www.k-state.co/media/nbaf/henry21908.html

[65] Carpenter, T.E., J. M. O'Brien, A. D. Hagerman, and B.A. McCarl. "Epidemic and economic impacts of delayed detection of foot-and-mouth disease: a case study of a simulated outbreak in California." J Vet Diagn Invest 23:26–33 (2011).

- PIADC, and to an extent NVSL-Ames are the hub laboratories for the National Animal Health Laboratory Network. Closure of PIADC without a replacement would likely negatively impact the NALHN system. If in-country diagnostic capability for index-case samples were to be maintained, expanding the capability of an existing laboratory such as the CDC, even on a small scale, and having it certified, staffed and equipped on a 24/7 basis would be costly.

- In the year-old case of FMD in South Africa, the animals were diagnosed with FMD but were asymptomatic. The causal strain had not been seen before, costing the government time in mounting an appropriate response. Loss of both PIADC and NBAF would impact the U.S.'s ability to correctly identify and respond to strains of new, modified or novel strains of new or emerging diseases. Part of the NBAF's mission is to study new and emerging diseases over the next 50 to 70 years.

- Another real-world example of the extreme disadvantages of reliance on international laboratories was the case study of Reston Ebolavirus in swine. In early to mid-2008, the Philippine government submitted samples from swine affected by unknown pathogens to PIADC. Diagnostic testing at PIADC in October 2008 revealed two known swine viruses and a strain of Ebolavirus (Reston subtype) that had never been found in pigs. Upon preliminary identification, all materials related to the case were immediately transferred to CDC's Special Pathogens Branch for further confirmation and processing of samples in the BSL-4 facility. Identification of the virus as Reston Ebolavirus was confirmed at CDC.[66]

  Immediately after the CDC confirmed the diagnosis, USDA-APHIS contacted the Australian Animal Health Laboratory (AAHL) in Geelong. The completion of the paperwork necessary to transfer select agents (import/export permits) required nearly 7 months, until May 2009. The reagents were received by AAHL on May 22, 2009 and the isolates were received on June 12, 2009. Results from the initial pathogenesis studies at AAHL were reported in November 2009; **therefore, resulting in a time-frame of one year after initial diagnosis. If the diagnostic samples from the Philippines had been received in the planned NBAF, analysis of the isolates could have been initiated immediately after diagnosis.**[66]

- The United States would lose the current hands-on, live animal teaching and diagnostic training offered to future FADDs. FADDs are the front-line field diagnosticians used the states and the USDA to identify potential FADs. A loss of PIADC or NBAF would greatly increase the cost of research and training because the U.S. would have to rely on international facilities to conduct our FAD research and train U.S. scientists. In 2010, the USDA-ARS Arthropod-Borne Animal Diseases Research Unit (ABADRU) moved from Laramie, Wyoming to Manhattan, Kansas and is now collaborating and sharing facility space with the BRI. One of the reasons the ABADRU moved was because it was an aging unit that needed major infrastructure investment and had been sending its scientists

[66] Presentation entitled "DHS Science Program Update" given by Dr. Michelle Colby at the USDA ARS 1st International Biosafety and Biocontainment Symposium on February 9, 2011 in Baltimore, Maryland. http://arssymposium.absa.org/pdf/Session6Colby.pdf

and research to the Winnipeg, Canada facility. This was proving to be very costly to send U.S. scientists out of the country to conduct research.[61]

In summary, these international facilities do not have the capacity to address the outbreak scenarios in the United States in a timely manner and cannot guarantee their availability to meet U.S. research, diagnostic, and training requirements. There is no guarantee that the research and diagnostic priorities of a laboratory in a foreign county will mesh with those of the U.S., nor is there a guarantee that the international laboratories will have the space and capabilities to carry out U.S. research in a timely fashion.