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GERMS, VIRUSES, AND SECRETS: GOVERNMENT PLANS TO MOVE EXOTIC DISEASE RESEARCH TO THE MAINLAND UNITED STATES

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MAY 22, 2008

Serial No. 110–120

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GERMS, VIRUSES, AND SECRETS: GOVERNMENT PLANS TO MOVE EXOTIC DISEASE RESEARCH TO THE MAINLAND UNITED STATES

THURSDAY, MAY 22, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:03 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, Green, Inslee, Dingell (ex officio), Shimkus, Whitfield, and Pickering.

Also present: Representatives Moran and Boyda.

Staff present: Scott Schloegel, John Arlington, John Sopko, Lisa Cody, Kyle Chapman, Alan Slobodin, and Krista Carpenter.

Mr. STUPAK. This meeting will come to order.

Today we have a hearing entitled "Germs, Viruses and Secrets: Government Plans to Move Exotic Disease Research to the Mainland United States." Each member will be recognized for a 5-minute opening statement. I will begin.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Good morning. This is the second in a series of hearings on biomedical research laboratories this committee has held. The first hearing was on the proliferation of high-containment bio labs in the United States. In future hearings, we expect to look at the proliferation of high-containment labs outside the United States including the role of government funding these labs.

Today's hearing will focus on the Department of Homeland Security's, DHS, proposal to close Plum Island Animal Disease Center and build a new, much larger high-containment lab which DHS calls the National Bio- and Agro-Defense Facility, or NBAF.

For 50 years, the Plum Island laboratory was owned and operated by the U.S. Department of Agriculture and was this country's leading foreign animal disease research laboratory. In June 2003, operational responsibility for Plum Island was transferred to DHS under the Homeland Security Act. While the research staff continued to be employed by Department of Agriculture. The majority of research carried out at Plum Island is concentrated on foot-and-mouth disease, which is a very highly contagious disease.

The Plum Island lab was built on Plum Island in order to isolate this extraordinarily hazardous virus and other diseases handled at the lab. The natural barrier of water surrounding the island along with its remoteness at the far eastern end of Long Island were seen as an effective buffer zone between Plum Island and farming activities in the rest of the country.

Now the Department of Homeland Security wants to close Plum Island and build a new facility on the mainland. This proposal is embodied in H.R. 1717, which would do three things: authorize the building of the National Bio- and Agro-Defense Facility, NBAF, which as proposed by DHS would be the world's largest animal disease research center and include the world's largest Biosafety Level 4 laboratory—the BSL-4 labs handle the most deadly diseases for which there is no cure; delegate to DHS broad new authority over animal disease research and zoonotic disease research, including their human health effects; and move live virus of foot-and-mouth disease to the mainland United States for the first time in history.

In summary, DHS proposes to become the primary agency for animal disease research and take over zoonotic disease research, which is now carried out by the Centers for Disease Control and Prevention and the National Institutes of Health. DHS seems to have given inadequate consideration to the risk of transferring foot-and-mouth disease to the mainland, which prompted this committee to examine this issue ourselves.

As part of this subcommittee's investigation, we looked at prior accidental releases of foot-and-mouth disease to see what the economic consequences might be. A 2001 outbreak in the United Kingdom was estimated to cost a little over $16.3 billion and nearly brought down their government. One of our witnesses testifying today has estimated that a major outbreak on the mainland United States could cost as much as $40 billion.

In 1978, there was an accidental release of foot-and-mouth disease from the Plum Island lab, which infected animals kept on the island. Fortunately, the virus never spread any further, due in part to the fact that the lab is buffered by water. In the investigative report that followed the 1978 outbreak, the Plum Island director at the time, Jerry Callis, concluded that the water barrier surrounding the island was instrumental in containing the spread of the disease.

What the report did not say, however, was even more significant. The Committee staff interviewed Dr. Callis and he revealed that at the time of the 1978 outbreak, he and others on the staff were able to persuade the World Animal Health Organization, known as OIE, not to issue an embargo of American meat products because the foot-and-mouth had not escaped from the island. Had the OIE declared an embargo, as it would today if such an outbreak occurred on the mainland, it would have halted the export of all American meat products for at least 6 months and the cost to the livestock industry would have been enormous. We will be interested to hear today how DHS and USDA would seek to balance devastating consequences of this magnitude with the convenience of opening a lab on the mainland.

We will also be interested in examining the costs of the proposed NBAF. The official DHS estimate is that NBAF will cost approxi-

mately $450 million to build but the Committee has learned that DHS engineers have also raised the estimate to between $600 and $750 million. Moreover, this does not include the cost of demolition, decontamination, and environmental cleanup of the existing facility at Plum Island if it is abandoned.

Earlier this year, DHS assured us that they had broad support for their proposal from the private sector. To test that theory, we sent letters to more than 100 livestock associations asking their views of moving this disease to the mainland. Today we will have with us representatives from some of the larger associations which responded. These are the farmers who have much to lose if something goes wrong, and I understand they have strong opinions on the subject.

Let me be clear: I do not oppose the creation of a National Bio- and Agro-Defense Facility, NBAF, but I do oppose moving the research of this devastating foot-and-mouth disease to the mainland United States. For more than 50 years, foot-and-mouth disease has been researched safely on Plum Island and moving it to the mainland would be a foolish tempting of fate that could cause countless farmers and ranchers their livelihoods and cause billions of dollars should a foot-and-mouth disease release occur.

I want to thank the witnesses appearing here today. I know that some of you have come a long way to testify, and I want you to know that we appreciate you taking the time to be here with us.

That concludes my opening statement.

Mr. STUPAK. I would next turn to my ranking member, my friend, Mr. Shimkus, for an opening statement.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman, and thanks for convening this important hearing.

Today's hearing will expose several issues surrounding the proposal and construction of the new National Bio- and Agro-Defense Facility. We all agree that it is our responsibility to protect the American public's health while ensuring the safety of our agriculture and food infrastructure by maintaining an up-to-date biocontainment facility capable of researching and developing cures for deadly and contagious zoonotic and animal diseases. The witnesses today will discuss the costs associated with this facility and whether this new facility should remain on Plum Island or be moved to the mainland.

The Homeland Security Act of 2002 transferred ownership of Plum Island Animal Disease Center, a small island off the coast of New York owned by the Federal Government where current research on both domestic and foreign animal diseases takes place, to the Department of Homeland Security. Since the transfer, DHS has been the lead agency for the center supported by the U.S. Department of Agriculture researchers and employees. The main issues surrounding the creation of a new NBAF include ensuring that the Department of Homeland Security and the United States Department of Agriculture have adequately assessed the health and economic risks and costs-benefits associated with the construc-

tion, operation, and maintenance of this new biocontainment facility.

Today we want assurance from the government and industry experts that the American public will remain safe independent of where the new facility is located. We want Americans to know that the proper precautions will be taken if a new biolab facility is created in their community. Several witnesses, including DHS, USDA, and livestock associations, will explain how that safety is to be ensured. I look forward to hearing from the witnesses about the advances in modern technology and the importance of proper training in relation to the construction and operation of a biocontainment facility of this magnitude. In fact, the new NBAF would be the world's largest animal disease research center and include the world's largest BSL-4 laboratory. DHS estimates the cost of this facility to be between $450 and $750 million.

Of particular interest to DHS and USDA and the livestock industry is the continued research of the highly contagious animal disease, foot-and-mouth disease. By statute, for the past 60 years the research on live foot-and-mouth disease has been limited to Plum Island. Releases of foot-and-mouth disease in England led to an outbreak in 2001 that cost England's economy an estimated $15 billion. The Government Accountability Office will discuss its evaluation of DHS's evidence supporting its decision that conducting foot-and-mouth disease research on the mainland is as safe as conducting it on an island. Under Secretary Cohen from DHS and Under Secretary Knight from USDA are here to explain how the agencies determined that the transfer of foot-and-mouth disease and other animal disease research to the mainland is safe and what the next steps in the NBAF process entail.

Today we are here to examine the facts, hear from government officials, the industry insiders and the outside experts that can explain the scope and needs for a new facility and examine the advantages and disadvantages of creating this facility on an island or on the mainland. I am not here to advocate a particular site. I am here to support this bipartisan oversight examination of the NBAF process and to gain clarity on the issues surrounding the construction of the facility while ensuring that we as lawmakers help protect the U.S. agriculture and human health.

Thank you, Mr. Chairman, and I yield back my time.

Mr. STUPAK. I thank you, Mr. Shimkus.

As you can see, there is a lot of interest in this issue. I expect Mr. Dingell will be here momentarily for an opening statement. Mr. Pickering is a member of the Energy and Commerce Committee, not of this subcommittee. At his option, we would allow him, if he wants to give an opening statement, we would allow that. Mr. Moran is not a member of this committee but is a valuable member of this Congress. If you would like to stay and at the end maybe have an opportunity to ask some questions, you are welcome to. Ms. Boyda is also not a member of this committee but is very interested in this issue, and I expect there will be other members who are not part of this committee who would come and we will show them the same courtesy and respect afforded to all members.

Of the full committee, Mr. Dingell, chairman, for an opening statement and then we will go to Mr. Pickering if he chooses.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, this is a very important hearing, and I congratulate you for shining much-needed light on the hidden world of bioresearch. I especially look forward to shining some of that light on the bio research activities of the Department of Homeland Security, DHS, today. It is a curious body. They appear to be much concerned about the efficiency of the agency but to care very little about the safety of the American public with regard to movement of diseases of animals into our society.

As I said at the first hearing on bio-labs, the DHS proposal to close the Plum Island Animal Disease Center and move the live foot-and-mouth virus to the mainland of the United States is not only baffling but dangerous. Following extensive investigation by the Government Accountability Office, GAO, and the committee staff, 7 months later the DHS proposal remains most curious. It also manifests significant, not only incompetence but arrogance and secrecy, something which should not be permitted by government agencies.

Foot-and-mouth is one of the most contagious diseases in the world. We know from recent incidents in the United Kingdom that it can escape from even a high-level biosafety lab. We know that an outbreak of foot-and-mouth disease could have a catastrophic effect on the livestock industry here in the United States just as it did in the United Kingdom in 2001. In fact, the U.S. Department of Agriculture told the committee staff just 2 days ago that an accidental outbreak in the United States could cause as much as $57 billion in damages.

Equally troubling, it appears that DHS is out of step with the rest of the world. GAO investigators visited major labs across Europe and found that in other developed countries, the trend is to do just the opposite of what DHS has proposed. Germany has built its new lab on an island. Denmark has built its new lab on an island. The Parliament in the U.K. is debating the relocation of its land to an island. Why? Because of safety concerns and preventing escape of the agents that bring these kinds of diseases into the broader world.

Why then would DHS propose to move live virus of foot-and-mouth disease from Plum Island to the American mainland? GAO was unable to find a scientific reason for the move. They found apparent agreement that the current Plum Island lab needs substantial renovation and it should be renovated, but they found no justification for moving the lab to the mainland. They also found no cooperation from DHS, which has refused to make available to GAO the information that it needs to properly carry out its responsibilities or to serve this committee or to assist in this inquiry. Indeed, DHS has refused to make available important parts of information sought by this committee on the grounds that it is "proprietary." I look forward to hearing an explanation as to why that information is proprietary at DHS.

In the end, DHS assures us that modern technology will make it perfectly safe to handle foot-and-mouth disease in a high-tech biolab in the heart of livestock country. I wonder if history will confirm their judgment or will make them look like a source of danger to the society. Mr. Chairman, on that score I would note that history is littered with the smoking, stinking wreckage of impregnable, indestructible, and unsinkable.

Given the potentially catastrophic effects that a release of foot-and-mouth could have on our livestock industry and on the national economy and on the national budget, it seems to me that DHS has the burden of showing to us why this is necessary and why it is in the public interest and why they cannot be open in answering the questions that this committee lays upon them.

In that regard, I must regrettably point out that DHS has not been forthcoming in providing the records and information requested by the Committee as I mentioned earlier. In several instances, the Committee has only been provided copies of certain key records after the committee staff discovered their existence despite the fact that the Committee has specifically requested all such records. At this late date there are still a number of relevant documents outstanding and missing after being requested by the Committee including the statement of work for the environment impact statement for Plum Island and the proposed National Bio- and Agro-Defense Facility, NBAF. I would note that the National Environmental Policy Act, of which I am author, requires that this process be open and that the public be included in the process. We want to know why it is that DHS presumes itself above the law on this particular matter and what question of national security here says that that information and that process may be suppressed to meet the convenience of DHS. Clearly this is unacceptable and grossly improper.

Finally, I am interested in the testimony from ranchers who own the livestock in this country on how they view the DHS proposal. All the consultants and technical experts that DHS can hire may stand behind this idea but it will still be the farmers and ranchers who bear the risk and suffer the consequences of they are wrong and the taxpayers will be called upon to make whole the American people who are put at risk or hurt by the follies of DHS.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Chairman Dingell.

Your option, Mr. Pickering as a member of this committee, the option of giving an opening statement if you would like or waive it.

Mr. PICKERING. Thank you, Mr. Chairman.

Mr. STUPAK. You will be recognized for 5 minutes then.

OPENING STATEMENT OF HON. CHARLES W. "CHIP" PICKERING, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI

Mr. PICKERING. Thank you, Mr. Chairman. I would like to make a brief statement. I want to thank you for allowing me to participate in the subcommittee and for this hearing. It is of critical importance that we get this right and I believe that we can get it right.

I believe that there is agreement that we need to have a new facility. The Plum Island facility is outdated. It is not modern and we can do a better job of this vital research and a new facility I believe is in everyone's best interest and there is agreement to do so. So the question becomes, should we do this on the mainland or should we continue to do it on an island? The new biocontainment facilities that we currently already do in places like Atlanta in the heart of Atlanta close to Emory where the CDC's BSL-3 and BSL-4 facilities are already studying the same type of pathogens, very dangerous diseases, very high risk to human health, and doing so safely. So we have modern facilities that are doing similar research in mainland facilities and around the world that is also the case, and as we look at why we should do this, one, that it is more economical, it can be done safely. This makes sense for the taxpayer and it makes sense for animal and human health.

The Farm Bill that we just passed, in fact that we just overrode the President's veto on, a majority of Republicans and a majority of Democrats on that committee called for the establishment of the new NBAF facility on the mainland, strong bipartisan support, overrode the President's veto to do so. I think the Congress has spoken very clearly in a very strong political bipartisan consensus-based approach that this should be the policy and it affirmed the policy that we have been taking over the last 3 years to do so. There is also strong support from the scientists and those most affected by this research. The American Veterinary Medical Association has sent a letter to both Congressman Stupak and Congressman Shimkus, and this is what they say: "The American Veterinary Medical Association supports DHS's decision to build a National Bio- and Agro-Defense Facility. A modern, well-designed and operated facility does not present an unacceptable risk to animal or human health and would be more economical to build, maintain and operate on the mainland." The chief health official in Mississippi makes the point that all the organisms to be studied at the new NBAF are already being safely studied in other biocontainment laboratories in the continental United States including CDC's BSL-3 and -4 laboratories located in the heart of a densely populated residential area of Atlanta and adjacent to Emory University's main campus.

So it is being done today and it is being done safely. It can be done more economically. We all agree a new facility needs to be built. Those most closely associated, the cattlemen and the farmers in the region of Mississippi and Louisiana, and I am sure Mr. Moran will say that the farmers and the ranchers and the scientists in Kansas believe that this can be done safely, and we believe very strongly that Mississippi is a better site. I think Mr. Moran may differ with that but we agree that a facility can be done on the mainland and that this is the wise and right policy of the United States that we have undertaken over the last 3 years and just yesterday overwhelmingly endorsed in the override veto of President Bush.

So I look forward to this hearing. There is strong scientific and political support for the policy to establish on the mainland a new NBAF, and I look forward to the testimony today. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Pickering.

Ms. Boyda is here from Kansas as well as Mr. Moran. They are not members of the committee. Therefore, they would not be allowed to do an opening statement under the Rules of the Committee in this House. However, when we get to our questioning rounds, both Mr. Moran and Ms. Boyda, if they would like to speak, I would with the unanimous consent of the Minority allow questions.

However, I am going to caution everyone right now, we are not here today to make a decision where NBAF should go. We have had requests from Mississippi, Texas, Kansas, Georgia, North Carolina. They all want to sit in the hearing today and they all want to advocate for their State. We are not here advocating for any one State. We are here talking about NBAF, should it be built or not built, and whether foot-and-mouth disease should be moved to the mainland. That is the purpose of this hearing. So I just want to put that forth so everybody understands why we are here and what we are doing. This is an investigative and oversight subcommittee. We want to make sure if we are going to do this, it is done right.

So with that caution, we have our first panel before us. Let me introduce them. Dr. Nancy Kingsbury, who is the Managing Director of Applied Research and Methods at the Government Accountability Office. Dr. Kingsbury is accompanied by Dr. Sushil Sharma, who is the Assistant Director of Applied Research and Methods at the Government Accountability Office, and Dr. Tim Carpenter, who is Professor and Co-Director of the Center for Animal Disease Modeling and Surveillance at the University of California, Davis. We welcome you to our committee.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the Rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel at this time? Everyone is indicating no. Therefore, I would ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. They are now under oath. We will begin with their opening statements, 5 minutes for an opening statement.

Dr. Kingsbury, if you don't mind, we will start with you, please, and thank you for being here.

STATEMENT OF NANCY R. KINGSBURY, PH.D., MANAGING DIRECTOR, APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; ACCOMPANIED BY SUSHIL SHARMA, PH.D., DRPH, ASSISTANT DIRECTOR OF APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Dr. KINGSBURY. Thank you, Mr. Chairman. Thank you very much for your invitation to appear at this hearing. As you know, in response to your request, we have been reviewing the evidence that the Department of Homeland Security says it relied on to make the decision to relocate NBAF on the mainland and in particular foot-and-mouth disease research on the mainland.

We recognize that there have been significant advances in the technologies of modern biocontainment laboratories and that some BSL-4 laboratories have operated without significant incidents on the mainland, indeed, in center cities. However, the research undertaken at Plum Island is unique in at least one respect and poses a special set of challenges because it includes, among others, research on the live virus strains that cause foot-and-mouth disease.

Foot-and-mouth disease is the most highly infectious animal disease that is known. Infection can occur from exposure to a small number of virus particles and nearly 100 percent of exposed animals become infected. The virus can spread from infected animals in various ways. In some circumstances, the wind can spread the virus. The traditional response once an infection is confirmed is to depopulate infected and potentially infected herds, usually resulting in the slaughter of tens of thousands of animals or more. From the research perspective, FMD poses special challenges because of the need to manage large numbers of large animals within biocontainment.

You asked us to evaluate the evidence DHS used to support its decision that research on live foot-and-mouth disease viruses can be done safely on the U.S. mainland, whether an island location provides any additional protection over and above that provided by modern high-containment laboratories on the mainland, and the economic consequences of an outbreak of foot-and-mouth disease on the mainland.

To address these questions, we interviewed officials from DHS and USDA, and visited Plum Island. We obtained and reviewed relevant legislation, regulations, literature on foot-and-mouth disease and the economic effects of outbreaks, and other documents including the study that DHS identified as the source of evidence for its decision. We also talked to experts on animal diseases and high-containment laboratories dealing with animal, zoonotic, and human pathogens including the directors of other facilities that do research on foot-and-mouth disease viruses in Europe and Australia. We also met with representatives of the American Society for Microbiology, the National Grange, the National Cattlemen's Beef Association. and the National Pork Producers' Council.

We found that DHS has not conducted or commissioned any study to determine whether foot-and-mouth disease research can be done safely on the U.S. mainland. Instead, DHS based its decision that work with FMD virus can be done safely on a 2002 USDA-sponsored study that addressed a different question. We found that the study was selective in what it considered, and it did not assess the history of releases of FMD virus or other dangerous pathogens. It also did not address in detail the issues of containment related to research involving large animals such as cattle. In addition, the study was inaccurate in comparing other countries' experience with foot-and-mouth disease with the situation in the United States.

Most of the experts we consulted during this work agree that while location in general confers no advantage in preventing an initial release of an infectious agent such as FMD, location can help prevent the spread of pathogens and thus a resulting disease outbreak if there is a release. The history of work at biocontainment facilities suggests strongly that there will always be some risk of

a release because of failure of technology or, more likely, human error. Thankfully, these events are rare. While it may be possible to engineer a facility to minimize that risk, the study that DHS told us it relied on to reach the conclusion that the risk is acceptable does not provide evidence of how that could be done successfully. More recently, DHS told us that it plans to also rely on the results of the environmental impact statements it has commissioned for each of the six potential sites it has identified to provide further evidence about the safety of conducting FMD research on the mainland. As Mr. Dingell mentioned, DHS would not provide us information about the requirements for the environmental impact statements it has commissioned so we cannot comment on whether the statements will, for example, assess the risk of technical or human error and the potential impact of the release of a dangerous virus outside the facility.

The 2002 study that DHS has relied on describes several facilities in other countries that do research on foot-and-mouth disease as evidence that it is safe to do so on the mainland setting. Some of the statements in the study about these facilities are not correct. The Pirbright facility in the United Kingdom is on the British mainland in an area of small farms. As recently as last summer, however, FMD virus escaped the facility and infected nearby animals. Both Denmark and Germany have recently built new agricultural and human pathogenic research centers but both countries chose to do so on an island because of the additional layer of safety that location provides. Australia has recently opened a facility on the mainland that is recognized as the most advanced in the world for research on dangerous pathogens, but at the present time live foot-and-mouth disease cannot be used there so Australia outsources its FMD research to Thailand. And Canada has built a facility in Winnipeg that is to conduct research on foot-and-mouth disease but the facility is located in an urban area away from farmland and has a very small capacity to conduct tests on large animals.

With respect to the potential economic impact, it is important to note that the United States has been free of foot-and-mouth disease since 1929. A single outbreak of the disease on the U.S. mainland could have significant economic consequences. Not only would it result in the slaughter of a large number of animals, it would likely result in a ban on imports of American beef by many countries. The value of U.S. livestock sales was $140 billion in 2007 without about 10 percent of those sales accounted for by export markets. Accordingly, this sector of the economy could be dramatically affected should an outbreak of foot-and-mouth disease occur.

In summary, Mr. Chairman, we believe that more evidence is needed to clearly demonstrate that research on live FMD viruses can be conducted as safely on the mainland as on an island. Release of a pathogen as infectious as FMD is likely to have significant consequences that need to be explicitly taken into account in making a location decision.

With that, I welcome any questions that you and the members may have.

[The prepared statement of Dr. Kingsbury follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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HIGH-CONTAINMENT BIOSAFETY LABORATORIES

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

Statement of Nancy Kingsbury, Managing Director
Applied Research and Methods

GAO-08-821T

May 22, 2008

GAO
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Highlights

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

HIGH-CONTAINMENT BIOSAFETY LABORATORIES

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

Why GAO Did This Study

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

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

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

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

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

What GAO Found

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

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

Figure 1: The Plum Island Animal Disease Center

Source: DHS.

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

Mr. Chairman and Members of the Subcommittee:

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

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

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

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

[1]21 U.S. Code §113a.

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

[3]6 U.S. Code §542(b)(3).

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

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

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

You asked us to evaluate

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

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

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

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

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

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

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

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

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

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

Results in Brief

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Background

FMD Is a Highly Contagious Animal Disease

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

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

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

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

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

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

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

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

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

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

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

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

Plum Island Animal Disease Center

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

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

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

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

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

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

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

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

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

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

[20]6 U.S. Code §542(b)(3).

National Bio and Agro-Defense Facility

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Source: GAO analysis of USDA data.

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

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

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

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

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

Source: GAO analysis of DHS and USDA data.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Potential Impact of an FMD Outbreak in the United States

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

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

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

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

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

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

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

Conclusions

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

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

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

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

Contacts and Acknowledgements

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

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Mr. STUPAK. Thanks, Dr. Kingsbury.

Dr. Sharma, did you wish to make an opening statement?

Mr. SHARMA. No.

Mr. STUPAK. Dr. Carpenter, your opening statement, please, sir.

STATEMENT OF TIM E. CARPENTER, PH.D., PROFESSOR, CO-DIRECTOR, CENTER FOR ANIMAL DISEASE MODELING AND SURVEILLANCE, UNIVERSITY OF CALIFORNIA, DAVIS

Dr. CARPENTER. Thank you for the invitation, and what I wanted to do is a little bit different. I am going to be talking from some slides, and based on what I am hearing, I think you have a fairly good knowledge of the disease but I would like to walk through some of these to give you some background for the modeling outputs ultimately.

[Slide shown.]

You know about the virus. It is highly contagious, survives in meat, milk, et cetera, in the environment and it affects cloven hoofed animals, so beef, cattle, et cetera. Its lesions and clinical signs, it can be detected fairly easily if they are obvious or it may not. It may be relatively unapparent in sheep and goats and may be missed. It depends. It can be confused with other diseases as well, diseases that are endemic in the United States. Transition, there are four routes: direct contact, animals moving, contacting one another, being shipped across the country; indirect contact, maybe human vehicles contacting infected environments or animals; airborne spread, it has been shown that possibly it can be spread for over 100 miles; and local area spread is a relatively obscure way of transmission to a neighbor close by.

[Slide shown.]

OK. These numbers, you have heard about FMD has not been in the United States for about 80 years and it has been in the U.K. a number of times. What I wanted to point out here is how variable it can be. In the United States, we had two outbreaks in the 1920s. The size of those outbreaks ranged from over 130,000 animals being killed to 3,000 or 4,000. In the U.K., there are four outbreaks that I have there. The most recent we have been talking about, it only affected eight farms. Previous to that in 2001, there were over 2,000 infected premises and a total of about 9,000 to 10,000 affected animals slaughtered. So the range of animals slaughtered ranges from 1,500 or so to over 6.5 million, same disease, a different serotype possibly but same disease.

[Slide shown.]

Geographically, going from left to right here, shows the 1967, 2001 and 2008 epidemics. You can see the 2001 in the center is much larger, extends up into southern Scotland, into Wales, compared with the western part of England in 1967, and in the most recent 2008, this area here is the area that was infected and that is where Pirbright is and that is where the eight farms occurred, and that was a very, very short-lived epidemic.

[Slide shown.]

Here is the devastation. In March of 2001, there were, I believe, about 3 million animals slaughtered, or about 80,000 a day in various ways: burial, burning. None of them, I don't think, are satisfactory.

[Slide shown.]

Economic impact, we have heard a lot of talk about that in the U.S. and in California. In the U.S., maybe $40 billion. These are old estimates, updated in 2001 dollars. In California, maybe it is around $8 to $10 billion estimated. And in the U.K., it was estimated about $15 billion U.S.

[Slide shown.]

OK. Here is what we are doing at Davis. We have got a model we have been working on for about 10 years and we are still going to keep working on it. We have collected data from different organizations around the country and collected information from the USDA on locations of premises. We have talked with experts to get their impression or subjective opinion of potential for transmission, for instance, or effectiveness of control strategies and we have collected information on animal movements, where do they go, how frequently are they moved and how many animals are moved. We put all that information in the model and do simulations, and that is what I want to show you some examples of now.

[Slide shown.]

And what I am showing you is focusing in California but at the end I have got a movie of what might happen if FMD were introduced into Kansas. So in California, I think the important points here are, it depends where the index, the first case is. If we are looking at a small backyard of beef, it is going to be a relatively small impact. If we are looking at an intensive dairy, it is going to be large. If we are looking at a sales yard, it is going to be very extensive. These are results that we did for California and I think the important point is that we estimated that if there were FMD, we would have approximately 400,000 or more animals infected. That could be reduced dramatically by a statewide movement ban, which would mean shutting down movement of animals within the State. Also, it could be reduced dramatically by vaccination. The important here I want to show is in the bottom slide with the figure with the little dots there, what they represent is number of carcasses that would have to be disposed on a daily basis, and it peaks there around 10,000 or 12,000, which is an incredibly large number of animals, much, much smaller than what they saw in the U.K. but these are cattle as opposed to sheep. OK. Time for the movie.

[Movie shown.]

Now, what I have got here is, when we do a simulation, we do maybe 1,000 of these runs. We try and recreate 1,000 epidemics, and this is just one and it is not meant to be a big one or a small one. It is just a random one, with the exception that it simulates that four animals being shipped to a sales yard and then dispersed. If it were a backyard, we may not ever see it. So here we go. We start off, and you can't really appreciate the coloring but it is showing the spread down to Texas, up to Nebraska, and it is going to be spreading out to Idaho, and then the black represents, we have got movement control. So we are not really sure what is going to happen with movement control. It could be on a statewide basis. It could be nationally for the first few days. That is one problem the U.K. had. They waited 3 days until they put in the movement ban, but we can evaluate that if it were on a nationwide level or on a statewide level. So that is what I have got.

[The prepared statement of Dr. Carpenter follows:]

Modeling FMD in the US

Tim Carpenter

Center for Animal Disease Modeling and Surveillance (CADMS)
Dept. of Medicine & Epidemiology
School of Veterinary Medicine, University of California, Davis

FMD virus

- Highly contagious
- Survives in meat, milk, blood, semen, moist environment.
- Affects cloven hoofed animals susceptible

  (pigs, sheep, goats, cattle, swine, deer, etc.)

Lesions and clinical signs

- High morbidity, low mortality
- May be inapparent in sheep and goats
- Clinically indistinguishable from VS, VES, BVD, IBR…

Photos source: http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGA/AGAH/EMPRES/GEMP/resources/resources.html

FMDV transmission

- Direct contact among animals
- Indirect contact
- Airborne spread
- Local area spread

FMD eradication strategies

- Baseline

- Vaccination

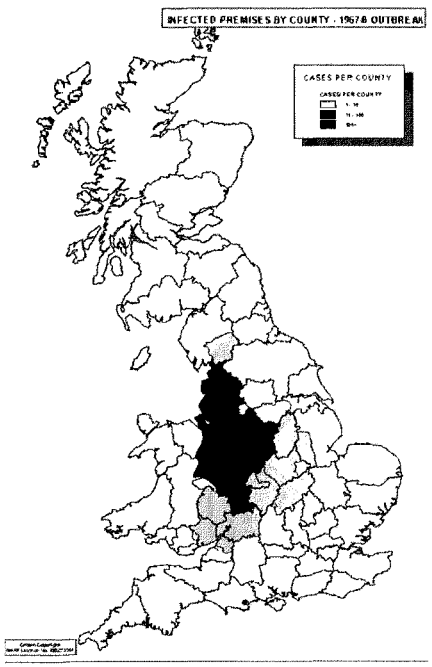
- Preemptive herd slaughter

FMD Epidemics (US and UK)

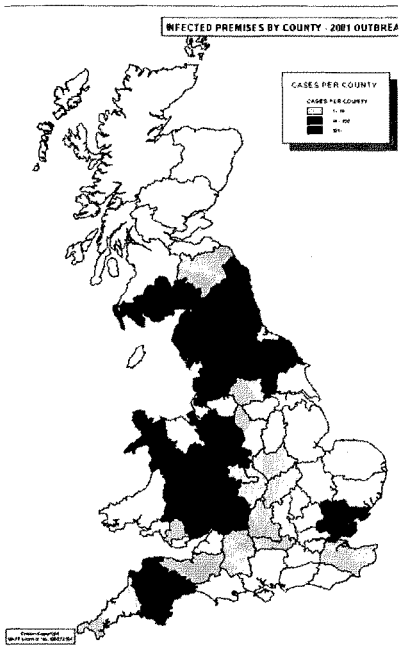
Country	Year	Herds affected	Animals slaughtered
US	1924	948	131,000
	1929	33	3,600
UK	1967/68	2,339	443,000
	1981	1	?
	2001	9,318	6.5 million
	2007	8	1,578

FMD Outbreaks in the UK

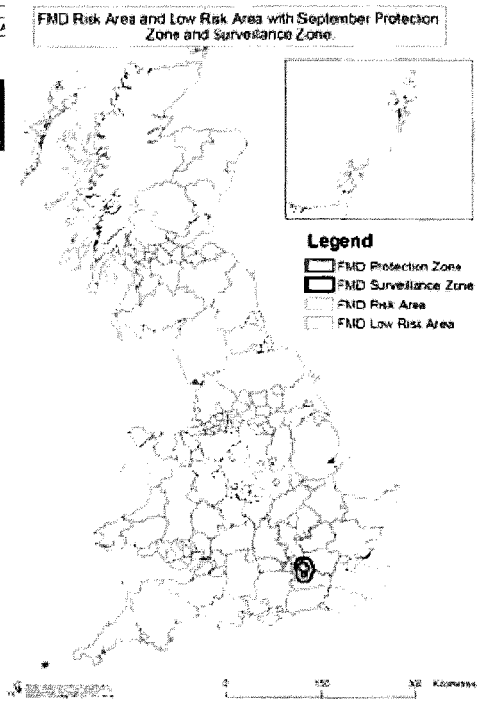
1967



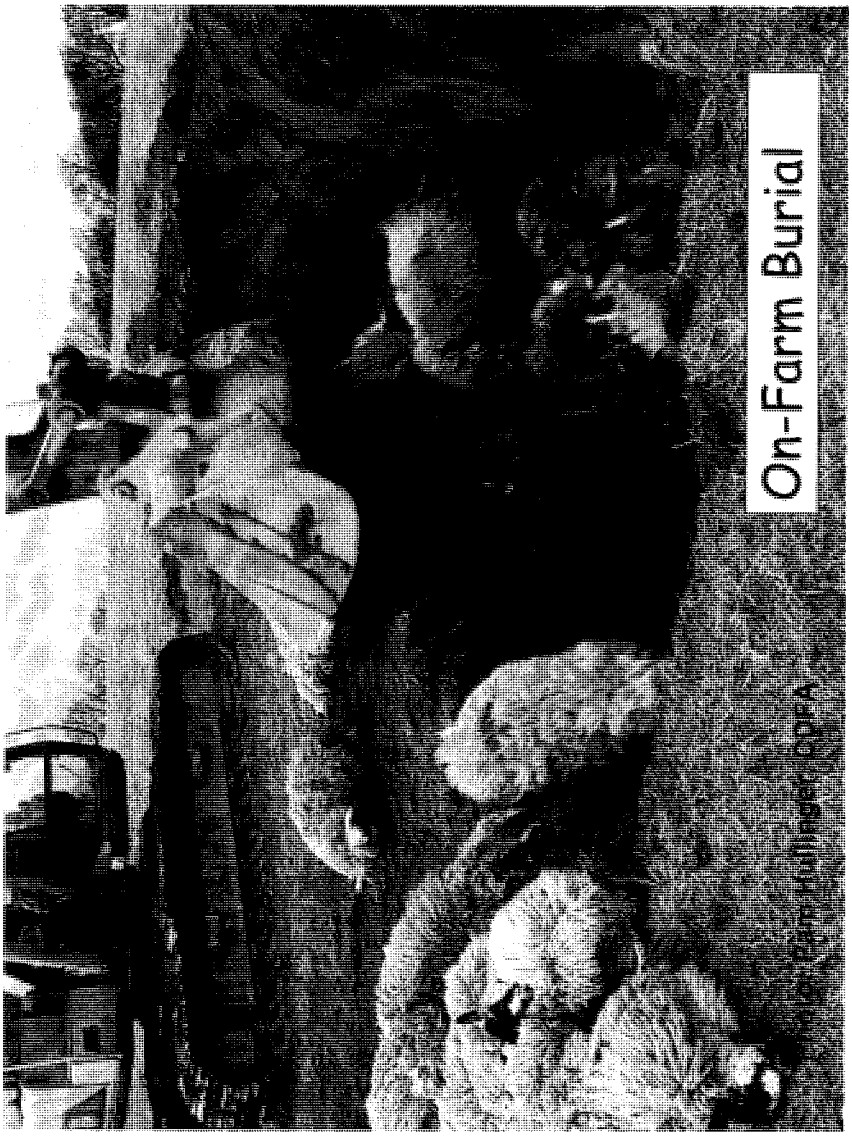
2001



2007



Slaughter/Disposal Numbers = 6-10 million livestock
("officially" 6,456,000: 10% of UK total)
Daily average of animals slaughtered = 9,000 - 80,000
Peak daily disposal = 100,000 carcasses
Photo: Pam Hullinger, CDFA



On-Farm Burial

On-Farm Pyres

Economic impact of FMD

- Trade restrictions on beef, dairy, pork exports
- $37 billion (2001 dollars) to US economy (McCauley *et al.*, 1979)
- $4-13 billion impact on US economy (Ekboir, 1998)
- 13% decrease in export revenue (Paarlberg, 2005)
- £9+ billion impact on UK economy (7/2001)

THE SUNDAY

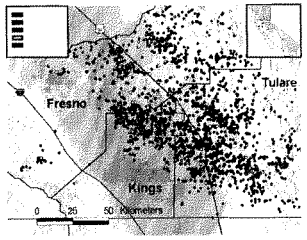
Online diagnosis

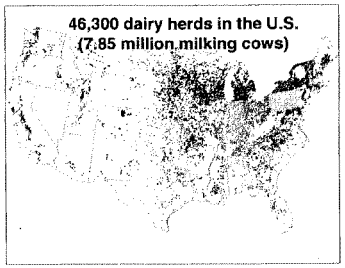
FREE WINE GU

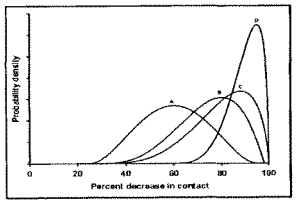
Bill for farms crisis hits £9bn

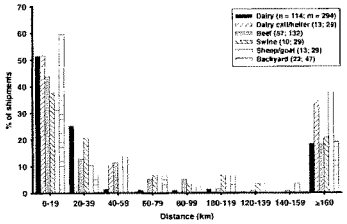
Vets revolt against cull 'too far'

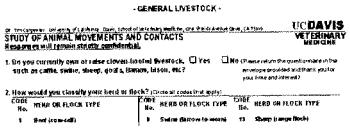
Davis Animal Disease Simulation (DADS) Model

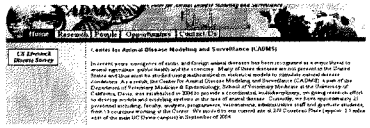






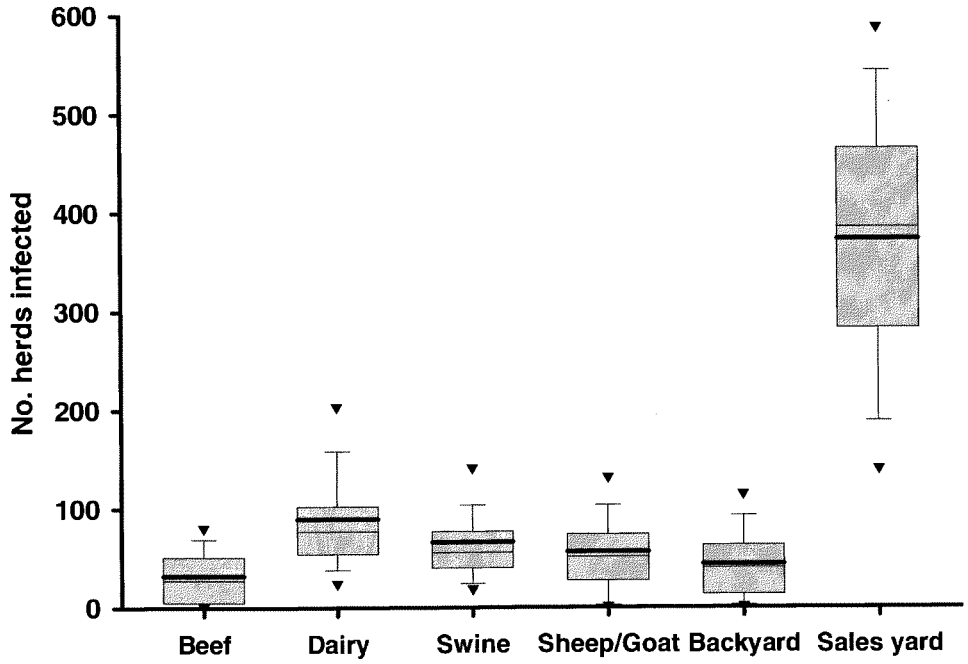






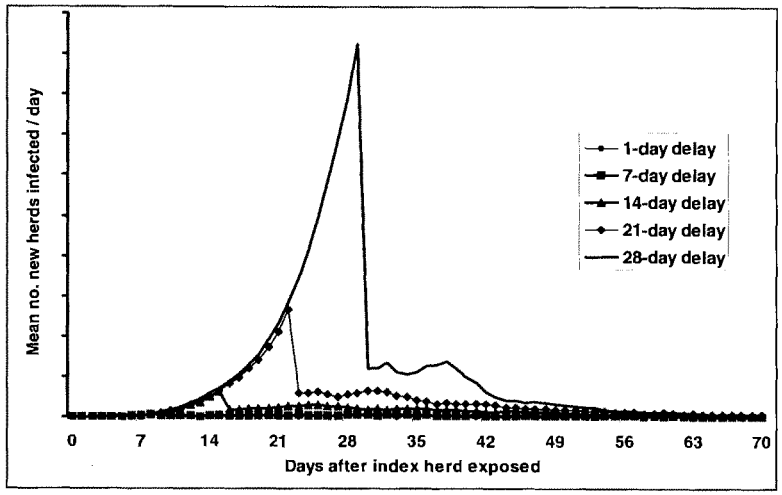
- 30 years FMD modeling
- Spatial
- Stochastic
- Data driven
- National level spread & control

Relative Importance of Index Case Type (3 co. CA)



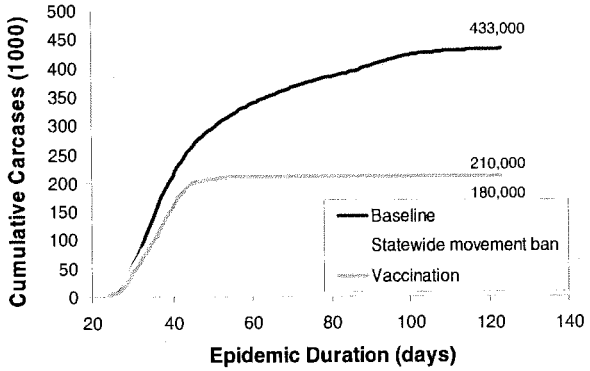
Impact of delays in diagnosis of the index case (3 co. CA)

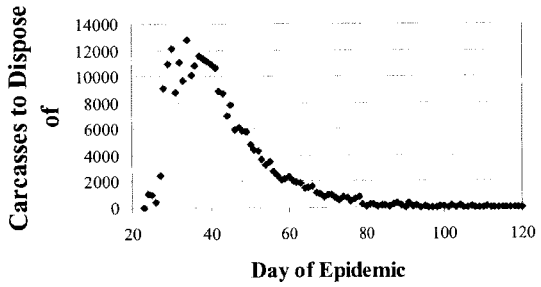
Delay (days)	IPs
7	1
14	12
21	46
28	111



Cost of secondary diagnosis delay = $2-3 million/hr.

Results (day/location-specific)





- Vaccination will reduce the impact by ½; trade problems
- Animal movement ban as effective; without trade restrictions
- As in UK 2001, we are unprepared to deal with carcass disposal

FMD in Kansas: the movie

Mr. STUPAK. Thank you. We will start with questions. I will begin. We will go 5 minutes so we can get through this.

Dr. Kingsbury, if I may, you indicated that in Winnipeg, Canada, they were going to do it at a lab in a somewhat isolated area. Is that correct? They were going to put a hoof-and-mouth disease lab in Winnipeg, Canada?

Dr. KINGSBURY. Yes.

Mr. STUPAK. And it was going to be small?

Dr. KINGSBURY. Well, we understand that they have relatively small capacity to handle animals like one or two at a time, so that is in comparison to what I understand is the plan for NBAF where that would be tens of animals managed at the same time.

Mr. STUPAK. All right. Did GAO find with regard to its investigation that DHS has conducted or commissioned any study to determine whether foot-and-mouth disease work can be done safely on the mainland?

Dr. KINGSBURY. They rely on a 2002 study that was originally commissioned by the Department of Agriculture that looked at the question of whether it was technically feasible to have foot-and-mouth disease research conducted on the mainland. That is a very different question from whether it can be done safely, and none of the actual evidence that is presented in that report goes directly to the question of how they assure the safety under these conditions. We talked——

Mr. STUPAK. Well, did they do a risk assessment?

Dr. KINGSBURY. There is nothing in this study that looks like a risk assessment.

Mr. STUPAK. Did they do anything like a—by "they" I mean the Department of Homeland Security—cost-benefit analysis, something like Dr. Carpenter did, where——

Dr. KINGSBURY. Not that we are aware of.

Mr. STUPAK. In your research, you can still do NBAF without having foot-and-mouth disease as part of that program. Is that correct?

Dr. KINGSBURY. Certainly.

Mr. STUPAK. DHS and Department of Agriculture both say that thanks to modern technology, the location of a high-containment laboratory performing foot-and-mouth disease research is no longer important. Do you agree with that?

Dr. KINGSBURY. I am not sure I understood that question.

Mr. STUPAK. OK. The way I understand it, DHS and Ag say that location of a high-containment lab performing foot-and-mouth disease is no longer important, you can do it anywhere because of modern technology.

Dr. KINGSBURY. Well, modern technology certainly reduces the risk and the comparisons that have been made including even here this morning between BSL-4 laboratories in the heart of Atlanta and the risks associated with foot-and-mouth disease research I think are not quite comparing apples and apples. The risk of a release from a facility is non-zero. It may be very, very small. The question is, is it smaller or larger if you are doing research on large numbers of animals inside a biocontainment zone. It may be possible to do that. We are not saying it is not. We are just saying, we have not seen any evidence that that has been fully evaluated.

Mr. STUPAK. Well, your testimony also seems to indicate that other countries have moved back or moved their research on foot-and-mouth disease to an island. I think you mentioned Germany and Denmark. Is the U.K., which we both highlighted, Dr. Carpenter, are they looking at any other way of doing their foot-and-mouth disease research, Dr. Sharma or Dr. Kingsbury or anybody?

Dr. KINGSBURY. I don't think we know that, although there may be some debate about that going on. I think the case of Germany is instructive because the original island facility was built in East Germany, and when East and West Germany came together, they built one on the mainland, but now that—rather West Germany built one on the mainland. When East and West Germany came together, they made a conscious decision to put it back on the island.

Mr. STUPAK. Dr. Sharma, do you want to add anything on that?

Mr. SHARMA. No.

Mr. STUPAK. Dr. Carpenter, if I may, you talk about the statewide movement. Who is responsible for the restrictions of a movement if there is a foot-and-mouth disease outbreak? Is it the State or would it be the Federal Government?

Dr. CARPENTER. That is a good question. Actually, when I was watching some of the hearings on the Commerce Committee, I was thinking maybe it was the committee that was in charge of that. But as I understand it, and others can correct me, it is the State until they call in the Federal Government, and if it is a national-level emergency, it would be the national government, I assume.

Mr. STUPAK. What would the effect of a major foot-and-mouth disease outbreak be on our exporting?

Dr. CARPENTER. The only numbers I have seen on that were from the Parlberg study, and the estimate was 13 percent decrease in exports.

Mr. STUPAK. Because it seems to me we have trouble trying to get our beef into Japan and some of these other Asian countries now. If there is any——

Dr. CARPENTER. Yes, and if there are any politics involved in import-export, I think it would be a very good excuse to stop the importation of U.S. meat. We are doing that with other countries that cannot export to the United States because they have FMD.

Mr. STUPAK. The pictures you showed us in your presentation of animals slaughtered that took place in England in 2001, those weren't isolated instances, were they? Isn't it true that they had to kill millions of cattle, pigs and sheep and it took days to accomplish this?

Dr. CARPENTER. Right. It is estimated 6 to 10 million.

Mr. STUPAK. Let me ask you this. In the Senate Armed Services Committee, this was "Emerging Threats" on the Senate Armed Services Committee. The title of the hearing was "Emerging Threats," March 14, 2003, Senator Roberts indicated, and he said the "Crimson Sky" study, are you familiar with that?

Dr. CARPENTER. Yes, I am.

Mr. STUPAK. And he said that if we had a hoof-and-mouth disease put forth in this country, we could end up losing as many as 50 million head of livestock, would have to be terminated, and he went on to say that he would actually have to extend, if you are going to bury it or even if you burn it, you have to have like that

of a football field 25 miles long just to take care of Kansas. Is that correct? Are you familiar with his testimony?

Dr. CARPENTER. I have no idea. I know that when we first started working on this in 2001, one of the first meetings was with people interested in carcass disposal and there were a lot of novel ideas, but there is a real problem associated with foot-and-mouth disease and moving animals that have been condemned, slaughtered, because of the potential for spreading the pathogen that way. So disposing of them onsite would be very difficult to do, and there would be major problems, I am sure, with EPA and the alternatives.

Mr. STUPAK. OK. I will submit for the record that Senator Roberts, when he said that if we had to terminate 50 million head of livestock just in Kansas, there would be a ditch 25 miles long and half a football field wide in Kansas alone just to handle the herds. That is if you are burying them. Does that sound realistic?

Dr. CARPENTER. Again, I really can't. I think the 50 million might be a bit of a higher number but——

Mr. STUPAK. I will move for the Senate Armed Services Committee Emerging Threats subcommittee, March 14, 2003, be part of the record.

Mr. SHIMKUS. No objection, Mr. Chairman.

[The information appears at the conclusion of the hearing.]

Mr. STUPAK. Questions, Mr. Shimkus?

Mr. SHIMKUS. Thank you, Mr. Chairman.

I am going to start with you, Dr. Carpenter, for the first question. I noticed that when you talked about exports and you said if politics were in the equation. I always tell folks politicians are the most honorable profession because we readily admit there is a political equation in everything we do. So you are at the right place if you want to talk about, are there political equations. We definitely have them here. And so I like that grin that you had on your face. But to the point of your presentation, we know foot-and-mouth disease is very contagious, we got that. What do you want me to extract from your presentation with respect to Plum Island?

Dr. CARPENTER. I don't want you to extract anything really. Seriously, I have never been to Plum Island and I don't really know that much about it. I do know basically what they are doing. You know, it sounds like there is always potential for escape, but personally, I would be more concerned with accidental introduction of contaminated meats or intentional introduction through terrorism.

Mr. SHIMKUS. So you are going to take a pass on this?

Dr. CARPENTER. Yes, I can't comment on Plum Island.

Mr. SHIMKUS. Because if I looked—and I am going to go to Dr. Kingsbury, but on your testimony, I have not been to Plum Island either, the chairman and I were talking. I have been to New York so it would probably be easy to get over there. But if you look at the picture in the GAO report, you have a picture of Plum Island and you have, there is another little land mass in that photo that looks very near. Because pathogens travel 100 miles. Dr. Carpenter, is that what you said?

Dr. CARPENTER. Right.

Mr. SHIMKUS. So Dr. Kingsbury, in the report, there is just a picture, and maybe that is Long Island. And how far is Plum Island from Long Island? Three miles?

Dr. KINGSBURY. Yes.

Mr. SHIMKUS. So, I mean, if we are talking about pathogens traveling, yes, I guess the issue is, if the pathogens travel over water, is that making any damage to the pathogens that they will expire over saltwater or something?

Dr. CARPENTER. And that was the cause of the 1981 outbreak in the U.K. It traveled, I don't know, over 100 miles up to an island actually, the isle of Wight.

Mr. SHIMKUS. Yes, so I mean, that is kind of the debate. I want to go back to the Germany facility. How far is the German facility off the mainland, the German island? Do we know?

Mr. SHARMA. About the same distance.

Mr. SHIMKUS. Three miles?

Mr. SHARMA. Yes. What I would like to comment on is how far travel is a function of many different things. From a modeling perspective, the temperatures, the humidity, daytime, nighttime, all of these factors affect how far the virus or the bacteria is going to move; also, about their survivability if it is during the daytime. The island does offer some advantages in that respect because there is, especially in Plum Island, we know a lot about the direction in which the air flows. We have been doing a lot of studies, monitoring of the air flow, and it typically flows toward the ocean rather than toward Long Island. The second factor is, if it escapes to the mainland, the location of the susceptible animal population. While we have not presented that information but we have looked at the number of animal data by county that USDA collects, Plum Island has the least number of animals in the immediate surrounding counties, whether it is the Connecticut side, the New Jersey side or Long Island.

Mr. SHIMKUS. And let me end with this. I am probably more concerned—we can never engineer a facility that human error will not undo. I mean, you can have all the failsafes you want. I believe we are a sinful human world and we make mistakes and some are—most of them are unintentional. Some are intentional. You look at data breaches and stuff, it is most people stealing data.

So let me just end with this. Dr. Kingsbury, would you respond? Is there a comparison between the CDC facilities in Georgia and Plum Island? Can we equate the two equally, being that the CDC is in the Atlanta area?

Dr. KINGSBURY. We don't believe they are equivalent because while both have high-containment areas, Plum Island deals with numbers of large animals that become infected, that become slaughtered at the end, that have to be disposed of and the like, and all of the research done with animals, as I understand it, at CDC are small animals inside containers.

Mr. SHIMKUS. That is all my questions, Mr. Chairman.

Mr. STUPAK. Thank you.

Mr. Pickering for questions.

Mr. PICKERING. Thank you, Mr. Chairman.

Dr. Kingsbury, you said that Australia contracts out foot-and-mouth disease research to Thailand. Is that correct?

Dr. KINGSBURY. Yes.

Mr. PICKERING. And what is your research on the Thailand facility? Where is it located and have there been any breaches of disease?

Dr. KINGSBURY. We haven't looked into that.

Mr. PICKERING. Have you ever heard of any outbreak in Thailand?

Dr. KINGSBURY. There have been outbreaks in a number of Southeast Asia countries.

Mr. PICKERING. But you don't know if there is——

Dr. KINGSBURY. But we have not studied the details of them.

Mr. PICKERING. Now, in the German island scenario, it is connected by a road. Is that correct?

Dr. KINGSBURY. A causeway, yes, sir.

Mr. PICKERING. A causeway, and so that really, there is no distinction between the mainland site and an island site——

Dr. KINGSBURY. It is still——

Mr. PICKERING [continuing]. As far as the road connection?

Dr. KINGSBURY. It is still largely surrounded by water.

Mr. PICKERING. Yes, but it is connected by a road and so you would agree that it is a mainland connected site?

Dr. KINGSBURY. It is connected to the mainland by a causeway, yes, sir.

Mr. PICKERING. And the possible outbreak scenarios, if it is connected by a road, are really not that much different. Is that correct? I mean, one of your concerns is that an individual or a car would be a carrier of a disease, but in the German example, do you have any examples of that occurring?

Mr. SHARMA. The only area where the road would affect would be the movement of people and transportation so yes, they have—if there is an epidemic or an outbreak——

Mr. PICKERING. But there is not——

Mr. SHARMA [continuing]. There is a risk.

Mr. PICKERING. But your study has shown in that case that has never occurred. Is that correct?

Mr. SHARMA. That is correct.

Mr. PICKERING. Now, you said that Germany constructed a facility at the end of the Cold War when East Germany and West Germany reconciled, and that was a mainland site. That would have been around 1990. Is that—or when was the other site in Germany?

Mr. SHARMA. After World War II when Germany got divided, the West Germans had to make a decision where to locate. They located on the mainland but in an urban area where they were not in close proximity to the susceptible animals.

Mr. PICKERING. Were there any outbreaks in the German facility?

Mr. SHARMA. I think there was one but they could not associate it with the lab.

Mr. PICKERING. So a fairly extensive period of time in Germany where a mainland site operated safely?

Mr. SHARMA. Correct.

Mr. PICKERING. Thank you. The Canadian site, remote, do we have any examples of the Canadian site having any outbreaks?

Mr. SHARMA. Two things. First of all, they are, relatively speaking, new, and their scale is small.

Mr. PICKERING. So they are new, kind of like the new NBAF would be new?

Mr. SHARMA. Yes.

Mr. PICKERING. And modern.

Mr. SHARMA. The scale is very small, not comparable to even the current work, and——

Mr. PICKERING. Any outbreaks in Canada?

Mr. SHARMA. No.

Mr. PICKERING. Thank you very much.

Dr. Carpenter, your concern over terrorism—really, terrorism, whether it is on an island or mainland, there is really no distinction or difference, is there?

Dr. CARPENTER. Well, actually I am not thinking terrorism of a facility. I am thinking terrorism of somebody infecting livestock on the mainland.

Mr. PICKERING. So the terrorism risk is really not an issue here of whether we have a mainland site or a Plum Island site?

Dr. CARPENTER. That is what I was talking about. Right.

Mr. PICKERING. Thank you very much, Mr. Chairman. I yield back.

Mr. STUPAK. Thank you, Mr. Pickering.

Mr. Dingell for questions, please. Mr. Dingell?

Mr. DINGELL. Yes, and thank you for your courtesy.

These are all questions that I would appreciate a yes or no answer to, Dr. Kingsbury and Dr. Sharma, as I go through because we have very limited time here. Foot-and-mouth disease is one of the most highly infectious and dangerous animal diseases known, and nearly 100 percent of exposed animals become infected. Is that so, yes or no?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. Isn't it also true that you found from your research that a single outbreak of foot-and-mouth disease on U.S. mainland could cause significant economic consequences to our economy with possible losses of as high as $30 billion to $50 billion?

Dr. KINGSBURY. Yes to there being significant economic consequences. We didn't actually try to quantify it.

Mr. DINGELL. Now, isn't it true that the cost to our economy would not only be the thousands of animals that would have to be killed but the devastating effect upon the Nation's transportation system, exports, not only in meats but also other food products because protective embargoes would be imposed by other countries on U.S. farm goods?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. And isn't it true that you found that since we moved all of the research of this dangerous disease to Plum Island, we have not had an outbreak like other countries?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. Isn't it true that your research found that the United Kingdom, which has a lab on their mainland, has had numerous outbreaks costing billions of dollars including one last year that was linked to their own government research laboratory?

Dr. KINGSBURY. In general, there have been outbreaks. I wouldn't use the word "numerous." I think it is more likely several, but the statement is correct.

Mr. DINGELL. Now, as a matter of fact, your research documented release of foot-and-mouth disease from labs in the United Kingdom, Denmark, Czechoslovakia, Hungary, Germany, Spain, and Russia, to name a few. Is that true or false?

Dr. KINGSBURY. Yes, true.

Mr. DINGELL. And didn't you also find that Germany and Denmark have moved their foot-and-mouth research to islands because of safety concerns at the same time DHS is contemplating moving our lab to the mainland?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. And isn't it also true that you talked to the Australian officials who have one of the newest and most advanced labs for the study of animal diseases, that their government refuses to let them do live virus foot-and-mouth research in it but requires them to have some other country to take the risk for them?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. Now, let me understand your testimony. When you asked DHS for any reports on cost-benefit analysis that justified their decision to move live virus research on foot-and-mouth disease to the mainland of the United States being done on Plum Island for almost 50 years they had none?

Dr. KINGSBURY. We have seen no cost-benefit analyses and we have asked for everything they have.

Mr. DINGELL. Now, Dr. Kingsbury, let us talk about the 2002 SAIC study that DHS claims justifies this risky move. Isn't it true that you analyzed it and talked to its authors and concluded that it did not support DHS's risky decision for a number of critical reasons?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. Now, let me highlight your findings about this SAIC report. You concluded this report could not support the conclusions that this research could be done safely on the mainland because it, one, addressed a different question; two, was selective in what it considered; three, did not assess the history of releases of foot-and-mouth disease virus or other pathogens either in the United States or elsewhere; four, did not address the issues of containment related to large animal work; and five, was inaccurate in comparing other countries' foot-and-mouth disease work experience with the situation in the United States.

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. Dr. Kingsbury, isn't it true that rather than supporting moving Plum Island to the mainland, the authors of the SAIC study actually concluded that if you included the cost of cleaning up the Plum Island site, it made economic sense to keep the research on Plum Island?

Dr. KINGSBURY. Yes.

Mr. DINGELL. So the bottom line is that someone at DHS either never read the report or is not being forthcoming and truthful in reporting to this committee or the Congress when they say the report justifies this move?

Dr. KINGSBURY. I am not going to speak for DHS, sir.

Mr. DINGELL. And I can assume that you are of the view that this is a risky move. Is that correct?

Dr. KINGSBURY. Yes.

Mr. DINGELL. Thank you.

Mr. Chairman, I believe I have about exhausted my time.

Mr. SHIMKUS. Would the chairman yield for one second?

Mr. DINGELL. I will be happy to yield.

Mr. SHIMKUS. Just to follow up on this, when did GAO share this report with DHS and USDA?

Mr. SHARMA. Tuesday.

Mr. SHIMKUS. Tuesday?

Dr. KINGSBURY. Yes.

Mr. SHIMKUS. That is all my questions, Mr. Chairman.

Mr. STUPAK. Let me just ask a question, Dr. Kingsbury or Dr. Sharma. The committee was disturbed to learn, as Mr. Dingell alluded to in his opening, that DHS was refusing to provide you with documents such as the statement of the work for the environmental impact statement. What excuses do they give for not providing you the documents you requested to do your analysis for this committee?

Dr. KINGSBURY. I believe they said that they were not going to give them to us because the documents were not yet public, but as you know, our access allows us to get access to that kind of information. We just haven't had the time to fully have the argument yet.

Mr. STUPAK. So there are still documents you would like to have from DHS?

Dr. KINGSBURY. If you want us to continue to look at this matter, yes, sir.

Mr. STUPAK. We may go another round of questions, but without objection, I will turn to Mr. Moran for questions.

Mr. MORAN. Mr. Chairman, thank you very much. Thank you for the courtesy that is being extended to me and Ms. Boyda for the opportunity to join you on this panel today, and I fully understand the desire of the Chair and the nature of this hearing to limit our discussion to the idea of moving the facility from Plum Island to the mainland.

Dr. Carpenter, the risks that you describe, what caught my attention, of course, was the episode that begins in the 1st Congressional district in Kansas in your slide presentation.

Dr. CARPENTER. Oops.

Mr. MORAN. But the reality, it seems to me, would be that the risks are minimized at a high-tech new facility and that when you do the model as if there is going to be an episode of hoof-and-mouth disease, the implication is that the risks are increased by the presence of a new facility located on the mainland, and it seems to me that the risks are actually higher from the natural or intentional introduction of hoof-and-mouth disease and so I just want to make sure that the suggestion is not, at least I would hope the suggestion is not that the facility would be the cause and effect or increasing the risk of hoof-and-mouth disease in cattle country as compared to hoof-and-mouth disease occurring naturally or——

Dr. CARPENTER. Right. Absolutely not. I went to my program and I said select a place in Kansas, so there was no intention to say

that there was a release from a facility. It was just if it were there and it were in four or five animals, what might happen.

Mr. MORAN. And I don't know that that is an appropriate question for you but just common sense tells me that the risk is higher for a natural occurrence or for intentional introduction of hoof-and-mouth disease for nefarious reasons than it is for its escape from a facility?

Dr. CARPENTER. One would think based on history, but based on history, there has been no intentional introduction that we know of in the United States, which is surprising but fortunate.

Mr. MORAN. So that assumption, is my suggestion correct, that the risks are not increased necessarily by a facility? There are other factors that may introduce hoof-and-mouth disease to the continental United States?

Dr. CARPENTER. Right, there are definitely other factors. As I said earlier, until 2007 I wasn't really thinking about the potential of a leak. More so, I think it is important for contaminated food coming into the country or intentional actions.

Mr. MORAN. It is sad that we would have to talk about the possibility of intentional introduction. And then finally, I know that the State of Kansas including colleagues of yours at the Kansas State University have done extensive studies on the introduction of hoof-and-mouth disease to our State, have done modeling and scenarios and actually have acted out the—I just was wondering if you are familiar with those studies and included them in your analysis or discussion?

Dr. CARPENTER. Yes, I am familiar with them. I didn't include those in the analysis though.

Mr. MORAN. Thank you, Mr. Chairman, for allowing me this opportunity.

Mr. STUPAK. Ms. Boyda for questions.

Ms. BOYDA. Thank you very much, and thank you for letting Mr. Moran and me join this hearing.

I am from Kansas as well, and, all of the "It's What's for Dinner" commercials, that is Kansas. You are seeing Kansas. So all of the discussion about how dangerous this is, we find to be something that certainly we all are very, very, extremely cognizant of. And I think what Mr. Moran was talking about and asked if you had taken into account, we have a procedure set up if anything happens in Kansas to get it to be under control within hours, not days, because again, this is something that we deal with. If you are in California, you know what you are going to do in the case of some kind of a disaster there. So we live and breathe this everyday. And having this whole discussion about how dangerous hoof-and-mouth is, I am glad everybody in the country knows about it, but I hope everybody hear understands that Kansas lives and breathes this danger every day. We export more beef than anybody in the country. We are the beef producer. So everything that you are talking about is nothing we haven't considered. It is what we consider each and every day, and keeping our herds safe is the most important thing that many of us would wake up and say is very important to Kansas.

So when we hear that Plum Island is 3 miles away and the virus can easily spread for 100 miles, it doesn't, and knowing that Plum

Island has not been well taken care of or maybe it is taken care of. It is old; it puts fear in our hearts knowing that in fact there could be a release from Plum Island and it could very, very easily get over to the mainland. And I just again very quickly would like you to address what, we all understand that there could be some politics playing with this. Is there a chance that putting it in some island is more for political reasons so that people feel some sense of safety because some way or another there is some water between the mainland, but in fact, is that a false sense of security for people and maybe that in fact might have some political edge to it?

Dr. CARPENTER. Is that a question?

Ms. BOYDA. Yes.

Dr. CARPENTER. Yes. Well, I am sure it would make people feel safer if they see a body of water out there. As far as the airborne spread, I am not sure of this but I know about the spread in 1981 in the U.K., that pigs are very effective producers of the virus, shedders of the virus in the air and that cattle are very good receptors. So if you have infected pigs producing the virus and shedding it and you have receptive cattle receiving it, that is a real problem. But airborne spread from a few infected cattle, I don't think would be a major problem.

Ms. BOYDA. I am talking about a release from Plum Island, and I only have a couple of minutes. I would like to ask just another question or two. In Kansas we are deeply concerned. We haven't had an outbreak since 1929, but if there were, then what do you do with those carcasses and how do you get them? Do they need to be transported off to Plum Island so that there can, in fact, be some research done on them? What are the risks of actually having to transport animals that are infected out to an island in New York versus being able to have an immediate chance to take these animals into a laboratory? Is there any benefit in that?

Dr. CARPENTER. No, but I——

Ms. BOYDA. And this is for Dr. Kingsbury as well.

Dr. CARPENTER. I couldn't visualize transporting 5,000 or 10,000 cows——

Mr. BOYDA. No, no, no, but would you need to transport some of the animals affected into the laboratory to see if there is any——

Dr. CARPENTER. I would assume that they would just take samples from the animals for confirmation.

Ms. BOYDA. But you are still having to take those samples, which are still going to house that and take them off to New York. I just wonder if there is any advantage in saying the laboratory is right there. If you needed to do anything, you would be within an hour of being able to begin a study in this country.

Dr. CARPENTER. Actually, that is a very good point that I forgot to make, that I think there would be a good move to put facility wherever it is that is doing the diagnostics in a location that is easily accessible because we are looking at millions of dollars for every hour of delay that——

Ms. BOYDA. That is right, my point being minutes. This is an instant. Kansas understands that this isn't about days, it isn't even about hours. It is about minutes and being able to react so quickly and making sure that you are containing things.

Let me just finalize by saying, Mr. Chairman, I am deeply appreciative of what you are saying about DHS, and from a political standpoint versus just making a good decision, ultimately Kansans want the right decision made here. We have so much at stake here that we want the right decision made, and if DHS is not forthcoming with things, that will cause everyone so much trouble politically but in making the best decision as well. And I certainly am very, very appreciative of hearing what you are saying DHS is. We need the transparency to make sure that the best decisions really are being made but that the American people and the cattlemen in Kansas also know that this process is something that was open and transparent and the best possible decision.

So I certainly appreciate what you are doing in that regard. I yield.

Mr. STUPAK. Mr. Dingell, questions?

Ms. BOYDA. Oh, I am sorry. I have a letter from the delegation that I would like to give to the Committee, if that is all right. This is from the Kansas delegation, Chairman Stupak. Thank you.

Mr. STUPAK. Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman. You alluded to a proceeding involving my good friend, Pat Roberts, who held a hearing with Admiral Jembresky and G.M. Bastiani and it occurred on March 28, 2003. I would like to read from it. Here are comments coming from Senator Roberts. He said, "I played the President under an exercise called Crimson Sky with the Department of Agriculture. Now, Crimson Sky was the misnomer label of what would happen if Iraq had launched a hoof-and-mouth disease infestation in the United States in 7 States. Now, that doesn't sound like much on the surface of it but if you have an infestation period of 6 days and on the 7th you have got to make some decisions and we didn't do it very well. We ended up with 50 million head of livestock that had to be terminated. Now, how do you do that? Just on the surface of it, how on earth do you do that and what do you do with the carcasses? Well, obviously it was the National Guard, and then obviously the National Guard couldn't handle it, so it was all active duty. And then we found we didn't have enough ammunition, and we found that you don't burn the carcasses because that we learned in Great Britain, that is not what you do. So you had to bury them, and there was a ditch 25 miles long and half a football field wide in Kansas alone just to handle the herds there. Then we had to put up a stop order on all shipments because you were having states and National Guards being activated by all the governors to stop other states and transportation of livestock, all export stock. The market went nuts and the people in the cities finally figured out that their food did come from farms, not supermarkets, and they rioted in the streets and there was a mess. And it was not only for 1 year but for several years. Then add in the problem of food security, that if you put a little anthrax in some milk, you have really got a problem on your hands. Now, I want to know, I know that at that particular time when different events happen, that DOD will be there. They are going to have to be there because they are the only outfit that can do it. I prefer the National Guard because people know them, trust them. They are the home forces and they are working toward it."

Now, I want to understand one thing, and this is a question to any of our panel, particularly to our two witnesses from GAO. You told the DHS that you were conducting an official congressional investigation for this committee. Is that correct?

Dr. KINGSBURY. Yes, sir.

Mr. DINGELL. And that Under Secretary Cohen or other members of his staff told you that you could not have the documents until after it was made public. Is that correct?

Dr. KINGSBURY. Yes, referring specifically to the statement of work for the environmental impact statement.

Mr. DINGELL. What did you just say?

Dr. KINGSBURY. We were asking for the statement of work for the ongoing environmental impact statement, and that is what they said was not public.

Mr. DINGELL. What was the reason they told you you could not have those documents?

Dr. KINGSBURY. They said they were going to be released at the end of the month, and when they were public we could have them.

Mr. DINGELL. But you couldn't have them before?

Dr. KINGSBURY. That is what they said.

Mr. DINGELL. Did they set forth a reason why you could not have that information or those documents?

Dr. KINGSBURY. I think I just said everything they said.

Mr. DINGELL. What was the reason? Was there a statutory reason or constitutional reason on which they set forth that they could deny you access to those documents?

Dr. KINGSBURY. OK. Dr. Sharma has just clarified that the argument that the statement of work could not be given to us was that it was proprietary and——

Mr. DINGELL. Why was it proprietary?

Dr. KINGSBURY. They did not say.

Mr. DINGELL. They did not cite any reason why those were proprietary?

Dr. KINGSBURY. No, sir.

Mr. DINGELL. Can you tell us why they are proprietary?

Dr. KINGSBURY. No, sir, and under our rules of access, I don't think there is any reason for them to deny them.

Mr. DINGELL. Is GAO denied any documents on grounds that they are proprietary?

Dr. KINGSBURY. Occasionally that issue arises, but once we have time for our lawyers to discuss the matter, we usually——

Mr. DINGELL. Why are these documents proprietary?

Dr. KINGSBURY. I am sorry, sir. I don't believe they are. But——

Mr. DINGELL. Well, is it because a contractor is doing it? The contractor has got some proprietary interests in the work that he is doing for the government?

Dr. KINGSBURY. I don't know why that word was used. It is not appropriate to deny GAO access.

Mr. DINGELL. We will ask those folks to explain their secretary.

Now, isn't it true that you had other problems getting records from DHS and USDA and that they even delayed your trip to Plum Island until this committee sent a letter threatening them with contempt?

Dr. KINGSBURY. It is true that it took us 6 weeks to arrange the trip to Plum Island and there have been occasional delays in getting documents. The most recent issue over the environmental impact statement statement of work is the most recent case in point.

Mr. DINGELL. Now, isn't it true that while our own DHS is delaying giving GAO documents and access to the Plum Island facility, you were having no problem getting information from foreign countries and visiting their facilities?

Dr. KINGSBURY. That is correct.

Mr. DINGELL. And you were received with courtesy and given full assistance and cooperation by Germans, Danes, and British as well as other countries?

Dr. KINGSBURY. Germans, Danes, and British, and the organization in France, yes, sir.

Mr. DINGELL. Thank you.

Mr. Chairman, I appreciate your courtesy.

Mr. STUPAK. I thank the gentleman.

Let me ask a question if I may, Dr. Kingsbury or Dr. Sharma or Mr. Carpenter; maybe I will start with you, Dr. Kingsbury. The exhibit book right there in front of you, tab number 12, you alluded to in your testimony, Dr. Kingsbury, and others have referred to it, the SAIC report, that is Science Application International Corporation, and it is tab 12 in our exhibit binder. And I understand you had concerns about this report, but I want to ask you, if I may, on page 16, second full paragraph, it says, "Biosafety lapses at any facility location likely have an equal risk of occurrence." Would you agree with that?

Dr. KINGSBURY. The document at tab 12, sir, only has about 5 pages in it.

Mr. STUPAK. OK. Page 16 is not included in that?

Dr. KINGSBURY. Not that I can see. It is just a table of contents.

Mr. STUPAK. All right. Let me ask you this then from it. My binder had it. I thought yours had it. "Biosafety lapses at any location have an equal risk of occurrence." Would you agree with that statement or not? In other words, the risk occurs really from lapse in biosafety practices resulting in the release of an agent or intentional removal by someone with access to the facility. That is how security lapses occur.

Dr. KINGSBURY. That is how these things occur. I wouldn't say it is the same at every facility because different facilities would have different levels of training and concern about the matter.

Mr. STUPAK. Correct. And let me ask Dr. Carpenter this question. When you showed your map up here, the United States and the animal populations, it looked like about the only place you could do it, and I just took a quick look at it while you had it up there, was basically Nevada. That is the only place in the United States, correct?

Dr. CARPENTER. Well, they have livestock in Nevada.

Mr. STUPAK. OK. Well, it looks pretty bare in your picture there.

Dr. CARPENTER. Right. I think what was happening was you didn't see infected premises because animals were not shipped there.

Mr. STUPAK. A way for this to occur, foot-and-mouth disease, either it is intentionally introduced or we have a lapse in safety, and

this committee has done enough oversight and investigations at the labs, whether it is the nuclear labs, Los Alamos, wherever, or Lawrence Livermore as we have an issue going on today with them; those are mistakes. They occur. Is it the key to your testimony then; since we know there is human error and these things occur, you would want foot-and-mouth disease where there is the least amount of animal population to infect, if there is a release, however it occurs. Is that fair to say, Dr. Carpenter?

Dr. CARPENTER. That makes sense.

Mr. STUPAK. And in all the sites we have seen, Plum Island, because they do not have animals in the immediate area, is probably about the safest spot we have in this country for the past 50 years for hoof-and-mouth disease research. Is that correct?

Dr. CARPENTER. I don't know. I don't know if there is access of animals to the island.

Mr. STUPAK. OK. Dr. Sharma, Dr. Kingsbury, you were both at Plum Island. Is that fair to say?

Dr. KINGSBURY. Dr. Sharma was there, yes.

Mr. SHARMA. There are no animals on the island other than the animals that are brought there for specific experiments. DHS has told us that occasionally, we don't know the frequency and the numbers, that deer swim from Long Island to the island and they shoot them.

Mr. STUPAK. Sure, to keep them off Plum Island?

Mr. SHARMA. Correct.

Mr. STUPAK. So you don't have spread of disease, correct?

Mr. SHARMA. Correct.

Mr. STUPAK. In my home State of Michigan, we have bovine TB, and Dr. Carpenter, it is in the small northwest part of lower Michigan, but all of Michigan, we are not allowed to transport dairy without numerous inspections, and some states still won't accept our dairy from Michigan because of bovine TB. So if you have an outbreak, and I think I asked you this before, who is responsible then for determining. In Michigan, it is bovine TB, but if it is hoof-and-mouth disease, who would make that determination? Since this is under the jurisdiction of DHS, is it going to be Department of Homeland Security, United States Department of Agriculture, State Department of Agriculture? Where would it be?

Dr. CARPENTER. I believe to a point it is the State, then it is the USDA, and we have the same situation happening in California with our second herd of TB.

Mr. STUPAK. Very good. Mr. Shimkus, then we will go around to the members who have just come in who would like to ask questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. I will be short.

I just want to follow up on just some of the details, and Dr. Kingsbury or Dr. Sharma or Dr. Carpenter, it doesn't really matter who answers as long as it is consistent. What are the details of the last foot-and-mouth disease outbreak in the United States, the 1929 outbreak? And what I am looking at, how did it happen, did it involve human error, did it involve a laboratory, what the cause of the outbreak determined and where did it occur? Can anyone update me on the 1929——

Dr. CARPENTER. I will embarrassingly say California, and I don't know the rest of the answer to that. It is in a document that I could look up but I don't know offhand.

Dr. KINGSBURY. We haven't gone back that far. We do report on some incidences in our testimonial statement but we didn't go back to the 1929 event.

Mr. SHIMKUS. Well, my colleague, Jerry Moran, is here from Kansas, and Congresswoman Boyda kind of mentioned Kansas. Were you guys involved with the 1929 outbreak at all? I am just asking. I am not trying to be goofy.

Mr. MORAN. I appreciate Mr. Stupak, the chairman's courtesy, extended to me. I am less enamored with yours, Mr. Shimkus. Thank you.

Mr. STUPAK. Well, I would have to put Jerry under oath and we don't want to do that.

Dr. KINGSBURY. I think it is fair to say there were no laboratories at that time so it had to have been a naturally occurring outbreak.

Mr. SHIMKUS. OK. I yield back my time. Thank you.

Mr. STUPAK. Mr. Inslee for questions.

Mr. INSLEE. Thank you.

This GAO report is very disturbing to me in concluding that there really has been no study done of the safety. It is kind of mind boggling to me, frankly, because obviously you lose a degree, another series of barriers if there is a release and we know there are releases on occasion from these facilities, try as we might. So I am kind of flummoxed as to why this decision has gone on.

Let me just ask you at the table, what type of cost-benefit analysis has been done. For instance, has there been any assessment of any additional costs for operating on an island compared to the costs to the U.S. economy if in fact there is a hoof-and-mouth outbreak in the United States? What is the ratio of those two numbers?

Dr. KINGSBURY. As far as we know, that study has not been done.

Mr. INSLEE. Now, if you are going to remove a pathological laboratory like this and remove one barrier of protection of Americans, which is the water, which works really, really well if there is a release, wouldn't you want to have that kind of assessment before you make a decision like this?

Dr. KINGSBURY. I think the point of our testimony is that there should be more analysis done before this decision is made.

Mr. INSLEE. And what additional costs were there in construction or operation that were considered? Did anyone present any ballpark figures?

Dr. KINGSBURY. There have apparently been estimates of what it would cost to build a facility although those estimates appear to be changing, and the costs of closing down the facility on Plum Island seem not to have been included in that analysis.

Mr. INSLEE. Which is a huge mistake, given the enormous costs for closing facilities like this, particularly with toxic material involved. I live on an island. I am an islander. I live on Bainbridge Island, Washington, so I have some sense of what it is like to live on an island, and I can tell you, life goes on on an island. You get

your business done. You get across the water. It is just stunning to me that without a real solid assessment of the costs that we would remove a layer of protection for Americans given the enormous economic consequences of an outbreak including apples from Washington State. You know it could even involve the apple products. We don't think of that in those terms.

So what would you recommend, if you could, to a department to really thoroughly evaluate this issue? You have told us that they need to evaluate whether or not they can safely do this, number one, but number two, what would you suggest on a full-scale evaluation involving costs or benefits?

Dr. KINGSBURY. Well, clearly, in our view, there needs to be more assessment of the specific risks involved, and then once you assess and estimate what the risks are, then you have to look at the consequences, and the consequences get at the economic issues that you raised. We are not in the position to say how such an analysis would come out. I can imagine an analysis and a particular laboratory structure and all that could be deemed to be sufficiently safe. Our point is, those analyses have not been done.

Mr. INSLEE. Was this island at one time used as a quarantine facility of some sort? I have this weird historical memory that this island was involved in this. Does that ring a bell?

Mr. SHARMA. No, but I think it will be very illustrative to talk about the 1978 outbreak and that would shed some light onto what you are asking. At the time Plum Island had a practice of keeping animals in the holding areas, and when the release occurred, these animals became infected, and this point is extremely important. There are two things that happened. The virus didn't escape to the mainland, and we were able to convince OIE that island is serving as the second recontainment. It is an extension of the lab and therefore OIE did not impose any sanctions on our exports. We asked them if there is a single case of an outbreak in the United States, would OIE impose a ban, and their answer was yes. So it is a matter of taking risks, but OIE's position is that an outbreak, if contained on the island, would not lead to a ban on our exports.

Mr. INSLEE. Well, given that enormous impact on the U.S. economy should that occur, I certainly would hope that somehow we put this decision off until there is a full cost-benefit analysis and we do have access to the environmental study. Would any of you disagree with that?

Dr. CARPENTER. No.

Mr. INSLEE. Then we are all of like minds. Thank you very much.

Mr. STUPAK. Mr. Whitfield for questions, please.

Mr. WHITFIELD. Mr. Chairman, thank you. I am sorry I was late getting here. But it seems to me, and I think our friend from Washington State pointed this out, the GAO in their report says very emphatically that the Department of Homeland Security has neither conducted nor commissioned any study to determine whether FMD work can be done safely on the U.S. mainland and instead they have looked at a study about is it technically feasible. So it seems to me that until Homeland Security has a more comprehensive look at this, that it is really premature for us to be discussing this issue.

With that, I will yield back the balance of my time.

Mr. STUPAK. I thank the gentleman.

Let me just ask one question, we will let this panel go, and I think we are going to have votes on the Floor here pretty quickly. We mentioned, and it has been placed in the record, Mr. Dingell read from it, this statement from Senator Roberts in which he played the President of the United States. So let me have each of you play that role for a moment and let me ask you this question. If you were the President of the United States, they came to you and said we are going to do this NBAF, part of it is going to be hoof-and-mouth disease, we have Plum Island or we can move it to the mainland. In your personal or professional opinion, would you move, the foot-and-mouth disease part from Plum Island, Dr. Kingsbury?

Dr. KINGSBURY. I would not want to answer that question without more analysis than we have seen today.

Mr. STUPAK. OK. Dr. Sharma?

Mr. SHARMA. Same.

Mr. STUPAK. Dr. Carpenter?

Dr. CARPENTER. Well, when we were trying to get it to Davis, I was in favor of it and I live right next to where the lab would be.

Mr. SHIMKUS. Mr. Chairman, can I——

Dr. CARPENTER. I feel comfortable with it.

Mr. STUPAK. Where it is now, you mean?

Dr. CARPENTER. In Davis, California.

Mr. STUPAK. You do hoof-and-mouth there?

Dr. CARPENTER. No, no. They were—Davis was one of the sites that was talked about early on.

Mr. STUPAK. Right. OK.

Mr. Shimkus.

Mr. SHIMKUS. If I can just follow up, would you advocate outsourcing, as Australia does, since Australia does have BSL-3 and -4 and they are highly—that they outsource? I mean, is that an option?

Dr. KINGSBURY. Having our work done in Australia?

Mr. SHIMKUS. Well, I am just—outsourcing like they do in Australia.

Mr. SHARMA. We had talked to some experts, and they had analyzed this issue and there are certain aspects of this work which are more risky than others. The riskier parts are if you are working with large animals, doing some challenging studies, they obviously are shedding a lot of virus, and that kind of work, if you want to minimize, you can outsource it. The diagnostic capabilities, present lower level of risk. That is the kind of expertise you want to have in-house because you need to diagnose as soon as possible. So there are aspects. It is not total or all.

Mr. STUPAK. Mr. Pickering, any questions before I leave this panel?

Mr. PICKERING. Just a couple brief questions.

Dr. Kingsbury, to sum up your testimony, tell me if this is correct. You are not saying that the decision to put a facility on the mainland is riskier than keeping one on Plum Island. You are simply saying that more analysis needs to be done to determine that risk. Is that accurate?

Dr. KINGSBURY. It is close. Most of the experts that we have talked to have said that an island provides an additional level of protection. The risks would be the same of a release but it is the risk, the downstream risk of an actual outbreak that the island provides a further layer of protection for

Mr. PICKERING. Dr. Carpenter, Plum Island is, I think, 3 miles from Long Island, 6 miles from Connecticut. Airborne pathogens can travel over 3 and 6 miles, can they not?

Dr. CARPENTER. Yes.

Mr. PICKERING. So really, Plum Island is a false sense of security, isn't it? So maybe if we had an island 20 miles or 50 miles offshore, that might be correct, Dr. Kingsbury, but the close proximity to shore, Plum Island really does give little, if no, additional protection. Would that be—and Dr. Carpenter, you said that you are in support of it. You live within minutes. There is no—and this is very, very important. There is a risk, an economic risk to our animal health and the economy based on that but there is no risk at all to human health. Isn't that correct?

Dr. CARPENTER. Virtually no risk, yes.

Mr. PICKERING. And again, there is not much difference between a site that is 3 to 6 miles offshore than one that would be at UC-Davis a few minutes from your home, and the other thing that I think that is important, Dr. Kingsbury, is that the U.K. facility where you had an outbreak, is you have apples and oranges comparisons. The U.K. facility is outdated, similar to the Plum Island facility, and as you look at modern facility to modern facility, probably the closest example would be Canada where there has been no outbreak, so I think from a policy point of view, a modern facility is most important. Plum Island is a false security because it really is close to population centers.

Dr. KINGSBURY. The issue is not population centers. The issue is, how close is it to susceptible populations of the animals that become diseased, and in addition to being an island, and we have to say, there has been no spread of the virus from that island in its history——

Mr. PICKERING. But you could also find other facilities, mainland facilities in countries where there have been no outbreaks as well.

Dr. KINGSBURY. That is correct.

Mr. PICKERING. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Moran, any questions?

Mr. MORAN. No.

Mr. STUPAK. Let me ask just one. You used false sense of security. It is really not a false sense of security, it is a proven sense of security, is it not, that you have had an outbreak there and it never spread to the mainland?

Dr. KINGSBURY. There have been releases on Plum Island. They have not left the island and therefore they haven't spread to animal populations, and as Dr. Sharma said earlier, part of that has to do with the prevailing winds in that area.

Mr. STUPAK. Sure, it blows it out and——

Dr. KINGSBURY. And those have been studied and understood, so I think it is not quite false that it is safe.

Mr. STUPAK. Now, Dr. Kingsbury, you have not gone to Plum Island but——

Dr. KINGSBURY. I have not, no, sir.

Mr. STUPAK. And Dr. Sharma, you have?

Mr. SHARMA. Yes, I have.

Mr. STUPAK. Dr. Carpenter, have you?

Dr. CARPENTER. No, I haven't.

Mr. STUPAK. Then Dr. Sharma, do you know, having been there, is there any reason why you could not build the new NBAF on Plum Island? Is there any reason why you cannot build a new research facility for foot-and-mouth disease on Plum Island?

Mr. SHARMA. Well, there is plenty of land. As a matter of fact, the islands in Denmark and Germany are significantly smaller in size. In addition to that, there are some assets on the island that would lower the costs and DHS since 2002 has invested significant amount of money, in particular, things like they have power generators, backup power generators. They are expensive. They are assets that can be used if they decide to build a new facility there.

Mr. STUPAK. Thank you. That will conclude questions of this panel. I want to thank the three doctors for being here and thank you very much for your testimony. You are welcome to stay for the rest of the hearing.

I would like to call up our second panel of witnesses. We have Mr. Ray Wulf, who is President and CEO of the organization American Farmers and Ranchers; Dr. Howard Hill, who is Chief Operating Officer of Iowa Select Farms; Mr. Leroy Watson, who is Legislative Director for National Grange of the Order of Patrons of Husbandry; and Dr. Gary Voogt, who is President-Elect of the National Cattlemen's Beef Association.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the Rules of the House to be advised by counsel during their testimony. OK. We have been asked to hold for a minute for Mr. Voogt. We will hold for a minute or two until he comes back.

As I was saying, Mr. Voogt, it is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right under the Rules of the House to be advised by counsel during your testimony. Do any of our witnesses wish to be advised by counsel during their testimony? Everybody is indicating no. Therefore, I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. Mr. Wulf, I am going to start with you, but I am going to ask you to wait 30 seconds because I think they are going to call us for a number of votes here. All right, Mr. Wulf, go ahead, start, your opening statement, please, 5 minutes. If you have a longer one, please submit it for the record.

STATEMENT OF RAY L. WULF, PRESIDENT AND CEO, AMERICAN FARMERS AND RANCHERS

Mr. WULF. Thank you, Mr. Chairman and Ranking Member Shimkus and the rest of the Committee. I am Ray Wulf, President and CEO of American Farmers and Ranchers. We are based in Oklahoma City.

Mr. STUPAK. Go ahead.

Mr. WULF. We are a general farm organization.

Mr. STUPAK. Our timing is not good today. All right, sir. Let us try it again.

Mr. WULF. American Farmers and Ranchers Insurance Company. We do business in 24 States, and as I said, we are located in Oklahoma City. Running through the questions that were posed to us, we are absolutely against and opposed to movement of the Plum Island Animal Disease Center to the mainland United States. As you may know, already we have heard, this is the only facility where certain highly infectious foreign animal diseases are studied, such as the foot-and-mouth disease. Foot-and-mouth disease is a highly contagious virus that affects cloven-hoofed animals such as cattle, sheep, pigs, goats and deer.

Foot-and-mouth disease can be carried by wind, clothing, footwear, skin, through nasal passages and any equipment. As a matter of fact, I am not aware of anything that this will not adhere to and can be transmitted. There are simply too many possibilities for error, either by negligence or accident, and could impose extreme economic impacts on U.S. agriculture, U.S. agriculture producers and our consumers. When dealing with this particular type of risk, it is better to deal with a known probability of an occurrence than to move a facility to a new location where you have no history and an unknown probability of an occurrence that can happen. Any event with or without history, there is a probability that can be assessed to a particular outcome and one certainly needs to be assessed here.

United States infrastructure for moving livestock, second to none. We allow livestock to move rapidly across the United States. As a matter of fact, in 5 days, cattle trucking out of Oklahoma City National Livestock Market arrive in 39 States. Infrastructure is really good here in the United States, in a matter of days livestock can be transported hundreds of thousands of miles and intermingled with other livestock. If we move the facility we have the potential risk of an outbreak inside the mainland United States, whereas currently it is not a high risk of probability of transporting at Plum Island.

The economic impact for AFR members would no doubt be severe, devastating, and reach far beyond the livestock industry. Direct economic losses would result from lost production, the cost of destroying disease-ridden livestock, as we have already heard, indemnification and costs of disease containment measures such as drugs, diagnostics, vaccines, veterinary services, and more. Indirect costs and multiplier effects from dislocations in agriculture sectors would include the feed and inputs industry, transportation, retail and certainly loss of our export markets, which is already a very, very sensitive issue.

A foot-and-mouth outbreak would not only be a problem in agriculture but in Britain in 2001, as we have already heard with that outbreak, and I have a CD disc, Mr. Chairman, that I would like to leave that documents that one-on-one account of that outbreak for you and the other members to view at your convenience.

Mr. STUPAK. Without objection, it will be accepted.

Mr. WULF. Thank you. Outbreak in 2001, as we know, resulted in postponing a general election for one month, cancellation of many sporting events, leisure activities, cancellation of large events likely to be attended by those from the infected areas.

And we talked about dollars and impacts from that alone. In an Oklahoma 1979 study that we saw, the economic impact could be anywhere from $2.4 billion, and that B as in bill—I have to put it that way for me because I am cowboy and don't count that high—anywhere up to $27.6 billion, as in B. California, we have already heard testimony about that alone, could be anywhere from $8.5 billion to $13.5 billion. We have had a lot of conversation regarding Kansas and those studies up there. Three scenarios were considered on the economic impacts of a foot-and-mouth disease outbreak in Kansas alone, and one was where the disease was introduced to a single, small cow-calf operation; another one, a medium-sized feedlot, 10,000 to 20,000 head. We had another one with five large feedlots, and there are a lot of feedlots in Kansas, Oklahoma and Texas. As a matter of fact, there are some 6 million head of cattle in Kansas, some 5 million head of cattle in Oklahoma, and 14 million cattle when we get into Texas. Under those scenarios, the small calf scenario, 126,000 head of livestock were infected and needed to be destroyed. In the medium-sized operation, 407,000 head in 39 days had to be put down. In five large feedlots, we had 1.7 million head of livestock that needed to be destroyed in the event of an outbreak that would last nearly up to 3 months. For the State of Kansas as a whole, those numbers could climb somewhere to the cost-economic benefit and loss of $945 million.

Other things—livestock markets are not the only impact from the outbreak. Feed and grain, potential feed mills would also be impacted. We know half of all of our grain goes toward U.S. feed for animal consumption. Total trade impact certainly has to be looked at here. Over 94 percent of our consumers for our livestock markets are outside the United States. We certainly cannot afford to lose that. Japan, Mexico, Canada, Korea already account for 75 percent of all the U.S. exports, 10 percent total production. Foot-and-mouth certainly is a trade disease that needs to be seriously looked at with the probability of occurrence. Global competition is fierce, as we all know, in agriculture, for dollars. In the event a foot-and-mouth outbreak occurred in the United States, life as we know it would cease to exist, not to mention the already highly sensitive trade issues that I mentioned earlier in regards to Korea and Japan alone with our beef.

In any outbreak of any magnitude, as I previously mentioned, there is a drastic drop in consumption. We only know that too well when we look at the episode with Food Lion, when we look at what has happened with trying to describe to the soccer mom with the 12-year-old out there the difference between mad cow disease and hoof-and-mouth disease and E. coli. Now, what does that do to the economic impact of an outbreak of any kind? You are looking at a barrier somewhere in the neighborhood of 20 miles and everything being destroyed within that 20 miles in the event that there is an outbreak and then another buffer zone outside of that 20-mile area. Nobody is going in and nobody is going out. And then you are going to inject with vaccine outside of that buffer, and once the disease

has been totally eradicated, you then are going to have to destroy those animals that were also vaccinated at that point in time to totally eradicate it. It is serious.

When you look at the map on my testimony——

Mr. STUPAK. May I ask you to summarize, please? We are way over.

Mr. WULF. OK. I appreciate the opportunity. I am sorry. I was trying to find a clock here and I didn't see it.

[The prepared statement of Mr. Wulf follows:]

Written Testimony of Ray L. Wulf
President & CEO, American Farmers & Ranchers

Submitted for the Record to the
House Energy and Commerce Committee
Subcommittee on Oversight and Investigations

May 22, 2008

Mr. Chairman, Ranking Member Shimkus, and Members of the Subcommittee, my name is Ray L. Wulf, and I am President and CEO of American Farmers & Ranchers (AFR) based in Oklahoma City. I have held this position since 2000. In addition I have a background as a small farmer/rancher, agriculture loan officer, and farm and ranch management instructor. AFR is a general farm organization that has been representing family farmers, ranchers and rural Americans since 1905. Our organization has recently expanded and is now doing business as AFR Insurance Group in 24 states.

On behalf of American Farmers & Ranchers we thank you for the opportunity to testify on the Department of Homeland Security's recent proposal to close the Plum Island Animal Disease Center and move it's biological research laboratory, including, but not limited to, research on foot-and-mouth disease, to a new location on the mainland United States. This is an issue that is of particular interest and concern to our organization and companies.

At the committees request I will address the following questions:

- Does your organization support moving foot-and-mouth disease from Plum Island to a research facility on the mainland United States?
- What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?
- Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease – or other contagious diseases affecting livestock – from a research facility located on the mainland United States?
- If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?

Does your organization support moving foot-and-mouth disease from Plum Island to a research facility on the mainland United States?

NO, AFR is ***opposed*** to the movement of the Plum Island Animal Disease Center to a research facility on the mainland U.S. The Plum Island Animal Disease Center is the only place in the country where certain highly infectious foreign animal diseases are studied, such as foot-and-mouth disease. Foot-and-mouth disease is a highly contagious virus that affects cloven-hoofed animals such as cattle, sheep, pigs, goats and deer.

Foot-and-mouth disease can be carried by the wind, on clothing, footwear, skin, through nasal passages, and on equipment. The current location or one with similar natural barriers should continue to be the site for research and diagnostic activities that protect our nation's food supply. There are simply too many possibilities for error, either by negligence, or accident, that could pose extreme economic impacts on U.S. agriculture producers and consumers.

Specifically foot-and-mouth disease creates a serious threat to the U.S. livestock industry, the overall agriculture economy, as well as the U.S. economy. A GAO report released December of 2005 stated that nationally recognized animal disease experts were interviewed and agreed that foot-and-mouth disease constitutes the greatest threat to American livestock. Furthermore

GAO provided a letter on December 17, 2007 stating that some of the pathogens maintained at Plum Island, such as foot-and-mouth disease, are highly contagious to livestock and could cause catastrophic economic losses in the agricultural sector if it was released outside of the facility.

Infrastructure

The results of a possible outbreak on the mainland are magnified and accelerated by the efficiencies of the U.S. infrastructure and the transportation industry. The U.S. infrastructure for moving livestock is second to none, allowing livestock to move rapidly across the U.S. As seen in figure 1, in five days cattle were trucked from the Oklahoma City National Livestock Market to 39 states. In addition, other animals that carry foot-and-mouth disease, such as swine, sheep, and goats are also rapidly distributed. Within a matter of days livestock can be transported hundreds to thousands of miles away and intermingled with other livestock. Amplifying the situation is the fact that foot-and-mouth disease is expelled over four to five days after an animal has been infected and may occur several days before the onset of clinical signs. In a matter of a couple of weeks the entire country could be infected.

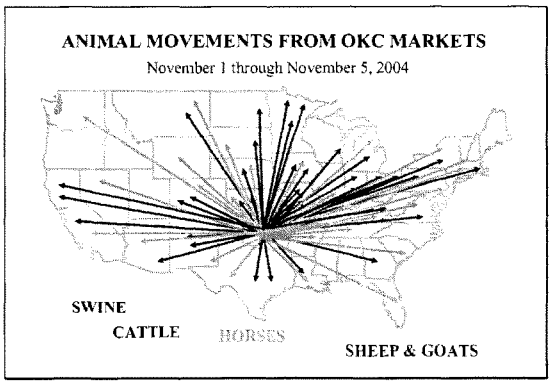


Figure 1 - Source: Oklahoma Department of Agriculture Food & Forestry

What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?

The economic impacts to AFR members would no doubt be severe and devastating and reach far beyond the livestock industry. Quarantines affecting large areas would be established stopping all incoming and outgoing commerce in the quarantined area. Depending on the time of year, a quarantine could halt grain harvest, a major economic impact to many areas. Trucks and equipment would not be allowed in or out for harvesting, milk trucks would not be allowed in or out and, in addition, travel to and from school, for business or leisure would be halted. The impact would not only be felt by the producer, but also the local community, region, nation and could cause irreparable damage to the financial community. In addition the U.S. could expect severe economic consequences in the global market.

Many studies have attempted to assess the economic implications of an outbreak of foot and mouth disease in the U.S. Results can vary, but at the same time all point out the significant economic losses as a result of a foot and mouth outbreak. Direct economic losses would result from lost production, the cost of destroying disease-ridden livestock, indemnification and the cost of disease containment measures, such as drugs, diagnostics, vaccines, and veterinary services. Indirect costs and multiplier effects from dislocations in agriculture sectors would include the feed and inputs industry, transportation, retail and the loss of export markets.

A foot-and-mouth outbreak would not only be a problem for agriculture. In Britain the outbreak of foot-and-mouth disease resulted in postponing a general election for a month, the cancellation of many sporting events and leisure activities, the cancellation of large events likely to be attended by those from infected areas.

Research at Oklahoma State University

Dr. Clem Ward of Oklahoma State University outlines how estimating the effects is difficult to gauge:

- First, the effects would depend upon how isolated or widespread the incidence was and how quickly it was contained.
- Second, the effects would depend upon the type of livestock operations that were infected and how frequently or recently animals have moved from the sites.
- Third, impacts would depend on how the media handles the news reporting of the outbreak.
- And fourth, markets would likely react immediately to the news, and how long it would take them to rebound to a more normal level would depend on the first three factors mentioned.

Dr. Ward also looked at two studies that estimate the economic impacts of a foot-and-mouth outbreak based on a given set of wide ranging scenarios.

1) A 1979 study with impacts adjusted to 2000; estimated economic impacts from $2.4 billion to $27.6 billion (McCauley, et al.).
2) A 1999 study estimated the impacts for California alone at $8.5 billion to $13.5 billion (Ekboir).

Kansas Research

An article in ScienceDaily (Nov. 29, 2007); Foot-and-mouth Disease Could Cost Kansas Nearly A Billion Dollars, referenced research by Dustin L. Pendell, John Leatherman, Ted C. Schroeder, and Gregory S. Alward -THE ECONOMIC IMPACTS OF A FOOT-AND-MOUTH DISEASE OUTBREAK: A REGIONAL ANALYSIS. The team of researchers analyzed a 14-county region in southwest Kansas that has a high concentration of large cattle feeding operations, as well as other livestock enterprises and beef processing plants. They considered three scenarios:

- one where the disease was introduced at a single cow-calf operation;
- one where a medium-sized feedlot, 10,000 to 20,000 head of cattle, was initially infected;
- one where five large feedlots, each with more than 40,000 head of cattle, were simultaneously exposed.

Schroeder said the first two scenarios were used to predict what could happen if the disease were introduced accidentally, while the larger scenario shows what could happen were there an intentional release.

Generally, researchers found that the greater the number of animals infected in an operation, the longer an outbreak would last and the more it would likely spread -- all directly correlating to the level of economic ruin.

- Under the small cow-calf scenario, researchers predicted that 126,000 head of livestock would have to be destroyed and that a foot-and-mouth disease outbreak would last 29 days.
- In the medium-sized operation, those numbers went up to 407,000 animals and 39 days.
- In the scenario where five large feedlots were exposed at the same time, researchers predicted that 1.7 million head of livestock would have to be destroyed and that an outbreak would last nearly three months.

From smallest to largest operation, that translated into regional economic losses of $23 million, $140 million and $685 million, respectively. For the state of Kansas as a whole, those numbers climb to $36 million, $199 million and $945 million.

"Kansas produces about 1.5 million calves, markets 5.5 million head of fed cattle, and slaughters 7.5 million head of cattle annually. The large commercial cattle feedlot and beef packing industries together bring more than 100,000 head of cattle per week on average into the state for feeding or processing," Schroeder said. "Such large volumes of livestock movement provide avenues for contagious animal disease to spread."

Leatherman estimated the statewide impacts of foot-and-mouth for this study and said the effects of an outbreak would go way beyond producers. "This study tells us what the overall stake of the region and state has in preventing such an occurrence," he said. "It isn't just farmers, ranchers, feed lots and packers who would suffer -- it's all of us, in some measure."

Other Research

Another report titled "Potential Revenue Impact of an Outbreak of foot-and-mouth disease in the United Sates" by Paarlbwerg, Lee, and Seitzinger was published in the Journal of American Veterinary Medical Association in April of 2002. The report stated an outbreak similar to that which occurred in the U.K. during 2001, would cause an estimated U.S. farm income losses of $14 billion. Losses in gross revenue for each sector were estimated to be the following: live swine, -34%; pork, -24%; live cattle -17%; beef, -20%; milk, -16%; live lambs and sheep, -14%; lamb and sheep meat, -10%; forage, -15%; and soybean meal, -7%.

Other Agriculture Markets Impacted:

Livestock markets are not the only markets impacted by an outbreak. Feed grains and protein meal feeds would also be impacted. A CRS Report titled "Agroterrorism: Options in Congress," December 19, 2001 states - According to industry officials, every other bushel of U.S. grain goes to animal feed. In addition, information from the U.S. Meat Export Federation states that:

- One milk cow will eat 3 tons of hay and 1,460 lbs of distiller's grain over the course of a year
- It takes 150 lbs of soybean meal to feed a pig to its finished weight
- Every pound of U.S. pork exported utilizes 1.5 pounds of U.S. Soybeans
- More than 54 million bushels of soybeans were exported through U.S. red meat in 2006
- More than 300 million bushels of corn were exported through U.S. red meat in 2006
- While direct corn exports have increased by 25% since 1990, indirect exports of corn through the value added process of exporting red meat has increased by 196%

Trade Impact

Ninety four to ninety six percent of the world's consumers live outside the U.S. making trade a critical part of U.S. Agriculture. Examples from the pork industry are as follows:

- Source: USDA
    - U.S. has 27% share of the world pork exports

- Source: U.S. Meat Export Federation
    - 2007 Pork Exports add $22.00 per hog
    - The net benefit of U.S. pork exports to the pork industry in 2007 equates to $22 added dollars per market hog
    - Japan, Mexico, Canada and Korea account for 75% of all U.S. pork exports – 10% of total production
    - One in every four pounds of pork traded in the world originates from the U.S.
    - The U.S. exports the equivalent of 49,500 market hogs daily

Foot-and-mouth disease is a *"Trade Disease."* To avoid foot-and-mouth disease it is common practice among foot-and-mouth disease-free countries to allow imports only from other foot-and-mouth disease-free countries. This action by countries that are foot-and-mouth disease free is consistent with the provisions of the World Trade Organization's "Agreement on Application of Sanitary and Phytosanitary Measures," which allows countries to adopt and enforce measures necessary to protect human, animal, or plant health. The World Organization of Animal Health (OIE), an independent international organization founded in 1924, monitors and disseminates information about animal diseases throughout the world, and provides a list of countries declared free of foot-and-mouth disease.

Global competition is fierce and in the event a foot-and-mouth outbreak occurred in the U.S., life as we know would no longer exist. Operating as a foot-and-mouth positive country would exclude the U.S. from premium meat markets.

While a foot-and-mouth disease vaccine is available it is used only in emergencies, to create a "disease-free" buffer zone around an infected area. Because vaccinated animals will test positive, they cannot be shipped internationally and protocols require the animals to be destroyed as soon as the disease is eradicated.

Consumer Issues

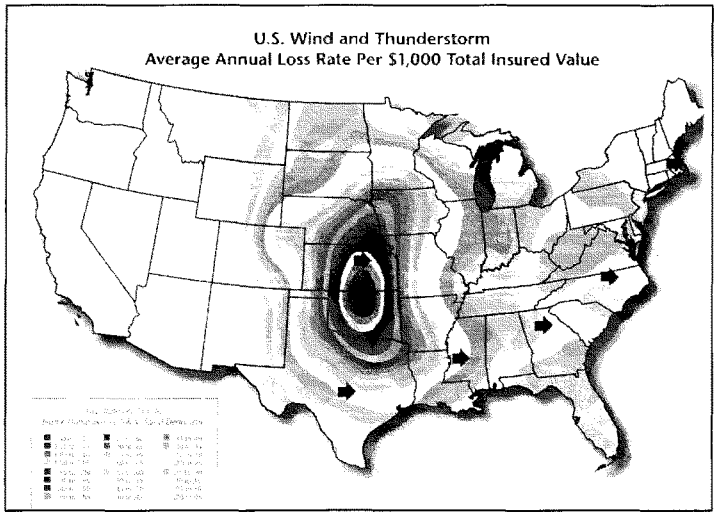
Foot-and-mouth is not readily transmissible to humans. Only a few cases of human infections, none requiring hospitalization, occurring as a result of direct contact with infected

animals have been documented. Even though foot-and-mouth disease does not pose a health risk to humans, consumer fear would occur. Because the average consumer has a lack of knowledge about the disease, more than likely there would be a drop in meat consumption.

Insurance Issues

American Farmers & Ranchers is no stranger to managing risk. Our membership is already a bulls-eye for weather disasters. If an outbreak were to occur, weather could play a major role in furthering the spread of an infectious disease. Currently the following sites have been chosen to advance to the next phase in the National Environmental Policy Act (NEPA) process to determine if and where the proposed National Bio and Agro-Defense Facility (NBAF) would be built and operated:

- South Milledge Avenue Site, Athens Georgia
- Manhattan Campus Site, Manhattan Kansas
- Flora Industrial Park Site, Flora Mississippi
- Plum Island Site, Plum Island, New York
- Umstead Research Farm Site, Butner, North Carolina
- Texas Research Park Site, San Antonio, Texas



Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease – or other contagious diseases affecting livestock – from a research facility located on the mainland United States?

NO, AFR does not believe that there are adequate technologies and safety precautions that can assure U.S. producers and consumers that there would not be an accidental or intentional release of foot-and mouth disease or for that fact any other contagious disease affecting livestock from a research facility located on the mainland U.S. Regardless of how much technology has improved, it does not safeguard from human error, harmful intentions or lack of preparedness.

Plum Island's research and diagnostic activities work to accomplish an important mission to protect U.S. animal industries and exports from deliberate or accidental introductions of foreign animal diseases. Although steps have been taken to implement better security measures at Plum Island, an outbreak is not out of the question. The U.S. should take note of the most recent U.K. outbreak in August of 2007. Investigations determined that the U.K. outbreak was caused by a strain of virus used for vaccine research at laboratories associated with the institute for Animal Health at Pirbright.

If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?

NO, Although Federal, State and local authorities continue to try to prepare themselves for a foreign animal disease outbreak, AFR believes there are entirely too many unknown variables that would hinder a successful containment of the disease. A U.S. Government simulated outbreak in 2002 called "Crimson Sky" ended with fictional riots in the streets after the simulation's National Guardsmen were ordered to kill tens of millions of farm animals, so many that troops ran out of bullets. In the exercise, the government said it would have been

forced to dig a ditch in Kansas 25 mile long to bury carcasses. In the simulation, protests broke out in some cities amid food shortages.

In addition, AFR has concerns about the transportation of infectious disease samples that may need to come into or out of the facility and travel through populated areas. Furthermore AFR has concerns about the number of employees that would be traveling in and out of the facility. The Department of Homeland Security states that a new proposed National Bio and Agro-Defense Facility would generally include between 250 and 350 employees.

Traceability Is Critical

AFR believes that a critical part of being able to control the spread of foot-and-mouth or any animal disease is a national animal identification system. The capacity to trace livestock and product movements is critical for the early control of an outbreak. USDA has been pursuing implementation of an effective animal identification system since the BSE discovery in a U.S. cow in 2003. The U.S. has yet to establish a workable I.D. program. Until traceability is mandatory and in place moving the Plum Island Animal Disease Center to the mainland should ***not*** be considered and even then it should be reviewed carefully and any consideration should be focused on a remote area with little or no livestock or wild game habitation.

Conclusion

In conclusion, AFR strongly supports full funding for the research performed at Plum Island, including research on foot-and-mouth disease. In addition AFR fully supports funding to update research facilities to the highest standards.

However, AFR believes the U.S. should not risk bringing highly contagious animal disease research to the mainland with so many variables that could wreak havoc on the U.S. livestock industry, communities, the U.S. and global economy.

AFR believes further activities are needed to prepare for an animal disease outbreak.

Activities should include:

- An analysis of communication between all stakeholders.
- A full economic study that includes control and compensation including businesses reliant on livestock and global trade impacts.
- How to adequately establish a quarantine area around an outbreak
- How movement restrictions will be handled
- Procedures in regard to slaughtering all infected herds and other herds that have been in contact with them
- Disposing of animals - Environmental impacts – burial contamination of ground water by leakages from a disposal pit
- Disinfecting properties
- Compensating stock owners for the livestock slaughtered
- Carrying out clinical inspection a surveillance to ensure the disease has not spread

We applaud the committee in your efforts to investigate this important issue and appreciate the opportunity to be here today. Thank you.

Mr. STUPAK. I will tell you what. We have got 5 minutes before we have to go down and vote. That is when the bells are going to go off here in about 20 seconds, so we are going to go down and vote. We will be back in, we have 3 votes, approximately; let us shoot for 30 minutes so that will give you time to stretch your legs. We will be back here at 12:25. We will be in recess until 12:25.

[Recess.]

Mr. STUPAK. The meeting will come to order.

Dr. Hill.

STATEMENT OF HOWARD HILL, D.V.M., PH.D., CHIEF OPERATING OFFICER, IOWA SELECT FARMS

Dr. HILL. Good afternoon, Chairman Stupak, Ranking Member Shimkus, and members of the subcommittee, my name is Howard Hill. I am a doctor of veterinary medicine and I spent more than 30 years in the pork industry researching animal diseases. I have spent the past 7 years as a chief operating officer for Iowa Select Farms and was on the faculty at Iowa State University for 20 years. I am testifying today on behalf of the National Pork Producers Council, an association of 43 State pork producer organizations that represents the country's 67,000 pork producers.

The U.S. pork industry represents a significant value-added activity in the agricultural economy and the overall U.S. economy, adding nearly $30 billion of gross national product and supporting more than 550,000 mostly rural jobs.

The Plum Island Animal Disease Center on Long Island has long been a centerpiece for the country's foreign animal disease diagnostic system and it is our understanding that the proposed NBAF will continue to fulfill this mission. The U.S. pork industry believes that NBAF should be located on the mainland. In its current state, the facility on Plum Island cannot continue its mission of foreign animal disease research, diagnostics, and education. While Plum Island is thought to be ideal from a risk mitigation standpoint, there are serious drawbacks to having the facility there. Constructing a new facility on the island would be prohibitively more expensive than on the mainland. It also has been difficult to recruit high-caliber scientists to Plum Island because of the area's high cost of living and inconvenience of boating to work every day. NBAF will require world-class scientists to conduct research and diagnostic work so the location needs to be appealing to these individuals.

Five sites for the new NBAF are now under consideration excluding Plum Island. The area for the new facility must be picked based on an assessment of risk which would include the following four areas: the existence of susceptible animal populations that could be exposed to an outbreak should disease organisms escape from the facility; two, the ability of the Federal and State governments to quickly control and eradicate a disease; three, the environmental consequences and impact on wildlife populations of an outbreak; and four, the economic consequences to the livestock industry if an outbreak were to occur.

Most of the current debate is focused on location and cost of the facility but very little has been said about the anticipated scope of work to be carried out at the NBAF. From our industry's perspec-

tive, it seems more prudent to define the capacity needed for the kinds of research and diagnostic work to be completed and to build the facility to meet those needs and objectives. The U.S. pork industry would request that DHS work with the animal agriculture industry to define the scope of work.

NBAF's mission is multidisciplinary and focusing on human and animal health, particularly zoonotic diseases. While we support the need for a high-containment Biosafety Level-4 facility for researching zoonotic diseases in large animals, the swine industry is concerned that the animal health portion of this mission will be subordinated to the more publicly supported human health agenda. Our industry needs assurance that USDA and DHS will work together to allocate to the NBAF the resources necessary to achieve and enhance its mission to protect U.S. animal industries and meat export against catastrophic economic losses caused by foreign animal diseases. To illustrate the importance of this to the U.S. pork industry, it is estimated that a foot-and-mouth disease outbreak would cost the U.S. livestock producers between $40 and $60 billion. Such an outbreak would immediately shut down our export markets.

In summary, we believe the location of NBAF must be based on assessed risk rather than on which entity is willing to build such a facility. Locations need to be reexamined to see if the island effect can be recreated by siting the facility in an area with low densities of livestock and wildlife, and we need the new facility to enhance the capabilities of our industry with regards to research, diagnostics, and treatment for all foreign animal diseases.

Thank you for the opportunity to share the views of the U.S. swine industry. I would be happy to take any questions.

[The prepared statement of Dr. Hill follows:]

Testimony of the
National Pork Producer Council

On

Germs, Viruses, and Secrets:
Government Plans to Move Exotic Disease Research
to the Mainland United States

Before

United States House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

May 22, 2008
Washington, D.C.

Introduction

The National Pork Producers Council is an association of 43 state pork producer organizations. NPPC serves as the voice in Washington, D.C., for the nation's pork producers.

The U.S. pork industry represents a significant value-added activity in the agriculture economy and the overall U.S. economy. Nationwide, more than 67,000 pork producers marketed more than 104 million hogs in 2007, and those animals provided total gross receipts of $15 billion. Overall, an estimated $21 billion of personal income, from sales of more than $97 billion, and $34.5 billion of gross national product are supported by the U.S. hog industry. Economists Dan Otto and John Lawrence at Iowa State University estimate that the U.S. pork industry is directly responsible for the creation of nearly 35,000 full-time equivalent jobs and helps generate 515,000 indirect jobs. All told, the U.S. pork industry is responsible for more than 550,000 mostly rural jobs in the U.S.

The U.S. pork industry today provides 21 billion pounds of safe, wholesome and nutritious meat protein to consumers worldwide.

In fact, 2007 was the sixth consecutive year of record pork production in the United States.

Exports of pork also continue to grow. New technologies have been adopted and productivity has been increased to maintain the U.S. pork industry's international competitiveness. As a result, pork exports have hit new records for the past 16 years. In 2007, exports represented nearly 15 percent of production. This year, approximately 2.8 billion pounds of pork and pork products are expected to be exported at a value of $4.1 billion.

Foreign Animal Diseases A Threat

To maintain its contribution to the economy and to continue to supply safe, nutritious, wholesome pork to consumers worldwide, the U.S. pork industry must rely on the United States Department of Agriculture (USDA) and the Department of Homeland Security (DHS) for protection from foreign animal diseases. This includes preventing the entry of pathogens via passengers and cargo through U.S. ports of entry, conducting diagnostic investigations on suspect cases of foreign animal disease, continuing research on foreign animal diseases, such as Foot and Mouth Disease, and developing better diagnostic tools and vaccines.

The Plum Island Animal Disease Center, located off the northeastern tip of New York's Long Island, has been the centerpiece of the United States' foreign animal disease diagnostic system. Its mission also includes research on and development of vaccines and treatments for foreign animal diseases. Training animal health professionals to recognize and diagnose foreign animal diseases is another critical element of the mission at the Plum Island facility. It is our understanding that the proposed National Bio and Agri-Defense Facility (NBAF) will continue to fulfill this mission.

Site NBAF On Mainland

Our industry believes it is time to move past the endless debate about whether to locate the facility on the mainland or maintain it on Plum Island. There is an urgent need to construct this facility; our industry is living on borrowed time until a new facility is built.

The U.S. pork industry believes the NBAF should be located on the mainland. In its current state, the facility on Plum Island cannot continue its mission of foreign animal disease research, diagnostics and education. While the environment on Plum Island is thought to be ideal from a risk mitigation standpoint, there are serious drawbacks to having the facility there. Constructing a new

facility on the island would be prohibitively more expensive than on the mainland, with operational costs increasing by at least 25 percent. These costs take away from funds that could be used for research and diagnostic work. It also has been difficult to recruit high-caliber scientists to Plum Island because of the area's high cost of living and inconvenience of "boating" to work every day.

NBAF will require world-class scientists to conduct research and diagnostic work, so the location needs to be appealing to these individuals. Additionally, local lodging and dining accommodations on and around Plum Island are very limited. This makes the area unattractive to visiting scientists and individuals involved in training programs. The local community also has been suspicious of work being done on the island. They have in the past opposed expansion of the facility. In 1999, local opponents and their congressional delegation prevented sheep from Vermont, thought to have a foreign animal disease, from being moved to the island for diagnostic purposes. USDA was forced to move the sheep to the less secure National Animal Disease Center in Ames, Iowa.

Several universities and their supporting cities and counties located in major livestock producing areas have asked to be considered for

the new location of NBAF. Our industry believes DHS needs to take a careful approach to choosing the location of the new facility.

Consider Risks To Proposed Sites

Five sites for the new NBAF are now under consideration, excluding the current Plum Island location. The facility has enormous importance to our industry, but it also has a high level of risk. Therefore, the location of the facility must be based on assessment of that risk. A prudent decision can be made only after completing a risk profile of the activities to be conducted in the facility. Such a profile would include:

- An assessment of susceptible animal populations that could be exposed to an outbreak should disease organisms escape from the facility.
- The capability of the Federal and state governments to quickly control and eradicate a disease.
- The environmental consequences and impact on wildlife populations of an outbreak.
- The economic consequences to the livestock industry if an outbreak were to occur.

The U.S. pork industry would not support building the facility at any of the proposed sites without a risk profile. If fact, we believe that measuring the activities against this risk profile should not exclude consideration of other sites.

We have confidence in the technology supporting the biosecurity of our U.S. laboratories, and their record of success is rather remarkable. The outbreak at England's Pirbright Laboratory, however, occurred because of a biosecurity breakdown. This breakdown highlighted the human component of applying technology and raised new concerns about the NBAF location. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated. The risk of disease introduction needs to be the most important element of the location decision.

Scope Of Work Must Be Considered

Most of the current debate has focused on the location and cost of the facility, but very little has been said about the anticipated scope of work to be carried out at the NBAF. From our industry's perspective, it seems more prudent to define the capacity needed for the kinds of research and diagnostic work to be completed and to build the facility to meet those needs and objectives. Without

such an approach, our ability to meet long-term needs and objectives will be determined by the size and design of the facility rather than the needs and objectives themselves. The U.S. pork industry would request that DHS work with the animal agriculture industry to define that scope of work.

There are lessons to be learned from construction of USDA's new National Animal Disease Center in Ames, Iowa. The facility was designed to meet the anticipated needs of animal agriculture, as defined by the scope of work developed by USDA and the livestock industries. Unfortunately, the design was modified during construction to meet budget constraints. These modifications may limit the capability of the facility to meet the original scope of work. The second major lesson to be learned from the Ames facility is that new buildings, with high bio-containment levels, are more expensive to operate. Higher maintenance and utility costs have left the facility with insufficient operating funds, thereby limiting the purpose for which it was built.

NBAF Must Protect Animal Agriculture

The commitment by DHS for continued support to animal agriculture research and diagnostic work is just as important as the facility. NBAF is described to have a multi-disciplinary mission, focusing on human and animal health, particularly zoonotic diseases. While we support the need for a U.S. high-containment biosafety level (BSL)-4 facility for researching zoonotic diseases in large animals, the swine industry is concerned that the animal health portion of this mission will be subordinated to the more publicly supported human health agenda. Our industry needs assurances that USDA will allocate to the laboratory the resources necessary to achieve and enhance its mission to protect U.S. animal industries and exports against catastrophic economic losses caused by foreign animal disease agents. We need assurances that the Plum Island mission of developing vaccines, treatments and diagnostics for foreign animal diseases, as well as training animal health professionals to recognize and diagnose foreign animal diseases, will not be lost in the new NBAF facility.

To illustrate the importance of this decision to the U.S. livestock industry, one has only to look at the cost of a foreign animal disease outbreak. In 2005, it was estimated that a Foot and Mouth Disease (FMD) outbreak would cost the U.S. pork industry

between $40 billion and $60 billion, an estimate that would certainly be higher today. The immediate loss of our pork export markets would cost our industry approximately $4.1 billion.

In summary, we believe the location of the NBAF must be decided based on assessed risk rather than on which entity is willing to build such a facility. Locations need to be reexamined based on a risk profile to see if the "island effect" can be recreated by siting the facility in an area with low densities of livestock and wildlife. We also need the new facility to enhance the capabilities of our industry with regard to research, diagnostics and treatment for all foreign animal diseases.

Thank you for the opportunity to share the views of the U.S. swine industry and the National Pork Producers Council on this critical decision affecting all of U.S. animal agriculture.

Mr. STUPAK. Thank you, Dr. Hill.

Mr. Watson, your opening statement, please, sir.

STATEMENT OF LEROY WATSON, LEGISLATIVE DIRECTOR, THE NATIONAL GRANGE OF THE ORDER OF PATRONS OF HUSBANDRY

Mr. WATSON. Mr. Chairman, Ranking Member Shimkus, members of the Committee, the National Grange would like to commend the Subcommittee on Oversight and Investigations for holding this hearing on proposals by the U.S. government to relocate the Plum Island Animal Disease Center to a location on the mainland United States as part of the National Bio- and Agro-Defense Facility, NBAF. We appreciate the opportunity to present our views opposing the development of an animal disease research facility on the U.S. mainland that will work with live strains of foot-and-mouth disease as well as other virulent foreign animal diseases anywhere near existing concentrations of commercial livestock.

While there are many scenarios for economic, social, and environmental damage from the outbreak of animal diseases, few come close to the nightmare of an outbreak of FMD. According to a 2004 USDA paper entitled "Economic Impact of Foreign Animal Disease Outbreak," the paper calculated that the direct cost to the domestic livestock industry of an FMD outbreak would exceed $60 billion. We believe those costs would come much higher when we add in all of the costs to the rest of society.

America's family farmers and ranchers have become unfortunately accustomed to the fact that after 9/11, our operations are considered soft targets for terrorist attacks. In 2006, the National Institute of Justice, which is the research arm of the Department of Justice, published a research and policy brief entitled "Agroterrorism: Why We're Not Ready," that identified FMD as the greatest agroterrorist threat facing our Nation today. For a number of years, the National Grange has called on government to address this threat. We commend DHS and USDA and other Federal agencies for moving to upgrade our Nation's bioresearch capacity but we are puzzled as to why the introduction of these dangerous pathogens on the mainland should be facilitated by Federal policy, especially in light of the successful record of research and containment that the existing geographically isolated Plum Island facilities have demonstrated for 50 years.

First of all, the National Grange is worried that the bioresearch facility management procedures that will be built into NBAF will be insufficient to guarantee that FMD is not accidentally or incidentally released into the environment. A better course, we believe, would be to combine all of the bio facility and management procedures and protocols, all the lessons learned from domestic and foreign operations of these types of facilities into the design and operation of an NBAF with significant geographic isolation such as the existing Plum Island facility. However, even if we accept that FMD can never be accidentally released from an NBAF, we remain concerned that the facility will become an inviting target for espionage, terrorists or criminal attacks aimed at getting those pathogens out of the laboratory and into the environment. We are also concerned that a mainland NBAF would become an inviting vicin-

ity for the criminal release of FMD. Not every terrorist takes public credit for their action. If FMD was released in the vicinity of NBAF, the assumption would be that the release came from the facility. Investigations could disrupt or delay research activity indefinitely. It would divert resources from apprehending those responsible and it would call into question DHS's management of the facility all in a dynamic political and media climate of economic and environmental disaster.

The National Grange has a high degree of respect for our Nation's counterespionage, antiterrorist, and law enforcement agencies. Our concern, however, is that a mainland NBAF facility will attract an extremely broad universe of potential terrorists or criminal organizations who could use an attack against this facility to advance their goals. The National Grange believes that geographic isolation of NBAF at a location such as Plum Island would add security to the facility and the vicinity. It would remove significant incentives to make the facility an active target. The National Grange is also concerned that NBAF will discourage private investment around the facility and reduce the viability of family farm and ranch operations in the vicinity as well as the social and economic fabric of local farming communities.

Perceived risks arise from general preparedness from FMD outbreaks. As the 2006 NIJ report points out, the laws in most States would place the responsibility for coordinating primary first response on State and local law enforcement. When, however, a Federal facility becomes the focal point for the outbreak, there will be inevitable jurisdiction and responsibility issues related to investigating the outbreak.

In summary, Mr. Chairman, we appreciate the opportunity to testify. We believe that the site selection process for NBAF has underappreciated the need for geographic isolation of this facility and it would be a prudent and cost-effective security measure to incorporate that that would assure our Nation that we can have a world-class bio- and agro-research facility and the assurance that this facility will not pose an undue risk potentially to tens of thousands of family farmers and ranchers. Thank you.

[The prepared statement of Mr. Watson follows:]

Statement by Leroy Watson, Legislative Director
National Grange of the Order of Patrons of Husbandry

Before

The Subcommittee on Oversight and Investigations
U.S. House of Representatives Committee on energy and commerce

For the hearing entitled:

"Germs, Viruses and Secrets: Government Plans to Move Exotic Disease Research to the Mainland U.S."

Thursday May 22, 2008
10:00am
2123 Rayburn House Office Building
Washington, D.C.

Mr. Chairman, Members of the Subcommittee:

My name is Leroy Watson. I am the Legislative Director for the National Grange, the country's oldest general farm and rural public interest organization. Originally founded in 1867, today the National Grange represents nearly 200,000 individual Grange members affiliated with more than 3000 local, county, and State Grange chapters across the United States. More than 70% of our local Grange chapters are located in communities of 5,000 people or fewer.

The National Grange would like to commend the Subcommittee on Oversight and Investigations for holding this timely hearing on proposals by the U.S. Government to relocate the Plumb Island Animal Disease Center to a location on the mainland United States as part of a new National Bio-and Agro Defense Facility. We appreciate the opportunity to present our views strongly opposing the development of an animal disease research facility on the United States mainland that will work with live strains of Foot and Mouth Disease (FMD) viruses, as well as other virulent foreign animal diseases (FADs) anywhere near existing concentrations of commercial livestock. Our comments here today expand on the points we raised in a letter we sent to U.S. Secretary of Agriculture Ed Schafer on April 14, 2008, on this issue. We believe that the economic risks of a potential outbreak of FMD to family farmers and ranchers across the nation with commercial livestock operations will far outweigh the advantages the Government has put forth to justify their proposals to bring this critical and sensitive research back to the mainland and away from the isolated island research facility where it has been successfully conducted for more than fifty years.

While there are many possible scenarios for the outbreak of animal diseases that would pose a significant economic risk to family farmers and ranchers as well as to their surrounding rural communities and their natural environments, few come close to the nightmare of an outbreak of FMD in dramatically impacting many aspects of American life. Containing a major outbreak

would be a Herculean, if not impossible task. FMD is twenty times more infectious than smallpox. It causes painful blisters on the tongues, hooves, and teats of cloven animals such as cattle, pigs, goats and deer that can render them unable to walk, eat, or drink. While people and other wild animals, such as predators or carrion, do not often contract FMD, once in contact with the virus they can carry the virus in their lungs to transmit to other susceptible animals for up to forty-eight hours. The animal-to-animal airborne transmission range for a local outbreak of FMD would cover a fifty-mile radius, or an area of more than 7800 square miles.

There is no known cure for FMD once it has been contracted. Once the disease was loose on the mainland U.S., it could require mass slaughter and disposal of potentially tens of millions of individual carcasses of domestic and wild animals to control the outbreak. It would require the imposition of draconian human quarantine and decontamination measures that would disrupt general commercial activities, outdoor recreational activities like deer hunting or hiking, as well as personal freedom of mobility both in and out of the agricultural sector. It would undoubtedly disrupt the domestic and international sale of meat and meat products throughout the nation for months or even years. A 2004 research paper published by the U.S. Department of Agriculture entitled "Economic Impact of Foreign Animal Disease Outbreak Across the United States" calculated that the direct costs to the domestic livestock industry of an FMD outbreak would exceed $60 billion. We believe the ancillary costs to general commerce, outdoor recreation, and impacts on future investments in the livestock sector by family farmers and ranchers would exceed the conservative USDA estimate of $60 billion in direct costs by several fold.

Living with the risk of a potential FMD outbreak is something that family farmers and ranchers have had to come to grips with reluctantly over the past few years. The United States has been blessed as free of active outbreaks of FMD for more than 80 years. However, the events of 9/11, the anthrax attack of 2001, and other threat assessments have highlighted America's diversified and highly dispersed family farms and ranches as "soft" targets for any terrorist, foreign power, or even organized crime organization that wanted to strike a blow against the nation's heartland. In 2006, the National Institute of Justice, the criminal justice policy research arm of the U.S. Department of Justice, published a Research for Policy brief entitled "Agroterrorism- Why We're Not Ready" that identified FMD as the greatest agroterrorist threat facing our nation. For a number of years now, National Grange policy resolutions, generated and adopted by our grassroots members and delegates on the local, state, and national level, have called on USDA, DHS, and the law enforcement community to work cooperatively to address this threat and take proactive measures to prepare for this type of outbreak. We actually strongly support and commend DHS, USDA, and other federal agencies for taking pro-active steps to upgrade our nation's frontline bioresearch capacity to combat future outbreaks of FMD and other FADs. Yet while family farmers and ranchers represented by the National Grange are currently resigned to living with the threat of the deliberate introduction of FMD or other FADs into their communities by individuals who are inamicable to our national interests, they are puzzled as to why the introduction of these dangerous pathogens onto the mainland U.S. should be facilitated by Federal Government policy, especially in light of the successful record of research and containment that the existing and geographically isolated Plumb Island facilities have demonstrated for more than fifty years.

Our threat assessment concerns for locating the proposed National Bio-and Agro Defense Facility, and especially the research facilities for FMD and other virulent FADs, on the mainland fall into three broad categories:

> First, failure to implement sufficient protocols and procedures to prevent accidental or incidental release of these pathogens from the NBADF;
>
> Second, an agroterrorist attack against, or in the vicinity of, the NBADF that deliberately releases these pathogens; and
>
> Third, ancillary economic and social damage to farming and rural communities in the vicinity of the NBADF due to the "Perceived Risk" of an outbreak. This damage would probably take two forms. First is the damage that will be derived by the individual assessments of local family farmers and ranchers to the possibility of either of the above scenarios that, in turn, create an agricultural economic investment dead zone around the facility as family farmers and ranchers avoid making future investments in any communities within a radius of at least fifty miles around the NBADF. Second is the damage from law enforcement and other prudent emergency preparedness measures that must be put in place by local, state, and Federal Government agencies in the vicinity of the NBADF that would potentially burden property, contractual and other civil rights of individuals living in the vicinity.

The National Grange believes that DHS has not demonstrated that it has the expertise and experience to safely conduct research on FMD on the U.S. mainland.

The National Grange is worried that any state-of-the-art bioresearch facility management protocols and procedures built into the NBADF would be insufficient, on their own, to guarantee that FMD or other FAD's are not accidentally or incidentally released from the NBADF. Our concerns are based on the recent experiences in Great Britain, where over the past eight years, two outbreaks of FMD have been attributed to release from bio-research facilities working with FMD. The 2001 outbreak of FMD in Great Britain caused at least $16 billion in damages, devastated the rural economy, and nearly caused the government to fall.

We understand that other bioresearch facilities in other nations have successfully conducted their research programs on FMD. However, the experiences in Great Britain lead us to conclude that conducting federal research on dangerous animal diseases on the U.S. mainland is a risk we do not have to take. We do not share the opinion of the Administrator of the USDA Animal and Plant Health Inspection Service who responded to our April 14, 2008, letter raising our concerns to U.S. Secretary of Agriculture Ed Schafer that "...we can use that example [of the recent suspected release of live FMD from a research facility in England] as a learning opportunity..." to design a better mainland bio-research facility. Instead, we believe that it would be a prudent, cost effective and sensible precaution to couple all of the state-of-the-art bio-facility management protocols and procedures and all of the lessons learned from the outbreaks in Great Britain that DHS plans to incorporate into the design and operation of the NBADF with significant geographic isolation, such as on the existing Plumb Island facilities.

Even if DHS is completely successful in designing a NBADF facility where accidental release of FMD or other FADs is impossible, the facility still poses significant risk to the local community because it will become a target for espionage, terrorist attacks, or as a site for a terrorist or criminal release of FMD or other dangerous pathogens.

Even if we accept DHS and USDA's claims that a mainland NBADF can be made so secure that FMD or other FADs can never be accidentally or incidentally released from the NBADF, we remain concerned that the facility would become an inviting physical target for espionage and terrorist or criminal attacks aimed at breaching the physical and procedural barrier built into the facility and getting these pathogens out of the laboratory to eventually be released into the environment.

Moreover, we are also concerned that a mainland NBADF would provide an inviting vicinity for the release of FMD by terrorist or criminal elements that would be looking to maximize not only the economic damage from an FMD outbreak, but also the social and political confusion and fallout from this outbreak as well. Not every terrorist or criminal immediately takes public credit for his actions. We still have no definitive knowledge about who launched the 2001 anthrax attacks that closely followed the 9/11 attacks. If an FMD strain were to be released in the vicinity of the NBADF, a logical working assumption would be that the release came from the facility itself. Investigating this assumption could disrupt or delay research activity at the facility nearly indefinitely. It would divert resources from quickly apprehending those actually responsible for the release, potentially allowing them an opportunity to plan and execute a similar attack in the future. It would call into question DHS's security protocols and management of the facility all in the dynamic political and media climate of a rapidly unfolding local, regional, or even national economic and environmental disaster.

The National Grange has a high degree of respect for our nation's counter-espionage, anti-terrorist, and law enforcement agencies. Our concern is not a reflection on our confidence that these dedicated public officials would do everything in their power to prevent or foil attempted espionage, terrorist, or criminal attacks. Our concern is that a NBADF facility located on the mainland would attract an extremely broad universe of potential terrorist or criminal organizations to use an attack on the facility to advance their goals. Domestic terrorist organizations, such as the Animal Liberation Front and the Earth Liberation Front have specifically avoided attacks against human beings in favor of attacks against "property" or 'research facilities" because they believe that their activities will have a greater moral acceptance. Criminal organizations, including the paramilitary drug cartels that are actively challenging the democratic sovereignty of several of our Latin American neighbors, including Mexico, could decide to use an FMD attack against, or in the vicinity of, the NBADF in the U.S. to send a propaganda message that they are above the law and that the Federal Government is powerless to stop them. The potential list of suspect organizations and even individuals is nearly limitless.

The National Grange believes that geographic isolation of the NBADF at a location such as Plumb Island remains a prudent, cost effective means of adding additional security to the facility and the vicinity. It would remove much of the incentive to make the facility an active target of espionage, terrorist, or criminal activity. The greater the isolation from livestock and wildlife, the

less economic and environmental fallout of an attack against, or in the vicinity of, the facility, and therefore the less the facility becomes a prime target. Unlike protocols, procedures, and design of the facility itself, which are largely within the control of DHS to assure that FMD or other FADs don't accidentally or incidentally escape from the facility, the time, means, and manner of an espionage, terrorist, or criminal attack against a mainland NBADF would be wholly determined by those who wish us harm.

"Perceived risks" from either accidental or deliberate release of FMD to the surrounding communities would discourage livestock related investment and impinge on the property, contractual or civil rights of residents in surrounding communities.

The National Grange is concerned that the establishment of the NBADF on the U.S. mainland will create a perception of risk that will stunt private investment in family farm or ranch livestock operations within the fifty-mile radius around the facility. Individual family farmers or ranchers do not have to share DHS's assessments that there are no risks associated with the location of this facility in their community. We believe that a significant portion of the family farm or ranch sized livestock production community will disinvest, move, or not expand livestock operations that they otherwise would have in response to the location of the NBADF. Over time, these individual decisions will have a significant impact on the viability of all family farm or ranch operations in the vicinity of the NBADF, as well as on the traditional social and economic fabric of the farming and rural communities that support them.

Modern family farm or ranch livestock operations often involve more than simple production that can be measured in annual sales or dollar terms. High value livestock operations, in fact, are far more likely to incorporate and market long term intrinsic characteristics of their animals as part of their livestock operations. For example, entrepreneurial animal breeding programs that are based on decades long commitments by family farmers and ranchers to add value to their animal herds through careful and systematic genetic management objectives could be lost in the blink of an eye. While we will, for the sake of argument, assume that in the case of an FMD outbreak associated with the NBADF, that reasonable monetary indemnification for the market value of a farmer's or rancher's animals would eventually be available from the government, the individual farmer's or rancher's lifetime investment of time and talent, as well as his expertise and commercial reputation in herd or breed genetic enhancement, would be forever lost.

Perceived risk also arises from a lack of general preparedness about and FMD or similar FAD outbreak in the United States at all levels. As the 2006 NIJ report points out, today the laws of most state and local jurisdictions require treating an FMD outbreak as a crime scene not an animal public health emergency. This would place the jurisdiction and responsibility for coordinating the primary first response on state and local law enforcement agencies. When a federal facility becomes the focal point for the outbreak, however, inevitably there will be jurisdiction and responsibility issues related to the conflicting responsibilities involved in investigating the outbreak and containing its spread. To date, while state officials have been forthcoming with proposals to coordinate future taxpayer expenditures to support their bid to host the NBADF, we have not seen any legislative initiatives to change state laws to clarify the role of state and local law enforcement and state animal public health officials to the increased potential for an FMD outbreak in their state that could be directly associated with a major

Federal facility. Federal and state officials seem unwilling to discuss these scenarios, especially in public, and will instead respond that a) this research is really important and b) an FMD or other FAD outbreak cannot occur from the proposed facility.

Perceived risk also manifests itself in the fact that even if farmers and ranchers are fully informed and aware of the risks to their individual operations, and even if local, state, and federal officials act in complete coordination, optimal FMD outbreak response plans will burden civil liberties, commercial and civic obligations, and possibly exceed physical ability or political will to execute these plans. According to the NIJ report, quarantine areas would have to be quickly established and enforced in the immediate vicinity around a six-mile radius. Additional roadblocks would also be needed to restrict traffic only to necessary travel over a much broader area, possibly state wide. On family farms and ranches, tissues from infected animals would have to collected and preserved. All commercial livestock would have to be destroyed and disposed of in a timely manner. Livestock production facilities, marketing facilities, or processing facilities would all be quarantined and face expensive and problematic decontamination procedures. Contractual obligations such as contracts to supply agriculture product to market or receive agricultural inputs would be defaulted. Civic obligations such as sending one's children to school, appearing in court for jury duty, or even responding to a call up of the National Guard to address this emergency would be problematic for anyone in the affected area.

If the disease works its way into the wildlife population, there may be no physical means to enforce a plan to destroy and dispose of infected populations of wildlife. For example, according to the North Carolina Department of Fish and Wildlife, the deer population in the vicinity of the proposed NBADF facility in that state is about 45-50 animals per square mile. This means that within a fifty-mile radius of the facility, conservatively speaking, there would be a population of 35,000 deer. According to Dr. John Fischer, professor at the University of Georgia college of Veterinary Medicine and Director of the Southeastern Cooperative Wildlife Disease Study, "There are no plans in place to systematically depopulate wildlife to control an FMD outbreak," both because, in his view, it is "...physically impossible and socially unacceptable." Lacking the physical ability or political will to control an FMD outbreak in both the domestic as well as wild animal populations, it is nearly inevitable in the view of the National Grange that even a minor outbreak of FMD in the vicinity of the NBADF could spread well beyond the initial containment areas.

We would have a greater degree of comfort if DHS was forthright in explaining the consequences of a potential FMD outbreak in each of the individual communities, specifically addressing the ecological, commercial, and civil liberties implications of an FMD outbreak at or near the NBADF facility as part of its site selection process, and also if we were assured that sufficient federal funds to address the contingency planning as well as implementation of any contingency plan were to be available before the construction of a mainland NBADF facility commenced. However, under Homeland Security Presidential Directive 7, funding for preparing and responding to an agroterrorism attack such as the release of FMD is discretionary for DHS, not mandatory.

However, in the view of the National Grange, a far better response that would mitigate potential risks from a potential outbreak of FMD from a federally funded research facility is to select a site for the NBADF that is geographically isolated as much as possible from the environmental, commercial, and civic infrastructure of the mainland, such as the Plum Island facility.

Mr. Chairman, the National Grange appreciates the opportunity to present our views on the future location of the National Bio-and Agro Defense Facility. We strongly believe that the selection process for this facility has under appreciated the need for geographic isolation of a facility like this as a prudent, reasonable, and cost effective security measure that will assure that our nation can have both a world class research bio and agro research facility and the assurance that this facility will not pose accidental or incidental risk to rural communities in which potentially tens of thousands of family farmers and ranchers live.

I would be happy to take questions about our testimony.

Sincerely,

Leroy Watson, Legislative Director
National Grange of the Order of Patrons of Husbandry
1616 H St. NW
Washington DC 20006

202.628.3507	(phone)
202.347.1091	(fax)
lwatson@nationalgrange.org	(e-mail)

The National Grange

Of the Order of Patrons of Husbandry

Building Communities

April 14, 2008

The Honorable Ed Schafer, Secretary
U.S. Department of Agriculture
Jamie L. Whitten Federal Building
1400 Independence Ave., S.W.
Room 200-A
Washington, DC 20250

Dear Secretary Schafer:

The National Grange, the nation's oldest general farm and rural public interest organization representing family farmers and rural citizens, strongly opposes the development of a Foot-and-Mouth Disease research facility on the United States Mainland. Currently this disease research is accomplished on an isolated island laboratory in New York's Long Island Sound, far away from U. S. livestock, and thus minimizing the risk for a catastrophic outbreak, which would devastate our domestic livestock industry. The research accomplished includes vaccine and drug development, testing of imported animals, and professional training.

The Bush administration is proposing additional highly sensitive research at a new National Bio Defense Facility on the U. S. mainland near hundreds of thousands of livestock. Proposed sites for the new laboratory include the states of Kansas, Georgia, North Carolina, Texas, and Mississippi. The National Grange strongly believes any outbreak containment would be more successful at the existing isolated facility than at a proposed mainland site. The Foot-and-Mouth virus, which does not affect humans, is nonetheless, highly contagious and can be carried by breath, clothes, and vehicles. Bio-security will always be an issue on the mainland so placing a new research facility on the continental United States greatly increases the risk of a catastrophic outbreak. Consequently we recommend renovating the existing facility to obtain the security necessary to perform higher-level research such as viral transfer from animals to humans rather than building a new facility on the continental U. S.

Proponents of a new mainland facility say modern safety rules at labs are sufficient to avoid any potential outbreak. But incidents in Britain have demonstrated that the foot-and-mouth virus can cause remarkable economic havoc, and that the virus can escape from a facility. An epidemic in 2001 devastated Britain's livestock industry, as the government slaughtered 6 million sheep, cows and pigs. Last year, in a less serious outbreak, Britain's health and safety agency concluded the virus probably escaped from a site shared by a government research center and a vaccine maker. Other outbreaks have occurred in Taiwan in 1997 and China last year and in 2006.

The National Grange urges you to consider bio-security and the devastating negative economic consequences of a domestic outbreak of foot and mouth disease. We need to minimize those risks by utilizing the existing research facility on an island removed from the domestic livestock. Thank you.

Sincerely,

Leroy Watson, Legislative Director
National Grange of the Patrons of Husbandry

United States Department of Agriculture

Animal and Plant Health Inspection Service

1400 Independence Avenue, SW

Washington, DC 20250

MAY 16 2008

Mr. Leroy Watson
Legislative Director
National Grange of the Patrons of Husbandry
shamfam5@verizon.net

Dear Mr. Watson:

Thank you for your letter of April 30, 2008, to Secretary Edward T. Schafer on behalf of the National Grange concerning Plum Island Animal Disease Center (PIADC) research and diagnostic activities.

We recognize your concern and appreciate this opportunity to respond. As you may know, in June 2003, operational responsibility for the PIADC transferred from the U.S. Department of Agriculture (USDA) to the U.S. Department of Homeland Security (DHS) under the Homeland Security Act of 2002. We have developed a strong, collaborative partnership with DHS, and are working together to establish the National Bio- and Agro-Defense Facility (NBAF), a next-generation facility to replace the current PIADC structures. Although DHS is ultimately responsible for the selection of an NBAF site, USDA has been closely involved throughout the process. Our Agency of USDA and USDA's Agricultural Research Service have provided detailed program requirements to DHS, and we have representatives on the site selection committee, the site inspection team, and the environmental impact statement (EIS) team. Because DHS is responsible for the selection of the NBAF site, you may wish to contact DHS directly, the address is DHS, Building 410, 245 Murray Lane SW., Washington, D.C. 20528. In addition, DHS has a Web page with information about the NBAF at www.dhs.gov/nbaf.

Since 1954, the PIADC has played a critical role in helping USDA develop the tools and expertise needed to protect U.S. livestock from foreign animal diseases (FAD) such as foot-and-mouth disease (FMD). However, the current state of the aging facility has created a backlog of needed space for important experiments, diagnostic development, and training efforts. For instance, USDA cannot carry out biosecurity level 4 (BSL-4) activities at the PIADC, meaning that the United States does not currently have a facility to address certain high-consequence, zoonotic diseases such as Rift Valley fever, Nipah, and Hendra.

DHS is currently preparing an EIS considering six site alternatives, including Plum Island and mainland locations. While we understand concerns about moving certain FAD research activities to the U.S. mainland, we assure you that, with today's much more advanced technologies, neither location nor physical barriers dictate abilities to manage effective biosecurity and biosafety practices.

A 2002 study commissioned by USDA and completed by the Science Applications International Corporation (SAIC), found that the FMD virus and other exotic foreign animal diseases of concern could be fully and safely contained within a BSL-3 laboratory, as was being done at the time in other countries including Canada, Germany, and Brazil. A second SAIC study also concluded that there was a valid USDA need for a BSL-4 facility, and that a BSL-4 facility for large animal work could be safely located on the mainland.

In planning for the NBAF, we recognize the absolutely essential need for state-of-the-art biosafety practices and procedures, including stringent and rigorous safety measures within the laboratories themselves, to prevent disease organisms from escaping into the environment. Situations such as the recent suspected release of live FMD virus from the Pirbright campus in England only serve to highlight this importance. In fact, we can use that example as a learning opportunity to make sure that the design and maintenance of the U.S. NBAF facility enables us to carry out the essential activities needed to protect the Nation from FADs while ensuring the highest level of biosafety.

We also wish to point out that, among other potential advantages, locating the NBAF in a more accessible location (i.e., on the mainland) would enhance the speed with which USDA could respond to a potential FAD threat. There are other benefits as well: the cost of living would be lower for employees; personnel recruitment would be easier; the facility would be more accessible if weather conditions or emergency situations force air traffic shutdowns; and, the facility would not be subject to the occasional wind closures that we experience at the PIADC due to rough waters.

We hope this information is helpful and demonstrates our commitment to ensuring that our diagnostic capabilities and resources reflect the new and changing FADs that continue to emerge.

Sincerely,

Kevin Shea /for

Cindy J. Smith
Administrator

United States Department of Agriculture

Animal and Plant Health Inspection Service

1400 Independence Avenue, SW

Washington, DC 20250

MAY 16 2008

Mr. Leroy Watson
Legislative Director
National Grange of the Patrons of Husbandry
shamfam5@verizon.net

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DHS is currently preparing an EIS considering six site alternatives, including Plum Island and mainland locations. While we understand concerns about moving certain FAD research activities to the U.S. mainland, we assure you that, with today's much more advanced technologies, neither location nor physical barriers dictate abilities to manage effective biosecurity and biosafety practices.

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We also wish to point out that, among other potential advantages, locating the NBAF in a more accessible location (i.e., on the mainland) would enhance the speed with which USDA could respond to a potential FAD threat. There are other benefits as well: the cost of living would be lower for employees; personnel recruitment would be easier; the facility would be more accessible if weather conditions or emergency situations force air traffic shutdowns; and, the facility would not be subject to the occasional wind closures that we experience at the PIADC due to rough waters.

We hope this information is helpful and demonstrates our commitment to ensuring that our diagnostic capabilities and resources reflect the new and changing FADs that continue to emerge.

Sincerely,

Kevin Shea /fs

Cindy J. Smith
Administrator

Mr. STUPAK. Thank you, Mr. Watson.

Mr. Voogt, am I saying that right? Voogt?

Mr. VOOGT. Voogt.

Mr. STUPAK. OK. Mr. Voogt, time for your opening statement, please, sir.

STATEMENT OF GARY VOOGT, PRESIDENT-ELECT, NATIONAL CATTLEMEN'S BEEF ASSOCIATION

Mr. VOOGT. Thank you, Mr. Chairman. My name is Gary Voogt and I am a cattle producer from Michigan. I appreciate the opportunity to visit with you about what has been known today as NBAF.

The introduction of foreign animal diseases, whether by accident or intentionally, is a huge threat to the U.S. cattle industry. We talked about foot-and-mouth disease. It is the most contagious animal disease known. An outbreak of foot-and-mouth disease in the United States could devastate the cattle industry. Our figures show a cost of $10 billion to $34 billion with an outbreak. There is an indirect cost that we haven't talked about here today and that is if the livestock industry is lost in this country, how are we going to feed our people? This country cannot afford to rely on foreign countries for our food. Oil is teaching us that lesson.

The need for diagnostic activities, prevention, and treatment research and the development of effective countermeasures is critical to the health and welfare of the domestic cattle herd. It is critical to cattle producers and it is critical to national security. This is why the National Cattlemen's Beef Association supports the construction and, as importantly, the ongoing maintenance of a state-of-the art foreign animal disease research center.

NCBA has had more than 100 years of experience working closely with local, State and Federal animal health officials to control and eradicate animal diseases and to prevent the introduction of foreign animal diseases into the United States. Facilities such as Plum Island have created strong barriers to foreign diseases. Because of that work, the United States has been free from foot-and-mouth disease for more than 70 years. The Federal Government is a vital partner in combating foreign animal disease but you should appreciate, we are not relying solely on the government to protect our industry. We have incident planning for disease outbreaks all over the country. Take many farms in Kansas, for example, and I know my home State of Michigan involves the FBI, the state police, the highway department, the sheriff department, livestock markets, anybody. We practice what would happen if there is an incident, and this plume does not go across the country unchecked. There is a virtual lockdown of all transportation facilities immediately. We don't have to call somebody. It is ready to go today. It is in place.

Now, Plum Island is old and worn out. We have established that. Over the years funding has not been adequate to keep up with today's technologies or today's research needs. Incidentally, we believe Plum Island is not the fortress many people think it is. The island has always had a problem with wildlife swimming over from the mainland at low tide. Boaters can get far too close without warning or consequences. It is critical that the United States have

a state-of-the-art large animal biologically secure lab to conduct research on all the foreign diseases that could sicken or destroy the food animal population. We believe modern biocontainment technology is adequate to protect our industry and to allow for safe research and diagnostics on the mainland. The Canadian center in Winnipeg is a good example of how mainland facilities can be safe.

In conclusion, NCBA supports and encourages the construction of this new facility. We have not, however, and we are not going to take a position on where the facility should be built. Our support for the new facility is contingent on two things. First, we need a commitment from the Congress and the Administration that this facility will be properly funded and maintained for the long haul. The United States cannot afford to let this facility become run down like Plum Island. The second contingency of our support is, we encourage your committee to work with the House Committee on Agriculture and the House Committee on Homeland Security. It is imperative that the needs of the agricultural community not be lost in the expanding focus of homeland security. Homeland security must curb their mission creep. They should not be doing animal research. We would be more comfortable with USDA doing animal research. USDA, on the other hand, must be retained and supported to continue their responsibility of conducting research on all foreign animal diseases.

Mr. Chairman, thank you for the opportunity.

[The prepared statement of Mr. Voogt follows:]

Testimony

on behalf of the

National Cattlemen's Beef Association

with regard to

The Proposed Construction of the National Bio and Agro-Defense Facility

submitted to the

United States House of Representatives - Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

The Honorable Bart Stupak, Chairman

submitted by

Mr. Gary Voogt

President-Elect
National Cattlemen's Beef Association

May 22nd, 2008
Washington, D.C.

National Cattlemen's Beef Association

Mr. Chairman, Members of the Committee, my name is Gary Voogt and I am a cattle producer from Marne, Michigan, and the President-elect of the National Cattlemen's Beef Association (NCBA). On behalf of the more than 247,000 members represented by NCBA, and our state and breed affiliates, I appreciate the opportunity to give you my views on the proposed National Bio and Agro-Defense Facility (NBAF). As you know, the United States Department of Agriculture (USDA) and the Department of Homeland Security (DHS) have been discussing the need for a state-of-the-art foreign animal disease research center for several years. The U.S. livestock industry has also advocated for improvements since this is the only facility in the U.S. that can conduct the appropriate and vital foreign animal disease research. NBAF will replace the research and foreign animal disease diagnostic facility currently at the Plum Island Animal Disease Center in New York. NCBA has been actively involved with the committees of jurisdiction and with the Administration to offer input and feedback on this new facility.

The introduction of foreign animal diseases, either accidental or intentional, is a huge threat to the U.S. cattle industry. One such threat is foot-and-mouth disease (FMD), the most contagious animal disease known, and it represents a worst-case scenario for cattle producers because of the variety of the species involved (cattle, sheep, swine, and wildlife such as deer), the rapid spread of the disease, and the difficulty in controlling outbreaks.

An outbreak of foot-and-mouth disease in the United States could devastate the cattle industry. Foot-and-mouth is a viral disease that is spread via contact and fomites, with

inhalation and ingestion being the routes of infection. Airborne transmission (virus can be spread by the wind and is influenced by weather conditions) has been reported, and cattle may be more susceptible to this route of infection.

It is estimated that a domestic outbreak would result in losses of $10 to $34 billion. This figure is a result of production losses, export losses, control costs (de-population, disposal, vaccination, disinfection, surveillance), and allied industry losses (feed suppliers, banks, veterinarians, equipment dealers). The 2001 foot-and-mouth disease outbreak in the United Kingdom cost $6 billion and resulted in almost 6.5 million animals being destroyed. Many of our members could immediately be put out of business, and the beef industry, which we have worked so hard to develop, could be crippled. As you can see, the need for diagnostic activities, prevention and treatment research, and the development of effective counter-measures are critical to the health and welfare of the domestic cattle herd and cattle producers across this country.

NCBA has more than 100 years of experience working closely with local, state, and Federal animal health officials, veterinarians, and animal scientists to control and eradicate animal diseases, and to prevent the introduction of foreign animal diseases into the United States. With the help of facilities such as Plum Island, we have created a series of formidable barriers to the introduction of foreign animal diseases, and we have been successful at eradicating many diseases that were at one time present in our domestic herd. It is because of this work that the United States has been free from foot-and-mouth disease for more than 70 years.

However, Plum Island is an old facility whose infrastructure has not kept up with today's technology, nor does it meet the demands of today's research needs. Technology has markedly improved over that available when the animal buildings were constructed more than 50 years ago. Throughout the years, funding has not been timely or adequate enough to constantly improve the Plum Island facilities.

In addition, Plum Island is not the "fortress" some people may contend. The island has long had a problem with wildlife swimming over from the mainland at low tide, and there have been numerous reports of how close boaters can get to the island without any warning or consequences. Regardless of its location, new and modern technology must be utilized to protect our food animal herd.

It is critical that the United States have an adequate large animal biosecurity level 3 and 4 (BSL-3/BSL-4) laboratory to conduct research on all of the diseases that could destroy or sicken the food animal population. We believe that modern biocontainment technology is adequate to protect our industry and to allow for safe research and diagnostics on the mainland, or wherever the NBAF facility is located.

The multiple layers of protection found in today's BSL- 3 and BSL-4 labs will protect from releases as long as the Administration and Congress commit to appropriate funding of the facility to make sure it is continuously and properly maintained and upgraded. Even more important is that USDA and DHS require strict adherence to the protocols of

biosecurity that such facilities need to deter accidental or intentional releases. In fact, the precedent for locating BSL-3/BSL-4 laboratories in populated urban centers has been set with such facilities as Canada's National Center for Foreign Animal Disease in Winnipeg. There have been no accidental releases at this facility, which is a testament that the population can be protected.

Because of the incredible impact this disease, and other foreign animal diseases, could have on the U.S. cattle industry, NCBA has long taken proactive measures to work with industry and government to address the response to an outbreak. NCBA has sponsored summits and has participated in training exercises to work with first responders, government officials, and others in the cattle and livestock industries to identify what does and does not work, and to try to find ways to improve the response.

Additionally, both USDA and NCBA have worked with foreign governments and industries, including those in Canada and Mexico, in response planning. Prevention is the primary goal, but we have been, and will continue to be, aggressive in our work with all of our partners to be ready with early detection, rapid response, and recovery in case of an incursion of any cattle disease, including foot-and-mouth disease. We understand that although the Federal government is a partner in combating foreign animal diseases, we cannot afford to sit back and rely solely on them to protect our industry.

Foreign animal diseases have to be taken seriously as a threat to the U.S. food supply and the welfare of our country's cattle producers, and we thank you for giving thorough and

careful consideration to this issue. NCBA supports coordination and collaboration, where appropriate, amongst the Departments to enhance each of their abilities to achieve the goals under their respective mission areas, as well as to avoid duplication of efforts which waste taxpayer dollars. However, we remain concerned that DHS does not understand agriculture and has an inherent tendency to want to extend their role beyond their mission area. It is imperative that the needs of the agriculture community not be lost within the larger focus of DHS. USDA has long had the expertise on studying animal diseases, and they must be given the ability to continue in that role. They must also have the ability to study all foreign animal diseases, and not just foot and mouth disease.

As you can see, our industry has given much thought to the closing of Plum Island and the construction of NBAF. NCBA supports the construction of NBAF because this new facility will give USDA and DHS better tools to study and protect against foreign animal diseases. We have not, and will not, take a position on where this facility should be built, and our support is contingent upon the ability of USDA to retain their mission of conducting research on all foreign animal diseases. It is also contingent upon seeing a commitment from Congress and the Administration to ensure this facility is properly funded and maintained. We cannot afford for this facility to be run down like Plum Island has been.

I appreciate your listening to cattle producers' concerns regarding this facility, and I hope that you will continue to work with our industry on this issue. I also hope that you will

work with the other committees of jurisdiction, the House Committee on Agriculture and the House Committee on Homeland Security, in order to ensure that USDA has the ability to carry out its own responsibilities at the new facility without the mission creep we have seen from DHS. The vital work that has been done at Plum Island over the past 50 years must not be diluted or lost in the broader direction of DHS.

Major Points

- Foreign Animal Disease Research is critical to protecting the U.S. cattle industry
- Plum Island is an old facility that has not been adequately maintained
- NCBA supports the construction of a state-of-the-art animal disease research facility to replace Plum Island
- NCBA does not have a position on where the new facility is located
- USDA's role in research has to be preserved, and the focus of the research needs to be on all foreign animals diseases, not just foot-and-mouth disease
- DHS should not be involved in animal disease research. Their job is to work with USDA to develop effective counter-measures
- Congress and the Administration must make a commitment to fund this new facility to ensure it remains state-of-the-art, and not be allowed to end up like Plum Island

Mr. STUPAK. Thank you, Mr. Voogt.

We will begin questions. Mr. Wulf, let me start with you, if I may. In your testimony, you state your organization is opposed to moving the foot-and-mouth disease from Plum Island to the mainland. Does this mean that you are opposed to building a modern lab on Plum Island?

Mr. WULF. We certainly support the research and additional dollars for research there on Plum Island. It certainly needs to be done.

Mr. STUPAK. Let me ask all of you this one. In 2003, the Department of Homeland Security took over the operational responsibility for Plum Island and is now proposing a broad expansion of its responsibilities for animal disease research. In your view as representatives of your organizations, should DHS be leading this country's animal research or do you think your members would be more comfortable if the responsibility for this research was conducted by Department of Ag. as opposed to the Department of Homeland Security? Let us just go down right down the line. Mr. Wulf, we will start with you and go right down the line.

Mr. WULF. Obviously, we would love to see the Department of Ag highly involved in this particular type of research. My opinion on DHS, I don't know that I had an opinion prior to coming here to the question, Mr. Chairman. However, due to the questions that were raised earlier in the first panel, I have serious concerns.

Mr. STUPAK. So you would rather see it stay with Department of Ag, the research on disease?

Mr. WULF. Yes.

Mr. STUPAK. Dr. Hill?

Dr. HILL. I am confident that our members would be more comfortable with the research being done by the Department of Agriculture.

Mr. STUPAK. Mr. Watson?

Mr. WATSON. Grange policy has historically supported keeping this type of research under the purview of the Department of Agriculture.

Mr. STUPAK. Mr. Voogt?

Mr. VOOGT. That was my testimony as well.

Mr. STUPAK. Let me ask you this, Mr. Voogt, because you lost me a little bit there. On page 3 of your written testimony, you say you believe that modern technology is adequate to protect the livestock industry no matter where the lab is located, but on the 5th page of your written statement, you then say, and I am quoting now, "We have not and will not take a position on where the facility is to be built." So does your organization support the transfer of hoof-and-mouth—I keep calling it hoof-and-mouth because I am old guy—foot-and-mouth virus to the mainland or do you prefer to see it stay on Plum Island?

Mr. VOOGT. We prefer that a modern facility be built with all the safeguards in it. If the decision is to leave it on Plum Island, we are OK with that, but we are very comfortable that it can be brought to the mainland, but we are not going to make that evaluation.

Mr. STUPAK. A little bit of confusion comes in, in the exhibit book; take a look at tab number 17. There is a Jay Truitt writing

a letter on behalf of your organization indicating they have concerns about foot-and-mouth disease being moved. So I guess I am a little confused. It sounds like you are unwilling to move it but it looks like Jay Truitt sort of doesn't feel that way.

Mr. VOOGT. If I am looking at the right page, the question was, does your organization support moving foot-and-mouth disease from Plum Island. The answer was yes.

Mr. STUPAK. OK. And then when you go on to it, other parts of it, we get the impression they are not in the same position you are, like it is neutral almost. All right. Let me ask you this question. GAO testified earlier about the risk assessments not being done. Are you still comfortable with moving foot-and-mouth disease off Plum Island onto the mainland?

Mr. VOOGT. Yes, I am.

Mr. STUPAK. Do you think those studies should be done first before we move foot-and-mouth disease off Plum Island?

Mr. VOOGT. Well, there are a lot of studies that have to be done first before we are ready to go. The risk assessment, I learned this morning, has not been done, but that doesn't mean that when it is done it will prove that it is a bad idea. So we don't have that answer yet.

Mr. STUPAK. You don't have the answer yet so I guess that is where my confusion comes in between Mr. Truitt's letter and your testimony. Even without knowing the end results of a cost-benefit analysis, the environmental impact statement, the risk assessment, your organization, the cattlemen's association, is in favor of moving the foot-and-mouth to the mainland?

Mr. VOOGT. We are not going to tell you where to put it but we are not afraid of moving it to the mainland. That is the testimony.

Mr. STUPAK. OK. You mentioned the deer swimming across. Did you ever see deer swimming across to Plum Island, or did someone just tell you that?

Mr. VOOGT. I have heard that. I have not been to Plum Island, Mr. Chairman, but I have been to Mackinaw Island, so have you, and it happens to be exactly the same distance.

Mr. STUPAK. Sure, but the deer usually come across on the ice.

Mr. VOOGT. And they cross on the ice. I also live on Beaver Island, and there are animals there that came across and so that is why I said, I don't believe an island by itself is the fortress that we thought it was, especially if the carrier is the wind.

Mr. STUPAK. OK. Dr. Hill, let me ask you this question, because on page 30—tab 30, I am sorry—we have a letter from your organization there, a Jill Appell, immediate past president, National Pork Producers Council. On page 2, while they support the immediate building of an NBAF, its location should be determined through assessment of potential risk with disease spread to susceptible livestock and wildlife population. The risk assessment of the six remaining sites should be conducted as part of final selection process. So on behalf of pork producers, are you saying we can move forward with it before we do these assessments or——

Dr. HILL. Absolutely not. The pork producers are very adamant about the fact that risk analysis needs to be done for any site including Plum Island. And in regards to the deer, deer have swum across and have multiplied on the island, and there has been de-

populations. At one point there were over 50 deer that were depopulated. So that is a major concern.

Mr. STUPAK. If the risk assessment came back and said that foot-and-mouth should stay on Plum Island, would your organization have a problem with that?

Dr. HILL. If the risk assessment came back and it said that it wasn't safe to put it on the mainland, I don't believe that our organization would oppose putting it on Plum Island. The problem we have is that we have had 25 years of not really being able to fund Plum Island to the extent that it needs to be funded to be a first-class operation. I have been on Plum Island. I have seen the facilities. The facilities are in very, very bad repair. I know there has been money spent recently since I have been there but we had a delegation of pork producers that were there and the researchers were talking about water dripping onto the lab bench.

Mr. STUPAK. Any reason why you couldn't build a new facility at Plum Island?

Dr. HILL. Cost.

Mr. STUPAK. OK.

Dr. HILL. A major problem is cost.

Mr. STUPAK. Well, isn't the cost going to be the same on Plum Island or Georgia or Kansas?

Dr. HILL. No.

Mr. STUPAK. What is the difference in cost?

Dr. HILL. Everything there has to be boated across. I am not an expert on building costs but I have heard figures as much as 25 percent increase to operate the operation and as high as 35 percent to 40 percent increase to build the operation because it all has to be boated across, cement, lumber, everything.

Mr. STUPAK. But it has worked well for 70 years, I think one of you said, since we have had an outbreak of hoof-and-mouth disease. And I think your testimony was it might be $40 to $60 billion. Isn't that cheap insurance for the possible outbreak they could have for this country's livestock?

Dr. HILL. It would be cheap insurance if you assume that we were going to have an outbreak from a mainland facility, but I think we can build a mainland facility that is just as secure or possibly even more secure than Plum Island.

Mr. STUPAK. I don't disagree. I mean, Plum Island is in bad disrepair. I agree with you. Anything you build is going to be better than Plum Island. The issue is where should it be, the safety and the risk assessment and the environmental impact statement, cost-benefit analysis, and if you build a new one on the mainland, you still have to clean up Plum Island, take down the buildings, environmental assessment. I think those costs would be greater than anything we can imagine. No one has given us an estimate on that yet.

Dr. HILL. And we need that estimate.

Mr. STUPAK. Sure. OK.

Dr. HILL. The other point which I make in my testimony is that we need first-class researchers and it is very, very difficult to attract people to that area.

Mr. STUPAK. But you also said in your testimony too, and I wrote it down. You said to recreate island effect with low animal population nearby, right?

Dr. HILL. Exactly. We wouldn't want to put it in Kansas right next to a big feedlot, for example. There are places in the States that are up for the possible location that would be isolated from large populations of livestock.

Mr. STUPAK. Thank you.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. My staff did just a little work on historical outbreaks in the United States: in 1924 in Texas, sailors from ships carrying live animals; 1924 in California due to ships' garbage; the last outbreak in 1929 due to Argentine meat scraps from cruise ships that docked in California. Because we want safety. We all have different views now as to how we are going to be safe. Obviously there is opinion on both sides. I think my opening statement says I am not weighing in on one side or the other but I am trying to get an understanding of the whole debate. I think what we haven't talked about is, I think we get the idea that Plum Island has been successful, it has been isolated. The question is, can you use something on the continental United States, not an island, that would be as safe? People are saying yes. Some people are saying no. Let us talk about the timeliness debate. Now, I would have asked the one who did the—Dr. Carpenter about the exponential aspects of the disease and once it gets to a herd, how quickly it spread and how quickly it grows. The question would be transportation of the virus, isolating it and location, is it quicker for that—is there a quicker response because of a new facility within the continental United States. I guess that the island would be considered CONUS, but I am an old military guy so I use those terms.

But can you address that, the timeliness of a Plum Island versus a facility in Kansas or a facility in Texas? Mr. Wulf, I will just go right down the line.

Mr. WULF. We look at it from technological advances that we have in communications today.

Mr. SHIMKUS. But I am talking about testing and getting the—and just getting it to the location. I said before, I know we are going to take a sample and we are going to send it to a location. Even with corporate jets or the Lear jet, it is still going to—in cattle country, it is going to still take some time, is it not?

Mr. WULF. I agree with you, and I agree with your comment. However, we are approaching it from the standpoint of, it is not a question that there is never going to be a leak from any of these facilities. We are approaching it as a matter of when and then assessing that probability——

Mr. SHIMKUS. Let me segue into that, but that is that whole debate of whether there is going to be a release from a facility wherever it is versus an intentional activity by—or a mistake like garbage on a cruise ship or something to that effect or nefarious activity by enemies of our country to insert this, so why don't we go to Dr. Hill, just the same, your response to that——

Dr. HILL. I worked in a diagnostic lab for 20 years. I am a virologist by training. We sent samples to Plum Island. We never had

to send a priority one when I was there but when you have a priority one sample you have clinical signs that could be foot-and-mouth or it could be some other disease. Those are either couriered by an individual, USDA, state individual, state health regulatory individual, or they are flown with a National Guard jet or whatever and taken to Islip Airport and transported out to the island. I don't know that the timing is a big difference. If we did have a facility in the central part of the United States. The timing would be obviously less than if it was in California and the sample had to get all the way to the tip of Long Island. Is that answering your question?

Mr. SHIMKUS. Yes. Timeliness in a vector or a disease that is exponential in growth, I am assuming based upon the analysis of the first panel, that is a lot.

Dr. HILL. Well, that all depends on what is the index case. Let us just take an example of air carrying the virus from Plum Island to a sale facility in New York, and if those animals got dispersed to 50 different farms the explosion is huge.

Mr. SHIMKUS. Yes, I am more concerned—I think we have established that a release from a facility may happen, but I am more concerned about intentional by enemies of the state going to beef production areas, and Illinois is part of that, and going to a feedlot or going to a large sector and then how do you control that as fast as possible? It would probably speak to not a Plum Island site.

Dr. HILL. The key to that, which you have made the point very well, I think, is the timeliness of the diagnosis because there are a lot of things that kick in once that diagnosis is made. We stop movement of the animals immediately, all that kicks in.

Mr. SHIMKUS. Who makes that call and how does that happen?

Dr. HILL. That is a good question, and is probably something that we need to work on in the animal health communities. But the State veterinarian has the jurisdiction first. He can stop all movements. If it becomes a foreign animal disease, the Federal Government, USDA, and Homeland Security get involved immediately. So there is a little bit of difference there of whether it is diagnosed or if it is a suspect.

Mr. SHIMKUS. Mr. Watson?

Mr. WATSON. Sure, and I think if I understand your question correctly, time is of the essence in sort of being able to control the vector process. As testimony we have heard this morning indicates, is that once the disease sort of presents and manifests itself, the possibilities of what it is fall fairly quickly, particularly for veterinary professionals who have a pretty good idea of recognizing what this is. Eventually there will be important necessity to do analysis on tissue and things like that. One of the things that we have learned in more discussion of FMD, one of the reasons it is so dangerous is because it mutates so fast. It is like the common cold. The reason we always have the common cold is because it is always changing. Flus are always changing. FMD is always changing and there are a number of strains, not just one strain but a number of strains, which is under confinement right now at Plum Island. And so eventually we would be looking at trying to figure out what strain we were dealing with, determining vaccination protocols and things like that, whether or not those vaccinations were available would

be necessary. But in almost any transportation of a biohazardous material like this, you are going to have to have a series of protocols built in. That means you are not just going to sort of throw it in the back of a car and drive it out to wherever you are going to be. So you have a time of the essence issue also related to protocols in making sure that you don't inadvertently spread the pathogen in your attempt to try and get it to the research facility, and that is going to be——

Mr. SHIMKUS. Yes, and then you——

Mr. WATSON [continuing]. Whether or not you go to the mainland or an island facility.

Mr. SHIMKUS. Just because of time constraints, let me go to Mr. Voogt real quick.

Mr. VOOGT. I think the answer is that if you are going to have a heart attack, you want to have it close to the hospital, and I think people in the cattle, in hog country are more sensitive than somebody offshore in New York to be ready and prepared for a lockdown. This analysis takes a while, but if there is lockdown, the people that have the most to risk are going to be most attendant to that.

Mr. SHIMKUS. And the disease itself, since I am not familiar, I am not a veterinarian, do you have it when—we saw the slides of the hooves that were scarred and broken open. We saw the tongue. We saw the lesions. How long does it take for an animal to get the virus and then for an outward sign?

Dr. HILL. I have never dealt directly with foot-and-mouth. They are excreting virus during the incubation period before they show clinical signs and then it is probably 3 or 4 days, or 5 days before they show the blisters.

Mr. SHIMKUS. And I see a lot of heads shaking so there is a lot of people that know that, and again, that ties into the timing factor.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Shimkus.

Mr. Watson, I want to get this point. In your testimony on page 2, you refer to a 2004 research paper by USDA that estimated foot-and-mouth outbreak on the mainland United States would cost the livestock industry as much as $60 billion.

Mr. WATSON. Yes, sir.

Mr. STUPAK. And that would just be the direct costs; that is not the indirect costs, right?

Mr. WATSON. Yes, sir.

Mr. STUPAK. OK. When we asked USDA for studies like that, they said they didn't have any. Do you have that study?

Mr. WATSON. I can see if we can find it. That actually was a reference material in the National Institute of Justice's policy program. They had reference directly to that. They had referenced their estimate to the USDA study in 2004. But I can——

Mr. STUPAK. So you took it from a Department of Justice report?

Mr. WATSON. Right. The Department of Justice is laying out their criteria, and it is somewhat interesting that again we are trying to point out that those who think they understand what the Federal Government or what the government response is going to be, this particular Department of Justice report, which is designed

to advise local and state law enforcement. They are basically telling local and state law enforcement as of 2006, if you see this, treat it as a crime, treat it as a terrorist attack, do not treat this as an incidental event or something like that. And that is one of the reasons they are trying to provide this education to local law enforcement, saying if we see it, we need to move as if this is a crime. So they go back and say important this is and the——

Mr. STUPAK. Well, I was just curious about——

Mr. WATSON [continuing]. Citation in that report was to this USDA——

Mr. STUPAK. Right. I was curious about the validity of the USDA report because they claim there isn't such a report.

Mr. WATSON. Well, we will go back and I will see if I can——

Mr. STUPAK. Let me ask you this. You all talked about costs; Mr. Voogt, I think you said that the costs and all this is inadequate and Congress has to pay for it and adequately fund it year after year in the future. Should your industries pay part of it since you seem to benefit from that? Should the cattlemen, should the pork and the Grange and all that, should——

Mr. VOOGT. Well, our industry is the consumer. That is who we are working for and so the consumer is either going to pay for it in the price of the meat or in support of the government, but it is not free. So that is not important. As to cost, I do have some experience. I built approximately $5 million worth of stuff on Beaver Island with Federal funds, airports, and the cost was approximately 40 percent more than it was on the mainland.

Mr. STUPAK. Mr. Watson, any comments on costs to your organization to pay part of it?

Mr. WATSON. We don't have any estimates on that, sir.

Mr. STUPAK. We have a couple votes on the Floor. We are going to have to recess again. We will recess until quarter to. We will dismiss this panel. Thank you for coming. Sorry to interrupt this hearing again with votes. It is one of these days and a lot of crazy stuff is going on on the Floor. So we will stand in recess for approximately 30 minutes.

[Recess]

Mr. STUPAK. We have our third panel of witnesses. On this panel, we have the Hon. Bruce Knight, Under Secretary for Marketing and Regulatory Programs at U.S. Department of Agriculture; the Hon. Jay Cohen, Under Secretary for the Science and Technology Directorate of the U.S. Department of Homeland Security, and Dr. Larry Barrett, Director of Plum Island Animal Disease Center.

Gentlemen, thank you for being here. We will start with opening statements. Mr. Knight, if you would like to go first, 5-minute opening—oh, I have to swear you guys in. It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the Rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? All are indicating no. All right. Then I am going to ask you to rise and raise your right hand, please.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. Mr. Knight, if you would

like to start with your opening statement, please, 5 minutes. Your full statement will be part of the record.

STATEMENT OF BRUCE I. KNIGHT, UNDER SECRETARY, MARKETING AND REGULATORY PROGRAMS, U.S. DEPARTMENT OF AGRICULTURE

Mr. KNIGHT. Good afternoon, Chairman Stupak, members of the committee, my name is Bruce Knight. I am Under Secretary for marketing and regulatory programs at USDA and I want to thank you for the opportunity to share USDA's views on the importance of establishing the National Bio- and Agro-Defense Facility, NBAF.

Agriculture, as we have heard repeatedly today, is vital to the U.S. economy. We expect record exports of $101 billion this year along with increase in imports that have already risen from $58 million in 2005 to an estimated $76.5 billion this year. As goods move back and forth across the border, we must remain vigilant to safeguard U.S. agriculture from unwelcome pest and disease threats which do not respect State or national borders. Intentionally or unintentionally contaminated products could quickly spread a pest, disease or other agent that could not only devastate our agriculture industry but also cause numerous animal casualties.

While I appreciate the focus today on the laboratories, I do want to note that USDA has many activities to prevent the introduction of FMD into the United States. We share import policies that ensure that we trade safely both in products and in live animals. We have a rigorous process to evaluate disease risks with the countries we trade with. We work with our colleagues at DHS to ensure port inspections and passenger traffic is safe. Historically, we know worldwide that outbreaks of FMD have been primarily traced to meat importations, mishandling of garbage, livestock importation, and that has been the primary focus.

Now, today, we are talking mostly about the need for NBAF and how vital it is to us being able to move forward. To guard against new diseases and potential bioterrorist releases, USDA must continually conduct research and diagnostics to better understand those pathogens. We recognized, even before the Department of Homeland Security was created, that there was a need for additional space and upgraded biosecurity measures to work on foreign and emerging animal diseases.

The current research facility located on Plum Island is aging, inadequate, and outdated. Since the Plum Island facility was transferred to DHS in 2003, we have developed a strong collaborative partnership with DHS that enables both departments to achieve our similar goals while making the most of each other's specialized expertise. More than 50 years ago, the Plum Island facility was built on an island to create physical separation from susceptible livestock. Today, with more advanced technologies including redundancies and the latest biosecurity and containment systems, coupled with employee training and monitoring, NBAF could safely operate on the mainland. A mainland facility would be less expensive to operate, more easily accessible than an island location, better enable quick response to potential disease threats, and offer the

opportunity for innovative collaboration if located near an established research community.

Although DHS is ultimately responsible for the selection of an NBAF site, USDA has been closely involved throughout this process. We support the criteria used to select the sites and are committed to the next steps in the process. DHS is currently preparing an environmental impact statement for the six site alternatives including Plum Island and the mainland locations. We need to move forward in a timely manner on NBAF to develop the diagnostics and the tools needed to protect U.S. agriculture from the threats of dangerous foreign animal diseases.

Lastly, I would like to mention that the Administration included in our Farm Bill proposal a suggestion of an authorization for USDA to conduct research and diagnostics for highly infectious disease agents on the U.S. mainland. This provision is included in the recently passed Farm Bill.

Again, thank you for the opportunity to discuss this important issue with the Committee today. We believe the planned NBAF is necessary to replace the aging Plum Island facility and protect U.S. agriculture and American citizens against foreign animal diseases.

[The prepared statement of Mr. Knight follows:]

STATEMENT OF BRUCE KNIGHT

SYNOPSIS

• Agriculture is vital to the U.S. economy. We expect record exports of $101 billion this year along with increasing imports that have already risen from $58 billion in 2005 to an estimated $76.5 billion this year.

• As goods move back and forth across the border, we must remain vigilant to safeguard U.S. agriculture from unwelcome pest and disease threats. Intentionally or unintentionally contaminated products could quickly spread a pest, disease, or other agent that could not only devastate our agricultural industry but also cause numerous casualties.

• To guard against new diseases and potential bioterrorist releases, the U.S. Department of Agriculture (USDA) must continually conduct research and diagnostics to better understand these pathogens. We recognized, even before the Department of Homeland Security (DHS) was created, that there was a need for additional space and upgraded biosecurity measures to work on foreign and emerging animal diseases. The current research facility located on Plum Island is aging, inadequate, and outdated.

• In response to Presidential Homeland Security Directive 9, USDA is working closely with DHS to develop the National Bio- and Agro-Defense Facility (NBAF) to replace the Plum Island Animal Disease Center (PIADC), after a construction and transition period of 7–10 years. NBAF would provide the facility we need to carry out BSL-4 activities not currently possible at PIADC, such as addressing diseases like Nipah and Hendra, as well as Rift Valley Fever (which requires vaccinated personnel; however vaccine is in short supply).

• Since the Plum Island facility was transferred to DHS in 2003, we've developed a strong, collaborative partnership with DHS that enables both Departments to achieve our similar goals while making the most of each other's specialized expertise.

• More than 50 years ago, the Plum Island facility was built on an island to create physical separation from susceptible livestock. Today, with more advanced technologies, including redundancies and the latest biosecurity and containment systems, coupled with employee training and monitoring, NBAF could safely operate on the mainland.

• A mainland site would be less expensive to operate, more easily accessible than an island location, better enable quick response to potential disease threats, and offer the opportunity for innovative collaboration if located near an established research community.

• A 2002 study completed by the Science Applications International Corporation and commissioned by USDA concluded that there was a valid USDA need for a BSL-4 facility, and that a BSL-4 facility for large animal work could be safely located on the mainland.

• Although DHS is ultimately responsible for the selection of a NBAF site, USDA has been closely involved throughout this process. We support the criteria used to select the sites and look forward to the next steps in the process.

• DHS is currently preparing an environmental impact statement (EIS) for the six site alternatives, including Plum Island and mainland locations. We need to move forward in a timely manner with NBAF to develop the diagnostics and tools needed to protect U.S. agriculture from the threats of dangerous foreign animal diseases.

• The Administration included in our Farm Bill Proposal an authorization for USDA to conduct research and diagnostics for highly infectious disease agents on the U.S. mainland. We recognize DHS' interest in the Secretary being directed, via statute, to issue a permit for live foot-and-mouth disease virus at the NBAF. We believe this direction will provide clarity as DHS moves forward in selecting a site and constructing the NBAF.

TESTIMONY

Good afternoon. I am Bruce Knight, Under Secretary for Marketing and Regulatory Programs at the U.S. Department of Agriculture (USDA). Thank you for the opportunity to appear before the Committee today to present the Department's views on the establishment of the National Bio- and Agro-Defense Facility (NBAF). Today, the Committee raises a timely and important issue—agriculture security—that we at USDA consider essential to our mission, which is to provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management.

Agriculture is a vital component of our Nation's economy. Of particular importance to homeland security is the significant increase in agricultural trade. This year, we expect agriculture exports to reach approximately $101 billion, making it the highest export sales year ever in our history—and significant to our balance of trade. Agriculture imports are rising as well—increasing from nearly $58 billion in 2005 to an estimated $76.5 billion this year.

We face many challenges in protecting this important infrastructure. As goods move back and forth across the border, we must remain vigilant to safeguard U.S. agriculture from unwelcome pest and disease threats. Our sector is particularly concerned about security because food production is not constrained by political boundaries, and as we all know, diseases and pathogens do not respect state or national borders. The interconnected nature of the global food system is our strength and allows us to feed the world, but it is also a disadvantage in the event of attack or natural disease outbreak. Additionally, one of the agricultural sector's greatest contributions to the quality of life is the fact that products flow quickly through interstate commerce—one of our greatest assets is also one of our greatest concerns because intentionally or unintentionally contaminated products could quickly spread a pest, disease, or other agent.

USDA works diligently to protect U.S. agriculture from the potential introduction of human and animal disease agents, whether unintentionally or through agroterrorism. Many of these pathogens such as the Nipah and Hendra viruses are zoonotic, that is, they cause both human and animal disease, and can pass from animals to humans. If a significant zoonotic or animal disease were to penetrate our borders, it could devastate the agricultural industry, cause numerous casualties, and harm the economy.

We've seen just how disastrous the effects of a foreign animal disease outbreak can be in the 2001 foot-and-mouth disease (FMD) outbreak in the United Kingdom. In that case, over 6 million pigs, sheep, and cattle were destroyed, with the epidemic costing the U.K. economy an estimated $13 billion. This example highlights the need for the best tools and diagnostics to safeguard the U.S. livestock industry from significant foreign animal disease threats such as FMD. At the same time, the 2007 suspected release of live FMD virus from the Pirbright campus in England amplifies the balance needed in undertaking such work. This is why USDA and the Department of Homeland Security (DHS) will use the most modern biosafety practices and procedures, and stringent and rigorous safety measures within NBAF.

Because of the continued emergence of new animal diseases, the leaping of dangerous animal diseases across species, and the possibility of a bioterrorist release, it is even more essential that USDA have a sufficient understanding of these diseases and be well prepared to protect the U.S. livestock industry from their damage. To achieve this, USDA works through its Agricultural Research Service (ARS) and

Animal and Plant Health Inspection Service (APHIS) to meet its responsibilities in animal health. ARS is the primary intramural science research agency of USDA, operating a network of over 100 research laboratories across the nation that work on all aspects of agricultural science. APHIS is responsible for safeguarding U.S. agricultural health from foreign pests and diseases of plants and animals.

In order to be able to rapidly identify, respond to, and control outbreaks of foreign animal and zoonotic disease, USDA needs secure, state-of-the-art biocontainment laboratories with adequate space for advanced research, diagnostics, and training. Recognizing this need, the President directed USDA and DHS, via Homeland Security Presidential Directive 9: "Defense of the United States Agriculture and Food," to develop a plan to provide for such facilities. As I will explain further, USDA is working closely with our partners in DHS to fulfill this important need.

PLUM ISLAND ANIMAL DISEASE CENTER

In 1954, USDA began work at the Plum Island Animal Disease Center (PIADC) in research and diagnostics on foreign animal diseases that, either by accidental or deliberate introduction to the United States, pose significant health and/or economic risks to the U.S. livestock industry. The Plum Island Animal Disease Center has served U.S. agriculture well. It's no accident that this country has the healthiest and most abundant livestock populations in the world. Producers and all of us at USDA work hard every day to keep this up.

An integral part of maintaining animal health is preventing the entry of exotic pest and disease threats. The Plum Island Animal Disease Center, through its diagnostic, research, and reagent production and distribution activities, has stood as American agriculture's bulwark against potentially devastating foreign animal diseases. Each working day since the facility opened over 50 years ago, the dedicated and highly skilled Plum Island Animal Disease Center staff has equipped veterinarians, scientists, professors, and other animal health professionals here and around the world with the tools they need to fight exotic disease incursions that threaten livestock. In addition to FMD and classical swine fever, other livestock diseases that our scientists have studied at the Plum Island Animal Disease Center include African swine fever, rinderpest, Rift Valley fever, West Nile fever, vesicular stomatitis, and Capri pox (sheep pox and lumpy skin disease).

As you know, in June 2003, operational responsibility for the Plum Island Animal Disease Center transferred from USDA to DHS under the Homeland Security Act of 2002. Since the transfer, we've developed a strong, collaborative partnership with DHS and put in place an interagency agreement to clarify roles and responsibilities. A Board of Directors and Senior Leadership Group were created to facilitate decision-making regarding facility operations and policies, while also allowing the three agencies to focus on accomplishing their specific missions and goals. I believe our relationship with DHS is a very positive one that allows both Departments to achieve our similar goals while making the most of each other's specialized expertise.

After the Plum Island Animal Disease Center transfer, USDA remained responsible for conducting basic and applied research and diagnostic activities at the Plum Island Animal Disease Center to protect U.S. agriculture from foreign animal disease agents. DHS, in turn, assumed responsibility for coordinating the overall national effort to protect key U.S. resources and infrastructure, including agriculture. Science programs at the Plum Island Animal Disease Center now include the APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL), ARS' Foreign Animal Disease Research Unit, and DHS' Targeted Advanced Development Unit.

APHIS' work at the FADDL aims to protect the U.S. agricultural system by providing the capabilities for early detection and diagnosis of foreign animal diseases. The FADDL is also the custodian of the North American FMD Vaccine Bank (owned by Canada, Mexico and the United States), which stores concentrated FMD antigen that can be formulated into a vaccine if a FMD introduction occurs. As such, FADDL employees are responsible for performing safety testing of new antigen lots and periodically testing the quality of stored antigen.

APHIS scientists perform diagnostic testing of samples collected from U.S. livestock that are showing clinical signs consistent with an exotic disease, as well as testing animal products and live animals being imported into the United States to ensure that unwanted diseases are not accidentally introduced through importation. APHIS scientists at the Plum Island Animal Disease Center have the capability to diagnose more than 30 exotic animal diseases, and perform thousands of diagnostic tests each year. They also prepare diagnostic reagents and distribute them to laboratories throughout the world, and test the safety and efficacy of vaccines for selected foreign animal diseases. Other APHIS activities include improving techniques

for the diagnosis or control of foreign animal diseases and validating tests for foreign animal diseases that are deployed to the National Animal Health Laboratory Network (NAHLN). Through the use of these tests in surveillance, the NAHLN provides for early detection and the surge capability needed in the case of an outbreak.

In addition, FADDL staff, in conjunction with APHIS' Professional Development Staff, train veterinarians, scientists, professors, and veterinary students on recognition of clinical signs and pathological changes caused by foreign animal diseases. This training provides the backbone of APHIS' animal disease surveillance and safeguarding programs. These foreign animal disease diagnosticians trained by FADDL are located throughout the country, and can be on-site to conduct an investigation and collect samples within 16 hours of receiving a report of a suspect foreign animal disease. Based on their assessment of the situation and prioritization of the threat, APHIS can then take appropriate steps if necessary to protect the U.S. livestock industry.

Through its involvement in the Plum Island Animal Disease Center, ARS develops new strategies to prevent and control foreign or emerging animal disease epidemics through a better understanding of the nature of infectious organisms, pathogenesis in susceptible animals, host immune responses, and the development of novel vaccines and diagnostic tests. The ARS Foreign Animal Disease Research Unit focuses on developing vaccines that can be produced safely in the United States and used safely on U.S. farms, diagnostic techniques to differentiate between a vaccinated and an infected animal, and methods for identifying carrier animals. Currently, ARS' work at the Plum Island Animal Disease Center includes active research programs working with FMD, Classical Swine Fever, and vesicular stomatitis viruses.

ARS scientists have recently carried out extensive work on FMD, including early development of a FMD vaccine that is safe to produce on the mainland; discovery of an antiviral treatment that prevents FMD replication and spread within 24 hours; and determination of many key aspects of FMD virus structure, function, and replication at the molecular level, leading to highly specific diagnostic tests.

MEETING THE NEEDS OF AMERICAN AGRICULTURE

The Plum Island Animal Disease Center has played a critical role in developing the tools and expertise needed to protect the country from the deliberate or unintentional introduction of significant foreign animal diseases. However, much has changed since the Plum Island Animal Disease Center was first built, and we are even more cognizant of the threat from foreign animal diseases due to the increasingly interconnected world we live in. This need is echoed by our American livestock industries that could be devastated by the introduction of a significant foreign animal disease. Groups such as the United States Animal Health Association and National Institute for Animal Agriculture have appealed for accelerated research to protect their industries. Also, the National Cattlemen's Beef Association, Animal Agriculture Coalition, and National Milk Producers Federation have written to Congress, to show their support for NBAF.

To continue providing U.S. agriculture with the latest research and technological services, as well as world-class approaches to agricultural health safeguarding and foreign-animal disease diagnostics, USDA needs additional space and upgraded biosecurity measures to work on those animal-borne diseases that pose the greatest risk to U.S. livestock industries, and those that can also be transmitted to humans. The Plum Island Animal Disease Center is aging and nearing the end of its lifecycle, and the state of current facilities has created a backlog of needed space for important experiments, diagnostic development, and training efforts.

In particular, USDA is in need of enhanced research and diagnostic capabilities for animal diseases, particularly zoonotic diseases of large animals that require agriculture BSL-3 and BSL-4 capabilities. However, since we cannot currently carry out BSL-4 activities at the Plum Island Animal Disease Center, the Nation is left lacking a large animal facility to address high-consequence animal diseases that can be transmitted to humans, such as Nipah and Hendra, as well as Rift Valley Fever (which requires vaccinated personnel; however vaccine is in short supply).

Specifically, USDA would utilize the BSL-4 space to develop diagnostic assays for Rift Valley Fever and Nipah and Hendra viruses, using specimens collected from animals in the BSL-4 lab. In addition, in the event of an emerging pathogen, it would often be necessary to inoculate animals in a BSL-4 suite in order to determine the clinical course of the disease, determine appropriate diagnostic specimens, isolate the agent, and develop diagnostic tools.

In order to protect U.S. agriculture and human health, it is critical that USDA have the capability of diagnosing and working with the disease agents I have men-

tioned, as well as any new highly infectious pathogen that may emerge. In response, our agencies have begun planning for the next generation facility which we call the NBAF, to replace the current structures at the Plum Island Animal Disease Center. NBAF will integrate research, development, and testing in foreign animal diseases and zoonotic diseases, which will support the complimentary missions of USDA and DHS. NBAF will address USDA needs that are currently not being met by the facilities at the Plum Island Animal Disease Center, including inadequate lab space for processing diagnostic samples, limitations in diagnostic capability for BSL-4 agents, and lack of space to expand to include the development, feasibility testing, and validation of new and emerging technologies for detection of exotic and emerging diseases. In addition, it will provide room to grow as we further enhance our abilities to respond to increasing threats to the U.S. livestock industry.

The NBAF will also have a synergistic effect, to the benefit of each of our agencies, by utilizing the expertise of the academic and scientific community in the area. In addition, we expect that by sharing a well-equipped core facility, we will see a more cost effective utilization of funding. This will also continue to provide a number of opportunities for enhanced interaction among the three agencies. For example, research done by ARS and DHS may identify possible new diagnostic tools that APHIS can use; APHIS' repository of foreign animal disease agents obtained from outbreaks around the world will provide a resource for ARS and DHS research and bioforensics; and APHIS' diagnostic investigations and surveillance will help identify emerging or re-emerging diseases in the field, in turn helping set research priorities for ARS and DHS.

SITE SELECTION

At the time Plum Island was built, biosecurity was much different than it is today. Agriculture biosecurity was defined by biological isolation, so that if there was a problem at the laboratory, there was physical separation from susceptible livestock populations and any breaches were localized. Today, with much more advanced technologies, the ability to manage effective biosecurity and biosafety practices is not dictated by location or physical barriers.

We recognize that there is concern about building the NBAF on the mainland. Since the determination was made over 60 years ago to build the Plum Island Animal Disease Center on an island, assessments have shown that technological advances would allow for safe research and diagnostics of foreign animal diseases to take place on the U.S. mainland. A 2002 study completed by the Science Applications International Corporation (SAIC) and commissioned by USDA found that the FMD virus and other exotic foreign animal diseases of concern to the Department could be fully and safely contained within a BSL-3 laboratory, as was being done in other countries at the time including Canada, Germany, and Brazil. A second SAIC study also concluded that there was a valid USDA need for a BSL-4 facility, and that a BSL-4 facility for large animal work could be safely located on the mainland.

In planning for the NBAF, we recognize the absolutely essential need for state-of-the-art biosafety practices and procedures, including stringent and rigorous safety measures within the laboratories themselves, to prevent disease organisms from escaping into the environment. Situations such as the recent suspected release of live FMD virus from the Pirbright campus in England only serve to highlight this importance. We can use that example as a learning opportunity and make sure that the design and maintenance of the NBAF facility enables us to carry out the essential activities needed to protect the Nation from foreign animal diseases while ensuring the highest level of biosafety.

This is why the NBAF will utilize the redundancies built into modern research laboratory designs and the latest biosecurity and containment systems, coupled with continued training and monitoring of employees, to effectively minimize any risks. Personnel controls for the NBAF will include background checks, biometric testing for lab entry, and no solitary access to BSL-4 microorganisms. The NBAF will also feature biological safety cabinets in the wet labs designed to meet the needs of BSL-3 labs, while in BSL-4 labs, these biological safety cabinets will include additional security measures or be used in combination with full-body, air-supplied personal protective suits.

In terms of facility design, the BSL-4 lab at the NBAF will employ a box-in-box principle with a pressure-controlled buffer. All water and air leaving the lab will be purified-that is, no research microorganism will enter the sewage system or outside air. All critical functions will have redundant systems. The design of the BSL-4 laboratories and animal space will comply with the appropriate recommendations and

requirements of the Centers for Disease Control and Prevention, National Institutes of Health, Department of Defense, and National Research Council.

I would also like to note some potential advantages to locating the NBAF on the mainland. For example, the lower cost of living, as compared to that in the communities surrounding the Plum Island Animal Disease Center, would likely make recruiting personnel easier for our agencies. This would also eliminate the costs of moving people on and off an island every day, as we currently do. A mainland facility would be more accessible if air traffic is shut down due to weather conditions or an emergency situation, and would not be subject to the occasional wind closures that we experience at the Plum Island Animal Disease Center due to rough waters. And, as I mentioned earlier, locating the facility near an established research community would facilitate innovative collaboration.

A key advantage to locating NBAF on the mainland would be the ability to quickly respond to a potential foreign animal disease threat. Placing the NBAF on the mainland could eliminate the need for additional transport of samples to the island via boat or aircraft, as is currently done at Plum Island. Having a more accessible location, where diagnostic capabilities could be utilized within the first 24 hours of an emergency, is essential. For example, in June 2007, APHIS conducted an investigation into swine showing signs consistent with a significant foreign animal disease. In such a situation, every hour counts when it comes to being able to quickly rule out major diseases. Incidents such as this can have a significant impact on the economy, stop movement and trade in multiple species of livestock, and spread fear throughout the industry.

Although DHS is ultimately responsible for the selection of a NBAF site, USDA has been closely involved throughout this process. APHIS and ARS have provided detailed program requirements to DHS, and have representatives on the site selection committee and site inspection team. We support the criteria used to select the sites: proximity to research capabilities linked to the NBAF mission requirements, site proximity to a skilled workforce, as well as acquisition/construction/operations, and community acceptance, and look forward to the next steps in the process.

DHS is currently preparing an environmental impact statement (EIS) looking at the six sites, which include Plum Island and five mainland locations. The EIS, on which USDA and DHS are working, will consider the risk and potential consequences of an accidental release of a foreign animal disease, and will be integral to moving forward with a sound NBAF site selection.

It is important that we move forward in a timely manner with planning and construction of NBAF so that we can develop the diagnostics and tools needed to protect U.S. agriculture from the threats of dangerous foreign animal diseases. Just as the science behind bioterrorism has advanced in recent years, and new and changing diseases continue to emerge, so too must we arm ourselves with more sophisticated ways of preventing harm to the U.S. livestock industry. If we don't, then bioterrorists will continue to find innovative ways to attack our livestock, new diseases will continue to emerge, and U.S. agriculture will be left vulnerable to these dangers. This is why USDA is committed to working with DHS to move forward with plans for NBAF, after a thorough analysis of the options and development of plans to ensure the utmost biosafety and biosecurity.

AUTHORITY TO CONDUCT FMD RESEARCH ON THE MAINLAND

Lastly, I would like to briefly mention recent legislative activity related to live FMD virus. Current statute (21 U.S.C. 113a) restricts research involving live FMD virus and other animal diseases that present a significant risk to domestic U.S. livestock to laboratories on coastal islands separated from the mainland United States by deep water. Research involving live FMD virus is carried out at the Plum Island Animal Disease Center under this statute, which dates back to the 1950s. The statute was amended by the 1990 Farm Bill to authorize the Secretary of Agriculture, when necessary, to allow the movement of live FMD virus, under permit, to research facilities on the U.S. mainland.

USDA recognizes DHS' interest in the Secretary being directed, via statute, to issue a permit for live FMD virus at the NBAF. This direction will provide clarity in this important area as DHS moves forward in selecting a site for the NBAF and then in contracting for the construction of the facility. For these reasons, the Administration included in our Farm Bill Proposal an authorization for USDA to conduct research and diagnostics for highly infectious disease agents, such as FMD and rinderpest, on the U.S. mainland. Consistent with the Administration's proposal, section 7524 of the Food, Conservation, and Energy Act of 2008 directs the Secretary to issue a permit for live FMD virus at NBAF, while preserving the Secretary's dis-

cretion and ensuring that all biosafety and select agent requirements are being met at the facility.

CONCLUSION

Thank you again for the opportunity to discuss this important issue with the Committee today. We believe the planned NBAF is necessary to replace the aging Plum Island Animal Disease Center and provide additional capacity for much needed animal disease research, diagnostics, training, and countermeasures development. The NBAF will play a crucial role in protecting against the future introduction of foreign animal and zoonotic diseases, and ensuring the continued health and vitality of our agricultural industries. We are committed to continuing our work in partnership with DHS in planning the NBAF and making the facility a reality.

Mr. STUPAK. Thank you.

Mr. Cohen, your opening statement, please.

STATEMENT OF JAY M. COHEN, UNDER SECRETARY, SCIENCE AND TECHNOLOGY DIRECTORATE, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. COHEN. Chairman Stupak and members of the committee and staff, I have had the privilege of being here from the start of the hearing and so Chairman, I wanted to thank you for your stated support for the NBAF facility. It is an honor to appear before this committee, and I thank the committee for bringing these very important issues before the American public.

I especially appreciate the testimony of the first two panels and I can assure you, we will incorporate, as we have been, their concerns as we move forward with this important NBAF initiative, the purpose of which is to make the Nation safer.

I am very pleased today to be joined not only by Under Secretary Knight representing the U.S. Department of Agriculture, who has already addressed the partnership that we enjoy, the productive partnership, but also Dr. Larry Barrett, who is the director of Plum Island. I look forward very much to your questions.

I would like to just add, if I may, there have been discussions relative to the age and the condition of Plum Island. I had the privilege of going up there and having an all-hands with the good people, the scientists, the animal workers, et cetera, on Plum Island. The Department of Homeland Security has put tens of millions of dollars into that facility. When we are done, it will be over $50 million, and in a recent morale survey conducted within the Department of Homeland Security, I am here to tell you that of all my laboratories, the Plum Island laboratory facing possible closure had the highest morale, and in two areas, including job satisfaction, all of the workers ranked Plum Island 100 percent. So the legacy of Plum Island will be, and we hope it will be, an efficacious vaccine to prevent foot-and-mouth disease, which is what we are talking about today.

I am so pleased that Chairman Dingell is here, and Chairman, I just wanted to say, as a member of the greatest generation, and my mother-in-law was a World War II Navy nurse, she was just up here for the 100th anniversary of the Navy Nurses Corps, and Senator Inouye and Senator Cleland had a chance to speak. I thank you so much for your service. It is a special privilege to be here in front of your subcommittee, and we thank you also for the NEPA legislation, which is the overriding legislation by which we

are conducting the environmental impact as we go forward, and has been indicated by the panels, this is a work in progress, and so this is an important hearing.

For Chairman Dingell, I know you know that words matter and for 42 years I had the privilege of serving in the United States Navy and then was asked to serve in Homeland Security, and public service, like you, is a great calling. We don't get rich in this business but words do matter, and the words "incompetent," "arrogant," and "secretive" were used. In the Department of Homeland Security, if I were to allow those to go unanswered, the 180,000-plus government service workers who are dedicated to making the Nation safer would believe that I either hadn't heard those or I agreed with them. And so sir, if at a convenient time you would just share with me who you think is incompetent, arrogant or secretive, I will certainly root them out because that is unacceptable in public service.

So Chairman, thank you so much and I look forward to your questions.

Mr. DINGELL. Happy to do so.

Mr. COHEN. Yes, sir, I know you will.

Mr. DINGELL. I think I will enjoy that discussion more than you will.

Mr. COHEN. Yes, sir. Thank you, Chairman.

[The prepared statement of Mr. Cohen follows:]

STATEMENT FOR THE RECORD

of

The Honorable Jay M. Cohen
Under Secretary
Science & Technology Directorate
Department of Homeland Security

National Bio- and Agro-Defense Facility (NBAF) Decision Process

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations

May 22, 2008

INTRODUCTION AND BACKGROUND

Good morning Chairman Stupak and Ranking Member Whitfield. I am pleased to appear before you today to discuss the Department of Homeland Security's (DHS) and Department of Agriculture's (USDA) proposed National Bio- and Agro-Defense Facility (NBAF). As you are aware, our Nation's animal health, agriculture, food supply, and economy are potentially threatened by numerous infectious disease agents, which are present throughout the world. Approximately 70-80 percent of emerging pathogens are zoonotic agents. These are disease agents capable of passing between animals and people.

DHS's Science & Technology Directorate focuses on the development of efficacious vaccines, therapeutics, and diagnostics to counter and mitigate these catastrophic agents. This effort requires a state-of-the-art agriculture bio-containment facility that allows safe, secure conduct of mission-directed scientific research, development, test, and evaluation (RDT&E) activities. This effort requires a secure, state-of-the-art agriculture bio-containment facility that allows scientists to perform their work in an environment where they can be isolated from the disease agents and where these agents can be isolated from the public and animal populations. Currently, the Nation's capacity is limited to only a few Biosafety Level -3 AG (BSL-3Ag) facilities, and there is no Biosafety Level 4 (BSL-4) research capacity to study threat agents that infect both large animals and humans, using large animal models. If the United States is to have adequate capability to rapidly identify and control outbreaks of high-threat foreign animal and zoonotic disease agents, whether natural or intentional, we must begin investing in sufficient bio-containment capacity and capability.

This investment is critical to DHS and USDA's Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS). ARS is the primary intramural science research agency of USDA, operating a network of over 100 research laboratories across the nation that work on all aspects of agricultural science. APHIS is responsible for safeguarding U.S. agricultural health from foreign pests and diseases of plants and animals.

To continue providing U.S. agriculture with the latest research and technological services, as well as world-class approaches to agricultural health safeguarding and foreign-animal disease diagnostics, ARS and APHIS need additional space and upgraded biosecurity measures to continue work

on those diseases that pose the greatest risk to U.S. livestock industries, and those that can also be transmitted to humans (zoonotic diseases). The state of the current facility has created a backlog of needed space for important experiments, diagnostics, and training efforts.

As an example of the potential consequences of a significant disease outbreak, recall the catastrophic losses from the 2001 foot-and-mouth disease (FMD) outbreak in the U.K. The economic loss reached well into the billions of dollars, directly affecting agricultural industries, and the outbreak had an even wider impact on tourism and other commerce. If the U.S. were faced with an equivalent outbreak, the impact could be far greater since the U.S. production is 14 (or more) times larger than that of the U.K. The U.S. uses concentrated animal feeding operations (CAFO) for many of its operational types of rearing, such as cattle and swine. This concentrates our vulnerability into even higher numbers.

In an effort to clarify and understand our R&D capacity and capability requirements, the White House's Office of Science and Technology Policy (OSTP) convened in 2003 a Blue Ribbon Panel on the Threat of Biological Terrorism Directed against Livestock, comprised of nationally and internationally recognized science leaders from multiple government, academic, and industrial institutions. The OSTP Blue Ribbon Panel report states that

> "... new investment in infrastructure will be required to conduct these types of research and develop new technologies. In particular, lack of infrastructure places severe constraints on our ability to perform research, and develop technologies, involving pathogens classified as BSL-3 or above. Furthermore, the United States has no BSL-4 capable facility for studies in large livestock species."

Emerging diseases represent a threat to our Nation's livestock and agricultural economy. Additionally, emerging diseases that are potentially zoonotic in nature reflect an even greater threat. An example of such emergent diseases are the Nipah and Hendra viruses. When the Nipah and Hendra viruses emerged in the 1990s, little was known about the mode of virus transmission, the duration of the virus' incubation period, or why certain hosts (both animal and human) died whereas others did not. Both the

Nipah and Hendra viruses, as well as unknown but emerging diseases, are reasons a BSL-4 large animal capable facility is needed.

To illustrate how a foreign pathogen can quickly become established here, and have significant effects, consider West Nile Virus, a mosquito-borne disease that had never been in the United States until 1999. Since then, there have been thousands of human cases of the disease, and hundreds of fatalities. In 2003 alone, CDC reported 9862 human cases of the disease, with 264 fatalities.

West Nile Virus is mild in comparison to Rift Valley Fever (RFV), which is also a mosquito-borne disease. In a 2007 report, Rift Valley Fever was identified as a "Top Priority Disease" by the National Science and Technology Council's (NSTC) Foreign Animal Disease Threats (FADT) Subcommittee. In animal hosts, Rift Valley Fever causes abortion, loss of condition, loss of young animals, loss of production in cattle, sheep and goats, and mass deaths of these animals. (One of the most notable episodes occurred in Kenya in 1950-1951, resulting in the death of an estimated 100,000 sheep.) The most severe impact is observed in pregnant livestock infected with the disease, resulting in abortion of virtually 100% of fetuses. Rift Valley Fever also has a high fatality rate in puppies and kittens and spreads through various routes from domestic animals to humans. (The CDC has stated that approximately 1 percent of humans infected by Rift Valley Fever would die; however, a 2007 outbreak of Rift Valley Fever in Sudan caused over 600 human cases of the disease, with over 200 fatalities. The number of fatalities far exceeds the CDC estimate.)

Presently our capabilities to research and to develop countermeasures against emerging diseases, Rift Valley Fever, and other large animal-associated disease with zoonotic potential are hindered by the absence of large-animal, BSL-4 laboratory space. Researching the disease and developing diagnostic tests and countermeasures, requires that researchers be protected in BSL-4 laboratory space, which would also protect the public and the environment from exposure. If sufficient vaccines were available to protect researchers against Rift Valley Fever, they could work with this virus in BSL-3 facilities, but because the limited amount of experimental vaccine is in a critically short supply that is almost depleted and requires multiple injections, safe work with this virus must be done in BSL-4. Additionally, there are unknown and emerging diseases for which we have no vaccine protection or other countermeasure protection available to our researchers. When researchers on

the front lines receive samples that contain an unknown infectious agent, this agent must be handled in BSL 4 containment until the agent's properties are understood. We cannot ask our researchers working with uncharacterized diseases and livestock to operate without adequate protection. BSL-4 containment for livestock (large animals) is a much needed capability in this country.

On January 30, 2004, in recognition of the threat of agro terrorism, the growing need for countermeasures to protect the Nation's agriculture, and the limitations posed by the current Plum Island Animal Disease Center (PIADC), the President issued Homeland Security Presidential Directive 9: "Defense of the United States Agriculture and Food." HSPD-9 requires the Secretaries of Agriculture and Homeland Security, Health and Human Services, as well as the Administrator of the Environmental Protection Agency to

> "develop a plan to provide safe, secure and state-of-the-art agricultural bio-containment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases"

and further states that

> "The Secretaries of Homeland Security, Agriculture ... will accelerate and expand development of current and new countermeasures against intentional introduction or natural occurrence of catastrophic animal, plant and zoonotic diseases. The Secretary of Homeland Security will coordinate these activities."

The proposed NBAF would fill a critical gap in our national preparedness and response capabilities, meeting both these requirements and ensuring that the Nation's animal health, food supply, and agriculture are protected for the next 50 years.

The Need for NBAF

For more than 50 years, the PIADC and its expert staff have been the front line of the Nation's defense against foreign animal diseases. PIADC's capability is a critical national asset and essential to protecting the U.S.

agriculture economy and food supply. No other facility currently exists in this country to perform this function. PIADC's research and diagnostic activities are an outgrowth of its mission to protect U.S. animal industries and imports and exports from the deliberate or accidental introduction of foreign animal diseases. PIADC has been a leader in researching foreign animal diseases, developing diagnostics and countermeasures (such as vaccines to prevent and contain these diseases), as well as training foreign animal disease diagnosticians to recognize diseases, collect appropriate diagnostic samples, and report disease. The Homeland Security Act of 2002 transferred the Plum Island facility to DHS to align with the DHS homeland security mission. Since that time, the DHS Science & Technology Directorate has been working jointly with ARS and APHIS to meet PIADC's shared mission objectives.

The working relationship between the agencies since the transfer of PIADC to DHS has been outstanding. Similar to the management of programs prior to the transfer, the agencies at PIADC operate under a Board of Directors and Senior Leadership Group structure that facilitates decision making regarding facility operations and policies, and also enables the Directors to focus on accomplishing their agency-specific missions and goals. Following the transfer of management of PIADC to DHS, USDA-APHIS, USDA-ARS, and DHS signed an interagency agreement that established this management structure and clarified the roles and responsibilities of each agency located at PIADC. The interagency agreement is reviewed each year and modifications made as necessary. I envision this same kind of very successful management structure to continue at the proposed NBAF.

The need for agro-defense has grown significantly over the past 50 years, fueled by a growth in the Nation's livestock industry, increased globalization of markets, increased air travel, and the serious threat of agro-terrorism. The current Plum Island facility is too small to meet the needs of the Nation and its dated facilities are increasingly costly to maintain. The facility's lack of large-animal holding space is particularly limiting. The inadequate space constrains our ability to develop countermeasures in a timely fashion, thereby leaving the Nation more vulnerable. These constraints limit us to the development of one countermeasure for one disease per year.

The currently available FMD vaccine requires 3-4 weeks of lead time to move from virus stocks to useable vaccine formulation and we must first identify the specific strain/serotype in order to formulate a useful vaccine.

For instance, a new generation vaccine against foot and mouth disease, deployable in 24 hours, requires the development of 10 to 14 separate vaccines to cover each of the major serotypes and sub-serotypes of the disease. Beyond this, we need to develop next-generation countermeasures for FMD, advanced vaccines that provide cross-protection and similar countermeasures for Rift Valley Fever, Classical Swine Fever, and African Swine Fever, as well as, emerging diseases such as Nipah and Hendra viruses. Work with Nipah and Hendra viruses requires BSL-4 laboratory space because these diseases are lethal to both human and animals and have no known medical treatments. To prevent the potential tragedy these diseases represent, we need to be able to study and develop appropriate countermeasures. But, again, we must conduct this work in an environment that protects scientists, animal populations, and the public. There are no BSL-4 facilities capable of handling large animals in this country and no facilities capable of handling the necessary number of large animals. If history is a guide, other new diseases requiring BSL-4 laboratory space will emerge and will need to be addressed.

Since taking over operations of the PIADC facility in 2004, DHS has invested over $80 M in corrective actions and facility upgrades based on the FY05 multi-year Corrective Action Plan Report to Congress. These projects are in five general areas: (1) security programs and systems; (2) information technology and communication systems; (3) environmental, health, and safety systems; (4) buildings, grounds, and infrastructure systems; and (5) administrative and management programs. Despite significant investments in the facility's infrastructure, Plum Island is unable to meet the research and diagnostic and training capabilities required to address the threat of agro-terrorism now and its capacity is certainly not adequate to meet future needs. The path forward for state-of-the art vaccines requires moving from scientific discoveries through developmental and testing phases for licensure necessary to include new vaccines in the National Veterinary Stockpile (the creation of which was mandated by HSPD-9) and for eventual use by first responders. Currently, because of capacity and bio-containment constraints, Plum Island concentrates on research and diagnostic activities for only a subset of the highest-consequence foreign animal diseases. The existing facilities at Plum Island cannot host expanded research into other high-priority foreign animal disease and emerging threats of concern.

Scope of NBAF

To address these limitations, the proposed NBAF would provide the infrastructure necessary to research and develop diagnostics for, and countermeasures to, high-consequence biological threats involving foreign animal and zoonotic diseases by:

- Providing state-of-the art bio-containment laboratories for development, testing, and evaluation of countermeasures (including vaccines and diagnostics) against foreign animal and zoonotic diseases and to support their inclusion in the National Veterinary Stockpile;
- Providing coordinated mission space for large animals. Other facilities do not work with livestock or do not have the capacity to incorporate foreign animal disease impacting livestock into mission space at both the BSL-3 and BSL-4 levels;
- Integrating animal and public health research to fulfill this mission; and
- Continuing to meet evolving needs in defending against agro-terrorism threats over the next five decades.

The proposed NBAF would enable us, over the next 50 years, to fully meet the challenges posed by the intentional or unintentional introduction of a foreign animal disease or diseases that could threaten the public health and the food supply. The facility design would enable concurrent development of multiple priority vaccine candidates, antivirals, and other countermeasures. It would also meet the shared interagency mission objectives of a successful agro-defense strategy, including:

- Performing basic research on how an organism infects an animal and how the disease is transmitted from animal to animal;
- Identifying 'lead candidates' for new vaccines and antivirals and novel delivery systems to better facilitate response actions;
- Testing of small pilot lots or batches of promising vaccines and antivirals developed at the facility;
- Developing molecular diagnostics to characterize the efficacy of the new countermeasures;
- Developing high-throughput diagnostic capability to cope with an influx of large numbers of samples that can be anticipated in the face of any outbreak;

- Providing clinical testing and evaluation of the countermeasures to support licensure by the USDA Center for Veterinary Biologics and inclusion in the National Veterinary Stockpile;
- Maintaining a vaccine bank that contains a secure inventory of antigens that would be used to formulate a vaccine in the event of an outbreak;
- Providing support and reference laboratory functions to the expanding National Animal Health Laboratory Network;
- Developing and validating new diagnostics to rapidly identify, characterize, and control outbreaks of emerging diseases; and
- Training veterinarians by giving them first-hand experience in recognizing and diagnosing high-consequence foreign animal diseases, and thereby establishing a clinical capability for rapid response throughout the U.S.

DHS, in close coordination with USDA, is actively engaged in the definition of these program areas and the conceptual design of facility aspects to best support them. A state-of-the-art BSL-3 and BSL-4 facility would synergize with existing veterinary, public health, and agriculture programs and would help attract, train, and retain future generations of researchers, technicians, diagnosticians, and veterinarians. The proposed NBAF would fulfill the above requirements by establishing a state of the art BSL-3 and BSL-4 laboratory with the capacity and capability to rapidly identify and control outbreaks of high-threat/high consequence foreign animal, emerging, and zoonotic disease agents.

NBAF Site Selection Process

In Fiscal Year 2006, Congress appropriated money for site selection and other pre-construction activities for the NBAF. DHS developed a site selection process because Congress did not designate a specific site upon which to build and construct NBAF. Based upon concerns about the adequacy of PIADC to support current and future needs, as well as local opposition to building a bio-containment facility with BSL-4 laboratory space at the Plum Island facility, DHS determined it would be appropriate to explore additional site alternatives on the mainland. The site selection process was used to solicit and evaluate proposals from consortiums across the country interested in hosting the NBAF. The site selection process began with DHS's publication of a public notice soliciting expressions of interest

(EOI) for Potential Sites for the NBAF in the Federal Business Opportunities on January 17, 2006 and the Federal Register on January 19, 2006. DHS received 29 EOIs by the March 31, 2006 due date stated in the Public Notice Soliciting EOIs. DHS conducted an initial evaluation of the 29 EOIs, using the 4 evaluation criteria set forth in the Public Notice Soliciting EOIs.

DHS and USDA jointly developed the evaluation criteria used to evaluate and narrow the selection to a small number of sites. The evaluation criteria included site proximity to research capabilities that could be linked to the NBAF mission requirements, site proximity to a skilled workforce with applicable expertise, acquisition/construction/operations, and community acceptance. A team of interagency Federal employees evaluated the EOI submissions, assessing their strengths, weaknesses, and deficiencies against the four evaluation criteria. At this First Round stage, sites were eliminated from further consideration due to weaknesses and/or deficiencies with respect to the evaluation criteria, including lack of proximity to existing BSL-3 or BSL-4 research programs that could be linked to NBAF mission requirements; difficulty in demonstrating ability to attract world-class researchers and scientists or skilled technical workforce with necessary experience; insufficient community support for siting of the NBAF; and insufficient feasibility for infrastructure build-out or other siting difficulties.

When I was sworn in on August 8, 2006, DHS had already narrowed the candidate sites to 18 sites, proposed by 12 consortia, for further review. I requested that the consortia provide additional information, limited to the broader categories of information falling within the originally published evaluation criteria in DHS's Public Notice soliciting EOI. In December 2006, DHS sent Additional Information Request letters to the consortia proposing the 18 remaining sites. In the December 2006 letters, DHS also communicated its preference for certain evaluation criteria which would be considered by the Federal employee evaluation committee in the second phase of DHS's site selection process. These DHS preferences were that:

> (1) the proposed site be located in a comprehensive research community with existing research programs in areas related to NBAF mission requirements;
> (2) the proposed site be located in proximity to skilled research and technical staff with expertise in operations conducted at biological and agricultural research facilities, and be in proximity to training programs for such expertise;

(3) title to a site of at least 30 acres would be deeded at no or minimal cost to the U.S .Government, and that all NBAF construction (BSL-3 and BSL-4 laboratories) could occur at the 30-acre site;
(4) in-kind contributions (e.g., deeded land, new utilities, roads, chilled and steamed water) would be donated by proposing consortia;
(5) proposing consortia would support the National Environmental Policy Act (NEPA) effort; and
(6) the proposing consortia could demonstrate that local and national agriculture stakeholder community members support, or at least do not oppose, locating the NBAF at the proposed site.

Upon receipt of this additional information from the consortia, a Federal team consisting of USDA and DHS employees conducted site visits to all the remaining sites. The intent of the site visits was to: (1) verify the information provided and representations made in the EOI submissions and additional information submitted; and (2) enable evaluation committee representatives to view any observable physical conditions and constraints at the proposed site and, if applicable, view the site's utilities and infrastructure. In addition, I separately visited each of the sites personally so I could reference first-hand knowledge when being briefed by the site-selection team.

Based on Federal employee evaluation team's analysis of the additional information and observations on the site visits, the evaluation team recommended to me which sites should advance for further evaluation. As the Selection Authority, I determined that **five sites** met the evaluation criteria and DHS preferences, and would therefore be advanced as reasonable alternatives to be studied in the Environmental Impact Statement (EIS).

Although not part of the competitive site selection process, Plum Island was determined to be a reasonable site to advance for study in the EIS, making a total of **six sites** for consideration. The basis for including Plum Island as a viable alternative was fourfold:

(1) NEPA specifically requires the proposing Federal agency to evaluate the range of all "reasonable alternatives" to a proposed action, where reasonable alternatives are defined as those which are "practical or feasible from the technical and economic standpoint and using

common sense, rather than simply desirable from the standpoint of the applicant.";
(2) Plum Island currently performs much of the existing research and houses the existing workforce assessing potential threats to animals from foreign animal diseases and zoonotic diseases;
(3) Plum Island currently fulfills a portion of the goals and mission identified for the NBAF and meets some of the NBAF criteria, including having a skilled workforce in a BSL-3 environment; and
(4) Plum Island could reasonably be internally evaluated throughout the EIS process, given that DHS already owns Plum Island and did not believe it appropriate to respond to "its own request-for-EOI [expression of interest]."

The Notice of Intent (NOI) to prepare an EIS, which was published in the Federal Register on July 31, 2007, listed the six site alternatives that will be studied in the Environmental Impact Statement (EIS) and began the NEPA process for the proposed NBAF. In accordance with NEPA, DHS is also considering as part of the EIS process a "no action alternative" (i.e., the NBAF would not be built).

DHS has established an evaluation process utilizing a team of Federal officials from DHS and USDA to review, for all six alternatives, the EIS analysis as well as other factors such as threat risk assessment, site cost analysis, site characterization, PIADC facility closure and transition cost, DHS's evaluation criteria and preferences used to down-select the sites, and other programmatic considerations. This will allow the team to recommend the site alternative which is most beneficial to the Government and to the public. The Draft EIS is scheduled to be released for public comment in May 2008, followed by public meetings at each of the six site alternatives. The Final EIS will be published at the end of September 2008. Following completion of the final EIS, a Steering Committee consisting of Federal employees will make a final recommendation to me.

I expect to publish a Record of Decision (ROD) in the fall of 2008. The ROD will notify the public of the decision on the proposed action of whether to build the NBAF and, if so, where to build and operate it. The ROD will also document the reasons for the decision. If the decision is made to build the NBAF, site-specific NBAF design efforts will follow, and NBAF construction would be planned for 2010, and the facility would be commissioned by the end of 2014.

I want to emphasize that no decisions will be made on the final site selection until the appropriate environmental and safety risk assessments have been completed. Those are presently underway as part of the Environmental Impact Statement process. If the NBAF is built, and no matter where it is sited, the utmost in biosafety and biosecurity will be utilized to make this a safe and secure facility.

In the intervening decades since the PIADC was built, significant advancements have been made in laboratory design and bio-containment measures and protocols. While there is always a risk of human error–the recent suspected release of live foot-and-mouth disease virus from the Pirbright Campus in England remains an isolated case in point–the redundancies built into modern research laboratory designs and the latest biosecurity and containment systems, coupled with continued training and monitoring of employees, effectively minimizes these risks. Consequently, I have every reason to believe that the assessments will show that, from a biosecurity and public safety perspective, siting the NBAF on the U.S. mainland is a viable alternative.

Regardless of which site is chosen, implementation would necessitate decommissioning the current Plum Island facility, and those costs plus the costs to transition to the new facility, regardless of location, would be considered in the final decision making analysis.

The estimated facility cost for this project is $451M, not including the cost for site infrastructure, IT, security, or utilities. The final facility cost is being determined as part of the decision process. To date, $46M has been appropriated for the NBAF to do planning, siting studies, and the Environmental Impact Statement.

Research involving the use of live FMD virus may occur on the U.S. mainland, subject to the Secretary of Agriculture making a determination that such study on the mainland is necessary and in the public interest and issuing a permit for such research to be conducted on the mainland. Prior assessments have determined that since the 1950s, when Plum Island was built, the subsequent evolution of bio-containment technology allows safe research and diagnostics of foreign animal diseases to take place on the U.S. mainland.

Conclusion

In summary, the planned NBAF would play a crucial role in protecting the Nation against current and future foreign animal and zoonotic diseases, whether naturally or intentionally introduced. The list of such high-priority diseases is growing. Plum Island has done and continues to do an excellent job in the defense of the Nation against foreign animal disease threats, but the age of its facilities and its limited capacity restricts research and diagnostic studies and is slowing the development of needed countermeasures. Further, there are no facilities in the Nation to fully handle large animals and address zoonotic diseases that affect both large animals and humans. NBAF is needed to attract and retain the scientists, technicians, researchers, and veterinarians needed to defend against current and future threats for the next 50 years and to fulfill the mandate of HSPD-9. Therefore, DHS is committed to creating the next-generation capability and supporting our USDA partners by making the planned NBAF a reality.

Mr. STUPAK. Thank you, Mr. Cohen.

Dr. Barrett, your opening statement, please.

Dr. BARRETT. I was asked to be a witness, not to provide an opening statement.

Mr. STUPAK. So you have no opening statement then?

Dr. BARRETT. I have no written opening statement. I can make a statement.

Mr. STUPAK. It is entirely up to you. It is at your discretion, you are under oath, and if you would like to make one, fine.

STATEMENT OF LARRY BARRETT, D.V.M., M.S., D.A.C.V.P.M., DIRECTOR, PLUM ISLAND ANIMAL DISEASE CENTER

Dr. BARRETT. I would like to make a few comments. Good morning, Chairman Stupak and Ranking Member Whitfield, I am pleased to be here before you today to discuss the important mission of Plum Island Animal Disease Center, which is to protect the U.S. livestock from the accidental or deliberate introduction of high-consequence foreign animal diseases.

I was raised on a cattle ranch in Oklahoma and I became a veterinarian due to my desire to protect public health and animal health. I have worked as California's state public health veterinarian and as a program manager for the State's food safety programs. I also served on active duty in the military as a veterinarian and just retired as a reserve colonel. I applied for the position of director of PIADC due to my strong support for protecting the Nation's livestock from high-threat foreign animal diseases with vaccines and biological countermeasures, and today we are working on a vaccine that next year hopefully we will have the first licensed vaccine that we can use in the United States, manufactured in the United States and with the ability to tell infected from vaccinated animals. This will hopefully move on to where we can put it in the national stockpile and the USDA will have the option then to vaccine animals in this country to live and not be slaughtered.

As Center director, I support USDA on a daily basis in its important mission. It is an important mission to protect the Nation from foreign animal diseases. As an example, if foot-and-mouth disease is suspected in the United States, the samples are shipped to Plum Island for confirmatory testing by the USDA Animal and Plant Health Inspection Service. What we do is provide operational support from DHS for these activities. We want to ensure the testing is conducted immediately. In addition, we support the Animal and Plant Health Inspection Service of the USDA in training its over 200 veterinarians a year in the Nation's only foreign animal disease diagnostic training classes. These are the veterinarians who would be the Nation's first responders in a foot-and-mouth disease or other foreign animal disease outbreak.

I also support USDA Agriculture Research Services at Plum Island, which is involved in basic and applied research on foreign animal diseases including classical swine fever and foot-and-mouth disease. As an example of their important work, ARS conducted research in early development of a new foot-and-mouth vaccine that does not use live virus as part of its production and can therefore be manufactured in the United States, as I mentioned previously.

The one thing that we also do in addition to providing operational support to the USDA to allow them to focus entirely on their mission now is, we are able to provide the additional support in taking vaccine products developed by the USDA and moving them onto manufacturing, and we have a Targeted Advanced Development unit established there of DHS scientists who now have the expertise for vaccine development. This is something unique that we didn't have before DHS came to the island. We are working with industry, USDA, ARS, and APHIS and the U.S. Center for Veterinary Biologics for obtaining licensing for this vaccine. It is an important step for this Nation and critical in responding to the things that we saw today because I totally agree, this is a highly contagious disease and probably the most catastrophic disease that is facing our animal industry.

DHS is committed to maintaining positive proactive relations with our surrounding communities too. We established a community forum with 28 members from the local New York and Connecticut communities, which meets on a quarterly basis. We use this method to keep the public informed of the important scientific work and other activities we do. We also just recently scheduled a Plum Island community day where we are having 25 people from the local community come out, and we want to explain to them the important things we do at Plum Island. It is time that we stopped having secrets and let the community know the important work that we are doing.

In addition, we have an industry stakeholders working group that I put together with representatives from agencies and organizations such as the National Cattlemen's Beef Association, which you heard speakers here today from, and the National Milk Producers Federation. I provided presentations to these organizations and communicated with other stakeholder working groups to keep them apprised of the important work we do at Plum Island.

At Plum Island, we also have a senior leadership group which, besides myself, is comprised of the Animal and Plant Health Inspection Service's director of the Foreign Animal Disease Diagnostic Lab and also the chief of research from USDA ARS. We work closely on a daily basis and meet regularly to ensure communication and partnership in supporting our important scientific activities. We also elevate issues as appropriate to our Plum Island board of directors, which is comprised of the administrator of Agriculture Research Services and APHIS, and a senior representative from the Department of Homeland Security S&T also sits on that committee. Senior leadership is conducting—right now we are doing strategic planning, working together in our senior leadership group at Plum Island identifying our current research strategies and how we are going to address future needs with the facilities we have but also moving into the future, and we will report these and coordinate those with the Board too.

We also have made many other improvements addressing other GAO findings of security violations, which we have corrected now. We have memorandums of understanding with local communities for support, and on a daily basis I work closely with the USDA.

In summary, Plum Island plays a critical role in the daily protection of our Nation against foreign animal diseases. As director, I

am committed to providing support to the USDA in fulfilling their important mission at Plum Island as well as providing a sense of urgency and support for the Department of Homeland Security and USDA's development of a new, improved foot-and-mouth vaccine for the protection of this Nation's livestock and nothing is more important to me, coming from a cattle ranch, than having that. Thank you.

[The prepared statement of Dr. Barrett follows:]

STATEMENT FOR THE RECORD

Of

Dr. Larry Barrett
Center Director
US DHS Plum Island Animal Disease Center

National Bio- and Agro-Defense Facility (NBAF) Decision Process

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations

May 22, 2008

Good morning, Chairman Stupak and Ranking Member Whitfield. I am pleased to appear before you today to discuss the important mission of the Plum Island Animal Disease Center ("PIADC"), which is to protect US livestock from the accidental or deliberate introduction of high-consequence foreign animal diseases.

I was raised on a cattle ranch in Oklahoma and became a veterinarian due to my desire to protect public health and animal health. I have worked as California's State public health veterinarian and as the program manager for the State's food safety programs. I also served on active duty in the military as a veterinarian and just retired as a reserve Colonel. I applied for the position of Director of PIADC due to my strong support for protecting this Nation's livestock from high threat foreign animal diseases with vaccines and other biologic countermeasures.

As Center Director, I support USDA on a daily basis in its important mission of protecting the Nation from foreign animal diseases. As an example, if foot-and-mouth disease is suspected in the US, the samples are shipped to PIADC for confirmatory testing by USDA APHIS. DHS provides operations support for these activities to ensure testing is conducted immediately. In addition, we support APHIS in its training of over 200 veterinarians a year in the Nation's only Foreign Animal Disease Diagnostics training class. These are the veterinarians who would be the Nation's first responders in a foot-and-mouth disease or other foreign animal disease outbreak.

I also support USDA ARS at PIADC which is involved in basic and applied research on foreign animal diseases including classical swine fever and foot-and-mouth disease. As an example of their important work, ARS conducted research and early development of a new foot-and-mouth disease vaccine that does not use live virus as part of its production and can therefore be manufactured in the US. PIADC's DHS science program – the Targeted Advanced Development

Unit -- was established with the mission of developing biological countermeasures. We are working with industry, USDA ARS and APHIS and the USDA Center for Veterinary Biologics in obtaining licensing for this new vaccine.

DHS is committed to maintaining positive, proactive relations with PIADC's surrounding communities. We established a Community Forum with 28 members from the local New York and Connecticut communities which meets on a quarterly basis. We use this method to keep the public informed of PIADC's scientific and other activities. In addition, we have an Industry Stakeholders Working Group with representatives from agencies and organizations such as the National Cattlemen's Beef Association and the National Milk Producers Federation. I have provided presentations to these organizations and communicate with the Stakeholders Working Group to keep them apprised of the important work being done at PIADC.

At PIADC, we have a Senior Leadership Group which, besides myself, is comprised of the APHIS Director of the Foreign Animal Disease Diagnostics Laboratory and the Chief of Research for ARS' Foreign Animal Disease Research Unit. We work closely on a daily basis and meet regularly to ensure communication and partnership in supporting our important science activities. We also elevate issues, as appropriate, to the PIADC Board of Directors which is comprised of the Administrators of ARS and APHIS and a senior representative from DHS S&T. PIADC's Senior Leadership Group is conducting strategic planning to identify current research strategies and address future research needs as we move toward a new facility. We will report and coordinate these plans through the Board.

We have also made and continue to make many operational improvements at PIADC, including enhancements to the security of our facility. A GAO inspection conducted in 2004 identified 26 findings and we have closed out 18 of them. We have also taken appropriate action to address the remaining six items and are

informing the GAO of our progress. Examples of the security improvements include the augmentation of physical infrastructure measures for perimeter protection and monitoring systems. We are also in the process of upgrading our critical infrastructure, including projects to expand animal housing and training space in the facility.

We also have Memoranda of Agreement with the Town of Southold for security support and with Suffolk County for Fire Rescue and Medical Support. In addition to our contract security guards, we have Federal Protective Service presence at PIADC.

As Director, I also coordinate on a daily basis with other components of DHS, including the Office of National Labs, the Chem Bio Division, the University Programs Office, the Centers for Excellence and the Health Affairs Office. I am also pleased to report I have a great relationship with USDA's upper management.

The scope of DHS' science activities at PIADC is focused on the targeted advanced development of countermeasures for foot-and-mouth disease. We are currently developing – in partnership with industry and the USDA – a new FMD vaccine that can be manufactured in the US and provides many improvements over the current, traditional vaccines which require use of live FMD virus as part of this production.

In summary, PIADC plays a critical role in the daily protection of our Nation against foreign animal diseases. As Director, I am committed to providing support to the USDA in fulfilling their important missions at PIADC as well as providing a sense of urgency and support for DHS' and USDA's development of a new, improved FMD vaccine for the protection of the Nation's livestock.

Mr. STUPAK. Thank you, Dr. Barrett. Dr. Barrett, I will need you to submit that. It looks like you read a written statement there so I will need you to submit that for the record. Kyle will make a copy and give it back to you. Thank you.

Mr. Dingell, do you wish to go first?

Mr. DINGELL. Thank you.

Mr. Cohen, I want to thank you for your kind words. Please tell me where is the environmental impact statement and when are you going to make it available to this committee at the request of this committee and at the request of GAO?

Mr. COHEN. I will be pleased to make it available to this committee, as I have made all other information——

Mr. DINGELL. Pardon me?

Mr. COHEN. I say again, I will be pleased to make it available to the Committee, as I made all other——

Mr. DINGELL. We would like to see first of all the state of this and we would like to see the statement of work that goes into that. When will that be made available to the Committee?

Mr. COHEN. It is my understanding that the statement of work was provided to the Committee either late last year or early this year.

Mr. DINGELL. I am informed that that is not true, and I am informed that GAO has been denied this because that is a proprietary document. Is that statement true?

Mr. COHEN. The statement of work is not a proprietary document, and I will find out why the Committee and the GAO does not have it. As to the draft environmental statement, while we are not required to conduct this selection for the NBAF location under the Federal acquisition regulations, I felt as the responsible individual that the closest we could come to those processes would give the most transparency and fairness and so in doing that——

Mr. DINGELL. This is all fine, but let me just repeat my question so that you understand it. When are you going to make available to us the statement of work? When are you going to make available the environmental impact statement? When are you going to make it available to GAO? Why have you refused it to GAO? Why have you stated that this is a proprietary document?

Mr. COHEN. I will see that the statement of work is delivered to your committee and the GAO this afternoon and then we will determine whether they had it——

Mr. DINGELL. Why have you withheld it from the GAO and why have you withheld it from this committee?

Mr. COHEN. I don't have——

Mr. DINGELL. You are the witness on behalf of the Department and said this is a proprietary document. Is it a proprietary document, and if so, what is a proprietary document and why it is a proprietary document not available to GAO and to this committee?

Mr. COHEN. Chairman, I have no personal knowledge that the word "proprietary" was used. I will accept the GAO——

Mr. DINGELL. You have heard——

Mr. COHEN. I will accept the GAO's testimony that they did to that effect, but the GAO nor did the Congressional Research Service at any point request to see me as part of their studies.

Mr. DINGELL. Dear friend, they are asking to have the document. I have 2 minutes and 26 seconds so I don't want to get into a long argument over this. I just want you to tell us why you have been withholding this from us at this committee and why you have withheld it from GAO and which is functioning at our request.

Mr. COHEN. We have not withheld a statement of work. I will make sure you have a copy on the draft environmental statement. We will make that available to the Committee. We will make it available to the public just as if it were a contract action.

Mr. DINGELL. We want the document now. We don't want it at some future time.

Mr. COHEN. Yes, sir.

Mr. DINGELL. And if you have a reason for withholding it from us, I want you to tell us what that is and why you are withholding it from us, and we want to know why we have to wait and why you are treating it as a contract action rather than seeing to it that it is made available to us forthwith and why did you not make this available to GAO on their request? Now, what are the answers to my questions? You mentioned the word "arrogant" and it sounds rather arrogant to me.

Mr. COHEN. It sounds arrogant to me that neither the Congressional Research Service nor the GAO would show me, the deciding official, the courtesy to even visit with me. We have heard testimony from the GAO that they couldn't get onto Plum Island, and who did they contact to get into Plum Island?

Mr. DINGELL. They had to wait 6 weeks.

Mr. COHEN. Me?

Mr. DINGELL. Please explain why they had to wait 6 weeks to get on the island.

Mr. COHEN. Because Dr. Sharma, I am informed, contacted the wrong people. Your staff has been on the island. In fact, my staff and your staff have bathed together on the island.

Mr. DINGELL. This sounds to me as if almost anybody in that department of yours is the wrong people. It sounds like you are speaking on behalf of the most profound disorganization and confusion. Why is it that the wrong people couldn't refer him to the right people? Is that incompetence or is that arrogance?

Mr. COHEN. As I said, if Dr. Sharma will share with me who he contacted, if we have a problem with customer service, I can assure you I am committed to improving the customer service.

Mr. DINGELL. On February 21, I had to send this letter to Secretary Chertoff: "Your failure to make complete response to our records request is troubling. Despite assurances of cooperation from Under Secretary Jay Cohen in a letter to this committee dated October 25, 2007, we continue to discover the existence of records directly related to our requests but which are not included in your response. For example, it was in the course of a visit to Plum Island by the committee investigators in November we became aware that DHS possessed two studies performed by SAIC analyzing Plum Island and NBAF issues. Similarly, it was only as a result of this committee staff interviews of certain DHS officials that we became aware of a study on Plum Island performed by the Homeland Security Institute in 2007. The SAIC studies have now been provided but despite staff requests, the HSI study has not yet been

produced." Why is it not produced and where is it and when are we going to get it?

Mr. COHEN. Well, Chairman, I am pleased, and Chairman Stupak, these are all of the studies that I have and I am glad to give them. I believe you will find that the staff already has those.

Mr. DINGELL. Let me inform you, Mr. Secretary, that the delivery of lots of paper is not the delivery of the specific requested documents, and I expect better cooperation from your department. You are not giving it, and it may be that you can treat other committees with arrogant disregard for their requests but you are sure not going to do it here because I am going to see to it, and I am sure Mr. Stupak, our chairman, will see to it that we lay subpoenas on you so that we get your cooperation willingly or otherwise.

Mr. COHEN. Yes, sir, and to the extent I control the documents, I have directed their release in a timely manner to the Committee. To the extent that they are shared amongst departments, as you have heard today earlier, USDA, Department of Justice, et cetera, it is appropriate that I ask those departments for clearance because I did not generate them. But I have nothing to hide here. This process is being done in an open and fair manner to the best of my ability, sir.

Mr. DINGELL. Well, I have to say that you are giving me quite a different impression, and you are giving this committee quite a different impression.

Mr. Chairman, my time is expired. I hope we will have a second opportunity to raise these questions.

Mr. STUPAK. I thank the chairman.

Mr. Cohen, you brought up this study on the economic impact of an outbreak in this country that the last panel brought up, and why wasn't that supplied to the Committee? Why wasn't that study supplied to the Committee?

Mr. COHEN. I am sorry. Is this the 2002——

Mr. STUPAK. The 2004 USDA estimate of what an outbreak would cost this country. Direct cost was $60 billion from the last witness. Why wasn't that report supplied our committee?

Mr. COHEN. I will refer that to Under Secretary Knight. It is a USDA study.

Mr. KNIGHT. I have had staff scrambling since the testimony to find that because I do know earlier this week——

Mr. STUPAK. Yes, they should scramble when we write letters though and ask for those reports, not when you come to the Committee. So where is the report and when can we have it?

Mr. KNIGHT. My best knowledge right now is that that study was in fact a PowerPoint presentation given by the chief economist's office. I am working to get confirmation on that. When I have got that tracked down, I will provide that fully to the Committee.

Mr. STUPAK. We want it, and we want it soon.

Let me ask you this. Have you done any risk assessment on Plum Island, Mr. Cohen?

Mr. COHEN. Well, we have done numerous studies.

Mr. STUPAK. I am talking about risk assessment on Plum Island. Have you done one, yes or no?

Mr. COHEN. Risk assessment is being done under NEPA as part of the environmental impact statement.

Mr. STUPAK. Has risk assessment been done in the State of Texas on the proposed site, State of Kansas——

Mr. COHEN. It is being done as part of the environment impact statement for the San Antonio site as is the case in all six sites.

Mr. STUPAK. All right. So it is being done. When is it going to be done?

Mr. COHEN. Well, the draft environmental impact statement should be out no later, in my opinion, than mid-June, and the final environmental impact statement should be out this fall, either October or November.

Mr. STUPAK. Does it include economic impact as to what happens when foot-and-mouth disease would hit this country?

Mr. COHEN. Yes, sir, it does.

Mr. STUPAK. All right. How about the cost-benefit analysis? Have you done that?

Mr. COHEN. We will do that as part of the economic——

Mr. STUPAK. Have you done it?

Mr. COHEN. It is in progress as part of the environmental impact statement. Many of these issues are very site-specific and require knowledge of the community. We couldn't even start these until we had down-selected to the six most probable sites.

Mr. STUPAK. And when did you narrow it down to six probable sites?

Mr. COHEN. Last July.

Mr. STUPAK. So it has been over a year?

Mr. COHEN. And we have been in progress with town halls, public hearings. We have over 2,000 documents that have been submitted by various interested parties including some of the representatives from panel number two.

Mr. STUPAK. All right. You indicated that the morale is very high at Plum Island. Do you have trouble recruiting scientists to go work at Plum Island?

Mr. COHEN. I will refer that to Dr. Barrett since he is the responsible individual.

Dr. BARRETT. When we recruit scientists at Plum Island, we usually go out and try to get post-docs and other people like that, like we recently hired one of our scientists——

Mr. STUPAK. Sure, but do you have trouble recruiting qualified people?

Dr. BARRETT. As senior-level scientists, we are trying to hire a research veterinarian now. That is difficult, and I know ARS is too. But most positions we can fill.

Mr. STUPAK. OK. Well, we have been told that your scientists are among the best in the world in their field. Is that correct?

Dr. BARRETT. Yes.

Mr. STUPAK. OK. And your scientific missions and goals are being accomplished at Plum Island, are they not?

Dr. BARRETT. Yes.

Mr. STUPAK. So there is not a concern then that if we put the new foot-and-mouth disease facility on Plum Island, you would have trouble recruiting people to work there?

Dr. BARRETT. No.

Mr. STUPAK. You indicated you grew up on a cattle farm or a ranch?

Dr. BARRETT. A ranch.

Mr. STUPAK. Do you still have family in——

Dr. BARRETT. Yes. I go back and visit my father and we go out and look at the cows, and one of the things that I am so interested in getting this vaccine out is because they are registered heifers and he can tell me, the mother for every cow and I have to listen to it every time.

Mr. STUPAK. Did you ever talk to him about moving foot-and-mouth research off Plum Island?

Dr. BARRETT. Yes.

Mr. STUPAK. What did your father say to that?

Dr. BARRETT. He didn't think it was a good idea. At the same time, I didn't have time to——

Mr. STUPAK. Well, let me ask you this. How many releases of foot-and-mouth disease have been from Plum Island?

Dr. BARRETT. Releases? We have only had the one release in 1978.

Mr. STUPAK. OK. DHS—and maybe Secretary Cohen or Director Cohen would like to answer this. DHS can either renovate the existing facility on Plum Island or build a new facility there, correct?

Mr. COHEN. Yes, sir.

Mr. STUPAK. And is Plum Island being considered as one of those sites?

Mr. COHEN. Absolutely.

Mr. STUPAK. DHS could still build NBAF but leave foot-and-mouth disease on Plum Island. That is another option, right?

Mr. COHEN. Yes, sir.

Mr. STUPAK. OK. A new NBAF would include animals that would be kept on the property, right?

Mr. COHEN. Yes, sir.

Mr. STUPAK. No matter where it is at?

Mr. COHEN. No matter where it is at, but those animals would be kept within the facility, not outside the containment.

Mr. STUPAK. OK. In 1991, 13 years after the 1978 outbreak, Plum Island stopped keeping animals outside the lab on the island. Isn't that correct?

Mr. COHEN. I was up there on Monday. I spoke with Dr. Callis, who was the director in 1978, and both Dr. Barrett and I tried to get an exact date, and Dr. Callis indicated that it was about that time.

Mr. STUPAK. OK. So you stopped keeping animals on the outside, and that was after 1978?

Mr. COHEN. Yes, sir, somewhere between 1978 and 1991. I think it was progressive.

Mr. STUPAK. Do you know how many outbreaks since 2004 of the biolabs 3 and 4? Do you know how many outbreaks there have been since 2004 through 2007?

Mr. COHEN. I will take for the record, but there have been—you are talking more than just——

Mr. STUPAK. I am talking accidents——

Mr. COHEN. BSL-3, BSL-4?

Mr. STUPAK. Yes.

Mr. COHEN. There have been a handful and they are documented.

Mr. STUPAK. OK. Well, actually with accidents and outbreaks, there have been 103. Would that surprise you?

Mr. COHEN. No.

Mr. STUPAK. OK. And——

Mr. COHEN. I assume you are talking worldwide?

Mr. STUPAK. No, I am talking about here in the United States.

Mr. COHEN. I don't have knowledge of that number. That would come under CDC and HHS and NIH and——

Mr. STUPAK. Sure. Let me give you one right there. There were 103 outbreaks since January 2004 through halfway through 2007. That is 3½ years, 103 of them. Ninety are caused by human error.

Mr. COHEN. Yes, sir.

Mr. STUPAK. So the issue here is not necessarily human error, but once the outbreak happens, how will it spread? Is that fair to say?

Mr. COHEN. I just didn't hear the——

Mr. STUPAK. Sure. If 90 percent of the errors or outbreaks or mistakes are human errors at these BSL-3 and BSL-4 labs, you are going to have that whether it is on Plum Island or Texas or North Carolina.

Mr. COHEN. Yes, sir.

Mr. STUPAK. And the critical issue then is how quickly it could spread to a surrounding population. Isn't that correct?

Mr. COHEN. If it would spread, and then at what speed, yes, sir.

Mr. STUPAK. If you had an outbreak that got out, one of the previous panelists said that you had to cordon off 20 miles; then there is another buffer, and then you might have to vaccinate the outer area. So the less impact, the less risk there would be in areas where there is less of an animal population to be infected. Is that fair to say?

Mr. COHEN. I don't know the basis for the 20 miles. Obviously people have shared with you, Plum Island is 1½ miles off the eastern end of Long Island and so that is viewed as the customary barrier. But certainly proximity, as was stated with a feed house or whatever, is certainly a consideration.

Mr. STUPAK. Sure, and in the books there, in fact, I think you handed some of those SAIC reports to Mr. Dingell. You were indicating in the one on tab 12, if you will, that is that SAIC report of August 15, 2002, and for the record, SAIC means Science Applications International Corporation. On page 16, third paragraph, it talks about biosafety lapses at any facility location likely to have an equal risk of occurrence, and I think you would agree with that statement, would you not?

Mr. COHEN. I do, sir.

Mr. STUPAK. OK. It goes on and says, "In this respect, not all locations can be considered equal, that is, facilities located where significant animal populations exist that are susceptible to agents under investigation have a greater degree of risk." Is that true?

Mr. COHEN. I agree with that, and that is exactly why under NEPA we are doing the EIS at all of the six sites.

Mr. STUPAK. Right, and even though this is a faulty report, according to GAO, because you only looked at limited circumstances, they still concluded, did they not, in the next paragraph that Plum Island was considered to have the lowest risk should accidental re-

lease from an agent from the facility occur in part because of its island location but mainly due to lack of commercial livestock farming in Long Island and surrounding areas. Is that true?

Mr. COHEN. As you have heard in prior panels, we have had——

Mr. STUPAK. Isn't that what it says? Isn't that what this report says, that paragraph right there?

Mr. COHEN. It does say that, and——

Mr. STUPAK. So it sounds like Plum Island would be the preferred location because of the island location and the lack of livestock to be infected if there is a contagious outbreak when you have had 103 in the last 3½ years.

Mr. COHEN. I certainly, Chairman, will stipulate that Plum Island is an island, it is remote, it is separated by water, but as you have heard from prior panels, there are deer that swim. I am a New York City boy. I was brought up in Manhattan Island. I thought wildlife was squirrels, rats, and pigeons. Then I moved to Long Island, close to Plum Island. So deer are susceptible to foot-and-mouth. Now, I was just out there on Monday——

Mr. STUPAK. And have we had any deer come back with hoof-and-mouth disease and infect the area? Even if they did, according to this report that you paid for, there is less chance of an infection because there is not enough livestock in that area to have a significant impact.

Mr. COHEN. Well, Chairman, you know I was just——

Mr. STUPAK. So your risk-benefit analysis, I think we just did it for you.

Mr. COHEN. I was just on eastern Long Island on Monday and I found out that their economy has changed and they are now doing an awful lot of shrubbery, decorative shrubbery because of the construction that is going on, and there is a real, just like in Maryland and other states, a deer population boom, and so deer can transmit this as well as any other of the cloven-hoof animals. So this will all be part of the EIS. I agree with you, it is an island and it makes sense from the testimony, as you have heard——

Mr. STUPAK. I am just trying to help you because apparently you have been having trouble getting it done and getting the documents to us, and your own documents sort of indicate Plum Island is the preferred place from a risk-benefit analysis.

Mr. COHEN. If those documents were the end-all, I would not have been working on this with a team of government service, DHS, USDA, and HHS——

Mr. STUPAK. It is not the end-all.

Mr. COHEN [continuing]. Going to every site for the last year and a half and continuing this for the next 9 to 10 months.

Mr. STUPAK. It is not the end-all. That is why we want these other reports.

Mr. COHEN. Yes, sir.

Mr. STUPAK. Even as flawed as it is, they still came with the conclusion.

Mr. Shimkus for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. To both secretaries, welcome, and I appreciate you sitting in to observe the other panels. We have learned—I have learned a lot and you all have been involved a lot in this process. Let me ask both of you, and Sec-

retary Knight, I would like you to answer first and then Secretary Cohen, just because left to right, kind of easy, Dr. Hill from the National Pork Producers gave testimony today stating that the location of the facility on the mainland should be based on an assessment of risk and that an assessment of the proximity of susceptible animal populations that could be exposed to an outbreak should be one of the factors considered when calculating that risk. Is that risk examined in the EIS, and if not, why?

Mr. COHEN. That is my responsibility, and the answer is yes, it is considered, absolutely.

Mr. SHIMKUS. Was it a consideration on picking the five finalists?

Mr. COHEN. It was not as direct a consideration as it is now that we are with the finalists and have a full-blown environmental impact statement. We have listed the public criteria by which we did that down-select and we used both numerical and adjectival scoring, and the Committee has been provided with that record of decision for their review.

Mr. SHIMKUS. Did either you, Secretary Knight, or Secretary Cohen, either from USDA or DHS, consult with or ask for input from the livestock associations when selecting the final sites for the NBAF?

Mr. COHEN. We took again in a very public way with public hearings, et cetera——

Mr. SHIMKUS. We like public hearings.

Mr. COHEN. We took input from everybody including people with protest signs on the side of the road when we visited the consortia proposed sites.

Mr. SHIMKUS. Secretary Knight?

Mr. KNIGHT. We were in a supporting role with DHS in that and everything was done in as open a process as possible with public participation.

Mr. SHIMKUS. As the process moves forward, will we continue to be in consultation with the industries affected?

Mr. COHEN. Absolutely, and I would say based on the information I received today and we continue to learn that we will to be more closely involved with them because under the economic impact, they know best.

Mr. SHIMKUS. Dr. Barrett, also welcome to you. As director for the past year, what have been the most common complaints made by current USDA employees at Plum Island about the facility and its location?

Dr. BARRETT. The most common complaint is about space. We just had our last senior leadership group. We spent the entire meeting talking about how we were going to be sharing one room because we only have one room to hold 26 animals for the large studies and we spent a lot of the meeting deciding which of the three of us would get to use it.

Mr. SHIMKUS. And obviously I walked in late, I missed some questions. Was there a follow-up question by the chairman about the assertion made about the inability to get qualified people at Plum Island versus other locations around the country? I mean, is that a——

Dr. BARRETT. I responded to that and I said that we do work just like any other scientific institution. We bring in post-docs and build

our own. At the same time, we do have difficulty in hiring senior scientists as you would at other locations. One of the things is because it would be nice if we were closer to a research institution so that you could do cooperative projects.

Mr. SHIMKUS. And a research institution, you are referring to associated with a major university?

Dr. BARRETT. Yes.

Mr. SHIMKUS. Mr. Chairman, that is all I have right now.

Mr. STUPAK. Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy.

Mr. Secretary, where is the cost-benefit analysis for this move?

Mr. COHEN. It is in process with the environmental impact statement.

Mr. DINGELL. You do not have it now?

Mr. COHEN. I do not have it now.

Mr. DINGELL. Will that be made available to the Committee as soon as it is available?

Mr. COHEN. Absolutely, sir.

Mr. DINGELL. Thank you. Now, let us talk about the SAIC study. Where in the SAIC study does it support the move of Plum Island to the mainland? What is the language? Where is it in that study?

Mr. COHEN. I have not memorized that study so I will take for that record, but that study was done under the auspices of the Department of Agriculture.

Mr. DINGELL. Where in the study is that language?

Mr. COHEN. I will take it for the record, sir. I will get back to you.

Mr. DINGELL. All right. Please submit it for the record with great specificity.

Mr. COHEN. Yes, sir.

Mr. DINGELL. Now, you have referred to HSPD-9 as supporting the move. What language in that study supports this move?

Mr. COHEN. As I read HSPD-9, it does not specify a move. It requires in coordination with the U.S. Department of Agriculture that we establish suitable facility in order to mitigate or prevent bioterrorism in this area.

Mr. DINGELL. Does it say that that should be moved, that Plum Island should be moved to the mainland?

Mr. COHEN. Not to my knowledge.

Mr. DINGELL. OK. Now, where does the study that in the 2003 White House Blue Ribbon Panel on Bioterrorism show either a cost-benefit analysis or a reason for moving Plum Island to the mainland?

Mr. COHEN. I have read that blue ribbon study. I appreciate the work that went into it, and as I read it, it specifies neither of those, sir.

Mr. DINGELL. So it doesn't show that. Now, what document do you have at the Department which justifies the move of this facility from Plum Island to the mainland?

Mr. COHEN. I do not have a document because we have not made the decision to move from Plum Island.

Mr. DINGELL. But you will have obviously decisionmaking documents which will be presented to you. Do you have any such——

Mr. COHEN. As they——

Mr. DINGELL. Please.

Mr. COHEN. Yes, sir.

Mr. DINGELL. Do you have any such documents that you can present to the Committee today?

Mr. COHEN. We have presented to the Committee the record of decision——

Mr. DINGELL. I am asking——

Mr. COHEN [continuing]. The five plus Plum Island that shows the methodology——

Mr. DINGELL. Reply, if you please, to my question.

Mr. COHEN. Yes, sir.

Mr. DINGELL. Do you have any documents which support this move? Any——

Mr. COHEN. The document that I have submitted——

Mr. DINGELL. Pardon?

Mr. COHEN. The document I have previously submitted, which is the record of decision, which shows the methodology that got us to the existing six. I will give you the——

Mr. DINGELL. Mr. Secretary, you are not being very helpful. What I want from you is any documents which you have which justifies the move.

Mr. COHEN. Sir, I am not presuming that there will be a move. I am in the process of the down-select of which Plum Island is one of the six finalists.

Mr. DINGELL. All right. Now, this question then to the witness from the U.S. Department of Agriculture. What documents do you have anywhere in the Department of Agriculture which justify or support the movement of this facility from Plum Island to some onshore position?

Mr. KNIGHT. I do not believe we have any documents other than what have already been provided.

Mr. DINGELL. What studies do you have that support that move?

Mr. KNIGHT. We have some experience in the logistical difficulties associated with testing in the event of a potential disease trace-back which has shown that there are logistical hurdles associated with getting samples to Plum Island in a timely manner.

Mr. DINGELL. Please present that study to the Committee, and please see to it that it is annotated to show where you have anything in that study which supports the move. And please also tell me whether you are telling me that this study tells you that there are large costs associated with the move and whether you are telling us that this study also makes the point that there is risk in moving. Now, what are the facts with regard to this study?

Mr. KNIGHT. I do not have a study to that effect. I replied to you, sir, that we had some experience on those logistical challenges.

Mr. DINGELL. You have experience. I am asking for studies, not pious statements. I want to know what studies you have that will tell us. I don't like people coming before this committee to say, oh, this is a great thing to do, and that is what I am hearing this afternoon about what a great thing this is to do and we have got a head of steam. Let me read to you something. I would like to have you hear what my friend Pat Roberts had to say in this, and he was referring to his experience, and this is in regard to an exercise where he played the President in something called Crimson Sky.

Now, Crimson Sky was a misnomer label of what would happen if Iraq had launched a hoof-and-mouth disease infestation in some seven States. He goes on to say this: "Now, that doesn't sound like much on the surface of it but you have an infestation period of 6 days and on the 7th you have got to make some decisions, and we didn't do it very well. We ended up with 50 million head of livestock that had to be terminated. Now, how do you do that? Just on the surface of it, how on earth do you do that and what do you do with the carcasses? Well, obviously it was the National Guard, and then obviously the National Guard couldn't handle it all, so it was active duty. And then we found we didn't have enough ammunition and we found that you don't burn the carcasses, because that we learned in Great Britain, that is not what you do. So we had to bury them, and there was a ditch 25 miles long and half a football field wide in Kansas alone just to handle the herds there." And he goes on to say, "And then we had to put out a stop order on all shipments because you were having States and National Guards being activated by the governors to stop other States and transportation of livestock, all export stock. The markets went nuts and the people in the cities finally figured out that their food did come from farms and not from supermarkets, and they rioted in the streets and there was a mess. And it was not only for 1 year but for several years. Then add in the problem of food security, and if you put a little anthrax in some milk, then you have probably got a problem on your hands. Now, I want to know, I know that at that particular time when different events happen, that DOD will be there. They are going to have to be there because they are the only outfit that can do it. I prefer the National Guard because people know them and trust them. They are the home forces and they are working toward it."

This is what happens when anthrax, rather than foot-and-mouth disease, gets loose. So I want to be sure that you folks down there are protecting yourself. We had have had all kinds of releases from onshore facilities. You have had none at Plum Island, and I have got here a list of the instances where these kinds of things have gotten loose, but none has gotten loose at Plum Island. Plum Island became the place where we put things like foot-and-mouth because it is exquisitely dangerous. All there has to be is one contact and the disease moves from one animal to another and it goes like a wildfire across Kansas, and I don't want to see the same thing going across Kansas because we have made a bad judgment, and I want to see—that is why this committee wants to see your environmental impact statement.

You folks down at DHS have the idea that because you are charged with protecting the country, anything you do is right, and that you can go ahead and do whatever you want in whatever high-handed fashion you so choose. And I don't see any sign that you have been cooperative with the Committee in enabling us to evaluate what is going on or in seeing to it that you are carrying out your responsibilities in a proper fashion. You have been high-handed and arrogant in your dealing with the Government Accountability Office, and you have been uncooperative in assisting this committee with the information that we have sought from you. This has to stop, and I will inform you that there are pleasant

ways to work with this committee and there are unpleasant ways. We will give you the choice but you, sir, are going to work with this committee and we are going to see to it that the people are safe from the Department of Homeland Security whether you people like it or not. Now, you have already got a fine record on Katrina and I want to see to it that you don't have a fine record on foot-and-mouth disease.

Thank you, Mr. Chairman.

Mr. COHEN. Chairman, may I have just a moment to respond, please?

Mr. STUPAK. That is your choice. It is your risk.

Mr. COHEN. And I thank you for that guidance.

Mr. STUPAK. This is a risk assessment I am giving you.

Mr. COHEN. Yes, sir, and I won't ask you for it in writing, sir.

Chairman, I believe you get more flies with honey than vinegar and I have enormous——

Mr. DINGELL. We have asked for stuff and we have done it in a nice way and we haven't got it. So now we are going to use either the nice way or the nasty way. Your choice is before you. I must tell you, we are going to get the information.

Mr. COHEN. And I vote for the nice way, sir. Having said that, I appreciate your sharing the Crimson Sky. I am familiar with that. I have read that and I have had long discussions with Senator Roberts on that, and I will stipulate that the release of foot-and-mouth in the United States would have a very significant effect, tens of billions of dollars and years of impact, and we take that very, very seriously. I hope that I am not hearing you presuming or believing that I as the deciding official have made a decision to select any of the six, five on the mainland or Plum Island. I have not, sir, and I am under oath and I will only take that decision when the appropriate information and analysis is done in consultation with the six committees as well as the agriculture committees and your committee as you desire and with the leadership of Department of Homeland Security, HHS and USDA, and that is how we got to the down-select. Everything I have done has been testified to in other committees and the appropriations committees, which fund me and USDA, have found it in their heart in a bipartisan way to provide the tens of millions of dollars necessary to do this important work.

Mr. DINGELL. You are running around promising these facilities to a whole array of states. Every time I run over to the Floor, there is somebody saying to me, oh, we want this facility in our state. I have the governors of two states in to see me about this. They are saying oh, we want you to get out of the way so we can get this facility, and it sounds to me like what they are trying to do is to take a gamble on getting a lot of money or maybe foot-and-mouth getting loose. So Mr. Secretary, you can do a lot for yourself and for the trust that this committee has in you and in the Department, and right now it is a rather low level——

Mr. COHEN. Yes, sir.

Mr. DINGELL [continuing]. By seeing to it that your people cooperate with us in producing the information that this committee asked for.

Mr. COHEN. And I will do my very best, sir.

Mr. DINGELL. That will be a remarkable improvement, and I thank you.

Now, what are you going to do about this? GAO is reviewing these people. Are you going to make your decision before we have the GAO's review of your decisions and review of the papers that they have been not receiving from your department?

Mr. COHEN. They will receive them in a timely manner, as I indicated, when the Committee does and the public does. I have great respect for the Congressional Research Service and the GAO, and in fact, the GAO helped us significantly when they identified security and other problems previously at Plum Island, 24 areas that needed improvement. Eighteen have already been corrected and the other six are in process. So I respect the process. I respect the GAO. I would ask that they communicate a little bit more with me, but I respect the process and we will work with them, of course.

Mr. DINGELL. So are you going to wait on your decision until we have had the GAO review this matter or are you going to go right on ahead and make the decision before that occurs?

Mr. COHEN. We will share the information in a timely manner with the GAO but I will make the decision as I am authorized to either by the enabling legislation or by Secretary Chertoff and the secretary of the Department of Agriculture, and then of course the Congress controls all of this either by the Farm Bill, which I am very pleased to see you voted for, or by the appropriations, which the Founding Fathers gave you the power to stop whatever the Executive branch——

Mr. DINGELL. Your answer is yes or no?

Mr. COHEN. I do not put the Government Accountability Office in my decisionmaking chain. I will share with them.

Mr. DINGELL. I accept that as a no. Thank you, Mr. Secretary.

Mr. Chairman, I thank you for your courtesy.

Mr. STUPAK. Thank you, Mr. Dingell.

Mr. Pickering, questions?

Mr. PICKERING. Yes, Mr. Chairman.

Is there any statutory language requirement that GAO's recommendation to you be considered in your decision? Is there any law, regulation or proceeding that GAO's recommendation is binding or directive and a government's decision authorized under law and in the Farm Bill that you are the deciding official?

Mr. COHEN. I will have to take that for the record, sir. I think that is a question for the lawyers.

Mr. PICKERING. I am not aware of any statutory language, and I have been on Senate staff and here for a long time. I have never seen GAO be given the decision. They are to report to agencies and to us and based on their information, we take that information and then make our best decisions upon that. The GAO is not the deciding entity here. Is that correct? As you consult with your lawyers, is GAO, have they been tasked by any act of Congress to make this decision?

Mr. COHEN. Congressman, I am going to have to take that for the record. I am not a lawyer.

Mr. PICKERING. I think the answer is clear. But the Department of Homeland Security is the deciding entity as designated by law. The GAO as well as communities across the country are making

public comment in a very open and transparent process, and you are doing studies, and I think that will all be part of the record of the draft EIS. Is that correct?

Mr. COHEN. To the extent that we have completed those studies, yes, sir, and this process has been ongoing for several years. I have been personally involved now for nearly 2 years in a full and open manner around the country.

Mr. PICKERING. Now, one of the questions here is cost-benefit. The other question, major question, is risk assessment. On a cost-benefit basis, would it cost more to build and operate and maintain a new facility on Plum Island?

Mr. COHEN. We would have to determine the exact differential, but as you heard from the second panel, an individual from—Mr. Voogt, I think, from Michigan indicated that his experience building on an island was 30 to 40 percent. Our best estimate is, it would be about a 25 percent premium to build on Plum Island. Having said that, we would save on the transition from Plum Island to a mainland facility. I don't know what that differential would be. And then of course you have, as was indicated——

Mr. PICKERING. But that would be——

Mr. STUPAK. Would the gentleman yield on that point?

Mr. PICKERING. But all that would be in the EIS, would it not?

Mr. COHEN. Yes, sir.

Mr. STUPAK. Will the gentleman yield on that point?

Mr. PICKERING. Yes, if it doesn't take any of my time.

Mr. STUPAK. I will give you back the time. How is that?

You mentioned Mr. Voogt. You mentioned your estimation.

Mr. COHEN. Yes, sir.

Mr. STUPAK. But you have your own report, your SAIC report there, that says it is only 17 percent, 140 versus 130, so which one are you going to use to make your determination, the report you commissioned, Mr. Voogt, or your own estimation?

Mr. COHEN. Well, I am not making the decision at this hearing and I am not making the decision any time soon. I will make the decision——

Mr. STUPAK. In response to——

Mr. COHEN [continuing]. When I have all of the information in front of me and I can then come in front——

Mr. STUPAK. Well, in your answer, it sounded like you were relying on what Mr. Voogt said because he——

Mr. COHEN. Oh, no, I was using his——

Mr. STUPAK [continuing]. Has something to do with Beaver Island in Michigan and in your own judgment but——

Mr. COHEN. I apologize. The only reason I referenced that was to indicate that there is an additional cost to transporting building material, workers to an island. How much that it, we will find out. I also indicated——

Mr. STUPAK. Page 31 of tab 13, I would suggest you read it. It says 17 percent.

Mr. COHEN. I don't accept the 17 percent. I don't accept the 40 percent. I don't accept the 26 percent that Dr. Barrett has given to me. I will accept the validated real-time 2008 number based on the facts as we know them.

Mr. STUPAK. That is why we hope you have GAO, Government Accountability Office, help you with that before you make the decision because they are more the experts on it since you seem to have some confusion what number we should use.

Mr. COHEN. I think we have a number of experts available and I certainly welcome GAO to the process.

Mr. STUPAK. Thanks to the gentleman for yielding. We will make sure you get the time there.

Mr. PICKERING. Thank you, Mr. Chairman.

Going to the GAO study, on page 6, and I realize this just came out, you probably didn't have time to review it, and again, I don't think anybody is saying that a decision has been made one way or the other. I think that we are getting upset about something that is really not time to be upset about or the anxiety is premature, and the reason I say that, and correct me if I am wrong, we are going through an EIS over the next months. You are supposed to make a decision in October. But even after the site selection, the research done on a new facility, whether Plum Island or on the mainland, does not begin until 2015. Is that correct? So the analysis of getting this right, we have—this is part of making sure that we get it right, but no decision has been made and the analysis will be done.

But going back to the GAO study, it says previously DHS had stated categorically that the SAIC study allowed them to conclude that foot-and-mouth disease work can be done safely on the mainland, and they go on in the next sentence to say that the EIS analysis in supplementing are validating your studies will also be part of that. But for some reason GAO sees it in conflict. How do you interpret it?

Mr. COHEN. Well, GAO has not contacted me personally. I have no knowledge of who or when the statement relative to the 2002 SAIC USDA study was made and I stand by the testimony I have consistently made over the last year and a half before my committees and the testimony I am giving here today.

Mr. PICKERING. When is the draft EIS scheduled to be released?

Mr. COHEN. I would say about mid-June, sir.

Mr. PICKERING. Mid-June?

Mr. COHEN. Yes, sir.

Mr. PICKERING. Are you providing the draft EIS to the Committee before the publication of the draft EIS?

Mr. COHEN. It was my intent to provide it to the Committee similar to a contracting action with the release to the public. If there is law that indicates that I can provide it to the Committee in advance of public release, I welcome that input. I am not aware of that, sir.

Mr. PICKERING. Is this the issue, the proprietary issue of whether you can—when you view it as a contracting issue that you can give it to this committee prior to release to the public? Is that what we are——

Mr. COHEN. Well, for instance in Department of Defense, we inform the Committee one hour before public release. The Appropriations Committee and Homeland Security requires 4 working days notice of all responsible committees before there is a commitment of funds because I have not previously dealt with the Energy and

Commerce Committee or Oversight Committee in this case, I don't know if there is similar law. If the Committee can produce that, I will certainly comply with the law.

Mr. PICKERING. So this is not a question of whether you are going to be fully open and transparent, it is a question of when you can release the information to the Committee and to the public. Is that correct?

Mr. COHEN. That is exactly right, sir.

Mr. PICKERING. The last thing, sometimes we have a failure to communicate with agencies, with interagency processes or from the Hill to the agencies. It seems to me a meeting with GAO may clarify some of the concerns and give them a fuller understanding so that everybody can have greater confidence in the process as well as in the outcome. Would you be willing to meet with anybody from GAO?

Mr. COHEN. I am pleased to meet with anybody from GAO at any time, anywhere, and I will even host them, as I have hosted CRS investigators to lunch.

Mr. PICKERING. Well, I think that that could go a long way to resolving some of the anxiety and the concerns, and I thank the chairman for my time. Thank you.

Mr. STUPAK. Thank you, Mr. Pickering.

Mr. Moran, did you have some questions?

Mr. MORAN. Mr. Chairman, thank you very much again for your courtesy extended to me as a non-member of this committee. I just wanted to explore with both under secretaries what are the deficiencies with Plum Island that you anticipate correcting with a different site or a new facility?

Mr. COHEN. Well, again, as I said in my opening statement, I am very proud of the work that the people do at Plum Island, and our goal and my dream is that they will shortly develop an efficacious vaccine for foot-and-mouth disease because that is really what we are talking about, and we are investing over $50 million, have been over the last several years with the help of the Congress, we appreciate that very much, to expand the facility that exists at Plum Island for foot-and-mouth disease as well as making it more secure, but the goal is to be able to work on more than one vaccine at a time. Now, having said that, when the opportunity presented itself and the directions of HCPD 9 and 10 and working with the Congress, and also looking at other zoonotic diseases, foreign animal diseases, we have just focused—and I appreciate that, Chairman, so much. You focused on the foot-and-mouth, and I heard loud and clear your support and I know your committee feels that way about the need for the other developing potential diseases that go from animal to humans and cause a pandemic and great loss of life, as it has overseas. We need a BSL-4, this is where you don't have a cure or vaccine, for those studies. We don't need that for foot-and-mouth disease. There we use BSL-3 agricultural standard and we think that that has been sufficient. That is the standard around the world.

And so what we are looking to do to see if there are synergies, and we have made this very clear in the public in the offering by locating near veterinary schools, and I have learned there are only 30 veterinary schools in the country. That was a surprise to me.

I thought there would be more. Locating near to medical research facilities, locating where the cost of living is such. In the five mainland sites, the median cost of a home is on the order of half to a third the median cost of a home on the tip of Long Island or Connecticut. Now, how does that affect us? Dr. Barrett has indicated that we are successful in getting world-class scientists, and we are because we are doing such exciting work. But I have to hire dozens of large-animal handlers. They can't afford to live proximate to Plum Island, and if they are rushing to get home, will they make mistakes in their long commute, or they might be tired. So what we tried to do was see, could we in a holistic way come up with the best solution, be that on the mainland or on Plum Island. But that decision remains to be made.

Mr. KNIGHT. If I could augment from the USDA perspective, the attractiveness of a new NBAF facility has to do with the ability to conduct more research, to stay ahead of zoonotic diseases. We are very constrained on space today, need the additional work regardless of where that facility would be located, to be able to handle more diseases. We are primarily focused on FMD, almost exclusively on that today. There needs to be the ability to respond very quickly in the event of another foreign animal disease outbreak or to do basic applied research on those particular things.

The second thing that is highly important for us is the ability to have a state-of-the-art facility that we can go to for diagnostics because the frontline work that we do as it pertains to FMD or any foreign animal disease is when we have an accredited veterinarian, has a suspicious animal, be able to pull those samples and get that test run in a very quick manner so that we can contain the outbreak of any disease, whether it is a fast-acting disease like FMD or a low-acting disease like bovine tuberculosis.

Mr. COHEN. Congressman, if I may just add, I was so pleased with the second panel, I don't think you were here for it, but they indicated that in a terror world, and of course, before 9/11, we thought the United States was an island. I mean, we may have land borders on the north and the south but the blessings of geographically we thought protected us. We now understand that is not true. And so a comment that was made, and I think we have to reflect on this, is no matter where the site is, if a terrorist were to release FMD, it didn't come from the facility but we then have to prove a negative, and I want to share with the Committee how easy it is to transmit FMD, and this does not have FMD in it, sir. But this handkerchief, if I were in a country where there was an FMD-infected animal and I put it under their nose and I put it in my pocket and I flew across any of the oceans and I went up to a susceptible animal, there is a very high probability that animal would now be infected. That is how easy it is and that is why whenever we come back to the United States on our declarations form, we state have you been on a farm, ranch or pasture, and because of the problems that have been well stated here in England, have you been in close proximity such as touching or handling of livestock? So the concerns that this committee have raised are very valid and, candidly, sir, keep me up at night. Thank you.

Mr. DINGELL. Mr. Chairman, could I ask a question, please?

Mr. STUPAK. Yes, sir.

Mr. DINGELL. We have asked through the staff of both departments that we have made available to us any studies of costs of housing for employees at Plum Island or at any other facility. Again, those studies have not been made available to this committee. Do you have such studies? If so, where are they? And what do they say and when will they be made available to the Committee?

Mr. COHEN. Chairman, by the end of the day, you will have whatever information I have. It comes from the Department of Housing, obviously, because that is not my lane, and if that is not satisfactory, I will see as part of our EIS that we have definitive studies and we will make those available.

Mr. DINGELL. Now, let me ask you—you work for the Department, I gather. I sent a letter on September 20, 2007, almost 1 year ago, requesting this kind of information. None has made been available to the Committee. How am I to assume that this committee you are making is any better than your refusal to deliver the information requested on September 20?

Mr. COHEN. Well, Chairman, refusal is a very strong word. I actually have a picture in my office of me standing next to the cartons and cartons on pushcarts of the information that I have gladly provided——

Mr. DINGELL. Beloved friend——

Mr. COHEN [continuing]. To this committee.

Mr. DINGELL [continuing]. Let me explain to you the volumes of papers and the wonderful pictures that you might have of them do not move me.

Mr. COHEN. Yes, sir.

Mr. DINGELL. It is whether you are delivering to us those things which we are requesting.

Mr. COHEN. Yes, sir.

Mr. DINGELL. There is a substantial difference. I don't want a lot of your waste paper. I want the answers to the questions that the Committee asks you. You seem to have some difficulty in understanding that. If I am being unclear, please inform me so that we may be of greater assistance to you.

Mr. COHEN. Chairman, I don't believe there is anyone who does not understand your clarity, sir, and I do.

Mr. DINGELL. Thank you.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Dingell.

Just so the record is clear, there is no law indicating there has to be an NBAF; is there?

Mr. COHEN. Not to my knowledge, no, sir.

Mr. STUPAK. And there is no law that says we cannot keep Plum Island doing foot-and-mouth research on Plum Island but make your NBAF anywhere else; is there?

Mr. COHEN. That is correct.

Mr. STUPAK. In my opening statement, I said that the Department of Homeland Security had estimated it would cost approximately $450 million to build NBAF, and then I said the Committee has learned that your engineers, DHS engineers, have already raised that to between $600 and $750 million. Is that correct?

Mr. COHEN. I don't know what their estimate is. I don't know what the price of oil will be at the end of this hearing. This is going to be an expensive facility. You heard Under Secretary Knight talk about being world-class. This is one of the reasons why in our solicitation we have asked States and locals for offsets, incentives in kind and we are looking at if we were to move off Plum Island to utilize the sale of that land to save the taxpayers money to pay for the facility, but I assure you that in the end, this facility will cost less than a Navy destroyer.

Mr. STUPAK. Well, that is not real reassuring. We are familiar with the cost of a Navy destroyer. It is quite a bit of money.

Let me ask you this. It seems like this process started without giving a lot of thought to it. Wouldn't it have been logical to say do we keep Plum Island or not,; do we renovate, build new, then start looking on the mainland? It seems like you starting looking to the mainland and then after objections from committee and elsewhere, you went back to Plum Island, throw that in the mix again. Did we sort of get off on the wrong foot on this process?

Mr. COHEN. I can't address all of the history. I can tell you that I was sworn in on the 10th of August 2006. That was a memorable day. You may remember, that was the day the liquid explosives plot with British Airways and no carry-ons and the impact it had on the airlines. I do remember that on Friday, 11 August, the Congress contacted me bipartisan as to why I had not solved the liquid explosives problem. Now, we have the 3-1-1 rule, which is risk mitigation. It is not the solution. So on day 2 of my tenure, I understood the responsibility I had to the American public and to the Congress. That is the same responsibility that I put in place for NBAF. On 10 August, I had 12 States and 18 sites.

Mr. STUPAK. That is fine, August 10, 11, 12. My question didn't ask about any of that. My question was, don't you think we should have made the decision about what we were going to do with Plum Island before we move to the mainland? It appears from where we sit and the work we have done on this, this is our second hearing on biolabs and we are going to have more hearings on biolabs, that DHS received money to do biolabs and they didn't start making biolabs without cost-benefit analysis, risk assessment, whether they are necessary. The more labs you have and the more harmful materials you deal with, the more chance of human error, which leads to more problems. It seems like a bunch of money was given to DHS and they just started spending money without knowing if it is even necessary, and that is sort of what my question is being asked.

Mr. COHEN. Well, I think in the aftermath—and I think it is a very good question, Chairman. I think in the aftermath of 9/11, both the Administration and the Congress—I was in the Navy at the time but I watched this and I know going to New York right after 9/11, speaking with the police and dealing with Arlington police, there was a feeling that the major threats to us were nuclear, whether that was a dirty bomb or nuclear weapon, or biological, radiological. You know, right after 9/11, we were delivering death by the U.S. mail, anthrax. Now, while this facility won't look at anthrax, because it is naturally occurring, the 9/11 Commission report said that we suffered from a lack of imagination. I can tell you

based on my 10 August story to you, sir, that while I am responsible, my component will not suffer from a lack of imagination.

And so there is a focus on bio. What has issued from that is the NBAC, which is at Fort Dietrich. We are going to commission that this fall with the full support, bipartisan, of the Congress and in cooperation with the FBI. This is a CSI-like facility but it is a biological laboratory. If we had had that, I believe, in operation on 9/11, we might very well know who was responsible for the anthrax. We are also partnered with the Department of Defense and others at Aberdeen for receipt facility——

Mr. STUPAK. What basis——

Mr. COHEN [continuing]. The third one——

Mr. STUPAK. What basis do you say if we would have had these labs available that we would have been able to trace the source of the anthrax? What this committee has shown through our hearings so far, and this is our second one, money was given to DHS. You started building labs before anyone even considers if it is necessary to build more labs, or can the work be done at the current labs we have in this country? Instead, we are building labs all over the place where the experts are warning us, the more labs you build, the more people handling it, whether it is the Ebola, whether it is foot-and-mouth disease, the more problems you are going to have.

Mr. COHEN. First of all, I don't have an unlimited number of labs that I am building. I have just shared with you the three laboratories——

Mr. STUPAK. Well, I know at least four or five you have built already, DHS has built, without even a benefit or if it is even necessary. It seems like we are throwing money and building labs and hoping the problems will come. It should be the other way around. We should identify the problems and then build the labs we need.

Mr. COHEN. I am only knowledgeable of the labs which I have shared with you but I will tell you, as stated in the second panel, there is great concern that these laboratories might be terror targets, and for that reason, inherently governmental, we have a responsibility not only to make them efficacious but to make them secure, and that is why NBAC is on Fort Dietrich.

Mr. STUPAK. And the second panel unanimously said to a question I asked each one of them, they would rather not have Department of Homeland Security deal with this. They would rather have USDA deal with it because they feel they have more expertise.

Mr. COHEN. And Chairman, I agree with them. I am the tenant. I am the caretaker. I am the steward. Because the reason I believe we created the Department of Homeland Security, this incredible experiment in nuclear fusion of 22 very disparate agencies, was to eliminate or minimize seams. I am very pleased to be the steward for my tenant, USDA, who does the research at Plum Island. I think that has significant advantages in a terror-enabled world.

Mr. STUPAK. And it also under H.R. 1717 which expands your authority in areas of agriculture. We think that, at least some of us feel, Ag. should do it, not DHS.

Mr. KNIGHT. And from the Department of Agriculture, if I might add, we are very comfortable with the relationship that has evolved since the authorities were provided in the creation of DHS. This has worked very well with them as the landlord taking care of

many of those logistics. Adding the skills that DHS brings to the table has freed up our USDA folks to focus on the core research needs, especially on FMD.

Mr. STUPAK. I am not arguing that. What we are arguing is, shouldn't you have made the decision on Plum Island before you started going to mainland and everything? It seems like we got the cart before the horse, the disease before the animal, whatever it is.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Secretary Knight, you were here for all the other panels. I posed a question about the timeliness of information and the exponential risks that could occur. Can you speak to that or—am I right, or just kind of add to——

Mr. KNIGHT. We have had some real-life experiences in the last year that are worthy of consideration in this process. About a year ago, we had a potential concern that we may have had FMD at a packing facility. The hogs were found with lesions on their face. It had all the signs, the visible signs of FMD. We needed to extract samples, get those to a lab to be—for diagnosis. We can only do that at Plum Island, and so we then lost many hours in the effort it took to actually get those physical samples to Plum Island. If I recall correctly, we had fog at the airport, closure there. Then we had the logistics of getting it over there. So there are some legitimate concerns associated with that facility and its ability to get samples to and bring out the results very quickly.

Mr. SHIMKUS. The new facility will not be operational until at least 2015. What do you propose to do in the meantime to ensure that America is protected from foreign animal diseases? So that brings in a lot of options—renovate Plum Island, begin preliminary research elsewhere, and then the follow-up question is, why the immediate need for a new NBAF? Secretary Cohen?

Mr. COHEN. Yes, sir. You know, terror doesn't take a holiday and they don't want for our building schedule, and this is why we have invested and are investing with the help of the Congress, and I appreciate that very much, over $50 million in Plum Island. We are doubling their capacity hopefully to get—and Dr. Barrett may want to address this more—possibly investigation for two efficacious vaccines and continue to build the workforce that is so critically important because it is about the people.

In terms of other diseases, we will have to look hard at what BSL facilities exist, what authorities we have. As was indicated earlier in the testimony, some of the BSL-4 that are looking at smaller primates already exist at universities and elsewhere. CDC, NIH, HHS, of course, are focused on those but these would be responsibilities that we would pursue once we had the NBAF.

Mr. KNIGHT. From a USDA perspective, certainly the potential of the disease risk is a constant. That is what keeps all of us in the Administration up at night and worried about that. Our first line of defense is generally border security, the work that is done. USDA provides an underlying information policy in support to Customs and Border Protection for that first line of defense. Then if there is a potential outbreak, we are building at USDA systems to be able to respond quickly, a national animal ID system that has been highly controversial but extremely important in being able to

build the baseline to be able to notify farmers and ranchers of a disease outbreak in a very quick manner. We also work in capacity building with our partners at the state level, the state veterinarians who are on the front line of making decisions with us, putting barriers up for movement of animals, each of those things. So we make that investment on a daily basis, on a weekly basis. That will continue to be there. That is one of the most important things we need. We need NBAF so that we can anticipate what are the next dangerous diseases out there that we need diagnostic tests for, be able to develop those tests. We need NBAF to be able to do the research for eradication of those diseases around the globe, not just in the United States.

Mr. SHIMKUS. Dr. Barrett, do you want to add to this?

Dr. BARRETT. Well, I was just wanting to make a comment that this is going back to the question, is it safe to move this to the mainland, and I would just like to say that there is risk in any operation, but if you go to the GAO report and you look at the listings of the 15 or so laboratories where there has been release of FMD. They took that from the Pirbright report and they left out one column. The column that they left out was the column that identified that every one of those releases except the top two that occurred in 1960 were the result of the production of live virus vaccine for foot-and-mouth disease. We don't even make live virus for foot-and-mouth disease because of that. We don't make foot-and-mouth disease vaccine in this country. So all of those were associated with the production of foot-and-mouth disease vaccine. In the new NBAF, we will not be producing foot-and-mouth disease vaccine. In fact, there will be a small vaccine capability in it, about 8 gallons, and that will be used for basically new vaccines going into development and then our scientists can test it there and then take them on into production. So the danger in these labs and the reason you had all these releases, because of making live virus vaccine with foot-and-mouth. In the future, we are not going to do that. Our new vaccine that we are producing right now and we are making in the United States, if it escapes, it doesn't infect the cow; it doesn't cause foot-and-mouth disease.

So I feel that you can move this safely to the mainland, and the reason is it is just like Under Secretary Knight is saying, this laboratory is part of this nation's emergency response system. If you see cattle out on the field and they have blisters on them, and as a veterinarian, you want to get that tested, you have to send it to this lab. I was in California working on the foot-and-mouth disease plan. I was at a meeting and the USDA veterinarian was there, and I had also, because I worked in public health, I was involved in developing our bioterrorism response plans. We can diagnose smallpox in California in 24 hours. In California, to get a diagnosis of foot-and-mouth disease, you have to send it to Plum Island across the country. We need to get the technology and the diagnostics out to these States so they can test it, but right now until we get that capability and that science, it exists at Plum Island. Plum Island is a great facility. As the director, I am proud to work there. My goal is to get a vaccine out and protect the livestock of this country. At the same time, to move this facility on the mainland provides a lot of protection too.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Mr. STUPAK. The same would be true no matter where it is. There could be a hurricane in Texas or the Carolinas or wherever we are going to put it, right?

Dr. BARRETT. Yes, there are always things that you have to take a risk. I mean, I basically took risk management off the Air Force flight line, put it in a model for food security that the FDA adopted and they use it for food security in this Nation. I am very well aware of risk assessment.

Mr. STUPAK. So there is a guarantee against 103 different, 90 percent being human errors.

Dr. BARRETT. We had seven cross-contaminations in Plum Island. Those cross-contaminations were within our primary laboratory environment. That is a box in a box. To get out of that facility, our researchers who work in there, to leave that, they have to take a shower and they have to change their clothes and they have to blow their nose. Our animal caretakers get two showers a day and get to blow their nose twice.

Mr. STUPAK. And that is no matter where they are located.

Dr. BARRETT. Right, and one of the things I wanted to add in of why I am so—about this issue earlier when I was giving my testimony, when I go out and see my dad's cattle, they are registered Herefords, and he tells me when he looks at those cows, I have to listen to him tell me the mother that was 20 years ago that was that cow, and so if you go in and you kill that herd off it is not coming back. You cannot—that is 50 years of genetic improvement. It is not coming back. We need to move forward in this country and develop a vaccine that we can effectively vaccinate our cattle to live with. Dr. Carpenter, who was sitting in this chair today, pointed out that in his paper, in his publication, he showed that if you vaccinate cattle, you can reduce this by 98 percent an outbreak.

Mr. STUPAK. Sure. That is why maybe we should leave it at Plum Island and continue the good work we are doing there.

Dr. BARRETT. I would love it to be at Plum Island. I just want a vaccine.

Mr. COHEN. Chairman, if I may, I would just like to share with the Committee that we resource Dr. Carpenter's research.

Mr. STUPAK. Mr. Pickering, questions?

Mr. PICKERING. Yes. Thank you, Mr. Chairman.

Dr. Barrett, I just want to understand what you just said just a little bit back in your answer. GAO raised the question of outbreaks but in those cases, it dealt with the outbreaks related to an FMD vaccine or doing the research. Is that correct?

Dr. BARRETT. Yes. What they left out, they left out one column in that report. They took that from the Pirbright report and they left out the one column. The column they left out was the one that showed that the outbreaks were related to live virus vaccine manufacturing release, which occurs. At Pirbright, the release didn't occur from their laboratory. It occurred from Merial, who was producing vaccine there because it matched that strain, and if somebody takes and releases——

Mr. PICKERING. Dr. Barrett, would you say the GAO leaving that out or not understanding that and that distinctive difference and the fact that whether at Plum Island or any of the new sites, we

are not going to be doing vaccines, that is extremely significant in the GAO review?

Dr. BARRETT. Yes.

Mr. PICKERING. I think that is probably one of the most significant things that we have heard today, that the hype of the risk was really based on a misunderstanding of the causes of outbreaks in other cases that has nothing to do with the new NBAF, whether it is at Plum Island or another site.

Mr. Knight, you talked about working with veterinarians and I know, Dr. Barrett, you are a veterinarian. The American Veterinary Medical Association has come out, and I would think that these are the most knowledgeable, the most involved, the ones with the most practical experience, the ones working with your father and building up his herd, and they are saying that you can do this site safely on the mainland. Dr. Barrett, what I hear from Mr. Cohen is that he is looking for the cost effectiveness of doing the research so that we can get to the vaccine that you hope for, and if we spend more money on facilities than in research, we are delaying that day of getting to the prize.

Dr. BARRETT. And I would just like to add in that Dr. Ron De Haven, he used to be the administrator for APHIS, now works for AVMA. He is in charge of those programs that helped make that decision.

Mr. PICKERING. Well, thank you, and I think it is extremely significant that GAO misunderstood and they increased their assessment of risk based on not knowing what the research is all about, and with that, I yield back, Mr. Chairman.

Mr. STUPAK. That is fine. What GAO missed, I guess we should let GAO speak for themselves on that one.

Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you. I have known since I arrived in Congress 12 years ago the desirability of serving on the Commerce Committee, and it has been highlighted for me today. I have missed something and probably too late in my time in Congress to start over in building up my seniority, but I understand the value of this committee and particularly this Oversight Subcommittee, and again I express my appreciation to you, Mr. Chairman, for allowing me to join you. I just had——

Mr. STUPAK. Well, let me interrupt you one minute. Back to Mr. Pickering's point, GAO report, page 13, they didn't leave it out. They didn't miss it. Table 2 lists known and attributed releases of FMD viruses from laboratories worldwide including those that produce vaccines, so GAO did take it into consideration. I knew that wasn't right.

Mr. PICKERING. Would the chairman yield?

Mr. STUPAK. You bet.

Mr. PICKERING. Did they know that the new NBAF would not be doing the vaccine?

Dr. BARRETT. We told Dr. Sharma and the GAO that when they visited us.

Mr. PICKERING. Thank you. I yield back.

Mr. STUPAK. Go ahead, Mr. Moran.

Mr. MORAN. Thank you, Mr. Chairman. I will now recognize that when I provide a compliment to you that you are not paying any attention, so I will forego any compliments.

But I want to follow up, and in part it is in regard to questions that you were raising that caused me to think about this. Recently I had a member of my staff visit Plum Island to get an understanding of what transpires there, how it operates, and I hope to do that myself, but one of the things that my staff member reported upon his return was that the workers, the local folks that they visited with were unwilling or uninterested in having the facility at Plum Island upgraded or its abilities enhanced from the BSL-3 to BSL-4 and reported that their Members of Congress would oppose that kind of upgrade. Is that anything that is of the record or is that just speculation? And I can understand perhaps where that comes from with its location so close to New York City and Connecticut that there obviously—maybe it is not obvious—that there could be concern with that about increasing the nature of that facility. Is that something that is an accurate assessment of local sentiments and Members of Congress who represent that sentiment?

Dr. BARRETT. We had recently a community forum as part of the NBAF process because Scott Russell, who is Southold Town Supervisor, wanted us to have it to speak to the community. When we spoke there, there were a lot of concerned citizens about having it there, and Congressman Bishop, I visited with him. He is concerned with his constituents having those concerns. One of the things that we are doing at Plum Island is we are having community day.

Mr. STUPAK. But did you explain to them you don't need a BSL-4 lab to foot-and-mouth disease, you only need a level 3 lab?

Dr. BARRETT. That is a concern that the community has is BSL-4.

Mr. STUPAK. And you don't need 4 to do foot-and-mouth?

Dr. BARRETT. No, we don't need 4 to do foot-and-mouth.

Mr. MORAN. Mr. Chairman, that was in a sense my follow-up question, which was that there is a consensus that we need a 4 laboratory. I mean, that is what this process is all about?

Dr. BARRETT. We definitely need a biolevel-4 laboratory for this, yes, we do. We do not have one in this country for livestock.

Mr. MORAN. Mr. Chairman, thank you.

Mr. STUPAK. Well, I thank both of you for sitting through this day, and you are always welcome at the Committee, so thanks.

Let me just ask one last question. Zoonotics, who is in charge of that, DHS, HHS, CDC? Who is in charge?

Dr. BARRETT. Two agencies, because zoonotic means communicable from animals to people. CDC will take care of the person. We take care of the animal side of it.

Mr. STUPAK. By "we" do you mean USDA or DHS?

Dr. BARRETT. Centers for Disease Control does the humans. USDA does the animals.

Mr. STUPAK. OK.

Dr. BARRETT. But they have to work together as partners because these diseases like avian influenza, West Nile, you have to

work together and use the animal model. And basically zoonotic diseases, you prevent them by keeping it out of the animals.

Mr. STUPAK. Well, Secretary Cohen had mentioned it, so I just wanted to make sure that was clear. I was a little confused on that one. OK.

Any other questions? If not, I will thank and dismiss this panel. Thank you very much for being here.

Mr. COHEN. And Chairman, we thank you for being part of this process.

Mr. STUPAK. It is a process that is going to go on a little longer, I am afraid.

That concludes all questioning. I want to thank all of our witnesses for coming today and for their testimony. I ask unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open.

I ask unanimous consent that contents of our document binder be entered into the record. Without objection, the documents will be entered in the record.

This concludes our hearing, and without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 3:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. GENE GREEN

Mr. Chairman, thank you for holding this hearing today on moving the study of foot and mouth disease from Plum Island, New York to the mainland US.

Food and mouth disease is the most contagious animal infection. It can travel by the air, through saliva, and on a person. It affects cloven-hoofed animals such as cattle, pigs, sheep, goats, and deer. Food and mouth disease is not usually fatal, but it will cause severe weight loss, hoof deformation, breeding problems, and diabetes.

When animals become infected with hoof and mouth disease, the usual course of action to stop the inevitable spread of the virus is to slaughter all of the animals in the infected area because it is almost guaranteed that all animals in the area will contract foot and mouth disease and it will spread at an alarming rate.

For 60 years researchers have been studying food and mouth disease at Plum Island Animal Disease Center. Everyone agrees the facility is outdated and in need of updating.

The Department of Homeland Security proposed opening a new National Bio and Agro Defense Facility (NBAF) on the mainland US instead of updating the Plum Island facility.

Supporters of the move to the mainland cite increased costs in shipping supplies to an island, updated technology to contain the disease, and difficulty recruiting scientists to work on Plum Island.

However, supporters of the Plum Island location cite the water barrier as the only way to keep foot and mouth disease safely contained.

The proposed NBAF would be the world's largest animal disease research center and have a Biosafety Level 4 Lab. Currently, 5 sites are being considered for the new NBAF lab including one associated with UT in San Antonio.

I look forward to the testimony from our witnesses today so that we may gain a greater understanding of the risks and benefits associated locating an NBAF lab on the mainland US.

Thank you Mr. Chairman, I yield back my time.

American Farmers & Ranchers Mutual Insurance Co.

RAY L. WULF, President
Chief Executive Officer

June 2, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight & Investigations
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Dingell and Chairman Stupak:

On behalf of American Farmers & Ranchers I want to thank you for the opportunity to testify on May 22, 2008 in the Germs, Viruses, and Secrets: Government Plans to Move Exotic Disease Research to the Mainland United States. We applaud the efforts of the Subcommittee on Oversight and Investigations for holding these very important hearings.

AFR represents approximately 100,000 family memberships in Oklahoma alone. Farmers and ranchers are price takers, not price makers. This not only comes into play with an outbreak but also in regard to the Chairman's question on rather the agriculture industry should pay for part of the costs involved in this research facility. An answer was given that the consumer will pay for the cost either through increased meat prices or through the government. If producers are assessed a fee to provide research or a research facility they will NOT be able to pass that cost on to the consumer, and the middle-man (e.g. the packers) will not compensate producers for the cost, that is simply not how the industry works. The cost will be the burden of the producer. It was also stated that the issue that was raised by the Chairman was, "not important." We represent farmers and ranchers and we are certain they would say that cost is a very important issue, and one that cannot be passed on in the value chain.

I apologize for exceeding my time limit for my opening comments. I had not located the clock which was behind the water pitcher and time got away from me as I spoke. We hope the information we provided was beneficial. Again we thank you for the opportunity to testify and your attention to this very important issue.

Sincerely,

Ray L. Wulf
President & CEO

Post-it® Fax Note 7671	Date 6/3/08	# of pages ▶ 1
To John Dingell	From Ray Wulf	
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Plum Island
Animal Disease Control Center

34 of 35 DOCUMENTS

FDCH Political Transcripts

March 14, 2003 Friday

CHAIRMAN HOLDS HEARING ON THE FY2004 DEFENSE AUTHORIZATION: JOINT FORCES COMMAND

LENGTH: 16161 words

COMMITTEE: SENATE ARMED SERVICES SUBCOMMITTEE ON EMERGING THREATS SUBCOMMITTEE

SPEAKER:
CHAIRMAN

LOCATION: WASHINGTON, D.C.

WITNESSES:

VICE ADMIRAL ARTHUR K. CEBROWSKI, PRESIDENT, NAVAL WAR COLLEGE, DEPARTMENT OF THE NAVY
VICE ADMIRAL EDMUND P. GIAMBASTIANI, JR., COMMANDER SUBMARINE FORCE, U.S. ATLANTIC FLEET COMMANDER SUBMARINES, ALLIED COMMAND ATLANTIC

U.S. SENATE ARMED SERVICES COMMITTEE: SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES HOLDS A HEARING

MARCH 14, 2003

SPEAKERS:
U.S. SENATOR **PAT ROBERTS** (R-KS)
CHAIRMAN
U.S. SENATOR WAYNE ALLARD (R-CO)
U.S. SENATOR SUSAN COLLINS (R-ME)
U.S. SENATOR JOHN ENSIGN (R-NV)
U.S. SENATOR JAMES TALENT (R-MO)
U.S. SENATOR SAXBY CHAMBLISS (R-GA)
U.S. SENATOR LINDSEY GRAHAM (R-SC)
U.S. SENATOR ELIZABETH DOLE (R-NC)
U.S. SENATOR JOHN CORNYN (R-TX)

U.S. SENATOR JACK REED (D-RI)
RANKING MEMBER
U.S. SENATOR EDWARD KENNEDY (D-MA)
U.S. SENATOR ROBERT BYRD (D-WV)
U.S. SENATOR JOSEPH LIEBERMAN (D-CT)
U.S. SENATOR DANIEL AKAKA (D-HI)
U.S. SENATOR BILL NELSON (D-FL)
U.S. SENATOR EVAN BAYH (D-IN)
U.S. SENATOR HILLARY RODHAM CLINTON (D-NY)

March 28, 2003

U.S. SENATOR PAT ROBERTS (R-KS) HOLDS A HEARING WITH ADMIRAL ARTHUR CEBROWSKI AND ADMIRAL EDMUND GIAMBASTIANI SENATE ARMED SERVICES EMERGING THREATS SUBCOMMITTEE

Senator Roberts, commenting on the Crimson Sky exercise:

"But if you get into homeland security and the threats that could happen, one of the things that fell into my lap when they couldn't find anybody else to do it, is that I played the president under an exercise called Crimson Sky (ph) with the Department of Agriculture. Now Crimson Sky (ph) was the misnomer label of what would happen if Iraq had launched a hoof and mouth disease infection in the United States in seven states."

"Now, that doesn't sound like much on the surface of it. But you have an infestation period of six days, and on the seven day, you've got to make some decisions, and we didn't do very well. We ended up with 50 million head of livestock that had to be terminated. How do you do that? Just on the surface of it? How on earth do you do that and what do you do with the carcasses? Well, obviously, it was the National Guard. And then, obviously, the National Guard couldn't handle it all so it was active duty. And then we found out we didn't have enough ammunition, and we found out you don't burn the carcasses, because that -- we learned in Great Britain that's not what you do. So you had bury them and there was a ditch 25 miles long and a half a football field wide in Kansas alone, just to handle the herds there."

"And then we had to put a stop order on all shipments, because you were having states and National Guards being activated by the governors to stop other states and transportation of livestock. All exports stopped, the markets went nuts, and the people in the cities finally figured out that their food did come from farms, and not supermarkets, and they rioted in the streets. And it was a mess."

#	Description	Date
	Background Information	
1	Congressional Research Service report, subject: "The National Bio- and Agro-Defense Facility."	05/19/2008
	News Articles	
2	Ag Journal article by Candace Krebs, "Foot and Mouth Disease Outbreak Spotlights Research Lab Risks."	08/15/2007
3	Science Magazine/AAAS article, "Reports Blame Animal Health Lab in Foot-and-Mouth Whodunit."	09/14/2007
4	Dallas Morning News article by Emily Ramshaw, "Animal Virus Research May Move Ashore Some Fear for Livestock as Texas Site Vies to Replace Island Facility."	11/12/2007
5	Associated Press article by Larry Margasak, "Dangerous Animal Virus on U.S. Mainland?"	04/11/2008
6	Memo to Secretary of Agriculture, "Replacement of the Plum Island Animal Disease Center"	04/27/2005
7	USDA After-Action Report on 1978 release of foot-and-mouth disease on Plum Island.	01/09/1979
8	USDA Summary of Crimson Sky Simulation (a simulation exercise of a foot-and-mouth disease outbreak in Kansas).	09/30/2002
9	Study by Biodefense Knowledge Center (at Lawrence Livermore) of possible exposure of cattle to a disease release at proposed NBAF sites.	08/06/2007
10	Study by Biodefense Knowledge Center (at Lawrence Livermore) of U.S. Government options for responding to a foot-and-mouth disease release in the U.S.	
11	Rand Corporation, Science and Technology Policy Institute report, Summary of Blue Ribbon Panel on The Threat of Biological Terrorism Directed Against Livestock (cited by DHS as indicating the need for the NBAF).	April 2004
12	SAIC 2002 Biocontainment Feasibility Study performed for USDA, "Biosafety Level 4 Facility." (Summary and Index only, full document can be found within the Subcommittee's files)	08/15/2002
13	SAIC 2002 Biocontainment Feasibility Study performed for USDA, "Plum Island Animal Disease Center." (Summary and Index only, full document can be found within the Subcommittee's files)	08/15/2002
	Livestock Association Correspondence	
14	Summary of Replies from Livestock Associations	

15	American Veal Association	02/27/2008
16	Kansas Livestock Association	03/11/2008
17	National Cattlemen's Beef Association	02/29/2008
18	South Dakota Cattlemen's Association	03/11/2008
19	American Farmers & Ranchers	03/11/2008
20	Missouri Cattlemen's Association	03/11/2008
21	National Milk Producers Federation	03/04/2008
22	North Dakota Stockmen's Association	03/06/2008
23	Oregon Cattlemen's Association	03/13/2008
24	South Carolina Cattlemen's Association	03/04/2008
25	Wyoming Stock Growers Association	03/07/2008
26	Illinois Pork Producers Association	03/11/2008
27	Iowa Pork Producers Association	03/11/2008
28	Mississippi Pork Producers Association, Inc.	03/24/2008
29	National Pork Board	03/10/2008
30	National Pork Producers Council	03/11/2008
31	New York Pork Producers, Inc.	03/10/2008
32	Pennsylvania Pork Producers Council	03/11/2008
33	Texas Associations	03/11/2008
34	Wisconsin Pork Association	03/13/2008
35	Letter to the Committee on Agriculture Chairman Peterson and Ranking Member Goodlatte on Farm Bill Provision to Relocate Plum Island, N.Y., Laboratory to the Mainland	04/29/2008
36	H.R. 1717, text, "To amend the Homeland Security Act of 2002 to establish a National Bio and Agro-defense Facility."	03/27/2007
37	21 U.S.C. 113a.	
38	Farm Bill Section 7524	
39	HHS Comments on H.R. 1717 - National Bio and Agro-Defense Facility	
40	Testimony of Dr. John Vitko, Jr., Science & Technology Directorate of DHS, before the Committee on Homeland Security.	05/23/2007
41	Testimony of Dr. Edward Knipling, Agricultural Research Service of USDA, before the Committee on Homeland Security.	05/23/2007
42	Dingell-Stupak Letter to USDA Acting Secretary Charles Conner, re: relocation of PIADC.	09/20/2007
43	Dingell-Stupak Letter to DHS Secretary Michael Chertoff, re: relocation of PIADC.	09/20/2007
44	Dingell-Stupak Letter to DHS Secretary Michael Chertoff requesting information related to the proposed closure of the Plum Island Animal Disease Center.	02/21/2008
45	Dingell-Stupal Letter to DHS Secretary Michael Chertoff requesting further information, follow up.	04/03/2008

Order Code RL34160

CRS Report for Congress

The National Bio- and Agro-Defense Facility: Issues for Congress

Updated May 19, 2008

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Congressional
Research
Service

The National Bio- and Agro-Defense Facility: Issues for Congress

Summary

The agricultural and food infrastructure of the United States is potentially susceptible to terrorist attack using biological pathogens. In addition to the impacts of such an attack on the economy, some animal diseases could potentially be transmitted to humans. These diseases are known as zoonotic diseases. Scientific and medical research on plant and animal diseases may lead to the discovery and development of new diagnostics and countermeasures, reducing the risk and impact of a successful terrorist attack.

To safeguard the United States against animal disease, Congress has appropriated funds to the U.S. Department of Agriculture (USDA) to engage in research at the Plum Island Animal Disease Center (PIADC), off the coast of New York, on animal diseases not native to the United States. When creating the Department of Homeland Security (DHS) in 2003, Congress transferred the PIADC facility from USDA to DHS. Both USDA and DHS, in cooperation with USDA, conduct foreign animal disease research at PIADC, but PIADC has been identified as outdated and too limited to continue as the primary facility for this research.

Homeland Security Presidential Directive 9 tasks the Secretaries of Agriculture and Homeland Security to develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories for research and development of diagnostic capabilities and medical countermeasures for foreign animal and zoonotic diseases. To partially meet these obligations, DHS has requested Congress to appropriate funds to construct a new facility, the National Bio- and Agro-Defense Facility (NBAF). This facility would house high-containment laboratories able to handle the pathogens currently under investigation at PIADC, as well as other pathogens of interest. Six candidate sites have been identified, one of which is Plum Island. The DHS plans to select the site in 2008 and open NBAF in 2014. The final construction cost will depend on the site location and may exceed the $451 million projected total cost. Additional expenses, such as equipping the new facility, relocating existing personnel and programs, and preparing the PIADC facility for disposition, may reach an additional $100 million. The DHS has not yet determined what actions to take with the PIADC when construction of the NBAF is completed.

The plans announced by DHS to establish the NBAF have raised several issues. Community concerns about safety and security, previously raised about PIADC and other laboratories being built to study dangerous pathogens, are also being raised about the NBAF. Coordination between DHS and USDA, as well as prioritization and investment in agricultural biodefense, may be reassessed once more high-containment laboratory space becomes available.

By law, research on live foot and mouth disease (FMD) virus is not permitted on the U.S. mainland. This policy would need to be changed before DHS could conduct FMD research at NBAF if it were sited on the U.S. mainland. The conference agreement to the 2008 farm bill, H.R. 2419, as well as H.R. 1717, address possession of live FMD virus by DHS.

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The National Bio- and Agro-Defense Facility: Issues for Congress

Introduction

The agricultural and food infrastructure of the United States is a key component of economic productivity and growth. A terrorist attack on this infrastructure could damage the public trust in agricultural safety and quality and the nation's ability to provide food and other agricultural products.[1] Additionally, many animal diseases can infect humans.[2] These types of diseases are termed *zoonotic*. Scientific and medical understanding of such zoonotic diseases in their animal hosts may protect the animals themselves and could also lead to the discovery and development of new medical countermeasures for humans.

To safeguard the United States against the impacts of naturally occurring and intentional animal disease outbreaks, the U.S. Department of Agriculture (USDA) engages in animal disease research, including research into highly contagious animal pathogens and animal diseases not native to the United States.[3] Such research activities have historically been performed at the Plum Island Animal Disease Center (PIADC), located on an island near Long Island, NY.

When creating the Department of Homeland Security (DHS) in 2003, Congress transferred the operation of the PIADC facility from USDA to DHS, though USDA still maintains an active research program at PIADC. The DHS, in cooperation with USDA, has established its own research and development program at PIADC. As the federal government undertakes new efforts in human biodefense and defense against agroterrorism, DHS has identified the PIADC facility as "reaching the end of its life cycle" and lacking critical capabilities to continue as the primary facility performing this research.[4]

Homeland Security Presidential Directive 9 (HSPD-9) tasks the Secretaries of Agriculture and Homeland Security to develop "a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop

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[1] For more background on the potential of terrorism against agriculture and food, see CRS Report RL32521, *Agroterrorism: Threats and Preparedness*, by Jim Monke.

[2] Examples include influenza, plague, West Nile Virus, and Rift Valley Fever.

[3] These diseases are sometimes referred to as foreign animal diseases (FAD).

[4] Department of Homeland Security, FY2006 Science and Technology Directorate congressional budget justification, p. 44.

diagnostic capabilities for foreign animal and zoonotic diseases."[5] The Secretary of Homeland Security is to coordinate an acceleration and expansion of the development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases, including

> countermeasure research and development of new methods for detection, prevention technologies, agent characterization, and dose response relationships for high-consequence agents in the food and the water supply.[6]

The Department of Homeland Security has announced that, to meet the obligations of HSPD-9, it will establish a new facility, the National Bio- and Agro-Defense Facility (NBAF).[7] This facility would have high-containment laboratories able to hold the pathogens currently under investigation at PIADC as well as other pathogens of interest. The plans announced by DHS to establish the NBAF have raised congressional and public concerns regarding its safety and security and policy questions about coordination between DHS and USDA regarding the research to be conducted at NBAF.

The DHS has narrowed the number of possible sites for the NBAF to six. The sites are located in Athens, GA; Manhattan, KS; Madison County, MS; Granville County, NC; San Antonio, TX; and Plum Island, NY.[8] Each site is currently preparing an Environmental Impact Statement for the location.

This report outlines current progress towards establishment of the NBAF, presents current and projected funding levels and timelines, and describes policy issues of potential interest to Congress, such as agency coordination, possession of viruses, construction timelines, disposition of PIADC, and community safety concerns.

NBAF Research Goals

The DHS intends the new NBAF to be more than just a replacement facility for PIADC; DHS intends it to exceed both the capacity and capabilities of the existing Plum Island laboratories. The highest level of biocontainment available at PIADC is Biosafety Level 3 Agricultural (BSL-3Ag).[9] Because DHS plans to perform

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[5] Executive Office of the President, The White House, "Subject: Defense of United States Agriculture and Food," *Homeland Security Presidential Directive/HSPD-9*, January 30, 2004.

[6] Ibid.

[7] 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

[8] 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

[9] Biosafety levels for pathogens and the recommended protective measures at each biosafety level are developed by the Department of Health and Human Services. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories,* 5th Edition,

(continued...)

experiments with some pathogens that require a higher level of protection, approximately 10% of the NBAF's net square footage would be BSL-4 laboratories.[10]

The DHS foresees multiple uses and goals for the new facility:

- serving as a unique BSL-3 and BSL-4 livestock laboratory capable of developing countermeasures for foreign animal diseases;
- providing advanced test and evaluation capability for threat detection, vulnerability assessment, and countermeasure assessment for animal and zoonotic diseases; and
- supporting countermeasure licensure.[11]

The research agenda for NBAF is to be at least partially based on current risk assessments and subject to change as the risk assessments change. The DHS predicts that the facility will focus on foot and mouth disease (FMD), classical swine fever, African swine fever, Rift Valley fever, Nipah virus, Hendra virus, contagious bovine pleuropneumonia, and Japanese encephalitis.[12] The DHS plans to perform research at NBAF to study how these pathogens enter the animal, what types of cell the disease affects, what effects the disease has on cells and animals, and how newly developed countermeasures help the animal develop protection against the disease.

NBAF Funding and Site Selection

Funding

In the DHS Science and Technology FY2006 congressional budget justification, DHS provided a NBAF project schedule that included a summary of major milestones, a projected time line for meeting the milestones, and projected funding

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[9] (...continued)
February 2007, available online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm]. The BSL-3Ag containment level was established by the USDA for research with certain pathogens in large animal species. U.S. Department of Agriculture, Agricultural Research Service, *ARS Facilities Design Standards*, 242.1-M ARS, July 24, 2002, available online at [http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf].

[10] For example, research on Nipah virus must be performed in a BSL-4 laboratory. Since the United States has limited space to perform large animal research under BSL-4 containment, U.S. scientists have gone outside the country, for example to Canada, to conduct such experiments. Testimony by James Roth, Director, Center for Food Security and Public Health, Iowa State University, before the Senate Committee on Agriculture, Nutrition, and Forestry, on July 20, 2005, available online at [http://agriculture.senate.gov/Hearings/hearings.cfm?hearingid=1572&witnessId=4472].

[11] 71 *Fed. Reg.* 3107-3109 (January 19, 2006).

[12] Department of Homeland Security, *Facility Research & Staffing for the National Bio and Agro-Defense Facility*, June 12, 2007. Available online at [http://www.dhs.gov/xres/labs/gc_1181073261627.shtm].

requirements by fiscal year to launch operation of a new facility in 2010. See **Table 1**.

Table 1. Initially Projected NBAF Construction Funding Requirements (2005)

($ in millions)

FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	Total
3	23	73	129	129	94	451

Source: DHS Science and Technology Directorate, FY2006 congressional budget justification.

Actual NBAF funding has not followed this schedule. See **Table 2**. The DHS has requested, and received, appropriations at a lower level than initially projected in 2005. The DHS Science and Technology FY2006 congressional budget justification stated that NBAF funding began in FY2005 when "$3 M was received for a planning and feasibility study from base funding of Biological Countermeasures."[13] However, DHS has subsequently clarified that the FY2005 funding was used elsewhere in DHS and that FY2006 and FY2007 appropriations funded these studies.[14] In FY2006, Congress appropriated $23 million to select a site and conduct other pre-construction activities.[15] In FY2007, an additional $23 million was appropriated for site selection and other pre-construction activities.[16] The FY2007 DHS Appropriation Act also included a $125 million rescission of unobligated prior year appropriations from Science and Technology Directorate accounts. As part of its implementation of this law, DHS removed $11 million from the FY2006 NBAF appropriation.[17] In FY2008, Congress appropriated $11 million to continue environmental studies necessary to select a site for the NBAF.[18] For FY2009, the President's budget requests $35.6 million to continue progress on the NBAF construction.

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[13] Department of Homeland Security, FY2006 Science and Technology Directorate congressional budget justification, p. 45.

[14] Department of Homeland Security, personal communication, September 10, 2007.

[15] H.Rept. 109-241 to accompany H.R. 2360 (P.L. 109-90), p. 78.

[16] H.Rept. 109-699 to accompany H.R. 5441 (P.L. 109-295), p. 168.

[17] Department of Homeland Security, personal communication, September 10, 2007.

[18] P.L. 110-161, Consolidated Appropriations Act, 2008.

Table 2. NBAF Construction Funding
($ in millions)

Action	FY2005	FY2006	FY2007	FY2008	FY2009
DHS Allocation	3				
DHS Reallocation	(3)				
P.L. 109-90		23			
P.L. 109-295		(11)	23		
P.L. 110-161				11	
FY2009 Budget Request					36
Total Appropriations	**0**	**12**	**23**	**11**	
Annual Costs Projected in 2005 (from **Table 1**)	3	23	73	129	129

Source: Funding rounded to nearest million. CRS calculations based on DHS congressional budget justification, H.Rept. 109-241, H.Rept. 109-699, and DHS personal communication.

The DHS has changed the expected completion date for the NBAF facility from 2010 to 2014.[19] An updated full cost schedule is not publicly available. In the February 2005 projection, DHS anticipated requesting funding throughout the construction process, including 2010, the year DHS expected to open the facility. This raises questions about whether the total cost of the NBAF facility will increase due to the extension of the construction schedule. Subsequent DHS budget requests have not updated the projected overall funding requirements. It remains unclear how this delay will affect the future annual appropriations requests and the total cost of the project.[20]

The DHS *Science and Technology Five-Year Research Plan* projects the NBAF costs to be $436.5 million for FY2007-FY2011. Including the $12 million in FY2006 brings the cumulative total for FY2005-FY2011 to $448.5 million. See **Table 3**. The DHS states that the overall construction cost will depend on the site selected and that site-specific infrastructure costs may increase the total cost above

[19] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[20] The DHS was directed to "submit a project schedule, including expected completion dates and funding requirements for all phases of the project, to the Committees on Appropriations." See H.Rept. 109-699 to accompany P.L. 109-295, p. 168.

$451 million.[21] Additional delays to the construction schedule may further change the final cost of the facility due to changing material and labor costs.[22]

Table 3. Changing NBAF Funding Projections
($ in millions)

Year of Projection	FY05	FY06	FY07	FY08	FY09	FY10	FY11	Total
2005	3.0	23.0	73.0	129.0	129.0	94.0	0	451.0
2007	0[a]	12.0[a]	23.0	11.0	45.6	184.9	172.0	448.5[b]

Source: CRS calculations and DHS FY2006 congressional budget justification; Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007; and DHS, personal communication September 10, 2007.

a. These numbers were not included in the DHS projection, but are taken from actual funding, see **Table 2**.

b. The DHS did not include costs beyond FY2011 in this five year projection, although they predict construction to continue until 2014.

The two DHS project schedules differ in the pace of anticipated funding requests. The initial NBAF project schedule planned to receive the bulk of its appropriated construction funding in the years immediately before facility completion. In contrast, the funding schedule provided in the *Five-Year Research and Development Plan, Fiscal Years 2007-2011* plans to receive the bulk of the NBAF construction funding up to four years prior to facility completion. The DHS may be attempting to account for NBAF's full funding requirements within the 2007 five-year plan.[23]

Not included in the projected construction costs are equipment and relocation expenses involved in transferring the research projects of PIADC to the NBAF.[24] These costs are variable, as they depend on the final location of the NBAF, the

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[21] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007 and Department of Homeland Security, personal communication, September 10, 2007.

[22] Material and labor costs may be higher or lower at the time of construction than at the time of the initial projection. An increase in total cost due to increased material expense occurred during construction of another DHS high containment biological laboratory, the National Biodefense Analysis and Countermeasures Center. See CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

[23] The DHS states that no additional funds beyond those reported in the five year plan are expected to be requested, barring site-specific infrastructure costs. DHS, personal communication, September 10, 2007, and DHS, personal communication, October 4, 2007.

[24] Similar move-in costs will be incurred following the completion of the NBACC facility. Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

number of research projects to be transferred, and the particular equipment needs identified. They have been reportedly estimated by DHS as up to $100 million.[25]

Facility Site Selection

The DHS has stated that the establishment of the NBAF would be a multi-stage process. This process involves:

- obtaining expressions of interest to be the site of the NBAF;
- selecting prospective sites from these expressions of interest and requesting further information;
- assessing the information provided and visiting these prospective sites;
- narrowing the number of prospective sites to a list of final sites;
- preparing environmental impact studies of the final sites;
- choosing a site for the NBAF; and
- constructing the facility.

The stages of the DHS process will be addressed below. The DHS is now at the stage of requiring environmental impact studies of the final potential sites. The final potential sites are listed below in **Table 5**. The DHS has stated it plans to choose the final site by October 2008.[26]

Expressions of Interest. In January 2006, DHS issued a Request for Expressions of Interest from consortia interested in hosting NBAF. Consortia responding to the DHS request included academia, industry, and non-profit institutes. In its request, DHS described four criteria that the agency would use when considering the expressions of interest:

- research capabilities,
- workforce,
- acquisition/construction/operating expertise, and
- community acceptance.[27]

Prospective Sites. In August 2006, DHS selected, from the 29 expressions of interest, 18 sites to submit more information with respect to the four criteria. One site was later removed from consideration by its sponsoring consortium. Although 17 sites were under consideration, only 12 consortia were involved, as some

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[25] As cited in *Letter from Marc L. Kesselman, U.S. Department of Agriculture, to Representatives John D. Dingell and Bart Stupak*, December 18, 2007.

[26] Testimony by John Vitko, Jr., Head, Chemical and Biological Division, Science and Technology Directorate, Department of Homeland Security, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[27] 71 *Fed. Reg.* 3107-3109 (January 19, 2006).

consortia submitted multiple possible sites that were selected by DHS.[28] See **Table 4**. An intergovernmental review group, which included DHS, USDA, the Department of Health and Human Services, and the Department of Defense, assessed the additional information. The DHS then visited each site to validate the information provided and to observe the sites.

Table 4. Consortia Selected by DHS after Expression of Interest

Consortium	Site Location
University of California/Lawrence Livermore National Laboratory	CA
Georgia Consortium for Health and Agro-Security (2 sites)	GA
Heartland BioAgro Consortium (2 sites)	KS
Kentucky and Tennessee NBAF Consortium	KY
Mid-Atlantic Bio-Ag Defense Consortium	MD
Gulf States Bio and Agro-Defense Consortium (3 sites)[a]	MS
University of Missouri at Columbia NBAF Consortium	MO
North Carolina Consortium for the NBAF	NC
Oklahoma State University Consortium	OK
Texas A&M University and the NBAF Consortium	TX
Texas Biological and Agro-Defense Consortium (3 sites)	TX
Wisconsin Consortium	WI

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].
a. One site was withdrawn from consideration in April 2007.

Finalists. Following the site visits, DHS selected five sites in July 2007 to complete an Environmental Impact Statement (EIS). Also, DHS included Plum Island as a candidate site. See **Table 5**. The DHS has requested public input into the selection process through the EIS process and public hearings.[29] Following completion of the EISs, DHS expects to choose a site by October 2008.

[28] See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[29] Additional information on the potential sites and dates for public meetings about the EIS are available at 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

Table 5. Finalists for NBAF Site

Consortium	Location
Georgia Consortium for Health and Agro-Security	University of Georgia Athens, GA
Heartland BioAgro Consortium	Kansas State University Manhattan, KS
Gulf States Bio and Agro-Defense Consortium	Flora Industrial Park Madison County, MS
North Carolina Consortium for the NBAF	Umstead Research Farm Granville County, NC
Texas Biological and Agro-Defense Consortium	Texas Research Park San Antonio, TX
Department of Homeland Security[a]	Plum Island, NY

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1184180641312.shtm] and 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

a. According to DHS, although not included in the competitive selection process described above, the DHS-owned PIADC will also be considered as a potential NBAF site.

Policy Issues

Policy issues relating to NBAF include limits on possession of certain pathogens, the need for and scope of NBAF, coordination among agencies, the NBAF construction schedule, disposition of PIADC or Plum Island, and community concerns. Congress has passed the conference agreement on the 2008 farm bill, H.R. 2419, and also considered H.R. 1717 as reported by the House Homeland Security Committee, both of which would affect NBAF operations. The Administration, through USDA, also has proposed legislative language to authorize the establishment of NBAF and, through DHS, to provide authority for the sale of Plum Island.

Level of Protection Against Pathogen Release

A release of pathogens is a potential risk of high-biocontainment laboratories, but the likelihood that a pathogen would be accidentally released from the laboratory into the surrounding area is generally considered to be low. To protect against such accidental release, the Department of Health and Human Services and the USDA have developed guidelines for the construction, maintenance, and operation of high-biocontainment laboratories. These guidelines take into account the properties of the pathogen and the types of experiments being performed. The established biocontainment levels have increasing levels of rigor, and these biocontainment protocols are adhered to as a matter of best practice in government, academic, and industrial laboratories.[30]

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[30] Centers for Disease Control and Prevention and National Institutes of Health, Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories,*

(continued...)

In addition to the safety precautions established by these biocontainment guidelines, some pathogens have been deemed to require additional layers of protection.[31] One pathogen so considered is foot and mouth disease (FMD). As it is considered highly contagious and to have the potential to seriously harm the national economy if domestic livestock or other animals are infected, importation of FMD virus is prohibited, and research on live FMD virus currently is limited to locations outside of the mainland of the United States. The conduct of FMD virus research on an island was perceived as providing a geographic barrier to infection of domestic livestock in the case of an accidental release. Only if the Secretary of Agriculture provides an explicit permit under 21 U.S.C. 113a may research on live FMD virus be performed on the mainland of the United States.[32] Currently, the USDA performs FMD research only at PIADC.

Security concerns regarding the potential for terrorist use of pathogens also has led to the application of registration of researchers and facilities that work with or possess certain "select agents." The PIADC must conform to the regulations of the Agricultural Select Agent Program promulgated by USDA, and the NBAF would as well.[33] Under these regulations, biological agents, such as pathogens and toxins, that pose a severe threat to public, animal, or plant health have been identified and listed as "select agents." The FMD virus is a select agent. Entities that possess, use, or transfer these select agents are required to develop security plans for protecting the select agents, register with the USDA Animal and Plant Health Inspection Service (APHIS), and become certified as eligible to possess select agents. Researchers handling select agents must pass a security review by the Department of Justice.

Even with these guidelines and regulations in place, some activists have been concerned that these protections may be insufficient. Operation of PIADC has engendered some controversy among nongovernmental organizations and others, who have expressed concerns about the potential for pathogen release, illicit research, and unintended consequences.[34] Local opposition also increased following suggestions of upgrading the biocontainment facilities from BSL-3Ag to BSL-4 to

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[30] (...continued)
5th Edition, February 2007, online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf].

[31] An example is smallpox virus, which is only allowed to be possessed by one U.S. laboratory, the Centers of Disease Control and Prevention in Atlanta, GA.

[32] Because of concerns about the economic damage that might arise from the release of the pathogen that causes foot and mouth disease into domestic animal stocks, Congress enacted prohibitions in 1948 against performing research within the mainland of the United States. 21 U.S.C. 113a prohibits the Secretary of Agriculture from introducing live foot and mouth disease virus to the mainland of the United States unless the Secretary determines it is necessary and in the public interest.

[33] The agricultural select agent regulations are codified at 9 C.F.R. 121 and 7 C.F.R. 331. A comparable program exists for select agents that might infect humans. It is overseen by the Centers for Disease Control and Prevention on behalf of the Department of Health and Human Services. These select agent regulations are codified at 42 C.F.R. 73.

[34] John Rather, " Heaping More Dirt On Plum I.," *New York Times,* February 15, 2004, and Beth Daley, "Danger Island," *Boston Globe*, September 11, 2001.

allow work on more dangerous pathogens. Those suggestions were not acted upon.[35] Questions regarding worker safety and the potential for human infections by pathogens that affect both humans and animals have also been raised.[36] The DHS, through informational sessions in the EIS process, has attempted to allay these concerns and has stated that community acceptance, or at least minimal community resistance, is one of the NBAF site criteria. However, continued community outreach may be a key factor in determining whether NBAF will suffer delays that have threatened construction of other high-containment laboratories.[37]

The focus of some community concerns has been the potential for an FMD outbreak to occur following an accidental or deliberate release of FMD virus from the proposed NBAF. The likelihood of such a release is difficult to quantify. Accidental releases of FMD virus from research laboratories have occurred in the United Kingdom.[38] Historically, FMD virus was accidentally released from PIADC in 1978, though no infected animals reached the mainland and the foot and mouth disease outbreak was contained to Plum Island.[39] More recently, in 2004, FMD virus was discovered outside of research laboratories but still within PIADC.[40] Should the NBAF be sited on the mainland, such an outbreak might be more difficult to contain. Some argue that FMD virus research should not be performed on the mainland but instead remain offshore and retain a geographic barrier to help contain an outbreak.[41] Biocontainment technologies have advanced since the PIADC FMD virus release,

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[35] John Rather, "East End Germ Lab Getting an Upgrade," *New York Times*, November 25, 2001.

[36] Occupational exposure to dangerous, federally regulated pathogens in a laboratory at Boston University and Texas A&M University are cited as examples of such events. (M. Anita Barry, *Report of Pneumonic Tularemia in Three Boston University Researchers, November 2004 — March 2005*, Boston Public Health Commission, March 28, 2005 and Emily Ramshaw, "CDC Suspends A&M Research on Infectious Diseases; CDC Suspends Bioagent Work after Exposures Not Reported Promptly," *The Dallas Morning News*, July 2, 2007.)

[37] Barbara Goodson, "Judge Hits BU Biolab; Ruling Calls for Safety Review, May Stall Plan," *The Boston Herald*, August 4, 2006.

[38] The July/August 2007 FMD outbreak in the United Kingdom has been associated with a likely breach of biosecurity in a waste water drainage system at the nearby Pirbright research facility. The investigation also identified inadequate controls on the movement of people and vehicles from the site. (Health and Safety Executive, *Final Report on Potential Breaches of Biosecurity at the Pirbright Site 2007*, September 7, 2007, available online at [http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf]. See also Martin Enserink, John Travis, and Jocelyn Kaiser, "Labs Suspected in Foot-and-Mouth Crisis," *ScienceNOW Daily News*, August 6, 2007.)

[39] Nicholas Wade, "Cattle Virus Escapes from a P4 Lab," *Science*, Vol. 202, October 20, 1978, p. 290, and Nicholas Wade, "Accident and Hostile Citizens Beset Animal Disease Laboratory," *Science*, Vol. 202, November 17, 1978, pp. 723-724.

[40] Bill Bleyer, "Clinton, Bishop Complain of 'Breach': Plum I. Lab Tightens Biosafety," *Newsday*, August 17, 2004, and John Rather, "Plum Island Reports Disease Outbreak," *New York Times*, August 22, 2004.

[41] Emily Ramshaw, "Texas May Be Home to New Foot-and-mouth Disease Research Lab," *Dallas Morning News*, November 11, 2007.

and DHS argues that modern biocontainment technology is sufficient to prevent an accidental release.[42]

The consequences of an environmental pathogen release would depend on the location of the laboratory. A release of an animal pathogen into an area without a natural host may have relatively low consequences. Alternatively, the release of a highly contagious pathogen into an area densely populated with potential hosts could have relatively high consequences. An accidental or deliberate release of FMD virus could lead to an FMD outbreak in domestic animals. The consequences of an FMD outbreak within the United States could be high.[43]

Permission to Work with Foot and Mouth Disease. When PIADC was transferred to DHS, the Secretary of Agriculture retained the authority to prevent FMD research from being performed on the mainland of the United States. If the NBAF is located on the mainland of the United States and is to perform high-value foreign animal disease research, researchers at the facility will likely need to receive such permission from the Secretary of Agriculture to perform FMD research.[44]

While some experts might construe this permission as a formality, since, under HSPD-9, DHS and USDA are to coordinate their activities in food and animal disease research, others might see it as a potential barrier to effective and efficient

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[42] See, for example, oral testimony of John Vitko, Head, Chemical and Biological Division, Science and Technology Directorate, DHS, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[43] Estimates of the economic impact of an FMD outbreak vary. A 2002 Purdue University and USDA study found that an FMD outbreak in the U.S. similar to the 2001 outbreak in the United Kingdom could reduce farm income by $14 billion. Price Waterhouse Coopers determined loss ratios for the 2001 U.K. outbreak. When applied to the U.S. livestock industry, the potential impact is estimated at $10 billion to $33 billion. A University of California study in 1999 estimated the potential impacts of an FMD outbreak in California at between $8.5 and $13.5 billion. (Beth Lautner and Steve R. Meyer, "U.S. Agriculture in Context: Sector's Importance to the American Economy and Its Role in Global Trade," in Terrence K. Kelly, Peter Chalk, James Bonomo, John Parachini, Brian A. Jackson, and Gary Cecchine, *The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock*, CF-193-OSTP, 2004, pp. 111, 113-114, available online at [http://www.rand.org/pubs/conf_proceedings/2005/CF193.pdf]). A 2002 National Defense University study estimated that a limited outbreak of FMD on just 10 farms could have a $2 billion financial impact. (Henry S. Parker, *Agricultural Bioterrorism: A Federal Strategy to Meet the Threat*, McNair Paper 65, National Defense University, March 2002, available online at [http://www.ndu.edu/inss/McNair/mcnair65/McN_65.pdf]).

[44] The Administrator of the Agricultural Research Service, Department of Agriculture, has testified, "It is our expectation that the Secretary of Agriculture will authorize FMD work to be done on the mainland in NBAF, and that would be for all agencies. The USDA programs now at Plum Island will be a component of the NBAF facility. So yes, the Secretary of Agriculture intends to do that." See Testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

use of the NBAF. They might seek to provide the Secretary of DHS with independent authority to perform FMD research.

2008 Farm Bill, H.R. 2419. On May 14, 2008, the House passed the conference agreement on the 2008 farm bill, H.R. 2419, by a vote of 318-106. On May 15, 2008, the Senate passed the same bill by a vote of 81-15. Section 7524 of the conference agreement would require USDA to issue a permit to DHS for live FMD virus research at the successor facility to the PIADC. The provision states that, once issued, the permit can only be suspended, revoked, or otherwise impaired if the Secretary of Agriculture determines that the FMD research is not being carried out in compliance with the select agent regulations.

The White House has promised to veto H.R. 2419 because of the size of funding for programs in the bill generally and a perceived lack of reform in farm subsidy programs. Given that the floor votes on the conference agreement exceeded a two-thirds majority in both chambers, a veto override may be possible.[45]

USDA's Proposal. The USDA's comprehensive proposal for the farm bill included a provision to revise 21 U.S.C. 113a.[46] The USDA provision would allow USDA to conduct research on foot and mouth disease on the U.S. mainland. It would prohibit anyone else from importing, transporting, or maintaining viruses that would be on a USDA-prescribed list, unless the Secretary of Agriculture issues a permit. However, the USDA provision also states it would not apply to select agents. This last section of USDA's proposal appears to negate the previous two provisions with respect to FMD virus, since FMD virus is an agricultural select agent.

The USDA proposal appears to be inherently contradictory, as it establishes a prohibition against entities other than the Secretary of Agriculture possessing FMD virus without the permission of the Secretary of Agriculture, but then exempts FMD virus from these prohibitions. The net effect of the USDA provision may be removal of any permitting restrictions for FMD virus, thus allowing research to be performed by those compliant with the agricultural select agent regulations.

The House-passed version of the farm bill in July 2007 contained most of the USDA proposal for foreign animal disease research laboratories (section 7108 of House-passed H.R. 2419), including the apparently contradictory language that exempts select agents from the permit requirements established in the bill.

H.R. 1717. As amended by the House Homeland Security Committee, H.R. 1717 would instruct USDA to issue a permit to DHS for FMD research at the NBAF. Other existing requirements under the agricultural select agent regulations would

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[45] For more information on the 2008 farm bill, see CRS Report RL33934, *Farm Bill Legislative Action in the 110th Congress*, by Renee Johnson, Geoffrey S. Becker, Tom Capehart, Ralph M. Chite, Tadlock Cowan, Ross W. Gorte, Charles E. Hanrahan, Remy Jurenas, Jim Monke, Jean M. Rawson, Randy Schnepf, Joe Richardson, Donald J. Marples, and Mark Jickling.

[46] See USDA's farm bill proposal, section 7303, online at [http://www.usda.gov/documents/fbresearch0507_1.pdf].

continue to apply, and DHS would have to meet them for the permit to remain valid. Although this provision would compel USDA to issue a permit allowing DHS to possess the virus, it would continue to vest authority for determining who may possess the virus with USDA. H.R. 1717, as introduced, would have given DHS independent authority to possess FMD virus, notwithstanding 21 U.S.C. 113a.[47]

Analysis. H.R. 1717, the conference agreement of the farm bill, and the Administration's proposal have different ramifications for DHS's possession of FMD and other high-consequence animal disease viruses. H.R. 1717 and the farm bill conference agreement would make DHS eligible to possess and conduct research with FMD and other high consequence animal viruses through a USDA permit under 21 U.S.C. 113a. This eligibility would be still subject to USDA's authority to revoke its mandated permit, as well as its authority under the agricultural select agent regulations.

Under the Administration's proposal, the language could have led to possibly contradictory interpretations. The apparent contradiction in establishing a permitting process for FMD virus possession — while excluding select agents, including FMD virus, from this permitting process — might have led to confusion in the interpretation of the regulatory effect of this language. This contradiction could be resolved if USDA chose to no longer regulate FMD virus as a select agent, a decision within its authority. However, this action might be viewed as weakening other important security controls on FMD virus. Additionally, the related House-passed version of the farm bill in July 2007 might be interpreted as revising 21 U.S.C. 113a or instead as retaining 21 U.S.C. 113a and establishing a parallel permitting process. Finally, a plain text reading might even lead to the interpretation that FMD virus research is not allowed, as this section authorizes the establishment of research laboratories working on "animal diseases in the United States," something that FMD arguably is not, rather than the establishment of research laboratories in the United States working on animal diseases.[48]

Need for and Scope of NBAF

Other agencies and organizations in addition to DHS have identified needs that could be met by the NBAF. At least as early as 1999, USDA recognized a need for a BSL-4 facility capable of handling large animals. In response to a mandate by Congress,[49] USDA commissioned a strategic planning task force that recommended that the "Agricultural Research Service must consider upgrading current Level 2 and Level 3 bio-containment units for animals and constructing a Level 4 unit."[50] In 2005, the National Research Council (NRC) echoed the need for a BSL-4 facility

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[47] See footnote 32.

[48] H.R. 2419, section 7108 (b) (2).

[49] P.L. 104-127, Subtitle D, section 884.

[50] USDA, "Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations," August 1999, p. 24.

capable of handling large animals. The NRC also concluded that PIADC was at the end of its life cycle and that it should be "replaced urgently."[51]

While USDA and DHS have repeatedly stated their need for a new BSL-4 facility, it is less clear how large this facility should be. In response to questions for the hearing record, DHS asserted that

> Site criteria and requirements for NBAF were developed by an interagency technical working group, including DHS, USDA, and HHS to evaluate sites that would best support research in high-consequence animal and zoonotic diseases in support of Homeland Security Presidential Directives, HSPD-9 and HSPD-10.[52]

The DHS has not publically released supporting documentation relating to the working group's deliberations.

The DHS projects the size of the NBAF to be approximately 504,000 gross square feet.[53] Approximately 55,000 gross square feet of the facility would be BSL-4 laboratory space. See **Table 6**. This facility would be more than twice as large as the existing PIADC facility.[54] This sizeable increase in laboratory capacity may meet the requirements put forth by HSPD-9, as well as establishing the expanded, modern facilities to replace PIADC and perform necessary research activities. Full use of this expanded laboratory space may pose a challenge to federal research planners as other federal agencies have also expanded their research laboratory capacity, including BSL-3Ag space, providing alternative venues for performing such research.[55]

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[51] National Research Council, *Critical Needs for Research in Veterinary Science*, (National Academies Press: Washington, DC) 2005.

[52] House Committee on Science, *An Overview of the Federal R&D Budget for Fiscal Year 2007*, Committee Serial No. 109-35, February 15, 2006.

[53] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification.* The NBAF was initially estimated at 500,000 square feet with ten percent being BSL-4 laboratory space. 71 *Fed. Reg.* 3107-3109 (January 19, 2006). Other scoping documents place the size of the NBAF at 520,000 square feet. See online at [http://www.dhs.gov/xlibrary/assets/nbaf-scopingmeetingmaterials.pdf].

[54] PIADC has a combined office/laboratory space of 226,560 square feet, excluding other buildings. USDA, "Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations," August 1999.

[55] For example, USDA has invested in expanded BSL-3Ag laboratories at both the National Wildlife Research Center in Fort Collins, Colorado, and the National Centers for Epidemiology and Animal Health in Ames, Iowa.

Table 6. Estimated Use of NBAF Space by Gross Square Footage

Space	Gross Square Footage
Office/Administrative	35,000
BSL-2	30,000
BSL-3	372,000
BSL-4	55,000
Vaccine Production	12,000
Total	504,000

Source: Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification.*
Note: BSL-2 space includes laboratory and support areas. BSL-3 space includes laboratory, agriculture threat containment, and training and support areas.

The ability of DHS to effectively use the newly constructed BSL-4 and BSL-3Ag laboratories may depend on efficient interagency cooperation in order to identify other agency research activities that could benefit from being performed at NBAF. The DHS and USDA investment into research areas done currently at PIADC may also need to increase to fill the expanded capacity. Analytic study assessing the current and future needs for BSL-3Ag and BSL-4 research may aid DHS and USDA in effectively using the NBAF.

Coordination of Research Activities with Other Agencies

Since the NBAF would replace PIADC, research at NBAF is expected to be collaborative between USDA and DHS. At PIADC, DHS and USDA cooperatively set research priorities, based on risk assessment and other information. Generally, USDA performs basic research activities while DHS develops the results of that research and attempts to translate them into practical applications.[56] However, since NBAF also represents an expansion in capacity and capabilities over PIADC, this relationship may change. Establishment of the new facility provides an opportunity to evaluate previous agreements and make adjustments. Assignment of lab space to the Department of Health and Human Services or other agencies may require reevaluation and updates to these procedures.[57]

The USDA and DHS have testified that their current agreements have served them well at PIADC, with respect to both daily operation and transfer of technical

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[56] For further discussion of how USDA and DHS cooperate at PIADC, see Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

[57] Because of the NBAF focus on foreign animal disease, agencies beyond USDA and DHS may have limited roles. Department of Homeland Security, personal communication, September 17, 2007.

information regarding research results and priorities.[58] Such interagency coordination may be essential in case of a crisis or in dealing with an outbreak of animal disease. The extent to which all agencies engaged in the NBAF agree on how to coordinate roles and responsibilities may prove to be a key factor in maintaining clear lines of authority and information and may be crucial to effective oversight of the facility.

The 110th Congress is considering these issues. Under H.R. 1717 (ordered to be reported by the House Homeland Security Committee on August 1, 2007), the NBAF would be run by a director appointed by DHS in consultation with USDA. The director's role would be limited to operating and maintaining the facility, including ensuring security and emergency response plans. This role is less broad than in a previous version of the bill, which would have also given the DHS-appointed director authority over all research programming at the facility, including USDA research. In the committee-amended bill, in addition to the director, separate directors of research would be appointed from DHS and USDA to oversee the research programs of each department. The USDA and DHS would develop a "joint strategy" defining the roles of USDA and DHS at the NBAF.[59]

Timeliness of Construction Activities

When complete, NBAF would eventually house all the research activities underway at PIADC. The DHS considers PIADC to be approaching the end of its design lifetime. Finishing construction of the NBAF and achieving operational status before down-sizing or decommissioning PIADC is dependent on timely construction activity. Because of the unique research currently performed at PIADC, the smooth transition of this capacity may be an issue of congressional concern. Beyond the transition of research projects, programs, and supplies, transfer of personnel and retention of an experienced workforce may also pose a challenge to DHS and USDA.

The original schedule for the NBAF, as presented to Congress, proposed finishing construction and commissioning the NBAF in FY2010. Since then, the

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[58] House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, "Reducing Threats to Our Nation's Agriculture: Authorizing a National Bio and Agro-Defense Facility," *Hearing Transcript*, May 23, 2007.

[59] In 2004, the USDA and DHS developed "A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs" to coordinate their activities with respect to activities at PIADC. While this strategy has not been made public by DHS or USDA, it has been discussed in congressional testimony. See Testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007. The DHS has not updated this strategy. Department of Homeland Security, personal communication, September 17, 2007.

proposed schedule has been extended twice, first having operations begin in FY2013,[60] and most recently having operations begin in FY2013 to FY2014.[61]

The extension of the NBAF construction schedule increases the time that PIADC will be in operation. The PIADC has historically had security, coordination, and other issues.[62] The DHS has developed and implemented a multi-year *Corrective Action Plan* to address these issues and maintain the operation of PIADC.[63] Since PIADC has been identified as approaching the end of its design lifetime, extended operation and maintenance of these facilities may not be as cost effective or as efficient for the research endeavor as completing and transitioning research to the NBAF. The DHS spent approximately $24 million in FY2007 and $17 million in FY2008 to upgrade the facilities at PIADC, and requested approximately $17 million more for FY2008. The DHS did not request additional appropriation for upgrades in FY2009[64] and does not plan to in future years.[65] The upgrades include designing a new animal wing and continuing activities described in the *Corrective Action Plan*. The DHS expects completion of these upgrades in FY2010.[66] Further NBAF construction delays may require additional funds be used to support PIADC's corrective maintenance.

Future Use of PIADC

The DHS has yet to determine what actions to take with the PIADC when construction of the NBAF is completed. The DHS has stated that one of the main goals of the NBAF is to expand upon the existing PIADC research. According to DHS, once NBAF is operational, PIADC research activities will transfer to it.[67]

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[60] See online at [http://www.dhs.gov/xlibrary/assets/NBAF_Timeline.pdf].

[61] See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[62] See General Accounting Office, *Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center*, GAO-03-847, September 2003; and Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

[63] According to DHS, the total cost of the *Corrective Action Plan* is approximately $56 million. The *Corrective Action Plan* was reported to Congress by DHS in FY2005. Department of Homeland Security, Office of Inspector General, *Additional Physical, System, and Management Controls Can Enhance Security at Plum Island (Redacted)*, OIG-07-43, May 2007.

[64] Department of Homeland Security, Science and Technology Directorate, *Fiscal Year 2009 Congressional Justification*.

[65] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[66] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[67] Ibid.

The fate of the PIADC, once current research activities are transferred from it, remains unclear. The DHS has identified that "proper decontamination and decommissioning (D&D) of the facility after the transition will be critical to meet regulatory compliance and eventual disposal of the site."[68] The DHS has not stated when or how this process might occur. In discussing the development and construction of the NBAF, DHS has stated, with regards to PIADC, that "no decision has been made as to the future of Plum Island."[69]

The DHS is currently investing money to improve and upgrade the laboratory facilities. Continued use of PIADC either by DHS in some other capacity or under the control of some other entity remains an option. Alternatively, following decommissioning, the laboratories might be removed and the site used for a different purpose. Although many local officials have opposed expanding the number or type of pathogens researched at PIADC, some have expressed support for the continued operation and existence of the facility, because of its economic value to the surrounding area.[70]

Selling Plum Island. One option raised by DHS has been to sell Plum Island and use the profit from such a sale to offset the construction costs of the NBAF, the decontamination and remediation costs for the island, and the demolition costs for the PIADC. Under this proposal, DHS would sell Plum Island in FY2009 or FY2010, arrange with the purchaser to allow operations to continue until the NBAF construction was finished, and transfer Plum Island to the purchaser only after clean up of the island had been completed.[71]

Most sales of surplus property are handled by the General Services Administration and any funds received redirected into the Treasury.[72] The DHS has proposed to add statutory language to the FY2009 DHS appropriations act providing express authority to liquidate the Plum Island assets and retain the proceeds of the sale. The proposed language indicates that these funds could be used to offset costs associated with construction of the NBAF; however, the proposed language would also allow the DHS Secretary to use the net proceeds of the Plum Island sale for "other real property capital asset needs."[73] Under this proposed language, the net proceeds from the sale of Plum Island would be retained by DHS until fully spent rather than reverting to the Treasury at a future date.

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[68] Ibid.

[69] Bill Bleyer, "Homeland Security Seeks Input on Plum Island Disease Lab," *Newsday*, August 21, 2007.

[70] Ibid.

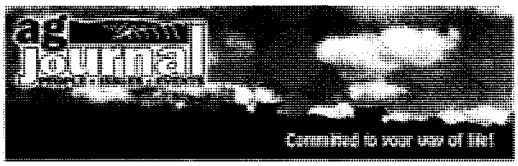
[71] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification.*

[72] For a brief overview, see CRS Report RS20630, *Surplus Federal Property*, by Stephanie Smith.

[73] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification.*

The amount of money that might result from liquidation of the Plum Island assets is uncertain. Fluctuations in remediation costs for environmental clean-up of the island and property values, for example, contribute sizeable uncertainty to any estimate of a future sale's proceeds. The sale might provide net funds insufficient for the construction of the NBAF or might provide substantial surplus funds even after the NBAF construction is complete.

Policymakers, in considering DHS's proposed language, may weigh the value of having offsetting revenue for current and future construction performed by DHS against the potential for lessened congressional oversight of DHS capital construction projects. By providing such authority, Congress may be lowering DHS's burden for justifying construction projects, as new appropriations might not need to be requested for each project. In contrast, having a secure, readily available source of funds might allow DHS great flexibility and efficiency in planning and executing future construction projects.



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Foot and mouth disease outbreak spotlights research lab risks

By Candace Krebs,
Regional Correspondent

COLORADO SPRINGS, Colo. - When the Department of Homeland Security sought a new home for the Plum Island Animal Disease Center, the prestigious high security research lab was considered a plum prospect. Potential sites in 14 states have been vying for the chance to house the facility, which is currently located on the northeastern tip of New York's Long Island.

An Ag Research Service facility in Central Oklahoma was one of many that hoped to land the lab. But Ray Wulf, president of the Oklahoma Farmers Union, had misgivings. He and others expressed fears over keeping some of the world's most dangerous animal diseases contained inside the proposed 30-acre complex. When news broke this week that a foot and mouth disease outbreak in England likely originated at a nearby research lab operated by the government and Merial Animal Health, Wulf's fears appeared well-grounded.

"Foot-and-mouth disease is one of the most highly contagious diseases among animals; the rate of spreading it is unbelievable," says Jack Carson, a spokesman for the Oklahoma Department of Agriculture. "We're not talking about one state if that happens." The incident in England is shining a spotlight, at least for the moment, on research lab security.

"We can't make anything 100 percent safeguarded but we can do the best we can," says David Von Tungeln, the chief veterinary medical officer for the Grazinglands Research Station at El Reno, which had sought to attract the new facility but is no longer in contention.

Foot-and-mouth disease is a highly contagious viral disease of cloven-hoofed animals, including cattle, sheep, goats, swine and several species of wild mammals. It causes blisters in the mouth, on the tongue and on the feet of affected animals. Infection causes dramatic loss of weight, loss of appetite, decreased milk production and poor performance, although mortality rates are low. It is not considered a human public health issue.

Researching infectious animal diseases is a double-edged sword, creating some risks along with the benefits, Von Tungeln says. "There's always the potential for human error," he says, a possibility that is now suspected to be at play in England's outbreak. Personnel issues can also arise, and there are concerns that the latest situation was intentional. But he says for the last 100 years the system overall has worked pretty well.

Kansas State University is among five sites on the short-list to get the new version of the aging Plum Island campus, which will be renamed the National Bio and Agro-Defense Facility and is intended to modernize homeland security. San Antonio, Texas, is also on the list for the 500,000 sq. ft. lab. The Department of Homeland Security has said it will make its site

selection based on research capabilities, workforce availability, acquisition, construction, and operations considerations and community acceptance.

K-State already houses the National Agricultural Biosecurity Center as well as the $50 million Biosecurity Research Institute, a level-three biosafety facility for the study of agriculturally important plant and animal diseases and food safety. There are also numerous animal health companies with private research facilities in Kansas.

"Nearly 30 percent of the animal health products used worldwide are researched, developed and produced by companies headquartered in the Kansas City area," says Dr. Dan Thomson, a K-State veterinarian and coordinator for the university's newly created Beef Cattle Institute.

Jim Mintert, a livestock marketing specialist at K-State, says so far the news headlines about the overseas outbreak have not generated much concern about KSU's operations but he said the long-term implications and public response remain to be seen.

"If the source of the contamination was the lab, there will likely be some kind of study or commission looking at whether the protocols were adequate. Often times, what they find is that it was not the protocol that was not adequate but that it was not being enforced adequately," he says.

Some experts say it is best to locate research facilities away from rural areas where large numbers of animals could become infected. But others are concerned about putting the labs in more populated areas where humans might potentially be at risk.

"There is a difference between housing something in Manhattan versus in Garden City," Mintert says, referring to K-State's main campus in the northeastern part of the state. "We're not right in the cattle feeding area."

Dustin Pendell, an assistant professor in Colorado State University's animal science department who earned his doctorate at K-State, understands K-State's interest in attracting the Plum Island facility but also has questions about locating it in a major agricultural region.

"It's all economics driven," he says of interest nationwide in attracting the lab. "K-State wants to be known as the biosecurity capital."

But he also says, "Where the location is now, I have a lot of confidence in the security. But when I think about the fact that they are moving it, I have to admit I don't fully understand why they would consider locating it where there are large population densities of livestock."

For the last two years, Pendell has worked closely with the federal Animal and Plant Health Inspection Service creating disease transmission models and using that information to evaluate the economic impact of a potential foot-and-mouth outbreak.

The disease can travel by air up to 10 miles. A former administrator for the facility under investigation in England says the virus could have simply blown out of a window. Professor Richard Barry managed the lab back when it was the Institute for Virus Research three decades ago. "It could be as simple as something being dumped down the wrong drain," Pendell adds.

Roger Pride, the English farmer who found his cattle sickened on land about five miles from the research facility, says he believes recent floods that caused sewage to run onto his land may have been the culprit. "There are the cleaning and disinfection costs to be resolved and our farming business will be closed down for many months," he said. He was compensated market price for his depopulated animals.

More than 300 head of cattle in the area have been slaughtered and incinerated.

Each week England's livestock industry is on hold because of the outbreak will cost producers a collective $20 million and may eventually result in meat shortages, according to the most recent reports.

British authorities confirm a "strong possibility" that it originated at the neighboring lab. The latest cases match a strain of the disease that was being stored at the government research facility and had not been seen among the nation's livestock herds in the last 40 years. That same strain was used in a batch of vaccine manufactured in July. As a precaution, Merial has agreed to voluntarily halt vaccine production.

Investigators are working to pinpoint any specific security breach. Merial has operated in Britain for 15 years without any disease escaping. The government-funded laboratory, the Institute for Animal Health, which is housed in conjunction with Merial's plant, had no known security problems, although a report earlier this year cited lack of funding as a concern and said investment was needed to keep the facility up-to-date. Adequate federal funding for public research has become more of an issue in the U.S., as well.

British authorities also reported the chance that the virus was transferred from the labs by flood water or an airborne release was negligible, saying it is a "real possibility" that a worker carried the disease out of the facility. The report did not rule out what they called "sabotage."

England's last outbreak in 2001 involved 2,000 confirmed cases and was estimated to cost the industry $16 billion. Officials are hoping to keep this outbreak more contained.

Jim Robb, director of the Livestock Marketing Information Center in Denver, told the press that English officials appear to be responding more quickly than they did when the 2001 outbreak occurred. He said all auction facilities and slaughter plants have been temporarily shut down.

Meanwhile, officials at the current Plum Island facility in New York are proud of their track record. No pathogens have escaped in its 50 years of operation.

A veterinarian at Colorado State University who declined to be named said lab-related outbreaks do occasionally occur in the U.S. and are not always widely reported.

Pendell, who did his dissertation on the economics and containment of a hypothetical disease outbreak in Southwest Kansas, says since there is no way to eliminate the risks entirely, the U.S. should be prepared to handle such a situation if it happens here.

He doesn't anticipate a backlash against research facilities but says England's event could push the adoption of greater traceability throughout the livestock industry.

"This situation might push the land grant and USDA facilities to revisit their security measures and plans," he observes. "If they find a security measure or plan that they can further strengthen, then it could be beneficial."

But, he adds, "I believe this raises a bigger issue in that it demonstrates the impact animal health can have on the livestock and livestock related industries. Regardless of how FMD was introduced - accidentally or intentionally - in England, it is apparent the need for animal traceability in the U.S. from an animal health standpoint. An animal ID system would help to limit the spread of an animal disease, enable faster traceback of infected animals, limit production losses due to disease presence, reduce control, intervention, and eradication costs to the government and livestock industries, and minimize potential international trade losses."

Close Window

BIOSECURITY

Reports Blame Animal Health Lab In Foot-and-Mouth Whodunit

Neglected, leaky pipes and England's record-setting wet summer likely combined to cause the country's recent outbreak of foot-and-mouth disease (FMD), according to two reports issued last week. The virus responsible probably escaped from a company, Merial, that grew vast amounts of it for vaccine production, the studies say. Yet the reports assign most of the blame for the outbreak to the Institute for Animal Health (IAH), a government lab at the same site in Pirbright that owned the aging network of underground wastewater pipes and was aware that it needed maintenance. IAH breached biosecurity in other ways as well, the reports found.

The findings are a blow to the reputation of IAH, a world-renowned FMD research center, says Andrew Mathieson, an environmental health expert at the University of the West of England in Bristol. But they should also serve as a more general warning. "My worry is: What about the many other research establishments of the same age?" he says.

Rapid government action helped contain the FMD outbreak, first confirmed on 3 August, to just two farms in Surrey (*Science*, 10 August, p. 732). Still, the National Farmers' Union puts the accident's economic impact at more than $100 million, and some politicians have called for resignations at the Department for Environment, Food and Rural Affairs (Defra), which oversees biosafety at IAH and also funds some 65% of its work.

Genomic comparisons of the outbreak virus to strains from Merial and IAH can't pinpoint from which of the two labs the virus escaped, according to the reports, one led by the U.K.'s Health and Safety Executive (HSE), a government agency, and the other by molecular epidemiologist Brian Spratt of Imperial College London. Still, the panels say, it's much more likely that the virus came from Merial, which grew it in two 6000-liter vats shortly before the accident, producing a million times more virus than IAH used in its small-scale experiments.

But how did it escape? The reports conclude that air leaks, contamination from solid waste, and foul play by terrorists or disgruntled employees are unlikely. Instead, both focus their suspicions on the site's wastewater system.

A two-step chemical strategy is used at Pirbright to prevent FMD from escaping in liquid waste. Both Merial and IAH first treat wastewater at their own buildings with a disinfectant such as citric acid. Then, a complex system of pipes takes the water to a shared effluent treatment plant, managed by IAH, where caustic soda is used to raise the pH to 12 and kill off any remaining virus during a 12-hour holding period. Finally, the liquid is released into the sewer.

Although the first treatment step probably killed off almost any leftover virus at IAH, it likely didn't inactivate the larger amounts in Merial's wastewater. The second treatment step would normally take care of that, but the network of pipes, pumps, and manholes leading to it suffered from leaks due to cracks, tree roots, and other problems. The reports hypothesize that live virus seeped into the soil as a result, especially because July's excessive rainfall may have caused the drains to overflow.

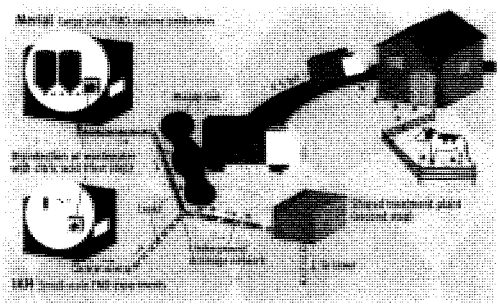
As it happened, construction crews were digging holes around the leaks at the time, and heavy trucks—without proper IAH oversight—drove through the presumably virus-laden mud. Some of these vehicles later took a road that went very close to the first infected farm. From there, the farmer may have carried the virus to his herd.

IAH, a part of the U.K. Biotechnology and Biological Sciences Research Council (BBSRC), owns the antiquated drainage system, the HSE report says. It was also aware of some of the network's problems. In fact, IAH, Defra, BBSRC, and Merial had debated an upgrade since 2003; the problem was money.

As to Merial's discharge of virus into its wastewater, HSE says this wasn't a breach of biosecurity, because Defra had approved the procedure used in the first disinfection step. But in a statement, IAH pointed its finger at Merial, suggesting that the company should have taken better care to inactivate any virus. Strangely, the Spratt report says, IAH didn't seem to know that Merial might release active virus into the system; biosafety officers from the lab and the company hardly ever talked.

Both panels question the wisdom of chemically inactivating wastewater altogether. Indeed, most modern labs use thermal inactivation—that is, pressure-cooking at 121°C—to destroy any pathogens, says Lee Thompson, a biosafety officer at the University of Texas Medical Branch in Galveston. Still, the second step, using caustic soda, "is very effective against FMD," Thompson says—but underground pipes that cannot be inspected "are a big problem."

Defra says it will adopt a range of recommendations to fix problems at Pirbright, such as keeping better track of visitors and making sure biosafety officers communicate. Merial has agreed not to grow live virus until U.K. authorities give it the green light. IAH, which was constructed in 1924, is due to be almost completely rebuilt by 2012, although some funding issues remain. Defra has also asked Health and Safety Commission chair Bill Callaghan to review the regulatory framework for animal pathogens. He is due to report by December. —MARTIN ENSERINK



Recipe for an outbreak. The escaped foot-and-mouth disease virus (red) probably originated at vaccine manufacturer Merial, two reports say, but the Institute for Animal Health owns the leaky drainage system that presumably let the virus seep into the soil. Trucks may have then carried it close to a farm.

SOURCE: J. NEWFIELD/SCIENCE

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NEWS

Animal virus research may move ashore Some fear for livestock as Texas site vies to replace island facility

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PLUM ISLAND, N.Y. - For a half-century, the nation's only experiments on the world's most devastating livestock virus have occurred on this clandestine government-run island, separated from the mainland by more than a mile of choppy water.

Now foot-and-mouth disease may be about to come ashore.

Texas and five other states are competing to win a mammoth biodefense facility - a new $500 million federal research center that would house foot-and-mouth and other highly infectious animal diseases.

The National Bio and Agro-Defense Facility is intended to replace the Plum Island labs, which homeland security officials say are outdated, inadequate and difficult to secure. The location will be chosen next fall.

But bringing foot-and-mouth research onto the mainland - a move that requires an act of Congress - has posed a quandary for ranchers and farmers, who want the best possible research but fear a U.S. epidemic.

Two outbreaks on British farms this summer, both linked to a government lab and a private vaccine manufacturer, have done little to bolster their confidence. A 2001 pandemic in Britain shut down trade and forced the country to incinerate 7 million sheep and cattle, costing more than $16 billion. Britain has a fraction of the livestock the U.S. does.

"Of course we support a new lab," said Texas Cattle Feeders Association President Ross Wilson, whose organization markets more than 6 million cattle a year in feed lots - 30 percent of the nation's supply. "The question becomes, can we do it safely on the mainland?"

The science says yes, said York Duncan, president of the Texas Research Park in San Antonio, one of six sites on the short list for the national biodefense facility.

Foot-and-mouth - often referred to as "hoof-and-mouth" disease - doesn't affect humans, just cloven-hoofed animals like cows, pigs, sheep and goats. And while a U.S. foot-and-mouth outbreak would be catastrophic to livestock industries, far more deadly diseases are already studied in high-security labs in San Antonio, he said - labs with flawless track records.

Already there's a major lab studying foot-and-mouth in Canada, separated from the U.S. by little more than an imaginary line.

"There's always the human-error factor. Nothing's ever 100 percent," Mr. Duncan said. "But I don't think you're going to find the capabilities we have [in San Antonio] anywhere else in the country."

Confining the disease

Plum Island became the nation's foot-and-mouth research base in the mid-1950s, following outbreaks of the virus in Mexico and Canada. Congress wanted the disease - so infectious it's been known to spread miles - to be confined to an island. Plum Island, a pork chop-shaped military outpost off the coast of Long Island, already had a secure and secluded barrack: the infamous and long-since defunct "Lab 257."

Plum Island scientists have since conducted the world's leading research on foot-and-mouth disease, operating in high-security labs tucked amid an eerie wonderland of gnarled underbrush and seal-lined beaches.

They're on the cusp of producing a landmark vaccine, the first that doesn't take a live virus to create. They've trained thousands of veterinarians to diagnose foot-and-mouth and dozens of other foreign animal diseases. And they've tested thousands of samples from animals showing symptoms of the virus in the U.S. and abroad, opening 200 disease investigations in 2006 alone.

So far, they've either been effective or lucky; the U.S. hasn't seen a case of foot-and-mouth since 1929.

"We have 100 million head of cattle in this country - if we had to kill 30 million [in a foot-and-mouth outbreak], it would be an enormous tragedy," said Dr. Larry Barrett, the veterinarian and epidemiologist who directs the Plum Island Animal Disease Center. "This facility is the first line of defense against that."

But concerns about the age and size of the labs on the 840-acre island, coupled with the economics of maintaining a facility only reachable by ferry or helicopter, have raised questions about the future of Plum Island.

And bad press hasn't helped.

It's not just the mention of Plum Island in the film Silence of the Lambs or the thriller novel that author Nelson DeMille set there. A glaring 2003 report from the U.S. Government Accountability Office found serious security problems at Plum Island - everything from insufficient control of its pathogens to malfunctioning alarm systems.

In two separate incidents in 2004, livestock were found carrying strains of foot-and-mouth they hadn't been intentionally infected with.

And in the book Lab 257, author Michael Carroll alleged safety breaches on the island and contended that American forces in Afghanistan had found files on Plum Island in the home of one of Osama bin Laden's contemporaries.

Homeland security officials disputed these claims, and employees on the island call the book fiction. Today, Lab 257 sits overgrown and gated off, the rusted cattle chute and age-faded biohazard signs the only relics of the work performed there until the mid-1990s.

An aging lab

The negative attention has subsided in the last three years, the result of $50 million in infrastructure upgrades at the facility's other labs - many of them security-related - and a push by Plum Island officials to educate the public about the facility.

On a recent visit, safety was so tight that a reporter's cellphone was confiscated, all labs were off limits, and everything but trips to the restroom required an escort.

Despite these efforts, homeland security officials say the Plum Island Animal Disease Center is old and nearly obsolete; it simply doesn't have the space to support new research initiatives. Nor does it have a lab secure enough to study zoonotic diseases - those that, unlike foot-and-mouth, can spread from animals to humans.

"We clearly cannot continue functioning in a 54-year-old lab," said Dr. Luis Rodriguez, who heads Plum Island's research division. "It needs to be replaced."

While the island could conceivably be home to the new national facility - by law, it must remain in the running - officials with knowledge of the site-selection process say it's probably not a front-runner. Conducting foot-and-mouth research on an island may have been necessary in the 1950s, they say. Today, it just doesn't make economic sense, they say, because it costs so much to transport anything to the island and to secure it.

Texas has competition to win the new lab: Kansas, Georgia, North Carolina and Mississippi are also vying for the 520,000-square-foot facility, which is scheduled to be operational by 2014.

The Texas pitch, which is being coordinated by UT-San Antonio, the UT Health Science Center at San Antonio and several research foundations, has a bastion of support - everyone from Gov. Rick Perry and Sen. John Cornyn to cattle raisers at the fabled King and Briscoe ranches.

And most state cattle associations appear to be on board, if tentatively - swayed by the argument that lab outbreaks in England this summer were the result of outdated and aging facilities.

"To have a good defense, we have to have great research," said Dr. Richard Thorpe, a board director for the Texas and Southwestern Cattle Raisers Association. "As a West Texas cattle producer, I'm more concerned about what foot-and-mouth could do to our cattle industry than I am about the possibility of a leakage."

But some ranchers and lawmakers still see mostly danger in moving foot-and-mouth research to a place where livestock is

nearby, particularly in the aftermath of recent high-profile biosafety problems at Texas A&M University.

A&M, which was knocked off the list of contenders for the new national facility this summer, has had its research suspended for failing to report an infection and several exposures to pathogens in campus labs.

"The proposal to close Plum Island and move foot-and-mouth virus to the mainland is utterly baffling," said Rep. John **Dingell**, D-Mich., at a hearing last month. "Why would [homeland security officials] move this biolab that works with the most dangerous animal diseases in the world from Plum Island to the heart of farm country?"

A NEW LAB

About the Department of Homeland Security's National Bio and Agro-Defense Facility:

The purpose: The $500 million high-security research center would study the world's most infectious foreign animal diseases, particularly those that could be used in a terrorist attack.

The work: Research on foot-and-mouth disease in the U.S. - currently permitted only on Plum Island, N.Y. - would be moved to the new 520,000-square-foot facility.

The contenders: Six sites are still in the running: San Antonio; Manhattan, Kan.; Athens, Ga.; Creedmoor, N.C.; Flora, Miss.; and Plum Island, N.Y.

What's next: The location will be chosen next fall; the labs should be in operation by 2014.

FOOT-AND-MOUTH DISEASE

-The virus sometimes referred to as "hoof-and-mouth disease" affects only cloven-hoofed animals, including cows, pigs, goats and sheep. It has no effect on humans.

-It is extremely contagious; outbreaks have shut down commerce and caused catastrophic economic and livestock losses in many countries, including England.

-The virus, which causes fever and blister-like lesions, isn't always fatal, but it sickens animals to the point they don't feed or produce milk.

-Foot-and-mouth was eradicated from the U.S. in 1929, and researchers like those at Plum Island are constantly surveying livestock to ensure it doesn't re-emerge.

PHOTO(S): Dr. Luis Rodriguez (left), head of the research division on Plum Island, N.Y., lectures visiting animal health experts. Six U.S. states including Texas are vying for a $500 million federal center to research foot-and- mouth and other infectious animal diseases. CHART(S): 1. A NEW LAB 2. FOOT-AND-MOUTH DISEASE MAP(S): (TROY OXFORD/Staff Artist) NEW YORK - Long Island/Plum Island

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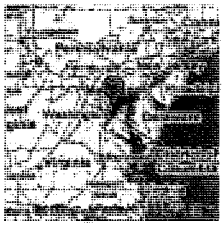

Dangerous Animal Virus on US Mainland?

By LARRY MARGASAK – 5 hours ago

WASHINGTON (AP) — The Bush administration is likely to move its research on one of the most contagious animal diseases from an isolated island laboratory to the U.S. mainland near herds of livestock, raising concerns about a catastrophic outbreak.

Skeptical Democrats in Congress are demanding to see internal documents they believe highlight the risks and consequences of the decision. An epidemic of the disease, foot and mouth, which only affects animals, could devastate the livestock industry.

One such government report, produced last year and already turned over to lawmakers by the Homeland Security Department, combined commercial satellite images and federal farm data to show the proximity to livestock herds of locations that have been considered for the new lab. "Would an accidental laboratory release at these locations have the potential to affect nearby livestock?" asked the nine-page document. It did not directly answer the question.

A simulated outbreak of the disease — part of an earlier U.S. government exercise called "Crimson Sky" — ended with fictional riots in the streets after the simulation's National Guardsmen were ordered to kill tens of millions of farm animals, so many that troops ran out of bullets. In the exercise, the government said it would have been forced to dig a ditch in Kansas 25 miles long to bury carcasses. In the simulation, protests broke out in some cities amid food shortages.

"It was a mess," said Sen. Pat Roberts, R-Kan., who portrayed the president in the 2002 exercise. Now, like other lawmakers from the states under consideration, Roberts supports moving the government's new lab to his state. Manhattan, Kan., is one of five mainland locations under consideration. "It will mean jobs" and spur research and development, he says.

The other possible locations for the new National Bio-and Agro-Defense Facility are Athens, Ga.; Butner, N.C.; San Antonio; and Flora, Miss. The new site could be selected later this year, and the lab would open by 2014. The numbers of livestock in the counties and surrounding areas of the finalists range from 542,507 in Kansas to 132,900 in Georgia, according to the Homeland Security study.

Foot-and-mouth virus can be carried on a worker's breath or clothes, or vehicles leaving a lab, and is so contagious it has been confined to Plum Island, N.Y., for more than a half-century — far from commercial livestock. The existing lab is 100 miles northeast of New York City in the Long Island Sound, accessible only by ferry or helicopter. Researchers there who work with the live virus are not permitted to own animals at home that would be susceptible, and they must wait at least a week before attending outside events where such animals might perform, such as a circus.

The White House says modern safety rules at labs are sufficient to avoid any outbreak. But incidents in Britain have demonstrated that the foot-and-mouth virus can cause remarkable economic havoc — and that the virus can escape from a facility.

An epidemic in 2001 devastated Britain's livestock industry, as the government slaughtered 6 million sheep, cows and pigs. Last year, in a less serious outbreak, Britain's health and safety agency concluded the virus probably escaped from a site shared by a government research center and a vaccine maker. Other outbreaks have occurred in Taiwan in 1997 and China last year and in 2006.

If even a single cow signals an outbreak in the U.S., emergency plans permit the government to shut down all exports and movement of livestock. Herds would be quarantined, and a controlled slaughter could be started to stop the disease from spreading.

Infected animals weaken and lose weight. Milk cows don't produce milk. They remain highly infectious, even if they survive the virus.

The Homeland Security Department is convinced it can safely operate the lab on the mainland, saying containment procedures at high-security labs have improved. The livestock industry is divided. Some experts, including the former director at the aging Plum Island Animal Disease Center, say research ought to be kept away from cattle populations — and, ideally, placed where the public already has accepted dangerous research.

The former director, Dr. Roger Breeze, suggested the facility could be safely located at the

Atlanta campus of the Centers for Disease Control and Prevention, or at Fort Detrick in Frederick, Md., home of The United States Army Medical Research Institute for infectious diseases.

Another possibility, Breeze said, is on Long Island, where there is no commercial livestock industry. That would allow retention of most of the current Plum Island employees.

Asked about the administration's finalist sites located near livestock, Breeze said: "It seems a little odd. It goes against the ... safety program of the last 50 years."

The former head of the U.S. Agriculture Department's Agricultural Research Service said Americans are not prepared for a foot-and-mouth outbreak that has been avoided on the mainland since 1929.

"The horrific prospect of exterminating potentially millions of animals is not something this country's ready for," said Dr. Floyd Horn.

The Agriculture Department ran the Plum Island lab until 2003. It was turned over to the Homeland Security Department because preventing an outbreak is now part of the nation's biological defense program.

Plum Island researchers work on detection of the disease, strategies to control epidemics including vaccines and drugs, tests of imported animals to ensure they are free of the virus and training of professionals.

The new facility will add research on diseases that can be transferred from animals to humans. The Plum Island facility is not secure enough to handle that higher-level research.

Leaders of the House Energy and Commerce Committee also are worried about the lab's likely move to the mainland. The chairman, Rep. John Dingell, D-Mich., and the head of the investigations subcommittee, Rep. Bart Stupak, D-Mich., are threatening to subpoena records they say Homeland Security is withholding from Congress. Those records include reports about "Crimson Sky," an internal review about a publicized 1978 accidental release of foot-and-mouth disease on Plum Island and reports about any previously undisclosed virus releases on the island during the past half century.

The lawmakers set a deadline of Friday for the administration to turn over reports they requested. Otherwise, they warned in a letter to Homeland Security Secretary Michael Chertoff, they will arrange a vote next week to issue a congressional subpoena.

A new facility at Plum Island is technically a possibility. Signs point to a mainland site, however, after the administration spent considerable time and money scouting new locations. Also, there are financial concerns about operating from a location accessible only by ferry or helicopter.

The Homeland Security Department says laboratory animals would not be corralled outside the new facility, and they would not come into contact with local livestock. All work with the virus and lab waste would be handled securely and any material leaving would be treated and monitored to ensure it was sterilized.

"Containment technology has improved dramatically since foot-and-mouth disease prohibitions were put in place in 1948," Homeland Security spokeswoman Amy Kudwa said.

Cattle farmers and residents are divided over the proposal to move the lab to the mainland.

"I would like to believe we could build a facility, with the knowledge and technology we have available, that would be basically safe from a bio-security standpoint," said John Stuedemann, a cattle farmer near Athens, Ga., and a former scientist at the Agriculture Department.

Nearby, community activist Grady Thrasher in Athens is worried about an outbreak from a research lab. Thrasher, a former securities lawyer, has started a petition drive against moving the lab to Georgia, saying the risks are too great.

"There's no way you can balance that equation by putting this in the middle of a community where it will do the most harm," Thrasher said. "The community is now aroused, so I think we have a majority against this."

In North Carolina, commissioners in Granville County originally endorsed moving the lab to their area but later withdrew support. Officials from Homeland Security ultimately met with residents for more than four hours, but the commissioners have taken no further action to back the facility.

"Accidents are going to happen 50 years down the road or one year down the road," said Bill McKellar, a pharmacist in Butner, N.C., who leads an opposition group that has formed a

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USDA REE

United States Department of Agriculture | Research Education Economics | Office of the Under Secretary | Room 216W Jamie L. Whitten Building Washington, DC 20250-0110

INFORMATIONAL MEMORANDUM FOR THE SECRETARY

THROUGH: Dale Moore
Chief of Staff

FROM: Joseph J. Jen
Under Secretary APR 27 2005

William T. Hawks
Under Secretary
Marketing and Regulatory Programs APR 28 2005

SUBJECT: Replacement of the Plum Island Animal Disease Center (PIADC)

ISSUE:

The Department of Homeland Security (DHS) proposes to plan and construct a new facility probably on the mainland. There are important issues that require Department of Agriculture (USDA) attention and involvement.

DISCUSSION:

USDA has had a presence on Plum Island for 50 years for research and diagnostics on foreign animal diseases that pose risks to the U.S. livestock industry. By U.S. statute, foot-and-mouth disease (FMD) research with the live virus can only be conducted at an offshore location. Additionally, only the Secretary of Agriculture can authorize bringing the FMD virus onto the mainland under two special circumstances--when "...necessary and in the public interest to conduct research..." or "in the event of an outbreak of FMD..."

The real property assets and liabilities of PIADC and the responsibility for its operations were transferred from USDA to DHS in June 2003 in accordance with the Homeland Security Act of 2002. DHS is obligated to accommodate the continued presence of USDA program functions, research - Agricultural Research Service (ARS), and diagnostics - Animal and Plant Health Inspection Service (APHIS), in the PIADC facilities. Collectively, ARS and APHIS maintain at the Center a technical staff of about 50 personnel supported by an annual appropriation of about $8 million. This work is essential in order for USDA to meet its program responsibilities to help protect the U.S. food and agriculture system.

PIADC facilities are very old, outdated, very expensive to operate, in extensive need of repair and modernization, and do not meet the highest level of biocontainment security, biosafety level 4 (BSL-4), and other program requirements of DHS. USDA acknowledges these facilities shortcomings and limitations. Several years ago, USDA developed tentative plans for a $225 million onsite modernization program, but these plans were preempted upon the transfer of the facility custodianship to DHS.

Biocontainment facilities to meet USDA and DHS needs would be both biosafety level 3 (BSL-3) and BSL-4. A BSL-3 facility as currently on Plum Island protects against environmental release of organisms such as FMD. A BSL-4 facility would protect against environmental release and provide personal protection to personnel against agents that infect both animals and man for which there is no protection such as a vaccine or anti-viral. The Nipah virus which killed both pigs and people in Malaysia is an example.

In response to social and political considerations, DHS has made a policy decision to not construct or operate a BSL-4 facility on Plum Island. Accordingly, DHS proposes to plan and construct a totally new and modern foreign animal disease facility which may be on the mainland at a location yet to be determined. The facility might even be BSL-3 and BSL-4 structures at different locations. The new facility will be designed to meet the program requirements of both DHS and USDA. The new facility will fulfill the requirement for biocontainment facilities identified in Homeland Security Presidential Directive-9 and is currently designated as the National Bio and Agrodefense Facility (NBAF). Once the new replacement facility is available, the existing facilities on Plum Island no longer will be occupied by DHS or USDA.

The President's budget for fiscal year (FY) 2006 includes for DHS a $23 million request to plan and design the new facility. DHS estimates a total of $451 million will be required by FY 2008 for construction. DHS expects to receive the requested FY 2006 design funds and, under that premise, is proceeding now with available FY 2005 funds to let a $3 million contract in May 2005 for a conceptual design of the new facility and to evaluate location options. DHS has requested ARS' and APHIS' assistance to define facility program requirements, identify suitable location options, and develop and implement a communication plan for customers and stakeholders.

DHS desires to deal with these matters promptly in the remainder of FY 2005 so that formal facility planning and design can begin in FY 2006. This latter process will require up to 2 years followed by a 3- to 5-year construction period, assuming full construction funding is available. In the meantime, existing USDA and DHS programs at PIADC will continue there.

There are numerous issues for USDA to consider:

1. What is the USDA policy position on the DHS proposal to plan for a new facility on the mainland and what is the USDA role?

Comment: By virtue that the DHS proposal is embodied in the President's FY 2006 budget request and that HSPD-9 delegates responsibility to DHS and USDA to plan for an adequate National Bio and Agrodefense capacity, USDA should publicly support the DHS concept and proactively assist in the planning.

2. Will the Secretary authorize FMD live virus research and other work to be carried out on the mainland?

Comment: Short of new legislation to repeal the limit on FMD work to an offshore location, the Secretary will have to exercise his delegated authority to allow FMD work to be conducted on the mainland in the new facility as being in the public interest.

3. Can FMD and other exotic animal disease work be carried out safely in biocontainment facilities on the mainland and not pose risk to the U.S. livestock industry?

Comment: A study commissioned by USDA in 2002 concluded that the FMD virus and other exotic animal pathogens of concern to USDA could be fully contained and safely handled within a BSL3-Ag facility, as is being done in other countries, including Canada, the United Kingdom, Switzerland, Spain, Germany, and Brazil. Thus, USDA judges that these pathogens would not pose a risk to the external environment and the livestock industry. A second study indicated that a BSL-4 facility for large animal work also could be safely located on the mainland. However, these issues will continue to be controversial among some parties (see further discussion below).

4. What is the agricultural need for a BSL-4 animal health biocontainment facility?

Comment: BSL-4 biocontainment facilities are designed and required to protect humans working with highly contagious exotic agents that can infect both humans and animals (zoonotic diseases) for which there is not adequate human protection (vaccines). DHS has stated its needs for a BSL-4 capability. The USDA needs are less definitive because there are relatively few known BSL-4 agents that pose a severe risk to the U.S. livestock industry. However, there is always the potential for new disease agents, either naturally occurring or intentionally bioengineered, that could cause harm to both humans and livestock species. Having the capability and readiness to work with such new and unknown agents under the highest level of biosecurity, when and if needed, would be an important asset for fulfilling USDA responsibilities for agrodefense.

5. What are the anticipated reactions by the U.S. livestock industry and associated stakeholders to the DHS plan and USDA policy position?

Comment: In the past, the food animal industries have strongly opposed having the FMD virus on the mainland, even in biocontainment, because of the perceived risk to the livestock population due to an accidental escape. This opposition can be expected to continue and be

intense. USDA will have to work carefully with these customer and stakeholder organizations to help inform them of the adequacy of the DHS plan and USDA support. Ultimately, the stakeholders can be expected to exert their influence one way or the other through the congressional appropriation process and other forms of legislation.

6. What are the potential cost ramifications for USDA?

Comment: DHS has implied to this point that it will seek the necessary construction funds through their own budgetary process. However, because of the large sum of total funding required, and if delays or other difficulties are encountered in the appropriation process, there is the possibility that DHS at some point might seek USDA funding assistance, especially since USDA will occupy a significant portion of the new facility. The existing statutory language requiring DHS to provide facility and operational support for USDA programs at PIADC, at no cost to USDA, may no longer be applicable to a new mainland facility.

In addition to the $451 million construction cost for the new facility, DHS also estimates up to $100 million will be required to equip the new facility, relocate existing personnel and programs, and prepare the old PIADC facility for disposition. USDA can be expected to be called upon by DHS to finance its share of the relocation and new equipment costs, as well as increased ongoing operational support. USDA should seek clarification of these funding matters with DHS early in the planning process.

7. What are the USDA views on the location options for the new facility?

Comment: DHS has not predetermined or expressed a commitment to a particular site location but desires to engage USDA and stakeholders in an open process to identify and evaluate options in accordance with certain criteria. We can expect, however, that Fort Detrick in Frederick, Maryland, will emerge as one prominent option because a Biodefense Campus of relevant Federal programs already exists there, including the Department of Defense, Department of Health and Human Services, DHS, and USDA. The USDA presence is the ARS foreign plant disease biocontainment research program. The facility housing this ARS program is also in need of modernization which is being supported by an FY 2006 budget request of $3 million for planning and design. USDA should also support Ft. Detrick as a high potential option for the site of the PIADC replacement.

It is plausible to expect that Ames, Iowa, will also be suggested as a location option in light of USDA's strong presence there and our ongoing $462.3 million modernization program for the National Centers for Animal Health. USDA should not support the Ames option because the new facility capacity there is already fully committed to domestic animal disease programs and it would be important to keep the exotic pathogen work at a completely separate location for biosecurity purposes.

Although general stakeholder resistance is anticipated for all potential location options on the mainland, we can expect a more intense and focused opposition at any particular location by local public and stakeholder interests. This would be an expression of the "not in my backyard" syndrome.

An exception to this principle might occur for some State and University co-location options where local interests might welcome the prospect of a new $451 million Federal facility.

The DHS Directorate for Science and Technology has offered to meet with the Secretary and other senior USDA officials to further brief them on the DHS plans for a new NBAF to accommodate existing PIADC programs and expanded homeland security activities.

SUMMARY:

DHS is launching an aggressive initiative to plan and construct a new NBAF, probably on the mainland, to replace PIADC and to sustain essential biosecurity work on exotic animal diseases that also potentially pose public health risks. The new facility will accommodate relevant USDA programs, but there will be increased cost ramifications for USDA. The plan can be expected to be controversial among the public and industry stakeholders with respect to safety, location, and the need for a BSL-4 capability. USDA will become very involved and will have to play a strong role in helping to shape the facility plan and location as well as in defending and communicating the need to the U.S. livestock industry and other USDA stakeholders.

The Secretary will be briefed on this issue at 2:00 pm on May 2, 2005, by William T. Hawks, Under Secretary, MRP, Joseph J. Jen, Under Secretary, REE, W. Ron DeHaven, Administrator, APHIS, and Edward B. Knipling, Administrator, ARS.

UNITED STATES DEPARTMENT OF AGRICULTURE
SCIENCE AND EDUCATION ADMINISTRATION

FEDERAL RESEARCH
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GREENPORT, NEW YORK 11944

January 9, 1979

Subject: Final Committee Report: Exploratory Analysis - FMD Outbreak in Animal Supply

To: J. J. Callis, Director

In your memorandum of September 19, 1978, this Committee was designated to make an exploratory analysis of the FMD outbreak on September 15, 1978, in Animal Supply. From information in that memorandum as well as in subsequent discussions with you, the Committee understands that its purpose is to determine and analyze how the outbreak occurred. The Committee further understands that the need for committees to make recommendations designed to prevent a similar outbreak in the future and to determine if a violation of our safety program led to the September 15 outbreak will be decided after receipt of this report. A separate report of the outbreak and steps taken to control it is attached. (Appendix I)

The Committee learned that the FMD virus isolated from infected cattle was Type O_1. Although there were cattle, pigs, and sheep in Building 62, only cattle in pens 5 and 6 were infected. The cattle in pen 6 were being routinely worked with because they were being used for serum production. Serum collected from some cattle at slaughter contained low levels of FMD antibody but no VIA antibody. From the appearance of lesions in slaughtered cattle and serological results, it was thought that 2 or 3 cycles of infection had occurred in cattle in Building 62. However, the absence of VIA antibody and the serological results indicated that the initial infection probably had occurred about September 8, 1978.

This report briefly covers the areas of investigation by the Committee and indicates suspect areas of possible contamination and virus transmission including an analysis of why they are suspect and possible causes. Well aware of the seriousness of its task, the Committee has devoted much time and effort to make its investigation as complete as possible as to the cause of the outbreak. The most likely routes by which the virus escaped from the laboratory and was transmitted to normal animals became apparent very early in the investigation. Believing that no possibility should be overlooked, however, the Committee continued to investigate every situation or condition that conceivably could have contributed to the outbreak. To

include all of the information obtained would make this report overly long and probably detract from the main issues. Therefore, the Committee has condensed its findings for the purpose of this report but has its notes of the investigation on file for any future need.

There are three main barriers, or lines of defense, designed to prevent the escape of exotic disease agents from this Center. These barriers are:

1. The design, construction and operation of the laboratory buildings.

2. Restrictions on movement of personnel, materials, supplies and equipment.

3. The island location.

An investigation conducted by APHIS on the mainland of Long Island revealed no evidence of FMD spread from Plum Island. The Committee investigation, therefore, attempted to determine what breaks may have occurred in the first two barriers that could have led to the escape of FMDV from a laboratory and transmission of the virus to normal animals housed in Building 62. No work on Type O FMDV had been done in Laboratory 257 in several months, but three of the four laboratories in Building 101 routinely worked with this virus during August and early September. The investigation on the source of the virus, therefore, was directed to Building 101. Particular attention was given to any possible relationship of new facility construction at Building 101.

The design and construction of Building 101 to prevent release of virus include building integrity, exhaust air filtration, negative air pressure, incineration, chemical and physical decontamination procedures, and sewage treatment. The new construction activities and these systems were investigated and the people concerned with their operation interviewed. These findings are summarized as follows:

Virus Isolation Attempts

Over 200 samples for virus detection tests were taken from various areas in and around Building 101, exhaust filter systems, as well as the sewage treatment lagoons; no virus was detected.

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New Construction

There was no evidence that the construction at the front and on the east end of the building was involved. Conditions related to construction of the new incinerator at the west end of the building caused concern. A temporary plywood partition had been built across the west end of the incinerator corridor so that after appropriate decontamination the masonry wall at the end of the corridor could be removed. There is no evidence that contaminated air flowed past the partition to the outside. There was evidence, however, that during heavy rains, water was able to seep under the barrier to the inside and presumably out again where contract workers would have had contact with it. Dirt from the excavation site was hauled to a site approximately 300 yards from Building 62 in July through August 2, 1978. According to information from E&PM, the dirt was leveled off by PIADC equipment and personnel between August 20 and September 5, 1978. However, this dirt was hauled from the excavation site before the masonry wall at the end of the incinerator corridor was removed.

During construction activities, it has been PIADC practice to delay the removal of a wall in a contaminated area until the new construction is sufficiently complete to serve as a barrier. In this case, the masonry wall was removed before excavation for the new construction had been completed. The Committee was informed that this was done so that the existing basement floor line could be used to establish the floor line of the new construction.

Building 101 As A Whole

This building is over 20 years old and contains much of the original equipment. Because of age and advances in containment technology the building requires a continual and increasing amount of maintenance, repair and replacement.

Exhaust Air Filters

The majority of exhaust air filters tested were below an acceptable filtration efficiency. On many filter units, the rubber gaskets used to seal the edges of the filters and thus prevent the flow of contaminated air around rather than through the filters were deteriorated so that the units were not effective. An E&PM program for changing filters at regular intervals was in practice. However, this program did not include replacement of gaskets, and there was no evidence that gaskets had been replaced for a significant length of time and were brittle with age. Filter changes were being done by an E&PM person assisted by animal caretakers. After changing, the filters were not inspected and tested by Safety. The reason given for employing animal caretakers for filter changes and no safety inspection was lack of sufficient personnel.

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The biological filter systems installed in Building 101 were of acceptable design at the time of construction 23 years ago but would not be considered acceptable for a high hazard biological laboratory facility utilizing today's standards.

Direct aerosol spread of virus from Building 101 to Building 62 received serious consideration, but the pattern of disease in susceptible animals did not support this possibility.

Negative Air Pressure

Several instances of air pressurization were detected or reported which may have permitted flow of virus - contaminated air from a highly contaminated area. Reverse air flow from the incinerator corridor to the north corridor has been a problem. Records of air balance for some areas of the building were deficient.

The deficiency in records in the incinerator area was attributed to insufficient personnel; the night foreman could not enter this area because the contamination level would prohibit inspection of other areas. Delaying inspections of the highly contaminated areas to the end of the shift was not an alternative because of the frequency of the same individual working consecutive shifts.

Smoke tests revealed that unfiltered air was escaping from the incinerator area to outside the building on a continuing basis. The air pressure in the incinerator rooms is normally set, according to design operating procedures at -0.2 inches of water except during burns when it was set at atmospheric pressure and then reset to -0.2 following the burn. The Committee found that this procedure had not been followed for at least several months during which time the entire area had been pressurized to the outside atmosphere. The incinerator charging room was designed to operate at atmospheric rather than negative pressure during a burn. In addition, the Committee was informed that the safety interlock system for the supply and exhaust air handling units was improperly wired so that the supply stayed on when the exhaust went off resulting in pressurization. As in other parts of the building, the exhaust air filters appeared to be in a poor state of repair, and the gaskets were brittle from age. The escape of smoke from this area during tests indicated that virus-contaminated air could have escaped just as readily.

Central standby generators in the Power Plant are available for continuance of air handling systems during commercial power interruption. In this instance, the electrical distribution systems to the laboratory while being old and in critical need of updating apparently did not contribute to the incident.

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Chemical and Physical Decontamination Procedures

The approved procedures for chemical and physical decontamination of items leaving the laboratory building were adequate and being followed.

Sewage System

Some sewage vent filters were in poor condition and a few were missing. There was no evidence of any break in a sewer line between Building 101 and the sewage decontamination plant. The records and maintenance of the sewage decontamination plant were to be commended. Because of the critical nature of this facility, concern was expressed about the frequent need of employees to work consecutive shifts. There was no evidence that contamination of the sewage aeration lagoons had occurred.

Movement of Personnel

Movement of personnel was investigated as exhaustively as possible usually by direct interrogation. The most questionable procedure involved the delivery of animals from Building 62 to Building 101. Before October 1, 1976, animal handlers from Building 62 delivered animals by truck to a receiving dock at the Building 101 compound wall. From there, personnel who worked in the compound or Building 101 drove the animals through a chute to the east end airlock which leads into the Laboratory Services corridor. The empty truck was driven to the Dock Guardhouse for decontamination, and the animal handlers returned to Building 62 to work with normal animals without taking a shower or changing clothes. At no time, however, did these animal handlers enter the laboratory compound. After October 1, 1976, the truck was driven into the Building 101 compound by animal handlers from Building 62 to make deliveries directly to newly established airlocks on the north and west ends of the building. As before, the truck was driven to the Dock Guardhouse after the delivery and decontaminated, and the animal handlers returned to work at Building 62 without changing clothes or showering.

Following these procedures, if an animal handler or his clothing became contaminated with virus during a delivery of animals then he would have been an excellent means for transmitting the virus back to the normal animals in Building 62. Showers and clothes changes were never required of personnel entering or leaving Building 62 although most of the persons working in this building did shower at the end of the day for esthetic reasons and put on their street clothes to wear home.

Although other personnel movements were investigated, the only problem area revealed was that of the animal handlers described above. There was, however, much concern by large numbers of employees about the present quality of the PIADC safety program. In describing what they considered

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to be a deterioration of the safety program during the last two years, employees cited such changes as removal of the laboratory compound fences, elimination of deluge showers, too much freedom of movement between contaminated areas and from contaminated to clean areas, a general breakdown of safety procedures that served psychologically as constant reminders of the need to practice safety, the loading and unloading of passengers at the dock by buses that were not decontaminated before passage through the Dock Guardhouse gate, lack of availability of the Safety Officer because of frequent travel commitments and other duties, and the widespread movement of contractors' personnel all over the Island although contracts specifically limited their travel to designated areas. These concerns in some instances were caused by a lack of complete information. However, without exception, all employees contacted, whether in a formal interview or a casual conversation, expressed whole-hearted support for a strong PIADC safety program.

The questions of why many of the filter systems were in poor condition; there was no filter testing program, air pressures were not properly maintained, the incinerator area was maintained at atmospheric pressure, and normal animal handlers were not required to shower and change clothes after being in the laboratory compound are questions which have to be answered. Certainly, however, the increase in scientific work at this Center, the age of the facilities in which this work is done, the reduction in staff, and restricted budgets coupled with inflation must be, at least partially, responsible for these problems. A number of persons interviewed stated that there are too few people in E&PM and in Safety to do the work required; but whether there are in fact too few or those available are not being properly utilized is a question to be answered.

CONCLUSIONS

It is unlikely that the exact route of infection of the animals in Building 62 will ever be known. The Committee's investigation suggests that the most probable routes of escape of foot-and-mouth disease virus from Building 101 were: (1) faulty air balance of the incinerator area, (2) leakage through inadequately maintained air filter and vent systems, and (3) seepage of water under or through the construction barrier at the west end of the incinerator corridor.

The most probable means by which FMD virus was transported from the area of Building 101 to normal animals in Building 62 was by contaminated animal supply personnel. This contamination of the personnel most likely occurred during delivery of animals directly to the airlocks at the laboratory Building 101.

The undersigned Committee members have agreed and concur on the contents of this report.

C. H. Campbell

W. Moulton

P. D. McKercher

J. Walker

C. Mebus

M. E. Wiggin

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APPENDIX I

OUTBREAK OF FOOT-AND-MOUTH DISEASE IN ANIMAL SUPPLY, PIADC, SEPTEMBER 15, 1978 - REPORT OF THE INCIDENT AND IMMEDIATE CONTROL MEASURES

I. Description of FMD Outbreak in Animal Supply

A. Detection of the outbreak.

1. Building 257

Dr. A. H. Dardiri was preparing to inoculate two steers with bovine herpes mammilitis virus on the morning of September 15, 1978 in Building 257. He and his technician noticed that the animals did not appear normal and examined them. He immediately suspected FMD and called Dr. J. J. Callis, Director, at 0930 hours. Dr. Dardiri proceeded to take samples and start laboratory diagnosis.

2. Animal Building 62

The two steers in question were part of a shipment of five from the Building 62 normal animal holding facility to Building 257 on September 14. Dr. Callis immediately contacted Dr. Louis Jennings, Chief of Animal Supply and Dr. J. S. Walker, Biological Safety Officer. Dr. Jennings was asked to proceed immediately to Building 62 and examine the rest of the steers in the pen from which the two steers in question had been shipped on the previous day. At approximately 1100 hours, Dr. Jennings notified Dr. Callis that the first steer he examined had signs of a vesicular disease resembling FMD. Dr. Jennings took tongue epithelial samples which were immediately transported by Safety personnel to Dr. Dardiri at Building 257.

B. Administrative Actions

At approximately 1200 hours, Dr. Callis assembled the laboratory chiefs and management staff in his office to notify them of the above observations and to discuss the course of action that would be taken if the clinical diagnosis of FMD was confirmed in the laboratory. The contingency plan updated in 1969 for this type of emergency was reviewed and agreed to. It was the unanimous decision of all that the alternative method of disposal (incineration) would be followed, because burial of the large number of animals on hand (94 cattle, 13 goats, 66 lambs, 6 horses, 87 swine, 28 rabbits, 27 chickens and 2 ducks) was not possible within a short time interval. The decision was made to move all animals as rapidly as possible into the laboratories for incineration. This was to commence as soon as all personnel not involved in decontamination and control procedures had showered, dressed in clothes provided by the Center, and left

the Island. The superintendent of the Joseph Morton Company, Inc., who was also asked to come to the Director's office was informed of the situation and what actions would be required by him. Between the two major contractors, an extra 65 individuals had to be processed off the Island the same way as PIADC employees. At 1430 hours, Dr. Dardiri telephoned Dr. Callis and informed him that the clinical diagnosis of FMD was confirmed by laboratory tests and that the virus appeared to be Type O, (This was reconfirmed as Type O by Dr. Dardiri and Dr. D. O. Morgan the following week). Dr. Callis immediately put the contingency plan into action.

C. Extent of Infection

It was determined from examination of the animals sent into the laboratories for destruction that animals from Battery Steele and Building 21 showed no clinical signs of FMD. In addition, of all the FMD-susceptible species in Building 62, only cattle had signs of FMD. From laboratory examination of specimens from the involved cattle, it was determined that the initial infection had probably occurred about September 8, 1978 and most cattle had been infected only a few days.

D. Action Taken

In accordance with the contingency plan, all personnel not involved in the operation were removed from the Island by 2037 hours on September 15. Wheel decontamination road baths were constructed and operational by the time vehicles began moving. The movement of the infected steers from Building 62 then started and the first load was delivered to the east animal wing of Building 101 at 2100 hours. All cattle in Building 62 were moved into the east animal wing of Building 101, while all goats, sheep, horses and swine were moved into the west animal wing of Building 101. As the pens were emptied and animals moved toward the loading platform, the pens were sprayed with 5% NaOH solution. Disposal and incineration was begun immediately in the laboratory building. All cattle were examined and sampled by Dr. Morgan and staff in Building 101 at time of disposal. Building 62 was emptied of all livestock by approximately 2300 hours, September 15. The stock truck was then decontaminated, the men changed clothes and began moving the animals from Building 21 and Battery Steele into Building 257. This operation was completed by 0600 hours, September 16. Again, livestock pens were sprayed with 5% NaOH as the animals were being moved out.

The burial and burning of feed, bedding and hay from Building 62 and the feed warehouse was begun at the same time as the movement of livestock and was completed by 1630 hours, September 16. The barns were physically cleaned of all manure Saturday, September 16. The manure was sprayed with 5% NaOH and buried. Vehicle decontamination with 2.5% NaOH

and/or paraformaldehyde gas began on September 16 and continued for several days. Buildings 62, 21 and Battery Steele were completely washed down and decontaminated with 5% NaOH by 1600 hours, Monday, September 18. Other main buildings and roads were decontaminated by 0800 hours, Tuesday, September 19. This continued for several days before all buildings were completed. On Sunday, September 17, Dr. Callis appointed a committee, consisting of J. S. Walker, P. D. McKercher, W. M. Moulton, M. E. Wiggin, C. A. Mebus, and C. H. Campbell to investigate the cause of the outbreak. Dr. J. McVicar was named as Acting Safety Officer to manage the cleanup and decontamination operation because Dr. Walker was appointed to the Investigative Committee. The first meeting of the Committee was held September 18 and site visits made to Laboratory 101.

As cleanup operations were beginning at PIADC, Veterinary Services, APHIS, moved an investigative team to Long Island on September 16 with headquarters in Riverhead. The team leader was Dr. Stanley Newcombe. The team examined all susceptible livestock on Long Island and questioned all contractor and service personnel to ascertain that they had abided by the quarantine requirement for working on Plum Island. Another team of Veterinary Service personnel was dispatched to Virginia to examine the Stuart Land & Cattle Company's livestock from which the steers in question had been supplied.

III. Testing of Animal Supply Facilities to certify them as being free of FMD Virus.

Battery Steele and Building 21 were cleaned, disinfected and remained vacant for two weeks and then susceptible swine and calves were placed in these facilities for a four week test period. The animals were free of clinical disease during the test period.

Samples (Serum and esophageal - pharyngeal secretions) were collected at the beginning and end of the test period and submitted to Laboratory 257. No FMD virus or antibody was detected in any of these samples.

The same procedures were followed in Building 62 with animals being placed in the building on December 4, 1978. Samples were collected on January 4, 1979. No clinical disease was detected during the four week observation period. The laboratory results are not yet available.

ANSER PROPRIETARY
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Draft Report

Bioterrorism Simulation for the Secretary, U.S. Department of Agriculture

ANSER
Arlington, VA
September 30, 2002

This document includes data that shall not be disclosed outside the Government and shall not be duplicated, used or disclosed—in whole or in part—for any purpose other than to evaluate the contents herein. This restriction does not limit the Government's right to use information contained in the data if it is obtained by another source without restriction. The data subject to this restriction are contained on all sheets.

Executive Summary

ANSER was tasked to support the development of the U.S. Department of Agriculture (USDA) Master Plan on Homeland Security through a mission area analysis (MAA). This MAA has two integrated areas of effort: (1) a series of six exercise simulations designed to uncover shortfalls and test solutions for USDA and its homeland security missions and (2) an MAA and mission needs assessment methodology designed to systematically and scientifically identify and prioritize shortfalls and related solutions. The first simulation, "Crimson Sky," demonstrated to USDA and interagency leadership that a deliberately staged bioterrorism outbreak of a highly contagious animal disease presents a grave threat to the security and economic stability of the Nation. Some important findings and lessons learned derived from the simulation:

- *USDA's role.* The USDA will be the lead Federal department in providing policy and direction for strategic animal health emergency functions (detection, control, and eradication).
- *Partnerships.* USDA will depend on support from other Federal agencies and the affected states to carry out regular emergency management and logistical response functions. At the same time, the states will be looking to the Federal government for fiscal resources and technical guidance and for coordination of an effective national response to a foreign animal disease (FAD) outbreak. Both Federal and state authorities will be working closely with industry stakeholders in disease control and eradication efforts. This synergy is essential to an effective response.
- *Command and control.* This interconnectivity and sharing of information among Federal, state, and local departments, agencies, and emergency response teams will be critical elements for an effective governmental response to the outbreak.
- *The media and information sharing.* A comprehensive campaign will be necessary to inform the public about the threat and impact that the disease presents to the nation. This is required to combat the public's fear and the spread of misinformation about the disease.
- *Economic impact.* A major outbreak of a contagious FAD that affects multiple farms in multiple states could result in billions of dollars in economic impact, including eradication costs, production losses, compensation, and market repercussions. Such outbreaks could have staggering economic consequences both nationally and internationally beyond the agricultural sector. The extent of these economic impacts needs further study in order to arrive at sound policies.
- *Jurisdiction.* The issue of jurisdiction—that is, which federal and state departments and agencies have the lead and which provide support in a strategic animal health emergency—occurs in a number of areas and levels. These divisions of roles and missions need to be better defined.
- *Stop movements.* A key element in mitigating the consequences of a FAD outbreak is the potential of its spreading through normal transportation channels.

The extent of the stop movement needs to be well defined, and econometric data are necessary in order to arrive at informed decisions.

- *Mobilization.* The mobilization of Federal resources is critical to the management and consequence mitigation of a strategic animal health emergency. Within USDA, resources from throughout the Department will be called upon. While turning to their own resources, states also will look to the Federal government for vital assistance. The extent of the Federal reaction will be largely gauged by the invocation of the Stafford Act, which is the principal basis for Federal funding and other assistance to the states in cases of natural disaster.

- *Disposition of herds.* The disposition of herds, both infected and healthy, has a number of related issues that were brought out in the simulation. Pre-emptive slaughter, culling, vaccination, and disposal are issues for which clear policies are not now prescribed.

- *Indemnity.* Indemnity for the owners of destroyed herds and animals is well acknowledged, but compensation for second-, third-, and fourth-tiered parties and beyond remains an issue.

Crimson Sky was an appropriate beginning to the series of six simulations, which are designed to uncover shortfalls and test solutions for USDA and its homeland security missions.

The Crimson Sky Simulation

1. *Introduction.* The Crimson Sky Exercise Simulation is one element of an extensive homeland security MAA conducted by ANSER for the USDA. In performing that MAA, ANSER will further USDA's understanding of its homeland security roles and responsibilities. The MAA process will also help the Department to characterize its ability to protect against, prevent, or effectively deal with an attack on agriculture and its infrastructure and to determine deficiencies and recommend solutions in dealing with such a threat. This report is a quick-look summary of the simulation; a more comprehensive study of USDA's homeland security mission will be provided as a final product of the ANSER MAA.

2. *Background.* The Secretary of Agriculture, with the Deputy Secretary, directed USDA to create a Homeland Security Council and to delineate the Department's homeland security roles, responsibilities, and requirements. The objective was to increase the organization's capability to ensure the safety of America's agriculture and food products. As a direct result, ANSER was tasked to support the development of the USDA Master Plan on Homeland Security through an MAA. This MAA has two integrated areas of effort: (1) a series of six exercise simulations designed to uncover shortfalls and test solutions for USDA and its homeland security missions and (2) an MAA and mission needs assessment methodology designed to systematically and scientifically identify and prioritize shortfalls and related solutions. The entire methodology leverages state-of-the-art qualitative data collection, management, and analysis tools. A diagram of the ANSER USDA MAA Methodology and Roadmap appears in Appendix I.

The six exercise simulations are being conducted as an alternating series involving the three functional organizations within USDA that are most directly involved in the homeland security mission—the leadership, including the sub-cabinet mission areas that provide management and support to the homeland security mission, and the two agricultural services most directly involved in the protection and defense of the Nation's food supply and agricultural infrastructure against a bioterrorist threat: the Food Safety Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS).

The first simulation, Crimson Sky, demonstrated to USDA and interagency leadership that a deliberately staged bioterrorism outbreak of a highly contagious animal disease presents a grave threat to the security and economic stability of the Nation.

FSIS and APHIS will have two simulations each. The first for each of those services will address a terrorist event and associated issues using current policies, procedures, and capabilities to help identify specific shortfalls. Afterwards, each service will develop solution options to rectify the identified shortfalls. The second simulation for each service will be cast in the future, where the solution measures will be incorporated and tested.

Finally, in a capstone sixth simulation, the interagency and USDA leadership will again be brought together and exercised in a scenario that incorporates improvements in policies, procedures, and capabilities, and their effects will be demonstrated. This methodology of identifying issues and shortcomings, developing corrective measures,

and validating these improvements should benefit the MAA and the interagency and USDA policymaking processes.

3. *Purpose.* Crimson Sky achieved its purpose by effectively demonstrating to interagency and USDA leadership that a deliberately staged bioterrorism outbreak of a highly contagious animal disease presents a grave threat to the security and economic well-being of the Nation. That fact was brought out not only in the scenario and the roles in which the players found themselves, but also in presentations on the United Kingdom's foot-and-mouth disease outbreak of 2001 and the North Carolina Department of Agriculture and Consumer Services' modeling of a foot-and-mouth disease outbreak in the United States. In simulating such a bioterrorism attack, the interagency, USDA, state, and industry participants were educated in a number of highly relevant issues. Drawing attention to these issues will set the stage for the next five simulations and, more important, will elevate the consciousness of key governmental and civil sector policy makers to the strategic importance of these matters.

4. *Learning points.* In the development of Crimson Sky and the associated scenario, the USDA and ANSER game designers directed their efforts toward attaining the following learning points for the participating department, interagency, and state leadership:

1. The USDA will be the lead Federal department in providing policy and direction for strategic animal health emergency functions (detection, control, and eradication).

2. The USDA will depend on support from other Federal agencies and the affected states to carry out regular emergency management and logistical response functions. This interconnectivity will be a critical element for an effective governmental response to the outbreak.

3. As the scope of the outbreak grows, the ability to effectively conduct intrastate and interstate command and control activities as well as allocate limited resources will become an increasing challenge.

4. A comprehensive campaign will be necessary to inform the public about the threat and impact that the disease presents to the nation. This is required to combat the public's fear and the spread of misinformation about the disease.

5. A major outbreak of a contagious disease that affects multiple farms in multiple states could result in billions of dollars in economic impacts, including eradication costs, production losses, compensation, and market repercussions. Such outbreaks could have staggering economic impacts both nationally and internationally beyond the agricultural sectors.

The simulation achieved all the learning points to some degree. Given such an ambitious agenda for a one-day event, this was a notable feat. The USDA possesses the resident expertise and organization to deal with a strategic animal health emergency; nevertheless, such a domestic crisis involves a multitude of Federal, state, and local departments and agencies, including the Office of Homeland Security. While the predominant position of USDA in managing the crisis was certain, the interagency initially had difficulty in

determining the leadership role and contributions of others within that group. The interconnectivity of the various Federal departments and agencies was amply demonstrated within the Interagency Group; however, given the national strategic level of play, operational and logistical aspects of the problem were not fully addressed.

The USDA will depend on support from other Federal agencies and the affected states to carry out regular emergency management and logistical response functions. At the same time, the states will be looking to the Federal government for fiscal resources and technical guidance and for coordination of an effective national response to a FAD outbreak. Both Federal and state authorities will be working closely with industry stakeholders in disease control and eradication efforts. This synergy is essential to an effective response. Those operational aspects will be pursued in the follow-on APHIS and FSIS simulations. The Interagency Group developed, and the "President" repeatedly conveyed, assurances to the American people regarding their safety and well-being. Both the scenario and the aforementioned presentations brought out the major economic impact of a FAD outbreak.

5. *Methodology.* The simulation was conducted by means of a scenario involving the deliberate introduction of a FAD into the United States as a bioterrorism attack against the nation's agricultural industry and overall economy. The simulation was presented on September 30, 2002—the morning presentation being the simulated events of "April 20, 2003" and the afternoon presentation being the events of "April 22, 2003." The baseline scenario and periodic injections of ensuing events and information and requirements generated by the "President" were intended to stimulate game play. At the end of simulation play, a scenario background and epilogue presentation concluded the day's activities.

During portions of the morning session, "presentations of interest" were available for those inclined to learn more about the offered topics: the North Carolina Department of Agriculture and Consumer Services FAD Outbreak Model used for the simulation and the ANSER MAA process. Following the simulation, at the end of the day, an Executive Session seminar was conducted for selected principal interagency and USDA participants during which key issues and lessons learned from the simulation were addressed. Due to the sensitivity of some of the issues discussed, participation was restricted and the content of that session is *for official use only*. A schedule of events as they occurred appears in Appendix II.

The simulation used three functional groups: the Control Group, consisting of ANSER staff and subject matter experts drawn from USDA, the North Carolina Department of Agriculture and Consumer Services and other organizations, facilitated the activities of the player groups and advanced the simulation scenario through a series of updates and injections of events as they would have occurred and other information as it would have been learned; the USDA Group, composed of USDA leadership and subject matter experts, was intended to identify and develop issues for presentation to the Interagency Group; and the Interagency Group, composed of leadership from throughout the Administration, was brought together to deliberate issues, develop policies, and coordinate necessary actions in response to the crisis.

An Observers Group included representatives of state governments and industry to witness the simulation as it evolved and to monitor the Interagency Group deliberations that were televised throughout the conference center on closed-circuit TV. State and industry representatives were also given the opportunity to raise issues to USDA facilitators for consideration in both USDA and interagency deliberations. The disposition of those issues was to be determined at the discretion of USDA and interagency participants.

USDA officials posing as the media were also within the Observers Group. These "reporters" were to directly participate in scheduled media events within the context of the simulation. A schematic of the simulation methodology may be found in Appendix III. Organizational group assignments are listed in Appendix IV. A diagram of the ANSER Conference Center and the locations of participants' groups and selected parties are given in Appendix V. A list of confirmed participants is offered in Appendix VI.

As it evolved in its design and development, the simulation methodology posed a number of challenges. As initially intended, the simulation was designed along a single track. The USDA Group participants were to be oriented to the simulation and scenario and develop issues in the morning. The Interagency Group participants were to come into the simulation later in the day for orientation and then to deliberate over and decide policy upon issues presented by the USDA Group. In this manner, the USDA players were afforded ample opportunity to develop key issues, and the interagency players would be presented with well-developed options and recommendations.

For the invited interagency deputies, state governors, and delegations and a number of industry representatives, a dual-track design was adopted in an attempt to engage them throughout the day, since they wouldn't be included in some of the events. The dual track was enabled by inserting into the agenda the 30-minute United Kingdom foot-and-mouth disease presentation for the Interagency Group, state delegations, and industry representatives. While that presentation was offered, the USDA Group was afforded time to develop its initial recommendations and issues for Interagency Group consideration.

While the purpose of the simulation and learning points was achieved, and numerous key issues were addressed, the dual-track methodology proved to be problematic. The thirty minutes allotted to the USDA Group to develop initial recommendations and issues was insufficient. That circumstance was exacerbated by an orientation period that went well beyond its intended length. The USDA players quickly found themselves inundated with many issues yet little time to address them. In the absence of well-developed issues presented by the USDA Group, the Interagency Group adopted its own agenda, and deliberated issues often without the necessary background or subject matter expertise in the room. During the simulation, the state and industry involvement was similarly complicated. Because the focus was to get the Interagency and USDA groups on track, less attention was paid to state and industry issues. As the simulation progressed into the afternoon, the players adapted to their roles, and matters began to be addressed in a more deliberate manner.

6. *Key issues.* During the simulation, key issues related to an FAD outbreak were raised to varying degrees. Those key issues and associated considerations were as follows:

a. *Jurisdiction.* The issue of jurisdiction—that is, which Federal and state departments and agencies have the lead and which provide support in a strategic animal health emergency—occurs in a number of areas and levels. For the purposes of the simulation, the Interagency Group was chaired by the Office of Homeland Security; but for an actual terrorist attack on the Nation's agricultural infrastructure, it is unclear how the interagency response will be managed. Many participants initially looked at the multi-state outbreak of a FAD as an issue for the involved states to manage, while state representatives looked to the Federal government for leadership and assistance. While USDA has responsibility for the management and consequence mitigation of a strategic FAD outbreak, the Department of Justice and Federal Bureau of Investigation have oversight for all domestic terrorism events. At the county level in many locales, local law enforcement will control the response. These divisions of roles and missions need to be better defined.

b. *Stop movements.* A key element in mitigating the consequences of an FAD outbreak is the potential of its spreading through normal transportation channels. States may be expected to implement stop movements early in any outbreak in order to prevent the spread of the disease both within and beyond their own borders. Others will implement stop movements to prevent the introduction of the disease into their states. In a strategic animal health emergency, the Federal government may be expected to order stop movements on interstate traffic. While the USDA Group recommended a national stop movement, the Interagency Group decided to impose a stop movement for the five states known to be infected. That decision was based upon the circumstances known by the Interagency Group at that time and the economic concerns raised within the group. In fact, due to the incubation time between infection and the symptoms and detection of the disease, the outbreak had already spread well beyond the initial five states. A lack of econometric data precluded the interagency from making an informed decision regarding the economic effects of a stop action. The extent of the stop movement needs to be well-defined in economic considerations—that is, the stop movement for carriers of susceptible animal populations, of all agribusiness, commercial carriers, and all traffic.

c. *Mobilization.* The mobilization of Federal resources is critical to the management and consequence mitigation of a strategic animal health emergency. Within USDA, resources from throughout the Department will be called upon. While turning to their own resources, states also will look to the Federal government for vital assistance. In a multi-state FAD outbreak at present levels of preparedness, certain USDA resources will be exhausted. States requesting Federal help will need to specify the numbers and types of assistance required. The extent of the Federal reaction will be

gauged largely by the invocation of the Stafford Act. In playing out the scenario, there were no clear thresholds for the application of the Stafford Act.

d. *The media and information sharing.* In managing the national outbreak of a FAD, the flow of information to the American people, the state governments, and the international community are essential. All these parties must be educated as to the true nature of the disease and its effects on humans and the food supply. They must also receive the assurance that the government has the situation under control. USDA must be pro-active in defining the message for the Administration and getting that message out. In the simulation, the "President" took talking points from USDA and the interagency and delivered those important messages to the American people.

e. *Disposition of herds.* The disposition of herds, both infected and healthy, has related issues that were brought out in the simulation. While the states were quick to put down infected herds, the extent to which seemingly healthy herds needed to be pre-emptively slaughtered or culled to contain the outbreak was unresolved. Vaccination as a means to contain the infection and its long-term economic effects were also discussed without conclusion. The disposal of hundreds of thousands of infected or susceptible livestock and wildlife presents logistical problems of immense proportion and also environmental and human health concerns.

f. *Indemnity.* Indemnity for the owners of destroyed herds and animals is well acknowledged, but compensation for second-, third- and fourth-tiered parties and beyond remains an issue. Will the feed grain producers, tanneries, shippers, and merchants in locally affected communities be compensated? By whom and for how much? An indemnification policy needs to be articulated early in an outbreak. Without such a policy, owners and growers will be rushing their livestock to market to sell their animals before the banks call in loans on the herds. The possibility of a stop movement precluding shipments to market will further aggravate this panic situation.

g. *Decontamination.* The methods and agents for decontamination of exposed persons and machinery were well understood within the USDA group. Nevertheless, when the process was raised within the interagency, the Food and Drug Administration and Environmental Protection Agency both aired concerns. Decontamination policy requires interagency coordination prior to the occurrence.

h. *Resume movement.* Directly related to the issue of stop movement and its economic implications, the question of when to resume movement needs to be considered. Again, econometric data is needed in order to arrive at informed decisions.

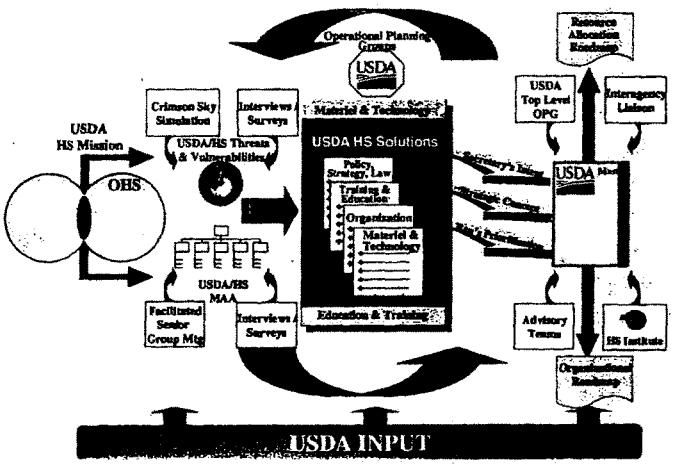
i. *Industry.* The commercial sector is an integral component of any FAD outbreak. Industry represents a pool of relevant technical expertise, facilities, and resources that need to be integrated into Federal and state responses to such an emergency.

j. *Econometric data.* The need for economic analysis permeated deliberations throughout the simulation. Such issues as euthanizing versus vaccinating herds, stop and resume movements, and levels of indemnity all require evaluation of cost versus benefits. Decision makers will be reluctant to make policies without such analysis and data.

These represent a few of the key issues captured by the simulation. Due to the time constraints of a one-day event, other issues could not be addressed, but they merit exploration—such as reconstitution of the herds and measures to deter, prevent, and mitigate such a terrorist act. The remaining five simulations will strive to address these and other issues.

7. *Conclusions.* The Crimson Sky simulation was an effective means of demonstrating to USDA and interagency leadership that a deliberately staged bioterrorism outbreak of a highly contagious animal disease presents a grave threat to the security and economic stability of the Nation. The simulation also brought out important lessons learned and key issues for further development and investigation. In bringing together these Federal and state departments and agencies responsible for homeland security, Crimson Sky advanced the ANSER USDA homeland security MAA and the interagency and USDA policymaking processes. Crimson Sky was an appropriate beginning to the series of six simulations, which are designed to uncover shortfalls and test solutions for USDA and its homeland security missions.

Appendix I: ANSER USDA MAA and Roadmap Methodology



Appendix II: Sequence of Events

8:30-9:15	Welcoming and Introductory Remarks *Dr. Ruth David, ANSER CEO* *The Honorable Ann M. Veneman, Secretary of Agriculture* *Senator Pat Roberts, R-Kansas*
9:00-9:45	United Kingdom Foot-and-Mouth Disease Outbreak Brief *Mr. James Hughes, First Secretary for Trade and Agriculture, British Embassy*

USDA Briefing Preparations (USDA Group)

9:45-10:15	*Briefing to the Interagency Group* SITREP as of 8:00 a.m., April 20, 2003 Dr. Ron DeHaven, Deputy Administrator, USDA/APHIS
10:30-10:45	Interagency Group Q&A Session
10:45-12:00	Morning Deliberations
12:30-12:35	"Presidential Statement to the American People"
12:30-1:00	USDA Briefing Preparations (USDA Group)
1:00-1:30	Briefing to the "President" and the Interagency Group SITREP as of 8:00, April 22, 2003 Dr. Ron DeHaven, Deputy Administrator, USDA/APHIS
1:30-3:00	Afternoon Deliberations
3:15-3:45	Presidential Press Conference *"President Roberts," "Secretary Moseley," Office of Homeland Security, Department of Justice, Environmental Protection Agency, Central Intelligence Agency*
3:45-4:15	Simulation Epilogue *North Carolina Department of Agriculture and Consumer Services Scenario Briefing—Dr. Tom McGinn and Mr. John Hoffman* *Concluding Remarks—Secretary Veneman*
4:30-5:15	Executive Session

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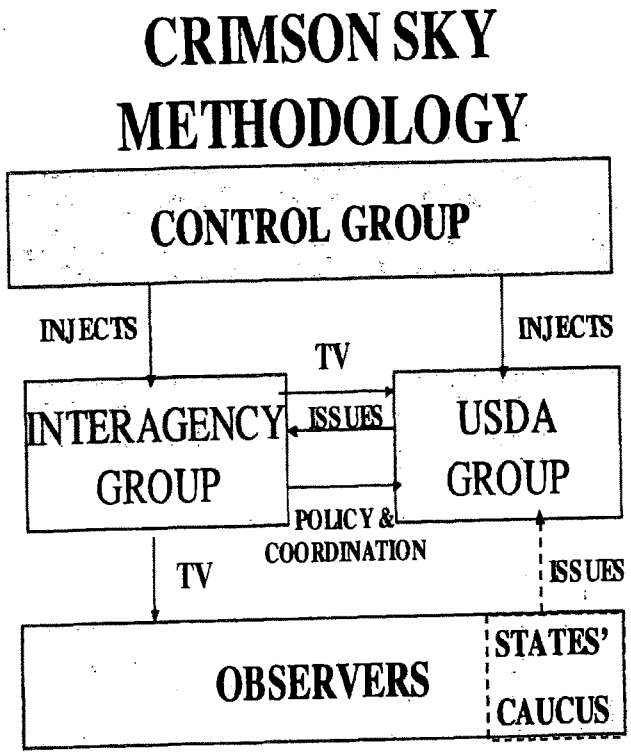
Appendix III: Simulation Methodology Diagram



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Appendix IV: Organizational Group Assignments

(* indicates Executive Session attendee)

Interagency Group

"Secretary of Agriculture"*
Department of Commerce*
Department of Defense*
Department of Health and Human Services*
Department of Interior*
Department of Justice*
Department of Labor*
Department of State*
Department of Transportation*

National Security Council Staff*
Office of Homeland Security*
White House Staff*

Central Intelligence Agency*
National Security Agency*
Joint Task Force–Civil Support*

Environmental Protection Agency*
Federal Emergency Management Agency*
Office of Management and Budget*
U.S. Trade Representative*

Members of Congress*

Commodities Futures Trading Commission*

USDA Group

"Deputy Secretary"*
Under Secretary for Farm & Foreign Agricultural Services*
Under Secretary for Food Safety*
Deputy Under Secretary for Food, Nutrition and Consumer Services*
Deputy Secretary for Natural Resources and the Environment*
Deputy Secretary for Research, Education & Economics*
Deputy Secretary for Rural Development*
Deputy Secretary for Market and Regulatory Programs (MRP)*
Assistant Secretary for Administration*
Assistant Secretary for Congressional Relations*
Administrator, Animal and Plant Health Inspection Service*
Deputy Administrator, Animal and Plant Health Inspection Service*
Administrator, Food Safety Inspection Service
Chief Financial Officer*
General Counsel*
Inspector General*
Chief Economist*
Office of the Budget and Program Analysis*
Press Secretary

Observers Group

State Delegations
Governors, State Veterinarians, Commissioners of Agriculture, and Directors of Emergency Planning/Preparedness

Industry Representatives
American Sheep Industry Association
Chicago Mercantile Exchange
National Chicken Council
National Milk Producers Federation
National Pork Producers Council
National Turkey Federation
National Cattlemen's Beef Association
American Meat Institute
National Food Processors Association
Grocery Manufacturers of America
National Renderers Association
National Corn Growers Association
National Association of Wheat Growers
National Cotton Council
American Soybean Association
American Veterinary Medical Association
Murphy-Brown LLC
American Feed Industry

"Media"

Others

Control Group

Subject Matter Experts
USDA Officials
North Carolina Department of Agriculture and Consumer Services
Other invited subject matter experts

ANSER Analysts and Staff

Appendix V: ANSER Conference Center Diagram and Group Locations

Conference Center Layout

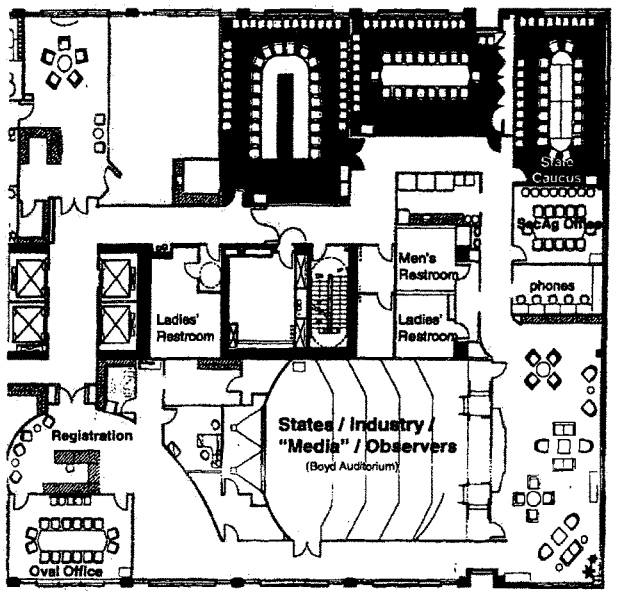
Interagency
[redacted]

USDA
[redacted]

State Delegations
[redacted]

ANSER Staff
[redacted]

Please Note: Access to rooms marked in red, green, and blue is limited to conference attendees with badges of that color and ANSER personnel.



Appendix VI: Confirmed Participants

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Homeland Security

Biodefense Knowledge Center
Rapid Tasker

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Tasking:
Given that DHS is heading into a process to select one of five possible locations for the National Bio and Agro-Defense Facility (NBAF), would an accidental laboratory release at these locations have the potential to affect near-by livestock?

Suspense timeline:
Provide initial response today and expect follow-on inquiries

Participants:
Systems studies team at LLNL
DHS-funded summer students working at LLNL
MESA Decision Support System development team
DHS Biodefense Knowledge Center

Contents of this response:

Previous accidental releases of FMD from laboratories 2
Livestock proximal to the proposed National Bio and Agro-Defense Facility sites 3
Texas Research Park, Texas 4
Manhattan, Kansas 5
Athens, Georgia 6
Flora Industrial Park, Mississippi 7
Umstead Research Farm, North Carolina 8

Previous accidental releases of FMD from laboratories

Historically, there have been several accidental introductions of FMD into domesticated herds of livestock. A summary of some of these incidents is provided here:

- In September 1978 FMD was detected in a herd of cattle located near Lab 257 on Plum Island. The animals were culled and the disease was not spread to the United States mainland.[1] Most of the workers on the island at the time of the disease incident were residing in New York City and these workers were not seen as a major risk of disease spread due to the routine decontamination procedures that were conducted for all facility personnel entering and leaving the laboratory. Based on a review of articles collected for this inquiry, the cause of the incident is unknown. However, the incident did result in a large amount of press coverage and eventually resulted in a release of a controversial book about Plum Island.[2]

- In January 1960 animals at a farm near Pirbright Institute (called the Animal Virus Research Institute at the time) became infected with a South African strain of the FMD virus (SAT-2). Improvements were made at the facility and similar ones around the world after this outbreak to ensure that similar outbreaks did not happen again.[3] Air filtration units were introduced to the isolation units and disease security measures were improved.[4]

- FMD virus was accidentally introduced into Sweden during the 1950s after a laboratory in Germany intentionally contaminated the air with sterilized hay dust end susceptible cattle were placed near an air draught 10 meters from the source. It is unknown whether this introduction was airborne or dustborne.[5]

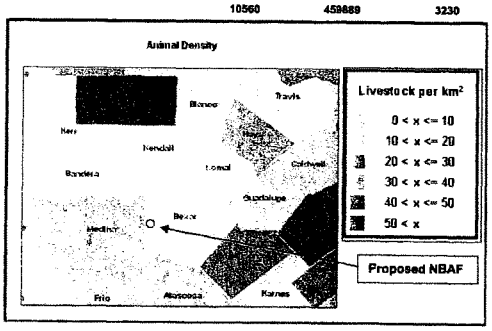
Livestock proximal to the proposed National Bio and Agro-Defense Facility sites

Openly available reports suggest that there are five sites currently competing for the NBAF facility (Texas, Kansas, Georgia, Mississippi, and North Carolina). Satellite imagery (from Google), National Agricultural Statistics Service data on livestock and poultry for the proposed host county and surrounding counties, and a livestock density map are summarized for each site below.

Texas Research Park, Texas 4
Manhattan, Kansas 5
Athens, Georgia 6
Flora Industrial Park, Mississippi 7
Umstead Research Farm, North Carolina 8

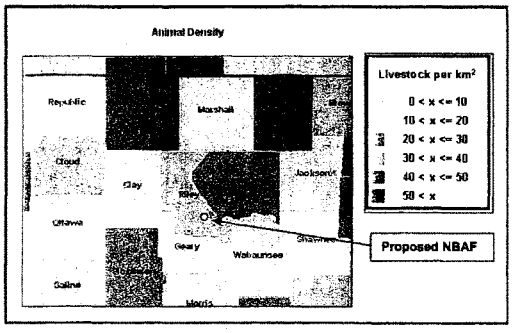
Texas Research Park, Texas

County & Surrounding Counties	Number of Herds	Number of Livestock	Number of Poultry Farms	Number of Poultry
Bexar	1823	58410	1011	26194
Kendall	815	33554	208	7296
Bandera	630	23983	253	2682663
Medina	1529	73909	360	8733
Atascosa	1344	92413	344	41141
Wilson	1839	94654	285	11476
Comal	684	18120	262	7279
Guadalupe	1896	54846	507	3626597
	10560	**459889**	**3230**	**6411379**

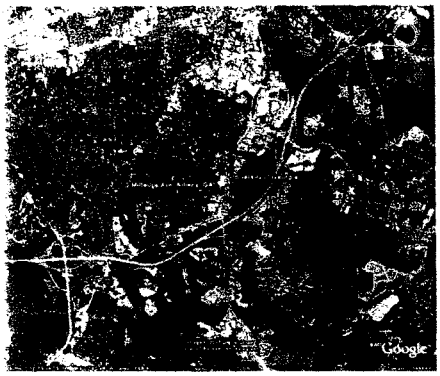


Manhattan, Kansas

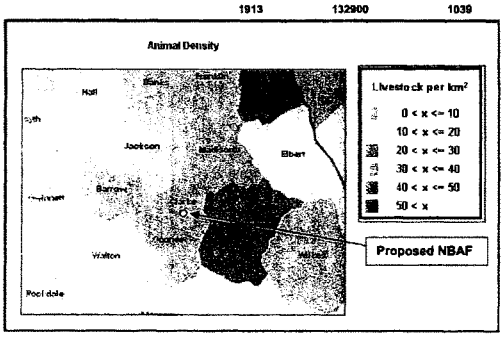
County & Surrounding Counties	Number of Herds	Number of Livestock	Number of Poultry Farms	Number of Poultry
Riley	262	46431	100	4575
Washington	523	155747	33	14338
Clay	333	55616	58	4068
Geary	139	41601	53	12260
Wabaunsee	379	75753	63	3974
Pottawatomie	589	91424	94	151483
Marshall	562	75935	70	1778
	2787	**542507**	**471**	**192474**



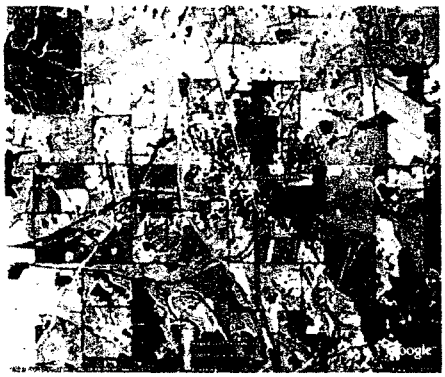
Athens, Georgia



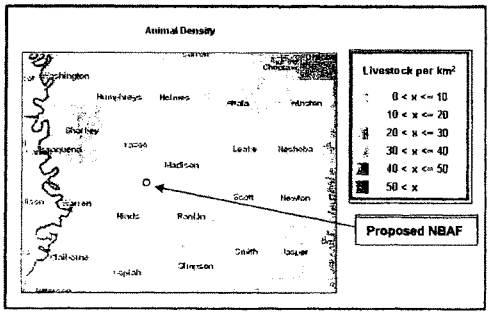
County & Surrounding Counties	Number of Herds	Number of Livestock	Number of Poultry Farms	Number of Poultry
Clarke	53	7511	89	1102891
Oconee	224	11078	123	5896898
Barrow	302	13356	179	4932261
Oglethorpe	252	52598	98	5191069
Madison	474	22072	252	1.65E+07
Jackson	608	26285	298	1.45E+07
	1913	**132900**	**1039**	**48199708**



Flora Industrial Park, Mississippi

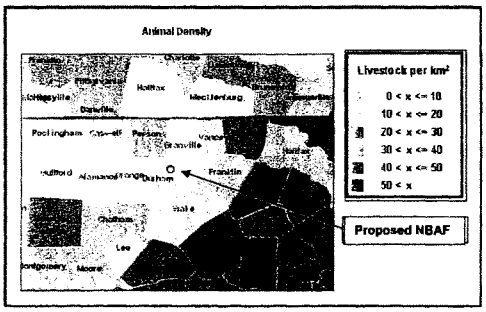


County & Surrounding Counties	Number of Herds	Number of Livestock	Number of Poultry Farms	Number of Poultry
Madison	324	191448	140	2675
Yazoo	231	13370	83	6760
Attala	268	10533	95	279024
Hinds	624	35300	253	968459
Rankin	424	18231	272	5035340
Scott	450	23639	288	3.16E+07
Leake	440	20270	253	1.11E+07
Holmes	238	11765	97	1477
	2999	**324556**	**1481**	**48945614**



Umstead Research Farm, North Carolina

County & Surrounding Counties	Number of Herds	Number of Livestock	Number of Poultry Farms	Number of Poultry
Granville	301	16674	229	10673
Halifax, VA	460	31893	150	33865
Mecklenburg, VA	355	24054	107	103959
Person	197	22583	99	20094
Durham	101	4611	162	10269
Wake	270	13835	513	338329
Franklin	236	40263	198	457200
Vance	77	2346	90	926070
	1999	**156059**	**1548**	**1900459**



[1] Eltman, F. (2004), New book says Plum Island may be responsible for disease outbreaks, terrorist target, Associated Press, Feb. 17, 2004, available online: http://www.sacnento.convec/sciencelib/4lyme/lab257-2.html.
[2] Carroll, M.C. (2004), *Lab 257: The Disturbing Story of the Government's Secret Plum Island Germ Laboratory*, William Morrow.
[3] Enserink, M. (2007), Labs suspected in Foot and Mouth Crisis, *ScienceNOW Daily News*, Aug. 6, 2007, available online: http://sciencenow.sciencemag.org/cgi/content/full/2007/806/1.
[4] Ministry of Agriculture, Fisheries, and Food (1965), *Animal Health, A Centenary 1865-1965*. Published by Her Majesty's Stationary Office, London, England.
[5] Hyslop, N.G. (1965), Airborne infection with the virus of foot and mouth disease, *Journal of Comparative Pathology*, 75: 119-126.

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CONFERENCE
PROCEEDINGS

The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock

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JAMES BONOMO, JOHN PARACHINI,
BRIAN A. JACKSON, GARY CECCHINE

CF-193-OSTP
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Prepared for the Office of Science and Technology Policy

RAND SCIENCE AND TECHNOLOGY

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I. Introduction and Summary

U.S. Agricultural Livestock,[1] Agro-terrorism[2] and Homeland Security

Over the past decade, the United States has moved to increase its ability to detect, prevent, and respond to terrorist threats and incidents. Much of this focus, which has involved considerable financial outlays, has aimed at upgrading public infrastructure using vulnerability threat analyses designed to maximize both anti-terrorist and consequence management efforts. While many gaps remain, investments in preparedness, training, and response have led to the development of at least nascent command structures that have incrementally begun to span the ambit of potential terrorist attacks, from conventional bombings to more "exotic" biological, chemical, radiological, and nuclear incidents.

Agriculture is one area that has received comparatively little attention in this regard, however. In terms of accurate threat assessments and consequence management procedures, the general farming sector exists somewhat as a latecomer to the growing emphasis that has been given to critical infrastructure protection (CIP). Indeed, agriculture was only incorporated as a specific component of U.S. national counter-terrorist strategy following the September 11, 2001, attacks on the Pentagon and World Trade Center.[3]

This lack of attention is problematic for three main reasons.

First, agriculture and the general food industry are highly important to the social, economic, and, arguably, political stability of the United States. Although farming directly employs less than 3 percent of the American population, one in eight people work in an occupation that is directly supported by food

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[1] This report only addresses threats to U.S. agricultural livestock; it excludes considerations relating to the food chain in general and does not deal with plant-related disease contingencies.

[2] For the purposes of this report, *agro-terrorism* is defined as the deliberate introduction of a disease agent into livestock herds for the purposes of undermining socio-economic stability and/or generating fear. Depending on the disease agent and pathogenic vector chosen, agro-terrorism is a tactic that can be used to cause mass socio-economic disruption or as a form of direct human aggression.

[3] It should be noted that Agriculture and Food Safety is included as one of eight sub-groups of the National Security Council's (NSC's) Weapons of Mass Destruction Preparedness Group, which was created in 1998 under the auspices of Presidential Decision Directive 62, "Combating Terrorism." The USDA serves as the chair of this sub-group.

production.[4] Cattle and dairy farmers alone earn between $50 billion and $54 billion a year through meat and milk sales,[5] while roughly $50 billion is raised every year through farm-related exports. In 2001, food production constituted 9.7 percent of the U.S. gross domestic product (GDP), generating cash receipts in excess of $991 billion.[6]

Second, the agricultural and food industries remain vulnerable to deliberate attacks as well as naturally occurring disruption. Several key considerations exist in this regard, notably:

- the highly concentrated and intensive nature of current American agri-business, which has worked to increase the potential speed of disease spread
- insufficient agricultural security and bio-surveillance[7]
- a hesitation on the part of agricultural producers to quickly report disease outbreaks at their facilities for fear that doing so will result in uncompensated culling and/or quarantine[8]
- a declining pool of veterinarians and diagnosticians appropriately trained in foreign animal diseases (FADs)[9]
- a continuing (and necessary) focus on aggregate livestock statistics as a result of the movement to larger breeding herds, which has lessened the option of individual animal health observation.

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[4] Agricultural Research Service, "Econoterrorism, a.k.a. Agricultural Bioterrorism or Asymmetric Use of Bioweapons," unclassified briefing given before the USDA, February 28, 2000. See also Henry S. Parker, *Agricultural Bioterrorism: A Federal Strategy to Meet the Threat*, Washington, D.C.: Institute for Strategic Studies, 2002, p. 11.

[5] Overall livestock sales in 2001 were in excess of $108 billion. See "Agro-Terrorism Still a Credible Threat," *Wall Street Journal*, December 26, 2001.

[6] Bureau of Economic Analysis, "Gross Domestic Product: First Quarter 2002 (Advance)," available on-line at www.bea.gov.

[7] Interviews with U.S. federal and state agricultural officials, Washington, D.C.; Sacramento; Boise, Des Moines; and Omaha, 1999-2003. It should be noted that, in 2002, the Bush administration announced plans to upgrade the screening of workforces employed at food processing plants and packing facilities.

[8] The USDA is currently considering a review of indemnity provisions specifically related to FMD, which would authorize payments to cover both disinfection costs as well as the full market value of destroyed animals and related products. For a detailed description of the proposed changes, see USDA, "Foot and Mouth Disease Payment of Indemnity, Update of Provisions," [Docket Number 01-069-1], RIN 0597-AB34, November 2002.

[9] Observations raised during the "American Farm Bureau Federation (AFBF) Commodity Advisory Meeting," Washington, D.C., January 2002.

Third, the capability requirements for deliberately exploiting these weaknesses are not significant. Not only are there a large number of potential pathogens to choose from,[10] but many of these microbial organisms are highly transmissible (something that is particularly true of foot and mouth disease, or FMD) meaning that there is no obstacle of weaponization to overcome.[11] Moreover, because most livestock diseases cannot be passed to humans, there is no requirement on the part of the perpetrator to have an advanced understanding of animal epidemiology, nor is there any need for elaborate containment procedures and/or personal protective equipment (PPE) in the preparation of the agent.

Finally, and perhaps most importantly, the ramifications of a concerted bio-assault on the U.S. meat and food base would be far-reaching and could quite easily extend beyond the immediate agricultural community to affect other segments of society.

A large-scale attack would, at the very least, have substantial economic repercussions in terms of containment and depopulation costs, revenue deficits suffered by industries directly and indirectly supported by agriculture, and losses resulting from protective embargoes instituted by major trading partners. As the United Kingdom's 2001 FMD outbreak demonstrated, the extent of the overall fiscal burden associated with emergency disease management can be enormous, running in this case to over 8 billion sterling (roughly U.S. $14.5 billion at current exchange rates).[12]

Aside from economic considerations, the successful introduction of biological pathogens among livestock could undermine popular confidence and support for government, especially if eradication procedures focus on instituting controversial mass culling and depopulation measures that are unlikely to be understood by the electorate at large. In the event that a zoonotic agent is released, a widespread public scare might also erupt—the psychological parameters of which would be extremely difficult to manage should human deaths occur. The angst and general fear triggered by the appearance of bovine

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[10] The Office International des Epizooties (OIE) has identified at least 15 "Class A" diseases that have the potential for serious and rapid spread and which pose serious risks to socio-economic stability, public health, and international trade. For further details, see OIE, "Classification of Diseases," available online at www.oie.int.

[11] This is an important consideration as the issue of weaponization is frequently cited as one of the main obstacles mitigating the non-state offensive use of biological agents. For a good summary of the technical constraints associated with bio-terrorism and bio-warfare, see Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century*, Washington, D.C.: National Defense University, Center for Counterproliferation Research, 1999, pp. 26–29.

[12] See Iain Anderson, *Foot and Mouth Disease 2001: Lessons to Be Learned*, report presented to the Prime Minister and the Secretary of State for Environment, Food and Rural Affairs, London: Her Majesty's Stationery Office, July 22, 2002, p. 2.

spongiform encephalopathy (BSE, which has been directly connected to a variant form of the human brain-wasting Creutzfeldt-Jakob disease) in the UK, continental Europe, and, most recently, North America provide just a partial insight into the type of social dynamics that could be unleashed in reaction to a contingency of this sort.

The catastrophic events of September 11 have, to a certain extent, focused greater national attention on some of the weaknesses inherent in the U.S. agricultural sector and the ramifications that would eventuate if these were to be exploited. Reflecting this, increased federal allocations have now been made available to support general emergency management and preparedness in the food and livestock industries. The Agriculture Research Service's (ARS's) counterterrorism budget for FY03, for instance, has been increased to $5.5 million from a FY02 base that had remained unchanged at $500,000. This amount is in addition to the $328 million in Emergency Supplementary Assistance (ESA) that the U.S. Department of Agriculture (USDA) as a whole has received to augment bio-security and surveillance efforts related to intentional attacks against the country's food supply.[13] More important is the extra funding that has been made available to the Animal and Plant Health Inspection Service (APHIS)—the USDA's main frontline unit when it comes to rapid disease response, containment, and control—which in FY03, amounted to $146 million.[14] This being said, federal fiscal resources that have been made available to the USDA remain relatively marginal when compared with other areas of homeland security.

The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock

Motivated by the various concerns discussed above, OSTP, in conjunction with RAND's S&TPI, organized a Blue Ribbon Panel to investigate policy options available for mitigating the potential threat of bio-terrorism directed against agricultural livestock. Key stakeholders and experts in the farming, food, and national security communities-including scientists, academicians, and policy-makers-were brought together for a two-day conference in December 2003 to identify and prioritize principal needs in the country's agricultural emergency management R&D portfolio for thwarting potential terrorist attack contingencies.

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[13] Interview with USDA officials, Washington, D.C., May 23, 2002. See also USDA, *Budget Summary 2003*, available online at www.usda.gov.

[14] USDA, "Agriculture Budget Proposes Increases in Key Areas," news release, no. 0031.02, February 4, 2002; USDA, *Budget Summary 2003*.

Papers and Power Point overviews addressing several important topics related to the livestock animal disease threat and control were presented during the meeting. These presentations[15] served to provide the context for subsequent breakout sessions tasked with articulating the major components that could become part of a future federal agro-terrorism defense agenda. Four specific groups were organized, covering the following:

- cross-jurisdictional surveillance and information technology (IT)
- infectious disease epidemiology
- vaccination and protection technologies
- detection, diagnosis, and forensics.

Each group was instructed to identify the main research needs in the assigned subject area; to prioritize these requirements; to recommend ways by which current gaps could be addressed from a technical R&D standpoint; and to project estimated timelines and budgets for instituting suggested changes and innovations.[16] The full narratives for each of the four breakout sessions, as well as the membership for each group, are included later in this report. It is hoped that the results of this conference will now be used as an important source of information to help inform future policy decisionmaking in these areas.

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[15] This report contains only full papers that were delivered during the conference. The following Power Point presentations and transcripts can be accessed at RAND's S&TPI website (www.rand.org/scitech/stpi/Bioagpanel/):

a) "U.S. Agriculture, Critical Infrastructure Protection and Homeland Security" (John Vitko, Department of Homeland Security)

b) "Advanced Animal Pathogen Research" (Colonel Gerald Parker, Department of Homeland Security)

c) "Attacks Further Down the Food Chain" (Jean Hellebone, Canadian Food Inspection Agency)

d) "Active and Passive Disease Surveillance" (Dorothy Preslar, Federation of American Scientists)

e) "Agro-Terrorism Modeling and Simulation" (Tim Carpenter, University of California, Davis, Department of Medicine and Epidemiology)

f) "Overview of U.S. Response Capabilities" (Larry Granger, APHIS, United States Department of Agriculture).

[16] Only two breakout groups managed to provide estimates of timelines and budgets within the schedule of the two-day workshops—Infectious Disease Epidemiology and Vaccine and Protection Technologies. Both sessions were able to meet this requirement largely because they had the benefit of being able to base their respective calculations on development and financial data bearing off innovations that have been made in the human disease science field.

8

Key Findings and Recommendations from the Breakout Groups of the Blue Ribbon Panel

Each breakout group reported its key findings and recommendations at the conclusion of the conference. While these respective narratives are discussed in more depth in Part II, we have summarized them here in the form of a primer for the convenience of the reader. This will allow policy-makers and analysts to quickly extrapolate the main themes that came out of the conference without having to go through the entire document. Unfortunately the schedule of the workshop did not allow the full panel to consider each recommendation. While the findings and recommendations were described to the full panel, only each breakout group can be said to have considered them carefully.

It is important to note the section that follows is neither interpretative nor analytical in nature; it merely summarizes the key R&D gaps and associated recommendations that were made by participants in the respective breakout sessions. It also uses the same structure and organization that each of these groups devised, so that the reader may more easily find the related discussion in Section II. The overall purpose of this part of the document is to encapsulate the major findings of the two-day workshop, not to independently assess how they might figure into broader federal government agricultural policy and programs.

Cross-Jurisdictional Surveillance and Information Technology (IT)

Key Weaknesses

1. An inability to electronically track livestock from birth to the slaughterhouse.
2. A dearth of standardized and widely accepted electronic data repositories appropriate for disease surveillance.
3. The lack of established standards and processing methods to integrate and evaluate the utility and relevance of data derived from dissimilar sources.

4. The inability of many agricultural producers, managers, and veterinarians to recognize quickly the clinical signs associated with foreign animal diseases (FADs) and/or uncommon health events.
5. Insufficient incentives on the part of potential disease data suppliers (e.g., zoos, environmental and resource agencies, rendering plants, international and national disease surveillance networks, accredited veterinarians, slaughterhouses, animal research laboratories, port of entry/customs officials) to make this information available to appropriate governmental authorities.

Recommendations

1. Design, develop, and implement a comprehensive national livestock premises and animal identification and tracking system.[17]
2. Undertake research and outreach programs to enhance education and awareness about FADs, outbreaks of new infectious diseases, and best practices in the commercial and government sectors when animal disease incidents occur.
3. Support research for a range of issues that contribute to the effective integration of animal disease incident data.
4. Support R&D of programs to bolster government and industry trust in the stewardship of a safe, healthy, and sustainable animal sector.
5. Support research to undertake a cost-benefit analysis of creating a comprehensive animal identification and surveillance system; support additional research exploring cost-sharing arrangements to construct such a system.
6. Provide support to increase the technological capabilities of the National Veterinary Services Laboratory.

[17] After initial start-up costs, the funding for such a system is expected to stabilize at $122 million per year.

Infectious Disease Epidemiology

Key Weakness

1. Inadequate human and infrastructure resources for conducting epidemiological research and supporting cross-state and regional studies.
2. The lack of end-to-end models that are developed with a practical definition of success and which are: (a) usually restricted to smaller geographic areas and often a particular state; (b) often unconnected to wider human/social behavior, including even basic socio-economic effects; and (c) frequently lacking in terms of mapping the full dynamic of infectious outbreaks, from disease introduction to recovery or reconstitution/repopulation of affected herds and flocks.[18]
3. The lack of (or lack of access to) GIS (Geographic Information System) and other data on animal locations and on transport to support the genesis of holistic and appropriately formulated epidemiological models.
4. Insufficient analysis of the negative social impacts of disease outbreaks and the role of risk communication in mitigating these effects.

Recommendations[19]

1. The development of a national consortium of ag-bio researchers, funded over a period of at least five years that would meet at least quarterly and would comprise a central hub of management responsible for stipulating requirements for the training and employment of graduate students, interns, and research assistants.[20]
2. More and better-directed infrastructure investment, including moves to create and fund epidemiological rapid response teams.

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[18] This is all needed to ensure modeling results will be useful in helping federal agencies determine response priorities and resource allocation should attacks actually take place.

[19] The list reflects the findings of the Infectious Disease Epidemiology breakout group in their entirety. No aggregation or synthesis of the recommendations was made.

[20] The creation of a national consortium of this sort would help facilitate communication, develop expertise, create unified directions for research activities, and allow greater involvement by decision-makers in evaluation and oversight. Such an arrangement could also take advantage of regional differences and integrate specific information from the local and state level into wider national models of disease control.

3. The establishment of an ag-bio equivalent to the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) that could serve as outreach agencies to facilitate global networks and accessible research relationships focused on emerging diseases.
4. Greater use of epidemiological modeling that draws on a coarser level of spatial granularity, perhaps to the level of the county and/or zip code.
5. The formulation of alternative data-collection strategies (and appropriate mechanisms for addressing confidentiality issues) that would reduce the current reliance on having the government demand information ahead of time.
6. The development of technology platforms able to support a real-time capacity to build large databases quickly.
7. Better leverage (and possible ownership) of existing corporate industry data relevant to the needs of academic epidemiologists by making more R&D grants available to commercial and other potential stakeholder groups.
8. Increased understanding of how to communicate risk to specific audiences and the use of this knowledge both to build fully inclusive models and to allow more productive uses of their results.
9. More and better use of systematic risk analysis to determine how an individual might intentionally introduce a livestock disease agent.
10. Increased interaction between federal government agencies and epidemiological modelers to improve the range and distribution of resource allocation parameter estimates.
11. More intensive analysis of the social and economic impacts of disease outbreaks to support the development of appropriate "end-to-end" modeling.
12. Suggested levels of research funding:
    a) expansion and refinement of epidemiological models: $2 million annually (number of years not specified)
    b) development of disease introduction and pathway risk analysis: $1 million annually
    c) evaluation of current disease interdiction and prevention efforts: $1 million annually
    d) development of academic/state/federal/industry research consortia: $5 million annually per livestock industry
    e) determination of GIS data needed for epidemiological modeling and response: $1 million

f) gathering of, or access to, GIS data needed for epidemiological modeling and response: $3 million annually

g) risk communication: $2 million

h) determination of socio-economic impacts associated with disease outbreaks: $2 million annually

i) development of an international outreach center: $10 million annually.

Key Weaknesses: Disease-Specific Issues[21]

1. Insufficient understanding of the overall transmissibility—particularly in terms of airborne distance—and environmental survivability of FMD.
2. A lack of knowledge on the cross-species existence and persistence of FMD.
3. The need to understand better climatic factors influencing the emergence and spread of FMD.
4. Inadequate strategies for: (a) disposing of animals contaminated with FMD; and (b) appropriately compensating agricultural producers affected by quarantine and depopulation measures.
5. Uncertainty as to the effects of cumbersome personal protective equipment (PPE) on the effectiveness of first responders dealing with zoonotic diseases.
6. Incomplete research on the general epidemiological dynamics of Nipah/Hendra.
7. Insufficient understanding of Highly Pathogenic Avian Influenza (HPAI) sub-strains and the distribution pathways by which they spread between different species, including factors that have allowed certain serotypes to "jump" to human populations.
8. Inadequate understanding of what causes the development of velogenic strains of Exotic Newcastle Disease (END) and, thus, how they might behave epidemiologically.
9. Inadequate knowledge of the transmissibility of Classical Swine Fever (CSF) and its potential to spread to wildlife populations in the United States.
10. The need to better understand Rift Valley Fever (RVF) wildlife reservoirs (which was seen as especially important given that the agent is essentially a disease of trade).

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[21] The group considered specific diseases in some depth. This is reported between pages 48 and 54.

11. Poorly developed risk communication strategies for allying public fears concerning the production channels, distribution pathways and overall transmissibility of various types of transmissible spongiform encephalopathy (TSE), which was seen to be especially salient to bovine spongiform encephalopathy (BSE).
12. A lack of basic science regarding the disease reservoirs of pox viruses (such as monkey pox) and the factors that affect their transmissibility among animal populations.
13. The lack of some rapid response capability to respond to emerging diseases, either newly arisen in the wild and so available for subsequent introduction, or perhaps deliberately created or engineered by or for terrorists.

Recommendations: Disease-Specific Issues

1. Increased laboratory experimentation focused on FMD aero-biology.
2. More intensive research to determine rough estimates of FMD survivability on various organic/inorganic surfaces and substances (including potential methods of smuggling).
3. Increased investment in capacity building to support the establishment of centralized rendering centers to dispose of FMD-ridden carcasses (drawing on the work that has been completed in the Netherlands in this area).
4. The provision of funding to develop PPE that is appropriate for handling zoonotic diseases, possibly leveraging off innovations that have already taken place in commercial settings.
5. Enhanced laboratory testing to ascertain the specific disease parameters and epidemiological dynamics of Nipah/Hendra and pox viruses.
6. The initiation of a dedicated R&D program focused on unknown agents and the factors that might cause specific viral families to "jump" the species barrier.
7. Suggested levels of research funding:
    a. transmissibility: $10 million annually
    b. carcass disposal: $3 million annually
    c. host/vector range: $2 million annually.

Vaccination and Protection Technologies

Key Research Needs: Common Requirements Across Disease Agents Defined as Seriously Threatening to U.S. Animal Health and Agriculture[22]

[Note: This breakout group focused much of its deliberations on animal pathogens highlighted in the following report: "Pre-Decisional Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group-Animal Pathogen Research and Development Subgroup," October 31, 2003. While this report, hereafter referred to as a Strategic Research Document (SRD), did not explicitly discuss selection of particular agents by terrorists, all members of the group agreed that it presented a generally complete list of seriously threatening diseases. The SRD is available on-line at www.usda.gov/homelandsecurity/homeland.html.]

1. The development of one-time, safe, cost-effective, and easy-to-implement vaccination strategies that have standardized government protocols for FAD suppliers (human vaccine protocols require one U.S. and one non-U.S. supplier).
2. The manufacture of "ideal" vaccines that:
    a) embrace marker detection mechanisms to differentiate: (i) vaccinated from non-vaccinated animals; (ii) animals that are infected and then vaccinated; and (iii) animals that are vaccinated and then infected
    b) offer broad serotype protection—preferably one vaccine for all serotypes
    c) have minimal need for re-application (relevant for delayed onset of infection [DOI] diseases)
    d) do not make animals unfit for human consumption
    e) are safe, economical, and easy to manufacture.
3. The creation of vaccine banks complete with appropriate logistical protocols for ensuring effective distribution.

[22] The list reflects the findings of the Vaccination and Protection Technologies group in their entirety. No aggregation or synthesis of the recommendations was made.

4. The development of effective, ground-tested implementation procedures to deliver all existing and future vaccination and protection technologies.
5. Consideration and assessment of viable alternatives to vaccination such as stamping out, pre-emptive slaughter (PES), and regionalization.
6. Increased leverage of university and private sector resources, including Requests for Development and Manufacturing Contracts for vaccine formulation, manufacturing, and stockpiling.
7. Providing for specific FAD and zoonotic disease courses (especially with regard to bovine, swine, and avian immunology) in accredited veterinary colleges, possibly to the level of Ph.D.
8. Maintenance of critical infrastructure facilities, such as Plum Island, and the improvement of national resources including the development of bio-safety level four (BSL 4) facilities capable of handling large animals.
9. The institution of an animal equivalent of Bio-Shield within the Department of Homeland Security (DHS) or elsewhere in the federal government.
10. Ensure that attacks against agricultural livestock are treated (and prioritized) as a specific national security issues.

Research Needs for Specific Prioritized Diseases

[Note: Prioritizations assigned to the pathogens listed below were based on seven criteria: (1) economic impacts; (2) virulence and potential for disease spread; (3) zoonotic potential; (4) morbidity or lethality of disease; (5) likelihood disease will spread to other species; (6) ability of terrorists to naturally acquire or otherwise manufacture a particular pathogen; and (7) difficulty associated with weaponization of the pathogen.]

1. FMD (designated as highest priority in terms of R&D because of its virulence, infectivity, potential impact on economic trade, and ease of access):
    a) the creation of an immediate, "ready-to-go" vaccine bank that has at least 6 million doses for all seven FMD serotypes and which can be delivered anywhere in the United States within 24 hours
    b) the creation of a supplemental vaccine bank that can deliver 10 million doses (bulk frozen, but ready for packaging) for all seven FMD serotypes within two weeks

c) the capacity to produce new vaccine stocks within a two-to-three-month time frame

d) the development of an ideal vaccine, which in addition to the broad criteria listed above, also inhibits persistent infections, prevents pathogenic "shed and spread," and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)

e) the incorporation of effective logistics and distribution protocols for appropriate vaccine disbursement

f) funding for additional research on treatments involving cytokines, interferon, and other anti-viral treatments

g) suggested level of research funding: $75-100 million annually over a seven-to-ten-year period (ten years being the time it will take to produce an ideal vaccine and other relevant therapeutics).

2. RVF (designated as high priority in terms of R&D because of its zoonotic potential, possibility of pathogen becoming endemic to the United States if transmitted to domestic animals, and likelihood of success-a vaccine is near completion):

a) complete development and testing phase of MP-12 vaccine that is currently being researched by the U.S. Army

b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also prevents transmission from host to vector and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)

c) development of a human RVF vaccine to protect animal workers (relevant given RVF's zoonotic potential)

d) suggested level of research funding: $20 million annually over a two-year period to establish a base RVF vaccine stockpile.

3. Nipah/Hendra (designated as high priority in terms of R&D because of its zoonotic potential):

a) continue evaluation of live vaccine currently under development (at both CDC and the BSL 4 facility in Winnipeg, Canada) in terms of safety and efficacy

b) examine alternative mechanisms for vaccine delivery

c) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity

d) consider the feasibility of constructing a BSL 4 facility with a significant large animal capacity to research existing and emergent highly contagious diseases

e) suggested level of research funding: $5 million for initial proof of concept; $20 million for the manufacture and stockpiling of a fully developed vaccine.

4. HPAI (designated as high priority in terms of R&D because of its zoonotic potential):

a) the creation of a vaccine bank containing at least 10 million doses for the two most common neuraminidase types of HPAI sub-strains (H5 and H7)

b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)

c) investigation of means to prevent cross-species transference of avian-to-swine, swine-to-avian, and human-to-swine

d) suggested research funding: $5 million annually for at least five years.

5. CSF (designated as high in terms of R&D because of its morbidity potential):

a) the institution of appropriate protocols to allow rapid importation of existing vaccine stocks (at least 5 million doses) from overseas banks to facilitate near-term outbreak control

b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)

c) suggested level of research funding: $10 million annually for five years.

6. END (designated as medium priority in terms of R&D because of its mortality and zoonotic potential):

a) modify existing Newcastle vaccine to produce an easy-to-deliver, cost-effective marker vaccine that is also effective for controlling END

b) develop appropriate distribution mechanisms that allow for routine use of new vaccine

c) suggested level of research funding: $2 million annually.

7. African Swine Fever (ASF, designated as medium-high priority in terms of R&D because of the uncertainty as to whether the creation of a vaccine is possible):

a) increase present efforts to determine whether a vaccine can be created

b) evaluate the terrorist potential of ASF (could or would terrorists attempt to harness ASF?)

c) investigate additional vector pathways for ASF (ticks, feral swine)

d) the development of an ideal vaccine, which in addition to the broad criteria listed above, also prevents pathogenic "shed and spread"

e) suggested level of research funding: $5 million annually.

8. Venezuelan Equine Encephalitis (VEE, designated as medium priority in terms of R&D because of the existing stocks of trivalent vaccine):

a) develop an animal vaccine research program that is informed by and draws off current Department of Defense (DoD) studies of human VEE infection

b) invest in general protective immunology to protect against VEE strains that have weaponization potential

c) the development of an ideal vaccine, which, in addition to the broad criteria listed above, offers sterile immunity

d) suggested level of research funding: $2 million annually.

9. Rinderpest (RP, designated as low-medium priority in terms of R&D because of the near eradication of the disease):

a) development of vaccine bank and maintenance of supplies to ensure defenses even in the event that the disease is fully eradicated

b) research into potential for the known existing RP serotype to mutate

c) suggested level of research funding: no recommendations.

Detection, Diagnosis, and Forensics Capabilities

[Note: This breakout group focused its deliberations on detection, diagnosis, and forensics for 11 main diseases: Avian influenza (AI), BSE, CSF, Cowdria ruminantiam (heart water), FMD, RP, bovine tuberculosis, RVF, END, and alpha/paramyxo viruses (such as Nipah/Hendra). Priority of these pathogens was based on the following six criteria: (1) level of morbidity and mortality; (2) level of disease transmissibility, including to human populations (i.e., is the disease zoonotic?); (3) presence of effective pathogenic vectors and wildlife reservoirs; (4) numbers of animal species susceptible to the disease; (5) availability of suitable control strategies; and (6) ability of the disease to survive in the environment.]

Key Weaknesses

1. A passive disease reporting system that is dependent on farmers and producers who may not have the necessary expertise to quickly "flag" potential FADs or bio-terrorism agents for subsequent diagnostic testing.
2. A lack of laboratories appropriately equipped with a comprehensive set of (positive and negative) diagnostic testing capabilities covering all main agents of concern.[23]
3. Diagnostic and testing capabilities that rarely take into account potential wildlife disease reservoirs for specific pathogens.
4. Insufficient funding to support versatile and/or on-going disease surveillance and testing over time.
5. The absence of clearly defined response protocols in the event that disease surveillance systems detect a potential pathogenic outbreak.
6. A lack of robust assay tests that are able to generate data which can assist with attribution analysis in determining the "who," "why," "where," and "when" of a deliberate disease introduction.

[23] The existing National Animal Health Laboratory Network (NAHLN) covers only 12 state facilities. Participants in this breakout group argue that a truly robust system will require the integration of at least 50 facilities in the NAHLN.

Recommendations

1. Strengthen the current passive system for disease detection and diagnosis by:
    a) addressing staffing needs at all levels to ensure sufficient system capacity
    b) improving the training for disease recognition
    c) increasing the availability of sophisticated diagnostics in testing laboratories
    d) instituting mechanisms to expanded data sharing within the National Veterinary Laboratory System (NVLS)
    e) increasing funding for diagnostic surveillance of potential agricultural bio-terrorism agents
    f) addressing IT requirements to improve the effectiveness of current diagnostic efforts.
2. Develop new technologies for active surveillance of FADs by:
    a) developing and improving field testing capabilities
    b) developing and fielding environmental surveillance systems.
3. Develop tests for diseases for which diagnostic methods are currently unavailable or inadequate by:
    a) promoting validation and deployment of prototype test methods
    b) addressing agents for which practical test methods are currently unavailable
    c) increasing information provided by specific test methods
    d) developing test methods that are applicable to different stages of the animal agricultural system
    e) developing and fielding faster testing methods.
4. Address the specific requirement of forensic applications by:
    a) validating assay test methods for specific forensic use
    b) improving laboratory and personnel capabilities for forensic analysis
    c) addressing procedural and data-sharing constraints associated with criminal investigations.
5. Promote and fund prospective emergency disease research and surveillance capability.

Observations

Several common themes are apparent across the different research areas described above. Most importantly, all four subgroups of the Blue Ribbon Panel fashioned their research initiatives in light of intensely practical concerns. The Cross-Jurisdictional Surveillance and Information Technology (IT) group generally focused on the steps needed to identify diseases and to usefully report them; the Infectious Disease Epidemiology group focused on making its models useful to decisionmakers during an outbreak; the Vaccination and Protection Technologies group focused on the creation of vaccines that are useful in practice, for example, by providing key "markers" to allow unfettered trade; and the Detection, Diagnosis, and Forensics Capabilities group focused on ways to validate current testing for prioritized agricultural bio-terrorism agents and increase their overall efficiency and diagnostic potential. Each of the breakout sessions were, thus, motivated by some precise, practical concerns.

This is an important shift, even for a research community that is already quite applied in its focus. While considerable attention has been paid to the individual needs of U.S. farmers, instituted mainly through the long-established Agricultural Extension Center (AEC), comparatively little research has been directed to the specific requirements of federal, state, and local agencies and departments when attempting to deal with large-scale disease outbreaks. The recommendations outlined above go a long way toward addressing this analytical gap. Thus, for example, the groups call for a comprehensive identification and tracking system for individual animals and for "end-to-end" models of disease spread, so that the various authorities have some basis for choosing one culling or vaccination strategy over another. This shift is important, and consistent with other developments taking place in homeland security as the U.S. government moves to grapple with the unfamiliar problems of terrorism post-9/11.

Other quite specific, practical initiatives abound in the groups' discussions. These initiatives ranged from the gathering of better geographic data on herds and flocks to the establishment of additional BSL 4 level facilities and the creation of less burdensome PPE for dealing with zoonotic diseases. Such recommendations flow naturally from the focus on providing better options for controlling any outbreak.

Another common theme across these research areas is the need for significant investments in infrastructure. Although several of the above initiatives are currently being considered for extra funding, such as the expansion of BSL 4 facilities, many larger and equally important areas require financing that has yet to be factored into federal budgetary allocations. Notable examples include: the creation of a national consortium of centers on epidemiology, to share results and methods; augmenting the scope and scale of the existing disease surveillance and health information networks; and the establishment of an international organization to both focus on emerging diseases, and allow U.S. researchers and veterinarians the exposure to FADs diseases not present in the United States.

The four groups additionally identified necessary advances in fundamental or basic research that is needed to *enable* important applied steps. In the best tradition of Pasteur's Quadrant,[24] these represent basic research tenets that are undertaken for purely practical purposes, ranging from the development of "marker" vaccines (or other appropriate treatments) for specific diseases to investigations of the competence of alternative (domestic) vectors in availing the transmission of pathogenic agents into and across the United States. Perhaps most dramatically, this aspect of the breakout groups' work also elucidated the relevance of the social and economic realms when considering responses to disease outbreaks and the concomitant need to factor these broader environmental concerns into epidemiological modeling. To the degree this work would be performed by other research communities, it will be important for respective funding agencies to keep the practical point of view firmly in mind; as it was this perspective that motivated the genesis of these particular policy recommendations.

Overall, the initiatives proposed by the subgroups represent a good start toward a future homeland security research agenda for making the industries associated with agricultural livestock more resilient to deliberate attack. Over time, and as new aspects become apparent to the research community, this list of policy suggestions will need to be revisited. For example, the existence of a cheap, effective vaccine might remove one disease from concern entirely; alternatively, epidemiological models might show that even more detailed geographic information is needed, which would have implications for data gathering and system development. That said, the recommendations contained in this report provide a useful initial framework for developing and refining tools to blunt bio-

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[24] For further details see Donald E. Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation*, Washington D.C.: Brookings Institution Press, 1997.

threats against an industry that remains critical to the economic well-being of the United States and its evolving system of homeland security.

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UNITED STATES DEPARTMENT OF AGRICULTURE
BIOCONTAINMENT FEASIBILITY STUDIES

STUDY REPORT:

BIOSAFETY LEVEL 4 FACILITY

AUGUST 15, 2002

This document reflects the opinions of SAIC and the independent Executive Panel and should not be construed as the official position of the USDA.

EXECUTIVE SUMMARY

In response to contract number GS-23F-8006H, delivery order 53-3K06-2-0701 from the United States Department of Agriculture (USDA), Science Applications International Corporation (SAIC) conducted a feasibility study that considered the national need, siting, programmatic, and operational considerations for a USDA Biosafety Level (BSL)-4 research and diagnostics facility. SAIC conducted this study concurrently with another feasibility study concerning facilities at the USDA's Plum Island Animal Disease Center, Plum Island, New York. The period of performance for both studies was May 9, 2002 - August 1, 2002.

The USDA tasks as stated in the statement of objectives for the BSL-4 study focused on providing an independent assessment for the following questions:

- What is the national need, including national security requirements, for a Biosafety Level 4 research and diagnostic facility for zoonotic diseases?
- What are the biosafety and biosecurity considerations in siting such a facility?
- What are the possible kinds of locations that would meet those considerations and research and diagnostic program needs?
- Should a BSL-4 facility be better linked physically or programmatically to an animal health or human health BSL-3 facility?
- What are the benefits/liabilities for joint research with universities or military researchers in a BSL-4 facility?
- Are there benefits/liabilities or collaborative research, e.g., is there a tangible benefit by having BSL-4 work accomplished in an atmosphere whereby other non-agricultural work may be ongoing?

In addition to SAIC's in-house expertise, an independent, 14-member Executive Panel was formed to address the study questions. SAIC and the panel concluded that:

- The USDA has a valid requirement for a BSL-4 facility to meet the growing national need and its increasingly difficult responsibilities to protect American livestock.
- To meet the national need, a BSL-4 facility would need to be designed, built, and operated as part of a consolidated BSL-3 Agricultural (Ag) facility that has the capability to seamlessly transfer between BSL-3 Ag and BSL-4 operations.
- Biosafety and biosecurity considerations are manageable at any site location. While biosafety may be addressed principally by facility design and practice considerations, biosecurity considerations are characterized principally as location issues that are site specific.
- A proactive program of joint/collaborative research with other agencies would benefit the USDA BSL-4 operational capability. Primary issues and challenges associated with collaborative research and diagnostic arrangements were identified as personnel reliability, competing priorities, program interfaces, and public perceptions.

Three etiologic agents of agricultural significance, the human-adapted strain of the avian influenza virus, as well as the Nipah and Hendra viruses, require BSL-4 containment and practices. This immediate need is reinforced by USDA readiness to conduct research and diagnostics on emerging and reemerging diseases. Since a viable BSL-4 program may be difficult to sustain on the basis of two known pathogens, the USDA would need to (1) establish a strategic plan that integrates BSL-4 and BSL-3 Ag operations, (2) locate this integrated facility at a large research/diagnostics campus, (3) assign a comprehensive mission to this facility, and (4) resource this facility to accomplish the strategic plan and mission.

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SAIC and a majority of the Executive Panel found that the USDA should consider conducting research and diagnostics of some agents normally associated with BSL-3 Ag conditions in a BSL-4 facility. This met with objection from 3 of the 14-member Executive Panel. Rationale for this finding includes the guidelines from the Centers for Disease Control and Prevention that call for BSL-4 containment when large amounts of pathogens normally associated with BSL-3 are required or when conducting operations that causes the aerosolation of these agents. In addition, BSL-4 containment of exotic foreign animal diseases may be a consideration to gain the approval of the agricultural, political, and other stakeholder communities to move research and diagnosis of these diseases to the mainland.

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1. INTRODUCTION

In response to a contract number GS-23F-8006 H, delivery order 53-3K06-2-0701 from the United States Department of Agriculture (USDA), Agricultural Research Service (ARS), Science Applications International Corporation (SAIC) provided the management and professional support services necessary to prepare reports for two feasibility studies. These two studies address a number of considerations including national facility requirements, benefits, costs, and risks, as well as site-selection implications of conducting agriculturally related biological research and diagnostic operations in Biosafety Level 3 Agriculture (BSL)-3 Ag and BSL-4 facilities.

Because of the timeframes involved, both studies were conducted concurrently during the period May 9 through August 1, 2002. This study report addresses the specific objective of determining the need, siting considerations, and programmatic and operational considerations for an USDA BSL-4 facility. The report is organized by the USDA statement of objectives (SOO) and specific tasks.

2. SCOPE OF THE TASK AND GENERAL UNDERSTANDING

2.1. Scope of the Task

The scope of this first study, Objective 1: Biosafety Level 4 Facility Study, was defined by the following tasks in the USDA SOO.

- What is the national need, including national security requirements, for a Biosafety Level 4 research and diagnostic facility for zoonotic diseases?
- What are the biosafety and biosecurity considerations in siting such a facility?
- What are the possible kinds of locations that would meet those considerations and research and diagnostic program needs?
- Should a BSL-4 facility be better linked physically or programmatically to an animal health or human health BSL-3 facility?
- What are the benefits/liabilities for joint research with universities or military researchers in a BSL-4 facility?
- Are there benefits/liabilities or collaborative research, e.g., is there a tangible benefit by having BSL-4 work accomplished in an atmosphere whereby other non-agricultural work may be ongoing?

The USDA requested an independent assessment of each task.

2.2. General Understanding

The latest threat of bioterrorism requires that USDA concerns become heightened with those diseases that pose a health risk to both animals and humans; that is, zoonotic diseases. USDA has long-standing interest in zoonotic viruses and already has several facilities dedicated to this type of research. Of particular interest and concern is the potential of animal diseases being transmitted to the general human population, either as a natural course of disease or as a bioengineered instrument of bioterrorism. Also bearing on the problem is the fact that USDA has limited capability for housing large animals in BSL-3 Ag containment for challenge studies that are vital to protecting U.S. livestock health as well as the population at large from zoonoses.

There are four biosafety levels of operation identified for laboratories involved with biomedical practices using infectious materials. These levels use laboratory technique, safety equipment, and facility design

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for containment and control of the hazards associated with infectious agents. BSL-4 identifies the highest biocontainment category for operations that involve dangerous or exotic human or animal pathogens that pose a high risk of life-threatening disease to man. The purpose of the design, equipment, and safety procedures of a BSL-4 facility is to prevent release of an agent into the environment and protect the human researcher from exposure to the agent. As can be seen in Table 1, within a BSL-4 facility all work performed must be either within a Class III biological safety cabinet (BSC), with working personnel wearing appropriate BSL-3 laboratory clothing or within animal rooms. Class I BSC or Class II BSC may also be used when working personnel wear a one-piece positive pressure personnel suit ventilated by a life support system. In addition, there are special engineering and design features to prevent etiologic agents from release into the environment.

Table 1. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench-top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste (to include animal effluent waste) • Decontamination of lab clothing before laundering • Baseline serum	Primary barriers = Class II or Class III BSCs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed[1]	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory
4	Dangerous/exotic agents that pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practice plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs <u>in combination with</u> full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decon systems • Other requirements outlined in the CDC/NIH reference

PPE = Personal Protective Equipment
Source: Department of Health and Human Services, *Biosafety in Microbial and Biomedical Laboratories*, 4th edition

The USDA, by virtue of its unique laboratory operational environment, has instituted an additional classification of biocontainment, BSL-3 Ag. A BSL-3 Ag facility is used with pathogens that present a

[1] There is a discrepancy in the BMBL where the descriptions on pages 52 and 75 (Tables) do not agree with the text of paragraph C4 on page 32. The more restrictive conditions are selected.

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risk of causing infections of animals and plants and causing great economic harm, foot and mouth disease (FMD) being the prime example. These facilities use the BSL-3 biocontainment level as a starting point, but also include many features associated with BSL-4, for instance [1]:

- Integral double-door steam and/or ethylene oxide sterilizers
- Lab contiguous with shower
- If windows are present, they are breakage resistant and sealed
- High-efficiency particulate air (HEPA)-filtered supply and exhaust; HEPA supply and two in series HEPAs exhaust for high-risk areas
- Decontamination of animal waste prior to disposal
- Seamless work surfaces
- BSL-4 entry and exit practices (i.e., clothing exchange, shower at exit, and decontamination of all material upon exit)

Thus, BSL-3 Ag has many features associated with BSL-4. The major difference is that BSL-3 Ag does not require personal protection via a BSC or positive-pressure suit.

2.2.1. Research Conducted and Expertise Used

During the initial phase of this study, SAIC staff efforts were focused on gathering technical data for review and use by a panel of independent experts to assess the national need for a BSL-4 research and diagnostic facility for zoonotic diseases. The panel consisted of 14 individuals with experience in animal health and agricultural sciences. The membership of the panel is provided in Table 2. Curriculum vitae for each member may be found at Appendix A. The panel met for two days, June 18–19, 2002, to discuss the issues, assess the national need for a BSL-4 research and diagnostic facility for zoonotic diseases, and propose recommendations. This provided the basis of this report.

Table 2. Executive Panel Members

Name	Organization
Dr. Richard Breitmeyer	California Department of Food and Agriculture
Dr. Corrie Brown	University of Georgia
Dr. Jerry Callis	U.S. Department of Agriculture, Retired
Ms. Regina Kowalski	Defense Intelligence Agency
Dr. Thomas Ksiazek	Centers for Disease Control and Prevention
Dr. Linda Logan	Texas Animal Health Commission
Dr. N. James MacLachlan	University of California, Davis
Lieutenant Colonel John Morrill	U.S. Army Southwest Plains District Veterinary Command
Dr. Kenneth Olson	Independent Consultant
Dr. Jean Patterson	Southwest Foundation for Biomedical Research
Dr. Jonathan Richmond	Centers for Disease Control and Prevention
Dr. Reynolds Salerno	Sandia National Laboratories
Dr. Alfonso Torres	New York State Animal Health Diagnostic Laboratory at Cornell University
Major Robert Wildzunas	U.S. Army Medical Research and Materiel Command

In addition to the Executive Panel, SAIC contracted for the services of a consultant, Dr. Richard O. Spertzel. Dr. Spertzel is recognized worldwide as an expert in matters related to bioterrorism and biological warfare (BW) defense. In this capacity, he served as the Head of the Biology Section and Senior Biologist for the United Nations Special Commission on Iraq (1994 – 1998) and has supported

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many U.S. Government agencies, to include the Department of Justice as an instructor in the Louisiana State University course "Emergency Response to Domestic Biological Incidences." While on active duty in the U.S. Army, Dr. Spertzel served in varied BW defense and infectious disease assignments, to include Deputy Commander and Deputy for Research of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland. Dr. Spertzel contributed directly to the preparation of this report.

2.2.2. USDA Participation in Panel Meeting

Additionally, during the second day of the panel's deliberations, four USDA personnel (see Table 3) were available to respond to questions raised by panel members.

Table 3. USDA Representatives Made Available to Executive Panel

Name	Organization
Dr. Caird Rexroad	ARS
Dr. Thomas Walton	APHIS
Dr. Peter Fernandez	APHIS
Dr. Randall Levings	APHIS

2.2.3. Documentation and External Information Sources

In addition to the information derived from the Executive Panel meeting, several reports, manuals, and other documents from the USDA were supplied as Government-Furnished Information (GFI). These reports and documents were reviewed for relevancy and used to corroborate other fact-finding initiatives. These documents were posted on a secure, password-protected website for all SAIC personnel and Executive Panel members to review. A listing of GFI is included at Appendix B. Non-GFI documentation used during this study is identified in Table 4.

Table 4. Non-GFI Document Sources

Document Title	Document Date
Biological Defense Safety Program, 32 *Code of Federal Regulations* (CFR) Parts 626 & 627	
Interstate Shipment of Etiologic Agents, 42 CFR Part 72	
Bioterrorism Preparedness and Response Act of 2002 (Agricultural Bioterrorism Protection Act), Public Law (PL) 107-188.	
Department of Health and Human Services Publication, *Biosafety in Microbial and Biomedical Laboratories*, 4th Edition	April 1999
U.S. Department of Agriculture Draft Departmental Manual, *USDA Security Policies and Procedures for Biosafety Level-3 and Other Facilities*	1 May 2002
J.S. McKenzie, Emerging Viral Diseases: An Australian Perspective, *Emerging Infectious Diseases*	1999
K.B. Chua, W.J. Bellini, P.A. Rota, et al., Nipah Virus: A Recently Emergent Deadly Paramyxovirus, *Science*	2000
Emerging Infections: Microbial Threats to Health in the United States, National Academy Press	1992
Control of Communicable Diseases Manual (CCDM), ASM Press, Washington, DC	1995

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Table 4. Non-GFI Document Sources (cont.)

Document Title	Document Date
"Selected Examples of Emerging and Reemerging Infectious Diseases in Animals," in Public and Scientific Affairs Board, American Society for Microbiology, Congressional Briefing for the House Agriculture Committee	April 1996
Biological Control of Vertebrate Pests: The History of Myxomatosis – an Experiment in Evolution (BCVP), CABI Publishing, NY	1999
Emerging Infectious Diseases of Animals: An Overview, in *Emerging Diseases of Animals*, ASM Press	2000
U.S. Animal Health Association, *Foreign Animal Diseases Book*	Revised 1998

2.2.4. Contingency Issues and Risk Factors

2.2.4.1. Political and Economic Considerations

Although extremely important, panel members were instructed to not allow political and economic considerations to influence their discussions or the findings contained in this report. Notwithstanding this unconstrained approach, the following are considerations in making a decision regarding establishment of a USDA BSL-4 capability.

- Influence of Agriculturally Related Associations (e.g., National Cattlemen's Beef Association, National Pork Producers Council, American Sheep Industry Association, and the American Association of Equine Practitioners). These groups have very real concerns regarding the research and diagnostic programs of the USDA that warrant consideration in any decision-making process regarding potential establishment and site selection of a BSL-4 capability for working with disease agents affecting livestock.

- Economics of Agriculture. The economics of the U.S. livestock industry alone has been conservatively estimated to be worth $100 billion [2] annually with approximately 20% of this figure dedicated to export markets. The economic importance and magnitude of the livestock industry is an important consideration in any decision to establish a BSL-4 capability on the mainland.

- Congressional Liaison. As with the agriculture industry associations, the concerns of the U.S. Congress, state, and local elected officials are considerations in the decision-making process.

2.2.4.2. Other Considerations

- Public Perception. Establishment of BSL-3 and -4 facilities have been accepted by the public and successfully operated generally when outreach programs that keep the public fully informed have been established. Implementation of USDA plans for a new BSL-4 facility would benefit by public involvement and outreach. Further, public confidence and trust in associated USDA animal disease programs would benefit from the programs remaining open and transparent.

- Competing Priorities. As part of any decision to enter into a collaborative research operation with other organizations, an important issue that surfaced is the competing priorities for research and diagnostic programs on foreign animal diseases (FADs) and/or zoonotic diseases with other collaborative research programs. It is generally agreed that there are benefits from

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collaboration with exotic animal disease research and human and animal medical research. Success of such collaborative arrangements requires that provisions be established to ensure exotic animal disease research retains appropriate priority and support among the collaboration partners even though the respective research missions might vary. There was strong sentiment and agreement among the Executive Panel members that the USDA strategic plan should include a detailed and comprehensive plan to establish and sustain a strong, well-supported USDA program so that animal disease work in a joint or collaborative setting would be adequately supported.

The potential for collaborative investigations also exist for programs that are not collocated. For example, if animal health aspects of Nipah virus were to be investigated by the USDA, it would need to be conducted at the BSL-4 safety conditions because of the human health manifestation of this virus; collaboration would be most beneficial with organizations such as USAMRIID or Centers for Disease Control and Prevention (CDC) whose interest would be the human health perspectives. This could be accomplished by collaborative exchange of scientists and development of a close working arrangement. Visiting National Research Council (NRC) scholars and postdoctoral work agreements could also provide a valuable adjunct to infusion of new ideas and fresh talent into the USDA FAD program.

Unless a BSL-4 facility is sustained at a working BSL-4 level, when it is needed, there could be a significant delay to be truly operational. Personnel need to be continuously exposed to working safely in fully contained protective suits. Otherwise, physical and psychological adaptations are likely to be required. Without BSL-4 work environment training and experience, the risk to personnel and environmental health increases.

3. WHAT IS THE NATIONAL NEED, INCLUDING NATIONAL SECURITY REQUIREMENTS, FOR A BIOSAFETY LEVEL 4 RESEARCH AND DIAGNOSTIC FACILITY FOR ZOONOTIC DISEASES?

3.1. General Considerations

In addition to the long-standing requirement of protecting American livestock from devasting animal diseases that are established abroad, the laboratories of the USDA will face new challenges from the continual emergence of new diseases and the possibility of the intentional employment of disease agents directed against livestock as an act of terrorism or other criminal act. The development of molecular biology has made it possible to investigate many aspects of disease prevention without utilizing whole, live infectious microorganisms. However, in light of the continuous emergence of novel diseases and the potential for employment of bioengineered agents directed with hostile intent against our agricultural economy, it will remain necessary for the USDA to retain the capability to safely perform experiments with live infectious organisms in livestock. Foreseeable occasions where experiments involving the live agent and infected livestock would include experiments directed toward an understanding of the means of transmission of disease, determination of the pathological effect of the microorganism upon livestock, tests of diagnostic procedures and reagents, as well as challenge studies to determine the effectiveness of vaccines or vaccine candidates in preventing infections.

BSL-4 is required whenever laboratory work involves dangerous or exotic agents that present a high risk of life-threatening disease, aerosol-transmitted laboratory infections, or related agents with unknown risk of transmission [3]. Aerosol-producing laboratory operations with dangerous organisms for which no medical countermeasures are available (immunizations or drugs) must be conducted under BSL-4 containment. The number of etiologic agents in this category that are of concern to agriculture are currently few. Recently, infections in horses in Australia caused by a paramyxovirus named Hendra

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caused fatal infections in humans in a high percentage of the limited number cases reported [4]. A major outbreak of a highly lethal infection in swine had a devastating impact on the livestock industry of Malaysia (1 million of the 3 million pigs in Malaysia were slaughtered containing the outbreak). This disease is caused by another closely related paramyxovirus called Nipah. Soldiers employed in containing the disease as well as food and agricultural workers contracted the disease, a third of the approximately 300 patients died of the infection [5]. Hendra and Nipah virus research must be conducted at BSL-4 containment [6]. Experiments with exotic organisms that are suspected of being related to known BSL-4 pathogens must be conducted in BSL-4 conditions [7]. There are circumstances in which handling large quantities of an etiologic agent, when vaccines are not available, a decision can be made to raise the required BSL [8].

3.2. Specific Considerations

Most infectious agents of interest to animal health do not require high levels of biocontainment for personnel safety because the majority of lethal agents are highly host specific; that is, etiologic agents that cause disease in one species of animal generally do not cause a clinically significant infection in other species. High levels of biocontainment and special practices are employed in agricultural research and diagnostic laboratories primarily to prevent escape of agents into the environment and potential infection of domestic livestock [9]. Obviously, zoonotic diseases present the additional concern of potential infections in the human population.

3.3. Do BSL-3 Agents Need BSL-4 Containment?

There are a number of agents of interest to agriculture that require BSL-3 biocontainment and special practices. Work on these etiologic agents, where the size of the culture is large or where procedures could result in the production of a significant risk for respiratory transmission, could require BSL-4 biocontainment if drugs for treatment of infection or vaccines for prevention of infection are not available: Venezuelan equine encephalomyelitis (VEE) virus, Rift Valley fever virus, Japanese encephalitis virus, louping illness virus, Piry virus, and Wesselsbron disease virus [10]. Large quantities of agent may need to be grown for vaccine production. The CDC guideline for biosafety specifically states that where large quantities of agent material are involved or when laboratory activities may create aerosols, consideration should be given to raising the biosafety containment one level higher. Fortunately, the majority of BSL-4 viruses, such as Ebola virus and Marburg virus, are not threats to American agriculture. However, there are viruses in the BSL-3 category that are significant threats and cause considerable losses in livestock abroad. An example is Rift Valley fever, a mosquito-borne disease of cattle and sheep, which causes substantial losses in the Rift Valley of Africa and in Egypt. The virus has recently caused epidemics in livestock on the Arabian peninsula [11]. No vaccine for humans is marketed so research on this vaccine may likely have to be performed at BSL-4, particularly for research aimed at vaccine development. Other viruses in this category would include the arboviruses responsible for louping illness, VEE, Piry, and Wesselsbron disease. For some of these agents, Investigational New Drug vaccines developed by DoD exist and have been used in the past to protect laboratory personnel engaged in investigations of diseases caused by these agents. Future availability of these vaccines cannot be ensured. The USDA laboratories in Ames, Iowa, and Plum Island Animal Disease Center (PIADC) at Plum Island, New York, conduct diagnostic tests for many BSL-3 agents, some of which are: Aino, Akabane, Getah, Ibaraki, Israel turkey meningioencephalomyelitis, Japanese encephalitis B, Rift Valley fever, and vesicular stomatitis. Elements of vaccine development programs (e.g., production of agent and animal challenge studies) for these disease agents could require BSL-4 containment.

A minority of members (3 of 14) of the Executive Panel objected to the SAIC finding that under certain circumstances, some BSL-3 agents may need BSL-4 containment. Their objections are summarized by stating that doing so could mislead people unfamiliar with FADs into believing BSL-4 containment is

required. They further state, and SAIC recognizes, that BSL-4 containment is only required for agents that cause severe illness or death in humans.

SAIC notes these objections but maintains that because of the extraordinary circumstances involved with the research and diagnostics of FADs on the mainland, BSL-4 containment is a reasonable consideration, but is NOT a requirement. SAIC also recognizes that because of the inherent dangers of working with or near large animals, the decision to do so in BSL-4 containment should not be taken lightly. Validated physical and procedural safeguards must be in place to protect the human researchers from injury.

FMD is a special case, in part due to its virulence in animals, as well as the impact it could have on the nation's livestock industry. While not requiring BSL-4 containment because it is not a dangerous human disease, SAIC finds that additional respiratory protection measures beyond those afforded by BSL-3 Ag containment should be considered to prevent the human workforce from becoming vectors of the disease.

3.4. Emerging and Reemerging Diseases

New human and animal diseases are constantly emerging or reemerging. This process is favored by the increasing encroachment of people and livestock into areas previously inhabited by only wildlife, allowing transmission of novel diseases into livestock. Some of these are caused by agents that were previously unknown in wildlife and were first reported in humans (i.e., HIV) [12]. Many are present in wildlife and "jump" across species lines to infect humans or livestock. Lyme disease [13] and West Nile fever [14] represent familiar examples. New diseases in humans seem to appear at a rate of about 1 per year. New diseases of livestock appear at a similar rate. Fortunately, only two BSL-4 agriculturally significant infections have appeared in recent times, the Hendra virus and Nipah virus [4,5]. Factors favoring the encroachment of agriculture into previously virgin habitat continue and with the increase international trade in food, importation and smuggling of exotic animals, human migration, and tourism, the likelihood of the importation of foreign animal diseases into the United States can be expected to increase [15]. The recent experience of the United Kingdom and the European Union with outbreaks of foot and mouth disease and of bovine spongiform encephalopathy provides salient examples of this rising global phenomenon.

There have been numerous examples in human history of pandemics of surprising lethality. Bubonic plague in Europe in the 14th century [16] and the global pandemic of Spanish influenza [17] of 1918-1920 provide examples of diseases normally endemic to animals that have crossed species barriers and spread through naïve populations with devastating effect. Influenza presents a continuing threat to fowl through the continuous genetic reassortment of the virus's virulence factors [14]. In this light, a human-adapted strain of the avian influenza virus has emerged as a candidate for BSL-4 containment.

Arthropod vector-borne diseases (diseases transmitted by blood-feeding arthropods such as mosquitoes and ticks) are an important class of disease in animals and humans. It is estimated that one previously unknown tick-borne infectious agent is discovered each decade [19]. These agents typically cause mild diseases in wildlife but may cause serious disease in species previously unexposed to them. A number of these diseases are exceptionally virulent. Central European tick-borne encephalitis, Kyasanur Forest disease, Crimean-Congo hemorrhagic fever, Omsk hemorrhagic fever, and Russian spring and summer encephalitis are all BSL-4 level viral agents [20,21]. Important agricultural and human mosquito-borne viral diseases requiring BSL-3 biocontainment and special practices include Japanese encephalitis, Wesselsbron disease, Rift Valley fever, West Nile fever, VEE, and St. Louis encephalitis [21]. Vesicular stomatitis (Alagoas), a BSL-3 agent, is transmitted by a blood-feeding fly. Piry is a BSL-3 virus suspected of being transmitted by arthropods [20,21].

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Because new diseases are continuously crossing species lines around the world, it is likely that arthropod diseases previously alien to us will appear in the United States. A recent example is the appearance and spread of West Nile fever, a mosquito-borne disease that was originally diagnosed in the West Nile province of Uganda, and has spread throughout the Mediterranean basin and recently into the Eastern United States [14,22]. In Europe and Africa, this virus infects birds, in particular, but also people and domestic animals. In view of the ease with which West Nile fever is becoming established in the United States, it is reasonable to believe that similar viral encephalitic diseases such as Rift Valley fever could pose a threat of becoming established here as well. The spread of VEE into the United States and the subsequent epidemic in Texas and the Gulf Coast is a salutary example [23]. These cited examples suggest that new agents requiring high levels of containment are likely to appear eventually within—or be introduced into—the United States. Hence, research programs will likely have to be initiated to protect livestock from these potentially serious threats.

Sometimes etiologic agents are encountered whose properties are unprecedented. The development over the past decades of our knowledge of prions as infectious agents demonstrates that there are still surprises to be encountered in the biology of infection. Investigation of the rare human neurodegenerative diseases Kuru and new variant Creutzfeldt-Jacob disease suggested that an infectious agent caused the disease. However, the causative agents, though filterable, could not be cultured, and furthermore, it was possible to show that in animals with similar diseases, nucleic acid-free extracts from infected animals were capable of causing disease when introduced into disease-free hosts. The discovery of this new class of infectious agents, separate from the long familiar quartet of microbial pathogens—viruses, bacteria, fungi, and parasitic organisms—is an astounding event in biology. These agents cause the transmissible spongiform encephalopathies (TSEs) of animals: scrapie (sheep and goats); bovine spongiform encephalopathy (BSE, mad cow disease); transmissible encephalopathy of mink; and chronic wasting disease (deer and other cervids) [24]. The agents are particularly resistant to chemicals commonly employed as microbiocides. Fortunately, the agents discovered to date are not easily transmissible and can be routinely investigated under BSL-2 conditions [25]. Nonetheless, the number of BSE cases in cattle in the UK exceeded 180,000 [26]. Statistical analysis indicates that more than 1 million cattle in the UK were infected with BSE, and that about 500,000 of these infected cattle entered the human food chain [27]. The pathological agent for BSE has been convincingly linked to new variant Creutzfeldt-Jacob disease in humans [26].

3.5. Intentionally Introduced Infections

The anthrax letter incidents demonstrate the susceptibility of civilization to seemingly easily accomplished acts of anonymous terrorism. The anthrax-laden letters caused unprecedented disruption to our postal system and government and business dependent on it. Fortunately, agro-bioterrorism and the susceptibility of the agricultural industry have not received widespread publicity, and American agriculture has not as yet been targeted. A search of the literature reveals few incidents of the intentional infection of animals. There have been government projects employing biological agents to control rabbits in Australia [28] and feral cats in South Africa [29], and two descriptions of individual efforts to control rabbit populations with viruses lethal to rabbits (in France in 1952 and more recently in New Zealand [30,31]). The rapid spread of highly lethal infections in these populations is indicative of the potential susceptibility of herds and flocks to deliberately introduced infections. The ease with which this might be accomplished is illustrated by events in New Zealand where farmers used kitchen blenders to prepare baits from the carcasses of rabbits that had died from rabbit hemorrhagic disease in Australia and distributed them in bait for feral rabbits on their property in New Zealand [31]. Another compelling argument is the documentation that other nations (e.g., Iraq and South Africa) have conducted offensive BW research [32,33].

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As part of its Public Health Emergency Preparedness and Response effort, the CDC has categorized biological disease and etiologic agents into three priorities (see Table 5). Most of these diseases are animal diseases that are diagnosed at the facilities in Ames or PIADC. Category A diseases/agents, the highest priority, include anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers. Smallpox and viral hemorrhagic fevers are the only two diseases/agents from this highest priority category not included in the Ames diagnostic repertory. Category B diseases/agents, the second highest priority, include brucellosis, *Clostridium perfringens*, food safety threat agents (salmonella, *Escherichia coli* O157:H7, and shigella), glanders, meliodosis, psittacosis (*Chlamydia psittaci*), Q-fever, ricin, staphylococcal enterotoxin B, typhus, viral encephalitis, and water safety threats such as vibriosis and cryptosporidium. The only Category B diseases/agents not diagnosed by the Ames laboratories are typhus, SEB, and the plant toxin ricin. Category C includes emerging infectious disease threats such as Nipah and hantavirus. With emerging new diseases and the potential for bioengineered agents, some reprioritization of agents within the three categories may occur.

Table 5. Biological Diseases/Etiologic Agents Categorized by CDC

CDC Category	Description	Agent Examples
A	Highest priority agents that pose a risk to national security because of ease of dissemination, high mortality rates, impact on public, and special action for public health preparedness	Anthrax, Botulism, Plague, Smallpox, Tularemia, Virual Hemorrhagic Fevers
B	Second highest priority that include agents moderately easy to disseminate, moderate mortality rates, and require specific enhancements for diagnosis and surveillance	Brucellosis, *Clostridium perfringens*, Salmonella, *E. coli*, Shigella, Glanders, *Meliodosis*, Psittacosis, Q-fever, Ricin, Staphylococcal enterotoxin B, Typhus, Viral encephalitis
C	Third highest priority that includes emerging pathogens that could be engineered for mass dissemination because of availability, ease of production/dissemination, potential for high mortality rates and major health impact	Nipah virus, hantavirus

Most diseases that deserve serious consideration as potential bioterrorism agents are caused by zoonotic etiologic agents that are of serious consequence to both human health and the livestock industry. A listing of agents thought to pose the greatest threat against livestock is contained in Table 6. Thus an incident of bioterrorism directed against the American public may well have a serious impact on agriculture by causing epidemics in livestock. Of course, bioterrorism directed at livestock is a major concern that could be viewed as a higher priority by some. It is possible that the initial cases of a bioterrorism incident will be diagnosed in a USDA facility. When agents applicable to bioterrorism are discussed, the possibility that bioengineered agents might be employed must also be considered. Properties that might be altered to make an agent more amenable to its role as a biological weapon are likely to include alterations that increase the agent's virulence and enhance its transmissibility, provide resistance to antibiotics or immunizations, as well as factors increasing the stability of the organism, allowing it to persist in the environment. Live agents encountered in an incident of bioterrorism may require BSL-4 containment during the initial phases of their investigation until their pathological properties are adequately understood.

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Table 6. Anti-Livestock and Anti-Poultry Biological Weapons [34]

• Foot and mouth disease virus
• Classical swine fever virus
• African swine fever Virus
• Rinderpest virus
• Rift valley fever virus
• Avian influenza virus
• Exotic Newcastle disease virus
• Venezuelan equine encephalomyelitis virus
• Blue tongue virus
• Sheep and goat pox viruses
• Pseudorabies virus (Anjeszky's disease)
• Vesicular stomatitis virus
• Teschan disease virus (porcine enterovirus 1)
• Porcine enterovirus type 9
• Lumpy skin disease virus
• Porcine reproductive and respiratory syndrome virus
• African horse sickness virus
• *Bacillus anthracis* (anthrax)
• *Chlamydia psittaci* (psittacosis)
• *Cowdria ruminata* (heart water)
• Screwworm

With the advancement of biotechnology and genetic engineering expertise around the world, the risk of intentionally genetically manipulated biological agents has increased. Animal or human pathogens, nominally classified as a BSL-2 or BSL-3 agent, may be bioengineered to have pathological characteristics that would require higher containment up to and including BSL-4. Thus, any agent used in a bioterrorism incident may require BSL-4 containment for diagnostic purposes until its identity can be verified.

3.6. Role in Homeland Security

The President's plans for homeland security, which were announced after award of this study, may impact any potential decision on a BSL-4 facility and its linkage to a BSL-3/BSL-3 Ag facility. Since the USDA operates a comprehensive national disease surveillance system, it is reasonable to assume that the Department would be expected to participate in the biosecurity of the nation, whether in animal health or the public health arena. The exact composition of a bioterror weapon cannot be predicted. As noted, biological weapons directed against the United States may be expected to have been bioengineered to enhance agent virulence, transmissibility, and ability to overcome medical protective countermeasures such as drugs and vaccines. USDA BSL-4 capabilities could be expected to play a significant role in the homeland response to a bioterror incident. In connection with the creation of the Department of Homeland Security, there are many issues that will require resolution.

3.7. Sustainable BSL-4 Program

Two etiologic agents of agricultural significance, the Nipah and Hendra viruses, require BSL-4 containment and practices. This immediate need is reinforced by USDA readiness to conduct research and diagnostics on emerging and reemerging diseases. Since a viable BSL-4 program may be difficult to sustain on the basis of two known pathogens, the USDA would need to (1) establish a strategic plan that

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integrates BSL-4 and BSL-3 Ag operations, (2) locate this integrated facility at a large research/diagnostics campus, (3) assign a comprehensive mission to this facility, and (4) resource this facility to accomplish the strategic plan and mission.

4. WHAT ARE THE BIOSAFETY AND BIOSECURITY CONSIDERATIONS IN SITING SUCH A FACILITY?

4.1. General Considerations

For the purposes of this report, the term "biosafety" is considered to address issues pertaining to the potential exposure of animals or humans to dangerous pathogens and the escape of pathogens from a facility due to natural phenomenon (e.g., weather-related disaster and human error). The term "biosecurity" is considered to address protection against the diversion of high-consequence pathogens and toxins that could be used by someone with malicious intent for bioterrorism or biological weapons proliferation. This includes the classic terrorist threats of an attack on a facility by a well-organized and motivated group of individuals and an insider(s) motivated to remove pathogens for illegal purposes.

4.2. Panel Findings

The panel concluded that today's technology for primary and secondary barriers (specialized equipment and facility design) is adequate to contain any biosafety risks at any site; however, they also noted that biosafety is only as effective as the individual who practices it. It is recognized that there is a need for adequate medical assistance at any high-containment facility. Both USDA facilities at Plum Island, New York and Ames, Iowa meet this criterion.

In regard to biosecurity, the panel only considered the issue of a terrorist threat to the facility. As such, the panel felt that biosecurity was somewhat of a "moving target" that will impact but not eliminate any site from consideration. That is, facility design considerations could mitigate the biosecurity-related differences for potential siting locations. To date, no biosecurity guidelines exist that are analogous to the *Biosafety in Microbiological and Biomedical Laboratories* [3] guidelines for biosafety. Entities such as the Biosecurity Subgroup of the DHHS Select Agent Group (established under PL 107-188) are in the process of creating biosecurity guidelines. However, the absence of established guidelines does not vacate the need to consider biosecurity issues in establishing and operating a facility that will be engaged in high-consequence biological agents research and diagnostics.

The record of panel deliberations did not capture the potential impact of location and lapse of safety measures on the community or nation as a whole. The panel deliberations also did not reflect the issues of security of the etiologic agent from workers and/or graduate students of the participating collaboration arrangement. High-containment biological laboratories require substantive personnel-screening policy, training, and procedures. These additional considerations could also be mitigated by policy, infrastructure, and design factors.

4.3. Federal and State Regulatory Considerations

Determining the biosafety and biosecurity considerations for the location of a BSL-4 facility began with a review of the relevant statutory and regulatory mandates. A thorough review of the federal and state statutes and regulations found that there are no location discriminators although the issue of where FMD virus work is located may arouse special congressional interest.

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Title 21 *United States Code* (USC) 113a sets forth rather stringent locality restrictions for work with live virus of foot-and-mouth disease as follows:

> "Provided, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States (except coastal islands separated therefrom by water navigable for deep-water navigation and which shall not be connected with the mainland by any tunnel)..."

However, 21 USC 113a goes on to provide an escape hatch to these restrictions thus allowing for the possibility of such work on the mainland with this ensuing language:

> **"...unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York)...."**

The current regulations and statutes apply the same measures to all facilities, regardless of location. Federal materials that were reviewed and found to have universal applicability were the *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition, May 1999 (CDC) Guidelines; the *Agriculture Research Service Facility Design Standards*, ARS Manual 242.1; *Interstate Shipment of Etiologic Agents*, 42 CFR Part 72, and the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Agricultural Bioterrorism Protection Act), PL 107-188.

State laws and regulations vary but only at the reporting level. See Table 7 for a summary of state legislative initiatives. States' enforcement of their rules and regulations at federal facilities also vary. If the facility was to be collocated with an academic institution, it would be necessary for the institution to follow all state-level structure and reporting requirements, which generally consist of maintaining a biosafety committee and officer, and minor reporting considerations. None of the states surveyed have statutory restrictions regarding BSL-4 laboratories. State legislative initiatives are currently under way in 12 states for the creation of a state-level Biological Agents Registry. The recent passage of PL 107-188 may alter the technicalities of the state legislation, but not to the extent that it would prove to be a location discriminator.

Table 7. State Legislation

State	Evolving Legislation
California	No legislation of note
Connecticut	S.B. 5288, for the creation of a state Biological Agents Registry, has been introduced
Iowa	No legislation of note
Maryland	H.B. 361, for the creation of a state Biological Agents Registry, has been passed and signed into law. Effective October 1, 2002
Minnesota	H.F. 2622, The Minnesota Anti-Terrorism Act of 2002, contains a section mandating the creation of a state Biological Agents Registry
New Jersey	A. 1968, for the creation of a state Biological Agents Registry, has been introduced
New York	No legislation of note
North Carolina	H.B. 1472, creating a state Biological Agents Registry, was passed and signed into law. Effective October 1, 2002
Oklahoma	No legislation of note
Pennsylvania	No legislation of note
Texas	No legislation of note
Wisconsin	S.B. 421, for the creation of a state Biological Agents Registry, failed to pass due to procedural issues

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4.4. Bioterrorism

The increased threat of bioterrorism directed against humans or animals (as well as plants) is generating new ways of looking at biosecurity at laboratories engaged in disease research and diagnostics related to high-consequence biological agents. High consequence may be illness and death of humans and animals but may also be economic with relatively low incidence of death or disease. A terrorist act resulting in a major biological event could come about by (1) physical damage to the facility by explosives, missile (auto, plane, etc.), rupture of facility, etc., (2) intentional disruption of secondary barriers by an individual with access to the facility, and (3) intentional removal of "seed" agent material that could then be used in a bioterrorist event potentially remote from the facility.

The risk of physical damage to a facility by a terrorist can be mitigated by physical security considerations such as structural and facility design. While the physical security issues may be location specific, such issues should be able to be mitigated by appropriate measures at any location.

Intentional disruption of secondary barriers or intentional removal of "seed" agent material are personnel reliability issues discussed in paragraph 4.5. With appropriate personnel screening and access control, these risks can also be minimized.

The location of the facility could play a role in the consequence of intentional release of agents dependent on the local susceptible population.

4.5. Personnel Reliability

As stated in paragraph 4.2, high-containment biological laboratories require substantive personnel-screening policy. There is presently a high level of concern about personnel reliability arising to a large extent from facts, rumors, and press coverage following the anthrax letters in September and October 2001. This concern extends to background screening for emotional stability as well as reliability in not abetting terrorist organizations, domestic or foreign. There are some who perceive that personnel reliability is a lower risk for U.S. citizens than for others and this is reflected in some security regulations.

The fact that microbial agents and toxins are easily removed from the laboratory environment and cultured for malevolent purposes makes the integrity and reliability of collaborating investigators, technicians, animal caretakers, and graduate students a primary concern. To best ensure worker integrity and reliability, screening policies and procedures, commonly referred to as personnel reliability programs, would need implementation at facilities dealing with high-consequence biological agents. Employee-screening considerations for such programs are undefined but might include qualifications, criminal conduct, substance abuse, poor credit, and foreign interactions and influences.

The practical aspects of implementing such a program when collaborating with a university could pose greater risk. This potential risk emanates from the relatively high percentage of foreign national students and faculty present in the university environment and the reality that screening such individuals in the areas of foreign interactions and influences will undoubtedly delay the screening process. Such delays would deny access to high-consequence biological agents as envisioned by present-day biosecurity concerns. The exact impact of this issue will not be fully appreciated until the implementing regulations currently being developed pursuant to PL 107-188 are in place.

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5. WHAT ARE THE POSSIBLE KINDS OF LOCATIONS THAT WOULD MEET THOSE (BIOSAFETY AND BIOSECURITY) CONSIDERATIONS IN SITING SUCH A FACILITY?

5.1. General Considerations

In practical terms, site discriminators are more likely to be resource and geopolitically specific—e.g., does the site have access to an appropriate quantity of water, what are the natural disaster possibilities, and what is the attitude of the local community? For example, many agricultural communities are likely to be less than enthusiastic about having a BSL-4 FAD and/or zoonotic disease facility near their pigs, sheep, or cattle. Any potential location for a BSL-4 facility will have its own unique set of terrorist and natural threats to the integrity of the facility that will need to be responsibly addressed.

Location of a BSL-4 zoonotic and/or FAD facility in a community with a sizeable, susceptible animal population presents a unique set of potential risks in terms of lapses in biosafety practices that will require special consideration. Additionally, reliability of collaborating investigators, technicians, animal caretakers, and graduate students could pose additional personnel reliability risks as they relate to the ability of security agencies processing security clearance requests. Inherently, universities seek diversity among their student body and, to a lesser extent, their faculty, including those from many countries. Tapping the scientific expertise of countries where these exotic diseases are endemic is an important approach to solving the problem. The U.S. has a significant interest in seeing scientific expertise enhanced and returned to the nations so they are better able to control these diseases within their own borders and participate in the international network of infection control. It would be difficult to subject all such individuals to the degree of screening expeditiously to enable access to high-consequence biological agents as envisioned by present-day biosecurity concerns.

5.2. Location Considerations

Biosafety needs for a BSL-4 facility can be met at any location provided the appropriate containment facility and biosafety operating practices are met. As such, biosafety is not considered to be a facility location discriminator. Different degrees of biosecurity can be anticipated for the various locations. Three locations discussed by the panel are considered: USDA facilities at Ames, Iowa (hereinafter referred to as "Ames"); PIADC at Plum Island, New York; and DoD (Fort Detrick at Frederick, Maryland). These examples should not be construed as recommendations for location of a BSL-4 facility.

In general, any facility could be constructed to withstand the highest consequence national disaster, but this must be specifically considered for each locale. Similarly, additional protection from terrorist breach of facility could be obtained at any location, but again would need to be specifically considered. The three locations cited in this section are to illustrate three different environments for discussion of the issues and not to signify a preference for one location over another. Additionally, it is expected that the audience for this report is familiar with these three locations, and it will facilitate their understanding of the issues.

5.3. Biosafety

Biosafety addresses issues pertaining to the unintentional exposure of animals or humans and the escape of pathogens from a facility due to natural phenomenon.

Ames is located in a high-risk tornado area and, although the risk may be low, the risk cannot be ignored when research on FADs such as Nipah virus or FMD virus is conducted in a high animal-populated community. Additionally, the present Ames facility is more easily accessed by the public than PIADC and Fort Detrick. PIADC is subject to Atlantic hurricanes but in its history, none have resulted in a

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breach of the containment area. Thus its risk from natural disasters is considered minimal. Fort Detrick is located in a very low tornado/earthquake risk area.

There are two main considerations pertaining to release of agent from a facility: (1) lapse in biosafety practices resulting in release of agent and (2) intentional removal by someone with access to the facility; e.g., staff, visiting scientists, and graduate students. Unintentional lapse in biosafety practices, if unintentional, is an issue common to all facilities and locations that can be mitigated by personnel biosafety education and training. There may also be a personnel reliability issue related to individuals behavioral characteristics. Intentional lapse in biosafety practices and intentional removal from a facility are biosecurity issues and are discussed under biosecurity.

Biosafety lapses at any facility location likely have an equal risk of occurrence. Thus, the impact of such a release becomes a more dominant consideration. In this respect, not all locations can be considered equal; that is, facilities located where significant animal populations exist that are susceptible to agents under investigation have a greater degree of risk.

Ames has a high degree of risk when consideration is given to the severity of impact should release of a FAD agent occur and infect the surrounding animal population. Fort Detrick was considered to have lesser risk because of a decreasing farm population immediately surrounding the facility. PIADC was considered to have the lowest risk should accidental release of agent from the facility occur in part because of its island location, but mainly due to the lack of commercial livestock farming in Long Island and the surrounding areas.

5.4. Biosecurity

Biosecurity addresses the diversion/release of high-consequence biological agents from the facility for bioterrorism or biocriminal purposes. The release from the facility to expose animals or humans in the local community could come about by physical penetration of the facility by explosives or missile penetration (car, planes) or by intentional lapse in biosafety practice. Diversion (removal of "seed" material) is an intentional act for personal motivational reasons by individual(s) with access to the facility and agents.

One of the inherent complexities of PIADC's island location is that by isolating the facility to reduce the impacts and concerns of agent release you may actually increase the biosecurity risk. Although physical location may deter casual or unsophisticated acts of terrorism, facilities located long distances from police, emergency personnel, and response teams pose greater biosecurity risks due to their isolation. Fort Detrick is a DoD military facility with limited access. Since September 11, two photo identifications are required for entry. Thus, it is expected this would provide a degree of antiterrorist security.

Employees with access to a high-containment facility could be motivated (financially or loyally to a terrorist group) to violate good safety practices to allow "natural escape" of agent from the laboratory into the human or animal community. Such intentional "lapses" in biosafety would be difficult to prove and would be unpredictable in occurrence, making it attractive to some terrorist group.

The risk level of intentional removal/release of agent is largely dependent on the screening that is given to all personnel with access to the facility. This becomes particularly important when consideration is given to academic collocation/integration and access by facility and graduate students.

At Ames, integration of a BSL-4 facility with an academic center (e.g., university) that enables access to the facility by students and others carries the increased potential risk of release. For Fort Detrick, it is expected that access to the facility, while still permitting visiting scientists and graduate students, would

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be more restrictive than if it were closely integrated with academics. Like the Fort Detrick consideration, PIADC's academic faculty and student access is unlikely to be a close integrated relationship and thus, while permitted and encouraged, could be more selective.

Although several examples of possible sites for BSL-4 facility have been discussed, including pros and cons, they should not be interpreted as a recommendation for facility location.

6. SHOULD A BSL-4 FACILITY BE LINKED PHYSICALLY OR PROGRAMMATICALLY TO AN ANIMAL HEALTH OR HUMAN HEALTH BSL-3 FACILITY?

6.1. Linkage to Another BSL-3 Animal or Human Health Facility

To derive the maximum benefit from the resource investment necessary to construct and operate a BSL-4 facility, it will be important to integrate the operations of the BSL-4 facility with a BSL-3 Ag facility. Programmatic linkages envision an alignment and integration of the mission, scientific objectives, methods, and personnel of the two capabilities. Physical linkage could involve either collocation of the facility, on the same campus or physical connection of the BSL-4 facility with the BSL-3 Ag facility. Another strategy might be a BSL-3 Ag module that can "swing" to a BSL-4 containment when required. That is, design a facility to accommodate both BSL-3 Ag and BSL-4 operations; operating as a BSL-3 Ag normally and as a BSL-4 only when needed. Given this strategy, an implied requirement is to ensure that personnel assigned to such a facility receive regular training and routinely operate at the BSL-4 level to maintain proficiency in safe operations at this level, especially when there are no or only a few active BSL-4 programs.

6.2. Programmatic Linkage

The facility could be located at a government research campus. The USDA operates four BSL-3 Ag facilities (Ames, Iowa; Arthropod-borne Animal Disease Research Laboratory, Laramie, Wyoming; PIADC, Plum Island, New York; Southeast Poultry Research Laboratory, Athens, Georgia) and these could pose attractive sites for collocation. Here the cultural and scientific inclination for a beneficial alignment of research efforts would be high. Ames would be particularly attractive due to its size and infrastructure as well as its proximity to the academic scientific and animal health programs of Iowa State University. The PIADC is an attractive option due to its large animal BSL-3 Ag facility and the biocontainment expertise of its staff. The extent of local academic connections and the relationship with the local population and their state and federal representatives could make PIADC more problematic than Ames with its small BSL-3 Ag facility; however, the large BSL-3 Ag facility at PIADC and their long-standing experience operating under BSL-3 Ag rules and regulations represent a very positive factor.

Competition of two programs for limited BSL-4 space and time might prove difficult to resolve. However, a major benefit to be derived is the assurance that this expensive resource is fully utilized. Responsibilities and access to resources would need to be clearly defined in the agreements establishing the cooperative efforts to prevent conflicts from ensuing.

6.3. Physical Linkage

Before this question can be addressed, the type of BSL-4 facility required needs to be stipulated. This study envisions a large animal BSL-4 facility capable of accommodating 12 to 24 cattle. This would enable the USDA to conduct vaccine trials involving challenge with live agent in a population sufficient to yield results of statistical significance to proceed to product licensure. A modest but small BSL-4 facility for animals can be established within a BSL-3 Ag facility without substantial investment.

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A BSL-4 facility capable of accommodating large animals would be required to allow vaccine trials in cattle or other large livestock. This type of a facility would probably have major components (animal stalls, autoclaves, animal waste disposal utilities, and incinerators) that would exceed the requirements of a human health animal facility that might require accommodating nonhuman primates (rhesus monkeys or chimpanzees). A major facility consideration is a waste disposal system capable of disposal of infectious animal waste. Thus, from a physical plant perspective, alignment with an animal health program is likely to be more economical. These considerations suggest that the most economical approach would be to collocate the facility with a BSL-3 Ag large animal laboratory that already has a sewer capable of accommodating a significant volume of large animal waste. Both the USDA facilities at Plum Island, New York and Ames, Iowa satisfy this need.

The Executive Panel consensus was favorable to linking a BSL-4 with either an animal health BSL-3 Ag or a human health BSL-3 facility due to the scientific benefits to be gained. However, the panel was concerned that scientific alignments and culture could create differences, which could prove to be difficult to reconcile and which could be detrimental to the USDA BSL-4 program. There was an underlying concern that priorities favoring human health would prevent agriculture research from obtaining a fair portion of shared resources and scientific support. In addition, the panel expressed concern that any BSL-4 initiative should not jeopardize the ongoing USDA efforts to upgrade their BSL-3 Ag facilities.

Although not part of the USDA study objectives, the issue of visiting foreign scientists warrants discussion. USDA research and diagnostic efforts can benefit from an international exchange of scientists, in that a great deal of the current expertise in the diagnosis and management of exotic diseases is overseas. Maintenance of close contact with foreign animal health scientists enhances the capability of foreign governments to recognize and react to outbreaks at an early stage. Similarly, location of American scientists in overseas laboratories also increases U.S. capabilities in FAD research and diagnosis.

Of course, the personnel reliability issues previously discussed must be considered when dealing with foreign personnel.

7. WHAT ARE THE BENEFITS/LIABILITIES FOR JOINT RESEARCH WITH UNIVERSITIES OR MILITARY RESEARCHERS IN A BSL-4 FACILITY?

In most important programmatic areas, the benefits and liabilities of locating a BSL-4 with an existing BSL-3 facility will depend on the scientific and personnel relations between the programs and are subject to the competition for resources. Collocation with a scientifically active human health program, particularly at a university setting, would expose the agricultural research effort to graduate students and university professors who would not ordinarily consider health issues of livestock and thus serve to broaden the intellectual resources and scientific techniques applied against agricultural research problems. Similarly, location at a university with a strong animal health program would provide an environment conducive to successful research. These include links to vigorous collaborative research efforts, access to the university library and information specialists, computer facilities, visiting scientists, and research efforts in the sciences allied to animal health.

The concerns for intentional clandestine acquisition of bioterrorism agents from government laboratories have increased in recent years and particularly since 2001. Microbial agents and toxins cannot presently be identified by currently available stand-off detection technology that would enable the prevention of intentional removal of micro quantities of disease agents sufficient for "seed" culture. Thus, security against the insider threat will depend on the integrity of the individuals who have access to the high-

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consequence pathogens. Eliminating or minimizing the "insider threat" requires substantive screening policies and procedures that may be difficult to require in a diverse academic atmosphere.

An additional USDA option is collocation at a military or other federal agency facility. The Defense Department has a BSL-4 facility at Fort Detrick and the scientists at Fort Detrick and PIADC have worked on collaborative projects of mutual interest in the past. The Department of Health and Human Services will soon operate a BSL-4 facility at the National Institutes of Health in Bethesda, Maryland, and operates one at the CDC in Atlanta, Georgia. The intense focus of these laboratories on priority national defense and homeland security issues makes it unlikely that serious collaborative effort and facilities sharing will be favorably entertained before sufficient capacity to meet the bioterrorism threat is available.

The Executive Panel recognized the invigorating scientific benefits of such collaborations. Their major concern was that sustaining a strong USDA animal program at the hosting institution will be essential to ensure agricultural research receives the resources and priorities envisioned in the conception of the program. Research performed in a BSL-3 Ag facility should not suffer from the competition of human health research with agricultural research because the host and guest programs derive from the same culture.

8. [illegible]E THERE BENEFITS/LIABILITIES OF COLLABORATIVE RESEARCH, I.E., IS [illegible]ERE TANGIBLE BENEFIT BY HAVING BSL-4 WORK ACCOMPLISHED IN AN [illegible]TMOSPHER[illegible] WHEREBY OTHER NON-AGRICULTURAL WORK MAY BE [illegible]NGOING?

[illegible]ted to derive from joint or collaborative work in a BSL-3 Ag facility result from alignment of common programmatic interests and shared infrastructure. With joint and collaborative research agreements, facilities become available to the USDA immediately upon ratification of the agreeme[illegible] [illegible]esign and construction of the facility. Furthermore, productivity of both the [illegible] [illegible]ns benefits because the facility is used more extensively, decreasing the cost per in[illegible] [illegible] that is, a critical scientific mass can be created rapidly and applied to priority programs. [illegible] in the numbers of scientists sharing the facility reduces program risks associated with temp[illegible] [illegible] The likelihood that scientific tools (reagents, equipment, and facilities) will be use[illegible] [illegible]t is high because of the program objectives of the two groups are similar in [illegible] [illegible]pathogens, and technical approach. The USDA program would benefit greatly from access to [illegible] vibrant university community and academic faculty and staff in all of the sciences allied [illegible] animal health, visiting scientists, seminars, technical support (DNA, RNA, and peptide synthesis services, and monoclonal antibody production), clinical laboratory support, and academic support.

The Executive Panel suggested that liabilities of the host–guest relationship derive principally from conflicts over access to resources. Whose experiments will obtain priority for scarce resources? Will the facility be available when the USDA requires it? These will be major concerns if the facility is envisioned as playing a role in homeland defense. These issues should be foreseen and addressed in the negotiation of the agreement. There may be scientific incompatibilities that preclude the use of certain agents or animals in the facility while a study is being performed due to the potential for cross-contamination.

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9. FINDINGS AND RATIONALE

9.1. Findings

- A USDA BSL-4 facility will meet the national need and the Department's growing responsibilities to protect agriculture, researchers, and diagnosticians against current and emerging biological threats. A proactive community outreach program with acceptance and support of the mission is critical.

- Biosafety is generally not so much a location issue as it is facility design (appropriate high-containment) and biosafety operational practices. Biosecurity, like biosafety, can be achieved at any facility or site. The cost of achieving acceptable performance levels for an individual biosecurity system will depend upon the design basis threat as well as the physical location of the site.

- The proposed BSL-4 facility would benefit from being designed, built, and operated as part of a consolidated BSL-3 Ag facility. This facility should have the capability to transfer to and from BSL-3 Ag operations seamlessly.

- Adequate biosafety and biosecurity can be achieved at any site location but would require more stringent operational and control measures than now exist and seemingly considered by the panel. Biosafety practices should include consideration of conducting work with some FAD BSL-3 agents at BSL-4 containment, depending on the nature of the work and facility location. A minority of Executive Panel members objected to this conclusion.

- A proactive program of joint research with universities or military research in a BSL-4 facility needed to create and retain the dynamic scientific atmosphere may be required to attain a leading-edge scientific program. This program could include visiting scientists, NRC fellow or postdoctoral arrangements. Such a program would be independent of facility location, but would be subject to biosecurity considerations. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

- A proactive program of collaborative research provides an additional venue for promoting a leading-edge scientific program. Such collaborative research could be established with academic and military medical programs of similar scope and designs. As with a joint program, this could include visiting scientists, NRC fellow or postdoctoral arrangements. Such a program would be independent of facility location, but would be subject to biosecurity considerations. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

9.2. Rationale

At present, there are three infectious agents that are significant to agriculture and that require BSL-4 containment (avian influenza virus, Hendra virus, and Nipah virus). Although these agents do not appear to pose a significant threat at present to American agriculture, there are presently no active research programs under way at USDA on these agents. Additionally, there is a high probability that the USDA program will include the diagnosis and study of unknown pathogens for which there is no information regarding risks to animals or humans.

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Terrorism using biological organisms, perhaps genetically enhanced, directed at U.S. agriculture poses a threat to national security.

Most of the high priority biological disease agents listed by the CDC as priorities for public health emergency preparedness are diseases of domestic animals. Many of these agents require BSL-3 Ag containment. If significant research efforts were mounted against a few of these selected agents, particularly efforts working with large volumes of infectious agent and challenge studies in large animals, as would be the case in a vaccine development effort, BSL-4 containment may be necessary. Additionally, augmentation of USDA research and diagnostic capabilities and priorities in light of increasing responsibilities in homeland security would be enhanced by a BSL-4 capability.

New agents with lethal properties are constantly emerging around the world. As previously mentioned, the recently discovered farm animal disease agents, Nipah and Hendra, require BSL-4 containment. It is difficult to predict how great a threat potential new diseases would pose to U.S. agriculture because it is difficult to predict how often highly dangerous diseases arise and how transmissible they will prove to be. Influenza is under constant global surveillance and the two most threatening strains to have emerged over the last 80 years since the great Spanish flu pandemic have originated in swine and ducks, with the avian influenza virus being a salient example. The reappearance of a highly contagious and lethal form of this disease is possible. The recent identification of the causative agents of the transmissible spongiform encephalopathies as prions demonstrates that extraordinary novel disease threats continue to emerge. The ability of the USDA to respond to outbreaks of highly communicable, emerging lethal diseases would be enhanced by access to BSL-4 capability.

The ideal location for a USDA BSL-4 facility would be at a large USDA research campus. It should be assigned a mission, be one part of an overall USDA biocontainment facility strategy, and resourced to support that strategic plan and mission. It also should be resourced to maintain strong collaborative and scientific exchange with academic research institutes conducting research in animal and human health. Such arrangements could facilitate recruitment of scientific staff, assure the research utilizing BSL-4 facilities was synergistically aligned with research projects, and that USDA priorities determined access priorities to limited resources. Concerns over facilities support and biosecurity would be less at a large federal campus than at a nongovernment location. Biological agent security could be addressed at any location by policies such as stringent personnel screening.

The impact of a USDA-owned and -operated BSL-4 facility is clear—the USDA will have a research and diagnostic facility that will be able to respond to natural and/or man-made threats of unknown or highly contagious threats to the U.S. agricultural economy. Just as important, the USDA, if it is to implement all findings contained in this report, will be required to complete a comprehensive strategic plan that will not only consider its BSL-4 operations, but also all of its BSL-3 Ag operations. This will serve to coordinate all research and diagnostic operations across the spectrum of USDA's mission and, in the end, lead to a more efficient and effective program for the two primary agencies involved—the ARS and APHIS.

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27. F.A. Murphy, Emerging Zoonoses, *Emerging Infectious Diseases*, 4, 429-435 (1998).
28. see "The Disease Myxomatosis in the European Rabbit," and The Introduction of Myxomatosis into Australia", Chapters 6 and 7, respectively in *Biological Control of Vertebrate Pests: The History of Myxomatosis - an Experiment in Evolution* (*BCVP*), F. Fenner and B. Fantini, CABI Publishing, NY (1999).
29. for the use of feline panleukopenia on Marion Island, South Africa, see *The Cat Eradication Program*, at http://www.geocities.com/RainForest/Wetlands/4119/html/history.html.
30. see Myxomatosis in France, Chapter 9, *BCVP*.
31. see The Use of Rabbit Haemorrhagic Disease Virus for Rabbit Control - Introduction of RHDV into New Zealand, Chapter 11, *BCVP*; as well as Agroterrorism, Biological Crimes, and Biological Warfare Targeting Agriculture, T.M. Wilson, L. Logan-Henfrey, R. Weller, and B. Kellman, in *Emerging Diseases of Animals*, C. Brown and C. Bolin, eds., ASM Press, Washington, DC, p. 31 (2000).

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32. G. Cameron, J. Pate, and K.M. Vogel, Planting Fear: How Real is the Threat of Agricultural Terrorism?, *The Bulletin of the Atomic Scientists*, Vol. 57, No. 5, pp. 38-44, September/October 2001.
33. R. Casagrande, Biological Terrorism Targeted at Agriculture: The Threat to U.S. National Security, *The Nonproliferation Review*, Fall/Winter 2000; P. Chalk, The U.S. Agricultural Sector: A New Target for Terrorism?, *Jane's Security*, February 9, 2001.
34. T.M. Wilson, L. Logan-Henfrey, R. Welley, B. Kellman, "Agroterrorism, Biological Crimes, and Biological Warfare Targeting Animal Agriculture" in *Emerging Diseases of Animals*, C. Brown and C. Bolin, ASM Press, Washington, DC, Chapter 3, p. 34 (2000).

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APPENDIX A
CURRICULUM VITAE OF EXECUTIVE PANEL MEMBERS

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CURRICULUM VITAE

Richard E. Breitmeyer, D.V.M., M.P.V.M.
State Veterinarian and Director, Animal Health and Food Safety Services
California Department of Food and Agriculture
1220 N Street, Room A-114
Sacramento, CA 95814

EDUCATION

California Polytechnic State University, San Luis Obispo
Animal Science - 1972 - 1976

University of California, Davis, School of Veterinary Medicine
Doctor of Veterinary Medicine - 1980

University of California, Davis, School of Veterinary Medicine
Master of Preventive Veterinary Medicine - 1990

LICENSED TO PRACTICE VETERINARY MEDICINE

California

PROFESSIONAL ASSOCIATIONS

American Veterinary Medical Association
California Veterinary Medical Association (Member Agriculture Committee)
United States Animal Health Association (Chairman of Food Safety Committee, Member of Brucellosis, Tuberculosis, Foreign Animal Diseases, Government Relations and Professional Oversight Committees)
National Assembly of Chief Livestock Health Officials
Western States Livestock Health Association (Past President)
American Association of Food Hygiene Veterinarians
National Institute for Animal Agriculture (Executive Committee, Past Chairman - Food Safety Assurance Committee)
United States Department of Agriculture Secretary's Advisory Committee for Foreign Animal and Poultry Diseases (Past Chairman)

EXPERIENCE

1993 - Present
Director, Animal Health and Food Safety Services, California Department of Food and Agriculture and State Veterinarian, California

As Director, responsibilities include oversight of the Animal Health Branch, the Milk and Dairy Foods Control Branch, the Meat and Poultry Inspection Branch and the Livestock Identification Branch; responsible for oversight of the contract with the California Animal Health and Food Safety Laboratory

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1992 – 1993
Chief, Animal Health Branch, California Department of Food and Agriculture

1989 - 1992
Veterinary Medical Officer IV - Staff Veterinarian - Emergency Diseases Program, California Department of Food and Agriculture

1989 - 1992 (simultaneous with Emergency Diseases Program responsibilities above)
Designated Epidemiologist - Brucellosis Task Force

1988 - 1989
Staff Veterinarian - Equine Programs, California Department of Food and Agriculture

1988 - Present
Foreign Animal Disease Diagnostician - United States Department of Agriculture Training Course, Ames, Iowa and Plum Island, New York

1984 - 1987
Veterinary Medical Officer - Range A/B, California Department of Food and Agriculture

1983 - 1984
Arroyo Grande Veterinary Clinic
Mixed animal veterinary practitioner (50% large and 50% small animal)

1980 - 1983
Arcata Animal Clinic
Large animal veterinary practitioner

HONORS AND AWARDS

1994 **Superior Accomplishment Award**, California Department of Food and Agriculture, for role as Designated Epidemiologist in the successful Critical Area Brucellosis Task Force.

1998 **Hammer Award**, Office of the Vice President, for efforts implementing the California Egg Quality Assurance Plan, recognized as a national partnership for reinventing government.

1998 **Honor Award**, National Association of State Departments of Agriculture, for outstanding accomplishment in service.

1999 **Alumni Achievement Award**, School of Veterinary Medicine, University of California, Davis, for contribution to animal health and food safety locally, nationally and internationally.

2000 **Pacific Egg and Poultry Association**, Scientist of the Year, for contribution to poultry science in California

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CURRICULUM VITAE

Corrie Brown
Department of Veterinary Pathology
College of Veterinary Medicine
The University of Georgia
Athens, Georgia 30602-7388

Educational History:

Doctor of Philosophy (Comparative Pathology) - University of California, Davis, 1986
Residency (Veterinary Pathology) -University of California, Davis (program combined with Ph.D.)
Doctor of Veterinary Medicine - Ontario Veterinary College, University of Guelph, 1981
Bachelor of Science - McGill University, 1973

Academic and Professional Positions Held:

2001 – present	Professor, Department of Pathology Coordinator of International Activities College of Veterinary Medicine, University of Georgia
1996 - 2000	Professor and Head, Department of Pathology, College of Veterinary Medicine, University of Georgia
1989 - 1995	Head, Pathology Section, Foreign Animal Disease Diagnostic Laboratory, Plum Island, U.S. Department of Agriculture
1988 - 1989	Veterinary Medical Officer, Pathology Section, Foreign Animal Disease Diagnostic Laboratory, U.S. Department of Agriculture
1987 - 1988	Research Scientist, Pathobiology, Agricultural Research Service, Plum Island, U.S. Department of Agriculture
1986 - 1987	Assistant Professor, Department of Veterinary Pathology, School of Veterinary Medicine, Louisiana State University
1981 - 1986	Postgraduate Researcher, University of California at Davis
1981	Clinical Veterinarian, Westfield Veterinary Hospital, Westfield, New York

Professional Organizations:

American College of Veterinary Pathologists (1986)
American Veterinary Medical Association
United States Animal Health Association
American Association of Veterinary Laboratory Diagnosticians
American Association of Avian Pathologists
American Society for Microbiology

Honor Societies, Awards, Special Recognitions:

Toronto Humane Society Award for Proficiency in Small Animal Medicine, 1981
Phi Zeta Veterinary Honor Society
USDA Certificate of Merit, 1991, 1992, 1993
USDA Women's History Award, 1993
Phi Beta Delta International Honor Society, 1999
Faculty Recognition Award (Excellence in Teaching, from Class of 2001), 1999
Faculty Recognition Award (Excellence in Teaching, from Class of 2001), 2000
Faculty Recognition Award (Excellence in Teaching, from Class of 2002), 2000
Norden Award for Teaching Excellence, 2000

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Faculty Recognition Award (Excellence in Teaching, from Class of 2002), 2001
Faculty of Discussants, C.L. Davis Foundation, 2001
Outstanding Lecturer, C.L. Davis Course on Gross and Morbid Anatomy, 2002
National SAVMA Excellence in Teaching Award, 2002

Reviews, Panels, Advisory Boards:

Extramural:

Editorial Board, *Veterinary Pathology*, 1995-1998
Ad Hoc Reviewer for: *Journal of Veterinary Diagnostic Investigation, Journal of Wildlife Diseases, Virus Research, Journal of Virology, Emerging Infectious Diseases*
USDA National Research Initiative Grants Program
Ad Hoc reviewer, 1997, 1998, 1999
American College of Veterinary Pathologists
Infectious Diseases Specialty Group, Co-Chair 1992; Chair 1993
Standing Education Committee, 1995-2000; Meeting organizer, 1999; Chair, 2000
Young Investigator Award Committee, 1994-1996
External Regulations Committee, 1992-1996
Councilor, 2000-2003
United States Animal Health Association Foreign Animal Disease Committee
Member 1990-present; Vice-Chair, 1999-2004
American Association of Veterinary Medical Colleges
International Affairs Committee, 1997-present
International Safety Advisory Board on Xenotransplantation, Novartis, Cambridge, England, 1997-1999
International Conference on Emerging Diseases, Atlanta, March 1998, Chair, Zoonoses Section
Armed Forces Institute of Pathology Wednesday Slide Conference Moderator, March 1999, March 2000, March 2001, February 2002
External Review, Department of Pathobiology, University of Pennsylvania, December 1996
USDA Foreign Agricultural Service Scientific Exchange, Kunming, China, April 1997
Faculty Exchange, Kitasato University, Towada, Japan, January 1999
Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases, 1999-present
External Review, Department of Pathobiology, University of Connecticut, October 1999
Panel Member on Agro-Terrorism, Senate Armed Services Subcommittee, October 1999
Team member, Development of Biological Weapons Convention Inspection Guidelines, Henry L. Stimson Center, Washington, DC, 2000-2001
USAID Middle East Regional Cooperation Grants Program, External Review, February 2000
Scientific Advisory Board, Armed Forces Institute of Pathology, 2000-present
National Institute for Animal Agriculture
Emerging Diseases Committee, 2000-present
Panel Member, Development of Guidelines to Safeguard Animal Health, National Association of State Departments of Agriculture, 2001
Co-Chair, International Conference, *Preparing the Veterinary Profession for Corporate and Trade Issues in the Americas*, Santiago, Chile, May 2001
Chair, Review Panel, USDA ARS Animal Health - Virology, May 2001
Rapporteur, General Session, Office International des Epizooties, May 2001
Moderator, National Academies of Sciences Workshop, Emerging Animal Diseases, January 2002
Member, Technical Advisory Committee, United States – Israel Binational Agricultural Research and Development Fund, 2002-2005
USDA Executive Panel on Biocontainment Feasibility, June 2002

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Intramural:

University:

Creative Research Medal Panel, Office of the Vice President for Research, 1996
Graduate Faculty Review Committee, Health Sciences Division, 1996-present
Search Committee for assistant professor, Center for Tropical and Emerging Global Diseases, 1999
State-of-the-Art Conference and Study in a Second Discipline committee, member 1999-2000, chair 2000-2001
Search Committee, Executive Director for Office of International Education, 2002
Member, Agroterror Task Force, 2002
Search Committee, Eminent Scholar in Emerging Diseases, Center for Tropical and Emerging Global Diseases, 2002

College:

Ad Hoc Search Committee for Associate Dean for Academic Affairs, College of Veterinary Medicine, Chair, 1996
Animal Health Research Center Steering Committee, Chair, 1996-present
Scholarship and Appeals Committee, member, 1996-present
Ad Hoc Committee for Development of New Awards, Chair, 1997
Ad Hoc Committee for Review of Assignment of Time, member, 1998-1999
Chair, Organizing Committee, International State-of-the-Art Conference on Emerging Diseases, August 1999 (funded by a competitive $11,000 grant from UGA Office of the Provost)
Ad Hoc International Affairs Committee, chair, 1999
Coordinator, International Activities, 2000-present
Faculty Advisor, Patheads Club, 1998-present
Faculty Advisor, Student Association for Global Awareness, 2000-present

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CURRICULUM VITAE

Jerry Callis

Education Auburn University, D.V.M., 1947
Purdue University, M.S., 1949

Work Experience

Entire professional career was with United States Department of Agriculture (USDA), 1947 through 1988
1947-1949, Work/Study, Purdue University
1949-1951, Work/Study, Veterinary Laboratory, Amsterdam
1952-1988, USDA laboratory at Plum Island

At this laboratory I held positions of investigator to in-charge of research, to Assistant Director to Director (1963-1986). The last 2 years, I was senior scientific advisor. As director of Plum Island (1963-1986), I was responsible for scientific and administrative direction for USDA program of diagnosis and research on animal diseases not present in the United States. As senior scientific advisor, I was responsible for advising two agencies of USDA, Agricultural Research Service and Animal and Plant Health Inspection Service, on several animal health programs including those at the international level.

Membership in Professional Organizations

American Veterinary Medical Association
U.S. Animal Health Association
American Association for the Advancement of Science
American College of Veterinary Microbiologists (Diplomate)

Committees Served

Pan-American Health Organization, Scientific Advisor
International Exchange of Fellows, Fulbright, 1972-1975
National Academy of Sciences, Institution of Laboratory Animal Resources
Board of Governors, American Association of Veterinary Lab. D.
Editorial Board, Elsevier Press, Dr. of Veterinary Microbiology
Rockefeller Foundation, Advisor, Tropical Animal Diseases
New York State Veterinary College, Cornell University Board of Advisors
IICA, RDNA Advisory Committee
FAO, Several advisory groups, the most recent being Survey Animal Health Vaccines in China

Honors

Doctor of Science, Purdue University, 1979
Doctor of Science, Long Island University, 1980
Distinguished Service Award, USDA, 1988
AVMA-XII, International Veterinary Congress Award

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Civic Contributions

Boy Scouts, Cub Master, 1964-1967
Board of Trustees, Eastern Long Island Hospital, 1968-1978

Scientific Contributions

Numerous (approx. 100) contributions to Journals, Annuals, and Books

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Ms. Regina Kowalski
Defense Intelligence Agency

CV Not Available.

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CURRICULUM VITAE

NAME: Thomas G. Ksiazek

BUSINESS ADDRESS:

Chief, Disease Assessment Section
Special Pathogens Branch, G14
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

EDUCATION:

1964-1969	B.S., Biological Sciences Kansas State University, Manhattan, Kansas
1966-1970	D.V.M., Kansas State University, Manhattan, Kansas
1974-1976	M.S., Virology, University of Wisconsin, Madison, Wisconsin
1980-1983	Ph.D., Epidemiology/Virology, University of California, Berkeley, California

PROFESSIONAL EXPERIENCE:

1970	Associate Veterinarian, Adirondack Animal Hospital, Glensfalls, New York
1971	Base Veterinarian, Sheppard Air Force Base, Texas
1971-1974	Chief, Veterinary Services, Royal Air Force Chicksands, United Kingdom
1974-1976	Air Force Institute of Technology, Civilian Institution Graduate Program, University of Wisconsin, Madison, Wisconsin
1976-1978	Head, Virology Division, Department of Microbiology, U.S. Naval Medical Research Unit No. 2, Taipei, Taiwan, Republic of China
1978-1980	Head, Zoonoses Department, U.S. Naval Medical Research Unit No. 2, Jakarta Detachment, Jakarta, Republic of Indonesia
1980-1983	Air Force Institute of Technology, Civilian Institutions Graduate Program, University of California, Berkeley, California
1983-1984	Veterinary Microbiologist, USAMRIID, Fort Detrick, Maryland
1984-1986	Deputy Head, Virology Department, U.S. Naval Medical Research Unit No. 3, Cairo, Arab Republic of Egypt
1986-1988	Veterinary Microbiologist, Disease Assessment Division, USAMRIID, Fort Detrick, Maryland

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1988-1991	Chief, Rapid Diagnosis Section, Department of Epidemiology, Disease Assessment Division, USAMRIID, Fort Detrick, Maryland
1991-present	Chief, Disease Assessment Section, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia
Aug 2000-present	Acting Chief, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia

MEMBERSHIP IN ACADEMIC AND PROFESSIONAL SOCIETIES:

American Society of Tropical Medicine and Hygiene
American Society for Microbiology
American Association for the Advancement of Science
Phi Zeta
American Veterinary Medical Association
Society of Tropical Veterinary Medicine

SERVICE AND CONSULTING:

1987	BOSTID Program, National Science Foundation: Epidemiology and Diagnosis of Arthropod-borne Viruses, Bangkok, Thailand
1990	APHIS, USDA: Equine Encephalitis in the Americas
1991	CDC, Atlanta: Crimean-Congo Hemorrhagic Fever diagnostic techniques
1994	ASM, ICAAC, Workshop on Hantavirus Diagnosis
1995	Australian Animal Health Laboratory, Biosafety Level-4 familiarization and training, Geelong, Australia
1995	Filovirus Investigation Planning, Ivory Coast, WHO, Geneva
1993-1996	Chairman, American Committee on Arthropod-borne Viruses
1997	*Ad hoc* editor, *Biosafety in Microbiological and Biomedical Laboratories* (CDC NIH Safety manual)
1999	Member, Review Panel, National Wildlife Health Center (USGS), Madison, WI
1998-2000	Member, Peer Review Panel, Military Infectious Diseases Research Program (Virology)
1999-2000	Member, Advisory Committee, Design of new BSL-4 laboratory, University of Texas Medical Branch, Galveston, Texas

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2000-	Member, USDA (ARS/APHIS) Biocontainment Advisory Committee
2000-	Member, Interagency Working Group on Biosecurity (USDA, DOD, HHS, DOJ).

HONORS AND ACCOMPLISHMENTS:

1970	High score, National Veterinary Board
1971	Veterinary Officer Basic Course (Honor Graduate)
1974	Squadron Officer School, Air University, Maxwell Air Force Base, Alabama (Distinguished Graduate)
1983	The Margaret Beattie Award for Excellence in Laboratory Science, School of Public Health, University of California, Berkeley, 3 June 1983
1990	The Army Surgeon General's Award of an "A" skill identifier for Veterinary Microbiologists
1990	Department of the Army Research and Development Achievement Award for Technical Achievement.
1992	Pekka Halonen Award for Diagnostic Virology, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention
1995	Founders Lector, American College of Veterinary Preventive Medicine
1996	Stitt Lecture, Association of Military Surgeons of the United States
1997	Senior Biological Research Service, CDC, USPHS

LICENSES:

Veterinary Medicine: Colorado

RESEARCH INTERESTS:

Epidemiology and ecology of the viral zoonoses
Diagnosis of viral diseases

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CURRICULUM VITAE

Name: Linda L. Logan

Office Address: Texas Animal Health Commission
2105 Kramer Lane
Austin, TX 78758

EDUCATIONAL BACKGROUND

1987	Doctor of Philosophy, Comparative Pathology, University of California, Davis, California
1983-1986	Postdoctoral Research, USDA, Plum Island Animal Disease Center, Cooperative Agreement with the University of California, Davis, California
1980-1982	Postdoctoral Fellowship, National Cancer Institute, Veterinary Pathology, University of California, Davis, California
1973-1976	Doctor of Veterinary Medicine, Texas A&M University, College Station, Texas
1972-1973	Master of Science, Veterinary Parasitology, University of Georgia, Athens, Georgia
1967-1971	Bachelor of Science, Zoology, Texas Tech University, Lubbock, Texas
1967	Diploma, American Community School, Addis Ababa, Ethiopia

WORKING RESEARCH EXPERIENCE

September 2000 - Present	Executive Director Texas Animal Health Commission Austin, Texas
January 1996 - September 2000	National Program Leader for Animal Health, National Program Staff U.S. Department of Agriculture, Agricultural Research Service, Beltsville, Maryland
February 1994 - December 1995	Program Area Leader, Host Resistance and Immunity, Trypanosomiasis Program, International Laboratory for Animal Disease Research (ILRAD), Nairobi, Kenya.
November 1991 - December 1995	Project Leader, Mechanisms of Anemia, Trypanosomiasis Program, ILRAD

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February 1994 - December 1995	"Acting" Project Leader, The Role of T-cells and B-cells in Resistance to Bovine Trypanosomiasis, Trypanosomiasis Program, ILRAD
April 1987 - November 1995	Scientist, Veterinary Pathology, ILRAD, Nairobi, Kenya
January 1983 - December 1986	Postdoctoral Research, USDA - ARS Plum Island Animal Disease Center, Greenport, New York
September 1978 - August 1980	Assistant Professor, Texas Agricultural Experiment Station, College Station, Texas
April 1977 - April 1980	Veterinary Parasitologist, Texas A&M University Contract, Tsetse Trypanosomiasis Research and Training Project, Bamako, Mali
September 1976 - April 1977	Research Associate, Institute of Tropical Veterinary Medicine, Texas A&M University, College Station, Texas
September 1974 - April 1976	Laboratory Assistant, Department of Veterinary Parasitology, College of Veterinary Medicine, Texas A&M University, College Station, Texas
January 1972 - August 1973	Graduate Research Assistantship, Department of Veterinary Parasitology, College of Veterinary Medicine, University of Georgia, Athens, Georgia
September - December 1971	Teaching eighth grade mathematics and science to my sister in Zaria, Nigeria
June - September 1971	Voluntary work and research in the Department of Veterinary Parasitology, College of Veterinary Medicine, Ahmadu Bello University, Zaria, Nigeria

APPOINTMENTS

Chair, Texas Foreign Animal Disease Working Group, Texas Emergency Management Council
Adjunct Professor, Department of Pathobiology, College of Veterinary Medicine, TAMU
TVMA Research Committee
TVMA Emergency Preparedness Committee
Member of USDA APHIS Veterinary Services Safeguarding Animal Health Review Team 2001-Present
ARS National Program Leader of Animal Health, 1996-2000
Team Member of ARS National Programs:
- Animal Health
- Animal Genome, Germplasm, Reproduction and Development
- Arthropod Pests of Animals and Humans
- Animal Well-Belling and Stress Control Systems
- Aquiculture
- Food Safety

National Animal Health Emergency Management Steering Committee
Member of the U.S. Delegation to the O.I.E. (World Animal Health Organization), May 15-21, 1999, Paris, France.

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Co-Chair USDA Liaison Committee to the Animal Agriculture Coalition on Biocontainment, 1997-2000
Chair, Industry-Agency Scrapie/BSE Consultants Working Group, 1996-2000
Co-Chair of the Research Committee, National Working Group on Johne's Disease, 1996-2000
Member, USAHA Blue Ribbon Task Force for Vesicular Stomatitis, 1996-present
Adjunct Professor, Department of Pathology, Virginia Maryland Regional College of Veterinary Medicine, Virginia Tech, Blacksburg, Virginia, 1993 - 1997
Chairman of the ILRAD Executive Staff Council 1994 -1995

ARS HONORS and AWARDS

Certificate of Merit, 2000: For excellent communication with stakeholders and customers of National Program 103.
Certificate of Appreciation, 2000: Communicating Animal Health Research Needs.
Certificate of Merit, 1999: For excellence in communicating with customers and stakeholders of the national program on animal health.
Certificate of Appreciation 1999: For extra effort and teamwork displayed working on the National Animal Health Monitoring System Review. APHIS, December 1999.
"Spot Award" 1999: North Atlantic Area Director for organization of an external review for the Plum Island Animal Disease Center and support to the program.
Certificate of Merit, 1998: For extra effort in developing the extensive network of communication that has enhanced the relationship of ARS with the agencies it supports and with its customers.
Time Off Award, 1998: 16 hours
Certificate of Merit, 1997: In recognition of excellence in communicating the priorities of ARS animal disease research.
Time Off Award, 1997: 32 hours
Certificate of Merit, 1996: In recognition of unique contribution in establishing an international symposium on bovine spongiform encephalopathy and scrapie, identifying the status and improving communications among regulatory agencies and commodity groups.

TEXAS A&M UNIVERSITY 1973-1976

Chairman, Honor Code Committee (1974 - 1975, 1975 - 1976)
Class Rep. to Student-Faculty Relations Committee (1974 - 1975, 1976)
Cum laude graduate, College of Veterinary Medicine, TAMU (1976)
AVMA Women's Auxiliary, Outstanding Achievement Award, Texas (1976)
Judge Marvin Jones Loan and Scholarship
Distinguished Student

TEXAS TECH UNIVERSITY 1967-1971

Dean's List
Alpha Chi Omega, Most Valuable Active (1971)
Beta Beta Beta (Biological Society Honorary Organization)
Student Union: Trophy Award (1970), Life Past Award (1971)
All University Recognition for Leadership (1969 - 1970, 1970 - 1971)
Who's Who in American Colleges and Universities (1970 - 1971)

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ASSOCIATION MEMBERSHIP

American Association of Veterinary Diagnosticians
American Association of Veterinary Immunologists
American Association of Veterinary Parasitologists
American Society of Rickettsiology
American Society of Tropical Medicine and Hygiene
American Veterinary Medical Association
American Association for the Advancement of Science
American Association of Bovine Practitioners
California Veterinary License
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary
...and Comparative Pathology 1987-1999
International Society of Animal Clinical Biochemistry
Kenya Veterinary Association 1987-1995
Society for Tropical Veterinary Medicine
Texas Veterinary License
Texas Veterinary Medical Association
U.S. Animal Health Association, Committee for Foreign Animal Diseases and
Committee for Sheep and Goats
Assembly of State Veterinarians

REVIEW PANELS

USDA APHIS Veterinary Services Animal Health Safeguarding Review, Exclusion Committee

Review all the ARS Animal Health Research Project Proposals on a 5-year cycle and provide comments and final approval.

Serve as a reviewer for ARS scientists performance as part of the Research Peer Evaluation System (RPES) used as a basis for grade promotion.

Plum Island Facilities Review Panel, meets twice a year.

ARS reviewer for a number of field research programs nationally and internationally in animal health, arthropod pests, animal production, and food safety.

Manuscript reviewer for *Journal of Wildlife Diseases*, *Journal of the American Society of Tropical Medicine and Hygiene*, *Theriogenology*, *Acta Tropica*, and *Journal of Clinical Immunology*.

Review of manuscripts for ARS scientists for subject matters classified as sensitive issues.

Chaired the peer review panel for animal and plant health proposals submitted to the Foreign Agriculture Service (FAS), USDA Scientific Cooperative Program, 1996.

Ad hoc reviewer for the National Research Initiative, Animal Health, Cooperative State Research and Extension Service (CSREES), USDA grants, 1998, 1999 and FAS grant proposals.

Panel participant for several programs within the USDA Animal Plant and Health Inspection (APHIS) on emerging disease and exotic animal disease issues such as BSE, scrapie, classical swine fever and vesicular stomatitis.

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Review Panel of the USDA APHIS national epidemiological surveillance program, i.e. National Animal Health Monitoring System (NAHMS) of APHIS.

Chair - Workshop on Cytokine and Cytokine Receptor Assays. International Symposium: Cytokines and the Type I, Type II Paradigm, Cairns, Australia, October 25-30, 1996.

Chair, External review team for the United Nations International Atomic Energy Agency, Vienna, October, 1997. Reviewed and declared the success of the IAEA tsetse fly sterile male release program on Zanzibar, Tanzania. Recommendations were made for continued parasitological and tsetse monitoring and surveillance for 2 years after sterile tsetse fly release discontinuation.

Chair for the Pre-harvest Food Safety Review Sessions on "Immunological Approaches to Pathogen Control and Preharvest Intervention Strategies." 19th Annual USDA Food Safety Research Planning Meeting, Athens, Georgia, December 1-3, 1998.

One of the three ARS scientists sent to Russia in September 1998 with representatives from the Department of State and Department of Defense representatives to initiate a new program of research between ARS scientists and Russian scientists formerly engaged in bioweapons development. This program of research has grown to $7,550,000 in FY2000 and will require several more trips to Russia and former states of the Soviet Union such as Kazahkstan. Second trip to Russia in October 1999. Eight projects in Animal Health identified for collaboration.

Chair for the session on *E. coli* O157:H7 on the farm. ARS Cattle Food Safety Pathogen Workshop. U.S. Meat Animal Research Center, Clay Center, Nebraska, June 17-18, 1998.

Chair, USAID External Peer Review Panel of the safety of release of the double recombinant vaccinia-rinderpest vaccine, June 2-4, 1999.

Chair, Workshop on Comparative Erythropoiesis, Gordon Research Conference, August, 1999.

Organized and hosted the National Animal Health Research Workshop for the Agricultural Research Service -USDA, September 21-24, 1999.

Organized and hosted an Animal Immunology Workshop for ARS scientists, March 27, 28, 2000.

Chaired Disease Session at World Buiatrics Congress, December, 2000, Punta del Este, Uruguay.

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CURRICULUM VITAE

Dr. N. James MacLachlan

NAME	POSITION TITLE
N. James MacLachlan	Professor and Chair

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
Massey University, New Zealand	BVSc	1976	Veterinary Medicine
University of Missouri, Columbia	MS	1979	Veterinary Virology
University of California, Davis	Dip ACVP	1982	Anatomic Pathology
University of California, Davis	PhD	1983	Comparative Pathology

RESEARCH AND PROFESSIONAL EXPERIENCE

1976 – 1977	Junior Lecturer, Department of Veterinary Pathology, Faculty of Veterinary Science, Massey University
1977 - 1979	Teaching Associate, Department of Microbiology, School of Veterinary Medicine, University of Missouri
1979 - 1982	Research Associate, Department of Pathology, School of Veterinary Medicine, University of California
1982 - 1988	Assistant/Associate Professor, Department of Microbiology, Pathology, and Parasitology, College of Veterinary Medicine, North Carolina State University
1989	Panel member USDA Special Research Grants Program
1991	Panel Manager, Molecular and Cellular Basis of Disease, USDA Competitive Grants Program
1992	Chair of the Faculty, School of Veterinary Medicine, University of California
1993	Norden Distinguished Teaching Award, School of Veterinary Medicine, University of California
1995, 1998	Panel member, Molecular and Cellular Basis of Disease (Virology), USDA Competitive Grants Program
1996, 97, 98	Scientific advisor to U.S. Trade Negotiating Teams in Agriculture with the People's Republic of China
1997	Panel member, Livestock/Aquaculture panel, Fund for Rural America
1998	President, American College of Veterinary Pathologists
1988 – present	Associate/Full Professor of Veterinary Pathology, School of Veterinary Medicine, University of California
1993 - present	Chair, Department of Pathology, Microbiology & Immunology, University of California (Acting 91,93,94)

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CURRICULUM VITAE

NAME: John Charles Morrill
LTC, U.S. Army
Veterinary Corps

Area of Interest: Virology

BUSINESS ADDRESS: Commander
South Plains District Veterinary Command
Attn: MCVS-GPP-C
80th & Engineer Dr., Bldg 4905
Fort Hood, TX 76544-4752

EDUCATION:

1964-1968	Texas A&M University, College Station, Texas, College of Science, B.S., Animal Science
1968-1971	Texas A&M University, College Station, Texas, College of Veterinary Medicine, D.V.M.
1980-1983	Texas A&M University, College Station, Texas, College of Veterinary Medicine, Ph.D., Veterinary Microbiology

PROFESSIONAL EXPERIENCE:
1999-Present

Commander
South Plains District Veterinary Command
Attn: MCVS-GPP-C
80th & Engineer Dr., Bldg 4905
Fort Hood, TX 76544-4752

Serves as Commander of the South Plains District Veterinary Command. Supervises approximately 62 military and 30 civilian personnel who provide veterinary services for Army, Navy, and Air Force installations located in 4 states. Manages food safety, animal medicine, veterinary preventive medicine programs, and human-animal bond programs throughout the District. Coordinates with federal, state, and local health and regulatory agencies on health-related issues. Provides administrative support to 3 District Branch offices and 6 Section offices. Serves as Veterinary Staff Officer for III Corps and Fort Hood and as Foreign Animal Disease Diagnostician member of Great Plains Regional Veterinary Command Special Medical Augmentation Response Team-Veterinary.

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1995-1999

Chief, Diagnostics Section
DoD Veterinary Laboratory
Attn: MCVS SCL
2472 Schofield Rd. Bldg. 2632
Fort Sam Houston, TX 78234-6232

Serves as Deputy Laboratory Director and Chief, Diagnostics Section, supervising 5 civilian laboratory supervisors and technicians. Responsible for diagnostic and serologic assays for zoonotic diseases to include rabies, Q-fever, brucellosis, leptospirosis, and toxoplasmosis. Assays are also performed for the detection of antibodies to babesia, ehrlichia, equine infectious anemia, rocky mountain spotted fever, bluetongue virus, Borrelia, and typhus. Performs fluorescent antibody virus neutralization test (FAVN) in support of Hawaii's modified rabies quarantine program. Responsible for the implementation of molecular biologic techniques, where practical and applicable, to enhance diagnostic capabilities. Implemented electronic data capture to increase efficiency of data handling and security. Serves as a consultant to the Military Working Dog Medical Records and Gulf War Projects. Advisor to Operation Baker Lifeline in support of the U.S. Army PACOM's Expanding Relations Program with the PDR Laos. Foreign Animal Disease Diagnostician (FADD).

1992-1995

Chief, Applied Research Division
U.S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21702-5011

Served as Chief of a medical research division composed of 64 civilian and military professional, technical, and support staff assigned to five branches (Rapid Diagnosis, Preventive Medicine, Epidemiology, Aerobiology, and Clinical Immunology), with an annual budget of $2.6 million. Implemented the Biological Defense Research Program by developing field-deployable rapid diagnosis tests, determining aerosol transmission characteristics of threat agents, defining risk of endemic diseases, and developing vaccination strategies. Successfully applied remote sensing and Geographical Information Systems (GIS) to field investigations of viral disease outbreaks in Florida and eastern Africa. Directed investigations, managed budget, supervised and evaluated senior staff, allocated resources, reported progress, and served as a technical expert for the United States Army Medical Research and Development Command. Served as WHO Consultant to Eastern Mediterranean Regional Office on Rift Valley fever during the RVF outbreak in Egypt in 1993. Member of WHO Working Group on Rift Valley fever virus.

1988-1992

Department of Pathogenesis and Immunology
Disease Assessment Division
U.S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21702-5011

Served as research virologist responsible for development and testing of vaccines against high hazard viral agents of military relevance. Responsible for all preclinical testing of a mutagen-attenuated Rift Valley fever vaccine for use in humans. Wrote and assembled investigational new drug application (IND) that was approved and allowed Phase I/II clinical testing of the mutagen-

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attenuated Rift Valley fever vaccine. Conducted epidemiologic studies on Marburg virus outbreak in western Kenya. Conducted virologic and serologic surveys of bats, wild rodents, and birds that included trapping or mist netting, identifying, and collecting blood and selected tissues.

1986-1988

Head, Virology Department,
U.S. Naval Medical Research Unit #3,
Cairo, Egypt

Served as Head of Virology Department, which consisted of two other senior American scientists, three senior and four junior Egyptian scientists, and a technical staff of eight Egyptian Nationals and one Navy corpsman. Responsible for country-wide epidemiologic studies on HIV and arboviral infections in Egypt. Conducted virologic and serologic surveillance for arboviral and rickettsial agents in Egypt, Sudan, Somalia, Djibouti, and Kenya. Studies involved trapping, netting, identifying, data recording, bleeding, and collecting tissues from birds and wild mammals. Conducted annual week-long training seminar on HIV diagnostics for northeastern African nations. While under my direction the Virology Laboratory was recognized by the Egyptian Ministry of Health for its outstanding contributions to medical research and by the World Health Organization as a "WHO Reference Center for HIV" in the Middle East region.

1983-1986

Department of Pathogenesis and Immunology
Disease Assessment Division
U. S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21701

Planned, organized, and conducted studies on the epidemiology, pathogenesis, prophylaxis, and treatment of Rift Valley fever virus (RVFV) infections. Developed prophylactic and therapeutic regimens for the use of recombinant human interferons in Rift Valley fever virus infections. Evaluated novel RVFV vaccines (i.e., mutagen-attenuated virus vaccines and vaccinia recombinant vaccines). Responsibilities included training of technical staff; collecting, processing, and assaying specimens for virus, viral antigen, antibody, and interferon; collecting, analyzing, interpreting, presenting, and publishing research data; BSL-3 level containment laboratory supervisor; acquisition of computer workstations and training of technical staff in their use.

1980-1983

U. S. Army-sponsored graduate student
Texas A&M University
Department of Veterinary Microbiology
Ph.D. Thesis: Pathogenesis of Quadritypic Bluetongue
Virus Infection in Cattle (1984)

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1978-1980

Deputy for Veterinary Activities and Officer-in-Charge
Food Hygiene Safety Quality Assurance Branch
U. S. Army Medical Department Activity
Fort Hood, Texas

Managed zoonotic disease surveillance and prevention program, responsible for rabies control program, conducted epidemiologic investigations of food-borne illnesses, and managed food safety and quality assurance program in support of a troop population of approximately 45,000 active duty personnel.

1975-1978

Owned and operated private veterinary hospital in Gatesville, Texas

Veterinary practice in rural central Texas included livestock and pets. Special emphasis on herd health programs for dairy cattle, beef cattle, dairy goats, sheep, swine, and brood mare operations.

1973-1975

Officer-in-Charge
Animal Care Branch
U. S. Army Medical Department Activity
Fort Hood, Texas

Managed rabies control and zoonotic disease prevention and surveillance programs. Duties included public education on prevention of zoonotic disease and food-borne illnesses, plague surveillance in cooperation with the Texas Department of Public Health, and arthropod-borne viral disease surveillance in collaboration with the Centers for Disease Control, Fort Collins, Colorado.

1971-1973

Officer-in-Charge
Veterinary Food Inspection Service
Kansas City, Missouri

Supervised inspection of government-owned subsistence and sanitation practices in U. S. government regional food storage warehouses in and around the Kansas City area. Responsibilities included food and sanitation inspections of more than 100 food-processing plants located throughout western Missouri and eastern Kansas.

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PROFESSIONAL ORGANIZATIONS:

American Veterinary Medical Association
American Society of Tropical Medicine and Hygiene
American Society of Tropical Veterinary Medicine
Phi Zeta
Phi Sigma
U.S. Animal Health Association

AWARDS AND HONORS:

Navy and Marine Corps Medal for Heroism
Meritorious Service Medal (5)
Army Commendation Medal (2)
Army Achievement Medal (2)
Army Superior Unit Award
Outstanding Volunteer Service Medal
National Defense Service Ribbon (2)
Humanitarian Service Medal
Army Service Ribbon
Overseas Service Ribbon
Expert Field Medical Badge
Army Science Conference award, West Point, New York, 1986
"A" proficiency designator - Microbiology
Fort Detrick Outstanding Man of the Year Award – 1994
Order of Military Medical Merit - 1998

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CURRICULUM VITAE

Kenneth E. Olson, Ph.D., PAS

EDUCATION:

University of Wisconsin-Madison
Ph.D. in Dairy Science (Dairy Cattle Breeding) 1976
Minors in Genetics and Statistics
M.S. in Dairy Science 1972
University of Wisconsin-River Falls
B.S. in Animal Science (Dairy Option) 1969
Minor in Mathematics

HONORARY SOCIETY MEMBERSHIP:

Alpha Zeta (Agriculture)
Kappa Mu Epsilon (Mathematics)

COMMUNITY SERVICE:

Member of Lord of Life Lutheran Church
Member of Church Council (2 terms) - President (4 years)
Co-Chair Capital Fund Appeal - 2001
Chairman of Computer Committee, Lord of Life
Delegate to Metro-Chicago Synod Convention - 3 years
Metro Chicago Synod Nominating Committee
Elected as voting member from Metro Chicago Synod to 2003 National Assembly
Past Treasurer, Board of Directors for the Resource Office for Social Ministry, Lexington, KY
Schaumburg Township District 54 PTA -Scholarship Committee
Schaumburg Township District 54 - Reporting to Parents Committee
Conant High School Booster Club - Member of Audit Committee

WORK EXPERIENCE:

Employment:

April 2001 – Present Principal - KEO Consulting (Dairy & Animal Health)
Project Leader for FASS/ARPAS Animal Care Project, served as member of Response Committee for the APHIS Safeguarding Review, analysis of dairy policy options for the Farm Bill, project coordination for publication of "Understanding Forage Quality," development of Johne's CD and industry communication on animal disease emergencies.

1989-April 2001 Dairy and Animal Health Specialist - AFBF
I served as the Dairy and Animal Health Specialist in the Public Policy Division of the American Farm Bureau Federation. I also worked in the areas of Animal Welfare, Agricultural Research, Food Safety (Animal issues) Biotechnology, and Hay and Forage. I served as the primary national resource person for the organization in these areas. In this role I provided information to state Farm Bureaus on these issues, developed comments and testimony as needed and served as a liaison with industry groups and governmental agencies.

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Employment (continued):

1987-89	Ext. Professor - Univ. of Kentucky
1981-87	Associate Ext. Prof. - Univ. of Kentucky
1977-81	Assistant Ext. Prof.- Univ. of Kentucky

Extension: I was employed as an extension dairy specialist with the Cooperative Extension Service, University of Kentucky from January 1977 through January 1989. My major emphasis was the Dairy Herd Improvement (DHI) program. I had responsibility for educational aspects of the program and served as an advisor to the state board of directors. I assisted in hiring of the management and laboratory personnel. I also had responsibilities for extension work in dairy cattle breeding and work with microcomputer applications.

Teaching: While I had no teaching component in my appointment, I did assist in teaching two courses; providing lectures on genetics and dairy sire selection for ASC 462 Artificial Insemination and Fertility of Farm Animals, and microcomputer use in ASC 420 Dairy Cattle Science.

Research Areas:

- Effect of days open on persistency in dairy cattle
- Effect of DHI management factors on production
- Effect of shipment on DHI milk samples
- Relationship of somatic cell counts to production
- Estimation of genetic trend in Wisconsin Holsteins from 1952 to 1972 using DHI records
- Estimation of the effect of two levels of nutrition, two genetic groups and two reproductive management systems on production and efficiency in dairy cattle

MEMBERSHIP AND ACTIVITIES:

National: National Institute for Animal Agriculture (formerly the Livestock Conservation Institute (LCI))

- Chairman, Board of Directors
- Vice-Chair of the Board of Directors
- Secretary of the Board of Directors

National Livestock Ethics Council

- Member of the Board of Directors

National Coalition for Food and Agricultural Research (N-CFAR)

- Member of Operations Committee

U.S. Animal Health Association

- Member of the Board of Directors
- Vice-chair District at Large

National Johne's Working Group

- Chair of Economics Subcommittee
- Treasurer for Working Group
- Chair Industry Implementation Committee

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MEMBERSHIP AND ACTIVITIES: (continued)

National Animal Health Emergency Management (NAHEM) Steering Committee
- Member of Education and Meetings Committees
- Member of the U.S. delegation for the "Tripartite Exercise 2000" on Foot and Mouth Disease

Dairy Quality Assurance Program
- Chair of the Board of Trustees
- Editor of Dairy Care Materials

Agricultural Databases for Decision Support (ADDS)
- Member Board of Directors (1999 - present)
- Editor - Genetics section of National Dairy Database

Member of McDonald's Animal Welfare Council
- This group advises McDonald's Corporation on animal welfare issues.

Member U.S. Dairy Forage Research Center Stakeholder Advisory Committee

Member of the Response Committee of the National Association of State Department of Agriculture's Animal Safeguarding Review

Member of USDA review panels for the U.S. Dairy Forage Research Center and the National Animal Health Monitoring System (NAHMS) of the Animal and Plant Health Inspection Service (APHIS) and selection committee for the director of the Center for Epidemiology and Animal Health (CEAH)

Executive Planning Committee for Food Animal Integrated Research (FAIR) 2002

Member American Dairy Science Association
- Member of Animal Care Committee (1996 - 1999)
- Chairman ADSA Microcomputer Subcommittee (1983-1985)
- Vice Chairman ADSA Microcomputer Subcommittee (1982-1983)
- Secretary ADSA Microcomputer Subcommittee (1987-88)

Member of:
- American Registry of Professional Animal Scientists
- Council for Agricultural Science and Technology (CAST)
- National Mastitis Council
- American Forage and Grassland Council
- Dairy Shrine

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CURRICULUM VITAE

Jean L. Patterson

EDUCATION:	Degree	Year	Major
Miami University, Oxford, Ohio	B.A.	1975	Zoology
University of Notre Dame, Notre Dame, Indiana	Ph.D.	1979	Biology

POSTDOCTORAL TRAINING:

1979 - 1980	NIH Postdoctoral Trainee, Department of Biochemistry, University of Wisconsin, Madison, Wisconsin
1980 - 1981	NIH Postdoctoral Fellow, Department of Biochemistry, University of Wisconsin, Madison, Wisconsin
1981 - 1984	Research Associate, Department of Microbiology, University of Geneva Medical School, Geneva, Switzerland

PRESENT POSITIONS:

1996 - present	Chairman, Department of Virology and Immunology, Southwest Foundation for Biomedical Research, San Antonio, Texas
1996 - present	E.M. Stevens Chair for Biomedical Research, San Antonio, Texas
1996 - present	Adjunct Professor, Department of Microbiology, The University of Texas Health Science Center at San Antonio, San Antonio, Texas
2000 - present	Member, Technology Area Review and Assessment (TARA), Department of Defense
2000 - present	Member, Graduate Faculty at University of Texas Health Science Center, Department of Microbiology
2000 – present	Member, NIH COBRE (Center of Biomedical Research Excellence)
2000 – present	Member, Biomedical Review Panel, Department of Defense

PREVIOUS POSITIONS:

1984 - 1986	Instructor, Department of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts
1986 - 1991	Assistant Professor of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts
1984 - 1996	Scientific Associate, Department of Medicine (Infectious Diseases), Children's Hospital, Boston, Massachusetts
1991 - 1996	Associate Professor, Department of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts

PROFESSIONAL SOCIETIES:

1976	Society of Sigma Xi
1986	American Society for Virology (ASV)
1989	American Society of Tropical Medicine and Hygiene (ASTMH)
1990	International Society for Antiviral Research

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1990 American Society for Biochemistry and Molecular Biology (ASBMB)
1993 American Society for Microbiology (ASM)
1997 American Association for the Advancement of Science (AAAS)
1997 Society for the Advancement of Chicanos and Native Americans in Science (SACNAS)

NATIONAL AND INTERNATIONAL COMMITTEE ASSIGNMENTS:

1988 - 1986	NIH Ad Hoc Study Section for AIDS Program Projects Currently a reviewer for: Journal of Virology, Virology, Journal of General Virology, Molecular and Biochemical Parasitology, Experimental Parasitology, Antiviral Research, American Institute for Biological Sciences
1991 - 1993	Chairman of the Study Group on Protozoal Viruses of the International Committee on Taxonomy of Viruses (ICTV) NIH Special Reviews: Tuberculosis Vaccine Development and Basic Biology and Pathogenesis of Human Tuberculosis
1995 - 1997	Program Steering Committee, American Society of Tropical Medicine and Hygiene NIH Ad HOC Study Sections: NINDS, NIAID

LOCAL COMMITTEE ASSIGNMENTS:

1985 - 1987	Subcommittee on Recombinant DNA, Harvard Medical School, Boston, Massachusetts
1987 - 1996	Committee on Biological Safety, Harvard Medical School, Boston, Massachusetts
1989 - 1990	Committee on Virology Seminar Series, Harvard Medical School, Boston Massachusetts
1989 - 1992	Programs and Admissions, Division of Medical Sciences, Harvard Medical School, Boston, Massachusetts
1990 - 1994	Chairman, Committee on Virology Graduate Admissions, Harvard Medical School, Boston, Massachusetts
1990 - 1993	Chairman, Virology Graduate Advisory Committee, Harvard Medical School, Boston, Massachusetts
1991	Graduate Program Re-evaluation Committee, Harvard Medical School, Boston, Massachusetts
1991 - 1996	Committee on Virology Steering Committee, Harvard Medical School, Boston, Massachusetts

TEACHING EXPERIENCE:

1976 - 1977	Lecturer in Comparative Anatomy and General Biology, University of Notre Dame, Notre Dame, Indiana
1977 - 1979	Lecturer in General Physiology and Comparative Physiology, University of Notre Dame, Notre Dame, Indiana
1985	Lecturer and lab instructor in Pathophysiology of Infectious Diseases Lab, Microbiology 701, Harvard Medical School, Boston, Massachusetts
1986	Lecturer in Seminar in Animal Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1986	Lecturer in Principles of Animal Virology, Virology 101, Harvard Medical School, Boston, Massachusetts
1987	Course Director of Principles of Animal Virology, Virology 101, Harvard Medical School, Boston, Massachusetts

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1988	Lecturer in Molecular Genetics of Neurotropic Viruses, Genetics 710, Harvard Medical School, Boston, Massachusetts
1989	Lecturer in Seminar in Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1990 - 1991	Course Co-Director of Animal Virology, Virology 200, Harvard Medical School, Boston, Massachusetts
1991 - 1993	Course Co-director of Seminar in Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1992 - 1995	Lecturer in Animal Virology, Virology 200, Harvard Medical School, Boston, Massachusetts
1993	Discussion Leader in Critical Thinking and Proposal Writing/Presentation, Genetics 330, Harvard Medical School, Boston, Massachusetts
1993 - 1995	Chairman, Responsible Conduct of Science Curriculum, Harvard Medical School, Boston, Massachusetts
1994	Lecturer in Basic Mechanisms of Microbiology Pathogenesis, HST 040, Harvard Medical School, Boston, Massachusetts
1996 - 1998	Lecturer in Microbial Pathogenesis, MICR 5031, UTHSC-SA
1997 - 1998	Lecturer in Medical Microbiology, MICR 1005, UTHSC-SA
1999	Lecturer in Virology, MICR 5041, UTHSC-SA

MAJOR RESEARCH INTERESTS:

1. Molecular biology of viruses infecting protozoan parasites
2. Transcription of bunyaviruses
3. Mechanisms of action of anti-viral agents

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CURRICULUM VITAE

Jonathan Y. Richmond, Ph.D.

Education:

1967, Ph.D., Genetics, Hahnemann University, Philadelphia, PA
1964, MS, Genetics, University of Connecticut, Storrs, CT
1962, BA, University of Connecticut, Storrs, CT

Employment:

1990-present: Director, Office of Health and Safety, Centers for Disease Control and Prevention, Atlanta, GA
1990-present: Director, WHO Collaborating Center for Applied Biosafety and Training, CDC, Atlanta, GA
1983-1990: Chief, Safety Operations Section, Occupational Safety and Health Branch, NIH Division of Safety, Bethesda, MD
1979-1983: Biological Safety Officer, Plum Island Animal Disease Center, USDA, Greenport, NY
1969-1979: Research Microbiologist, PIADC, USDA, ARS, Greenport, NY
1967-1969: Post-Doctoral Resident Research Fellow, PIADC, Greenport, NY

Professional Interests:

Biological Safety; General Occupational Safety and Health, including Animal (Bio) Safety; Communication and Training; HIV/AIDS Education (Director of HIV/AIDS Workplace Education, CDC/ATSDR)

Professional Affiliations:

American Biological Safety Association (ABSA)
President 1986-1987; Chesapeake Area Chapter, President 1989-1990; *Anthology* editor
American Society for Microbiology (ASM)
Coordinator Biosafety Workshops (1986, 89, 94, 98, 99)
Member Lab Safety Committee (1993-present)
Chairperson, CDC's National Symposium on Biosafety (1992, 94, 96, 98, 00, 02)

International Consultations:

Laboratory Design Project, San Juan, Puerto Rico: Consult on the design of a BSL-3 laboratory for work with *M. tuberculosis*, 1993-present.

Project RETRO-CI, Abidjan, Côte d=Ivoire, Africa: Design and certification of BSL-3 laboratories for work with *M. tuberculosis*, HIV, and other bloodborne pathogens, 1994.

Plasma-derived Hepatitis B Vaccine Project, Bulandshar, Uttar Pradesh, India: Conduct biosafety evaluation of a new HBV vaccine production facility, an Indo-U.S. vaccine action program, 1994.

Viral Diagnostic Laboratory, Toronto, Canada: Review and public discussion of safety matters associated with a BSL-4 laboratory (glove box line) for work with exotic human pathogens, 1995.

International Center for Diarrheal Disease Research, Dhaka, Bangladesh: Biosafety review, training, containment certification, 1996, 1997.

HIV/AIDS Program, Bangkok, Thailand: Biosafety review, training, containment certification, 1997.

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National Institute of Biologics, New Delhi, India: Biosafety training, new facility review, 1997.

National Institute of Infectious Diseases, Tokyo, Japan: Biosafety facility and program review, training, 1997.

National Laboratories for Human and Animal Health, Winnipeg, Canada: Biosafety facility and program revier, Tier 2 Commissioning phase, 1997.

Selected Honors:
Elected **Fellow**, American Academy of Microbiology (1980).

Presented the **Arnold G. Wedum Distinguished Achievement Award**, the highest honor of the American Biological Safety Association, in recognition of outstanding contributions to biological safety accomplished through teaching, service and leadership (1999).

Selected **Distinguished Fellow**, Centers for Disease Control and Prevention, 2000.

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CURRICULUM VITAE

Reynolds M. Salerno

International Security Center
Sandia National Laboratories
PO Box 5800, Mail Stop 1373
Albuquerque, NM 87185

CURRENT PROFESSIONAL POSITION

Senior Member of the Technical Staff, International Security Center, Sandia National Laboratories, Albuquerque, New Mexico. Since June 1999.

- Program Manager, Biosecurity and Biodefense Initiative
  - Vulnerability analyses, conceptual designs, security systems implementation, security policy and standards development for U.S. Department of Agriculture and U.S. Department of Defense
  - Policy and standards development for international arms control and nonproliferation applications for U.S. Department of Energy
- Member of U.S. Interagency Working Group on Biosecurity

SELECT SANDIA PUBLICATIONS

"Analysis of U.S. Bioterrorism Legislation," Prepared for Office of Nonproliferation Policy, U.S. National Nuclear Security Administration, SAND 2002-forthcoming, July 2002.

"U.S. Laboratory Biosecurity Policy Paper," Prepared for U.S. Office of Homeland Security, SAND 2002-1068P, February 2002.

"Biological Laboratory and Transportation Security and the Biological Weapons Convention," Prepared for U.S. Delegation to the BWC, U.S. Department of State, SAND 2002-1067P, February 2002.

"Enhancing the Security of Dangerous Pathogens: A Workshop Report," Prepared for Office of the Secretary of Defense, U.S. Department of Defense, SAND 2001-0289P, January 2002.

"Mitigating the Threat of Biological Weapons and Novel Infectious Diseases: Real-time Syndromic and Epidemiological Surveillance," Prepared for U.S. Defense Threat Reduction Agency, SAND 2001-2014, July 2001.

"Enhancing the U.S. Response to the Bioterrorist Threat," SAND2000-0076, January 2000.

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EDUCATION

Yale University, Ph.D. in History, 1997; MPhil, 1994; MA, 1992

Middlebury College, BA in History, 1989

SELECT SCHOLARLY PUBLICATIONS

Vital Crossroads: Mediterranean Origins of the Second World War, 1935-1940 (Ithaca, NY: Cornell University Press, 2002).

"Britain, France and the emerging Italian threat in the Mediterranean, 1935-38," in William Philpott and Martin Alexander, eds. *Anglo-French Defence Relations Between the Wars* (London: Palgrave, 2002).

"Italy's pirate submarine campaign of 1937," in Greg Kennedy and Keith Neilson, eds. *Butterfly Wings: Incidents and International Relations, 1795-1940* (New York: Praeger, 2001).

"Global independence versus regional interdependence: France and Italy in the Mediterranean since 1945," in John Hattendorf, ed. *Naval Policy and Strategy in the Mediterranean Sea, Past, Present and Future* (London: Frank Cass, 2000).

"Naval strategy and the origins of the Second World War in the Mediterranean, 1938-40," in William McBride, ed. *New Interpretations in Naval History: Selected Papers from the Thirteenth Naval History Symposium* (Annapolis, MD: NIP, 1998).

"The French navy and the appeasement of Italy, 1937-39," *The English Historical Review* cxii:445 (February 1997).

"Multilateral strategy and diplomacy: The Anglo-German naval agreement and the Mediterranean crisis, 1935-36," *Journal of Strategic Studies* xvii:2 (June 1994).

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CURRICULUM VITAE

Name: Alfonso Torres

Work Address: NYS Animal Health Diagnostic Laboratory
College of Veterinary Medicine
Cornell University
Upper Tower Road
Ithaca, NY 14853

EDUCATION

Academic Degree	Year	Institution
D.V.M.	1968	National University of Colombia Bogota - Colombia **Major:** Veterinary Medicine
M.S.	1971	University of Nebraska-Lincoln Lincoln, NE **Major:** Veterinary Pathology
Ph.D.	1973	University of Nebraska Medical Center Omaha, NE **Major:** Medical Microbiology (Virology)

PROFESSIONAL EXPERIENCE

Title	Dates	Institution
Associate Dean for Veterinary Public Policy, and Director, New York State Animal Health Diagnostic Laboratory	Feb. 2002 to Present	College of Veterinary Medicine Cornell University Ithaca, NY
Deputy Administrator for Veterinary Services and Chief Veterinary Officer	Jan. 1999 to Feb. 2002	U.S. Department of Agriculture Animal and Plant Health Inspection Service Washington, DC
Director, Plum Island Animal Disease Center	Sep. 1996 to Jan. 1999	U.S. Department of Agriculture Agricultural Research Service Plum Island Animal Disease Center Plum Island, NY.
Acting Director, Plum Island Animal Disease Center	March 1996 to Sep. 1996	U.S. Department of Agriculture Agricultural Research Service Plum Island Animal Disease Center Plum Island, NY

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Chief Foreign Animal Disease Diagnostic Laboratory	Oct. 1995 to Sep. 1996	U.S. Department of Agriculture Animal and Plant Health Inspection National Veterinary Services Laboratories Foreign Animal Disease Diagnostic Laboratory Plum Island, NY
Head Diagnostic Services Section	April 1991 to Oct. 1995	U.S. Department of Agriculture Animal and Plant Health Inspection National Veterinary Services Laboratories Foreign Animal Disease Diagnostic Laboratory Plum Island, NY
Manager Virology Development	Dec. 1987 to March 1991	SmithKline Beecham Animal Health (Former Norden Labs) Lincoln, NE
Associate Professor	Oct. 1983 to Dec. 1987	New York State College of Veterinary Medicine Veterinary Diagnostic Laboratory Cornell University, Ithaca, NY
Assistant /Associate Professor	Feb. 1978 to Oct. 1983	Department of Veterinary Science University of Nebraska-Lincoln Lincoln, NE
New Products Manager for Latin America	Apr. 1976 to Jan. 1978	Ames, Company Division of Miles Laboratories, Inc. Cali, Colombia
Assistant Professor	Dec. 1973 to Oct. 1975	Department of Veterinary Science University of Nebraska-Lincoln Lincoln, NE
Graduate Student Fellow	Sep. 1971 to Dec. 1973	Department of Veterinary Science University of Nebraska Lincoln, NE
Instructor (On academic leave)	Jul. 1969 to Aug. 1971	College of Veterinary Medicine & Zootecnics National University of Colombia Bogotá, Colombia
Instructor	Jan. 1969 to Jun. 1969	College of Veterinary Medicine & Zootecnics National University of Colombia Bogotá, Colombia

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OTHER APPOINTMENTS

Adjunct Professor Dec. 1987 to Feb. 2002	New York State College of Veterinary Medicine Cornell University Ithaca, NY
Adjunct Professor Aug. 1989 to Aug. 1997 Lincoln, NE	Department of Veterinary Science University of Nebraska-Lincoln

DESCRIPTION OF PROFESSIONAL EXPERIENCES

Administrative Experience

Private industry

- During my employment with Miles Laboratories, I managed the marketing activities for human diagnostic products throughout Latin America, including preparation of technical information, implementation of marketing plans, and support for sales personnel in 19 countries.

- As a Manager at SmithKline Beecham Animal Health (and its predecessor Norden Laboratories), I coordinated all regulatory licensing of the company's veterinary biologics in the United States and in several European countries. Later, I managed and supervised research and development teams involved in projects dealing with new or improved vaccines for viral and bacterial diseases of domestic animals and livestock.

Academia

- During my years of service at the University of Nebraska, I supervised and managed my own virology and electron microscopy research laboratory. I served the Nebraska Agricultural Experiment Station on several academic committees related to teaching, research, and international programs.

- As faculty at Cornell's College of Veterinary Medicine, I had joint responsibility for the administration of the diagnostic virology services, and financed and managed my own research laboratory. I served on administrative committees of the Diagnostic Laboratory and College, and the search committees for department heads and a dean.

- Serving currently as Associate Dean for Veterinary Public Policy and Director, New York State Animal Health Diagnostic Laboratory, College of Veterinary Medicine at Cornell University.

Public Service

- I managed the USDA's Foreign Animal Disease Diagnostic Laboratory, the leading laboratory in the United States responsible for the diagnosis of exotic animal diseases.

- As Director of the Plum Island Animal Disease Center (PIADC), I was responsible for the administration of an annual budget of approximately $15 million dollars, and 160 employees. PIADC is a complex research, diagnostic, and training center, the premier high security bio-containment laboratory in the United States. While at PIADC, I gained extensive experience on

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the design, operation, and maintenance of high biocontainment (BL-2, BL-3 and BL-3 Ag) facilities. Due to the nature of the mission of PIADC, and its joint operations involving the USDA Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS), I have strong connections with the veterinary diagnostic community and the biomedical research community of the United States, and all major commodity groups representing the U.S. animal industries. I have also cultivated cooperative programs with similar high security animal research centers around the world.

- In my immediate past position as APHIS' Deputy Administrator of Veterinary Services, I was responsible for all aspects related to the animal health safeguarding programs for the U.S. Department of Agriculture. The APHIS Veterinary Services programs under my leadership included approximately 1,400 employees (with over 400 veterinarians) in all 50 states and U.S. possessions, with an annual budget of about $130 million dollars per year. Reporting to me were six units:

  i. Animal Health Programs, a headquarters staff responsible for domestic and foreign animal disease prevention, control, and eradication activities, as well as regulatory oversight of international trade of animals and animal products.
  ii. Field Veterinary Service Programs, organized in two Regional Centers and some 44 state offices, responsible for coordination and management of all field activities in the U.S. and overseas possessions.
  iii. Management and Support Services, a headquarters staff responsible for budget preparation and monitoring, and communications.
  iv. The Centers for Epidemiology and Animal Health at Fort Collins, Colorado, responsible for monitoring the health of the U.S. animal population, the epidemiologic and information systems in support of domestic animal health programs, and for the monitoring and evaluation of emerging animal health issues.
  v. The Center for Veterinary Biologics at Ames, Iowa., responsible for the licensing and other regulatory aspects of all animal biologics and diagnostics marketed in the United States; and
  vi. The National Veterinary Services Laboratories at Ames, Iowa, and Plum Island, New York, responsible for providing diagnostic services for all domestic and foreign animal diseases.

- I served as the Chief Veterinary Officer of the United States before the International Office of Epizootics (OIE) in Paris, France. The World Trade Organization has delegated to the OIE the leadership for the development of international animal health standards for trade in animals and animal products.

For these reasons, I have wide experience in multilateral and bilateral trade negotiations, development of international standards, harmonization activities, and other aspects of international cooperation. As the head of the main regulatory agency for animal health in the United States, I handled multiple complex issues which affect national and international animal health and veterinary practices. I enjoyed effective communication and interaction with domestic and international academic and professional organizations, state government representatives, commodity groups, and industry representatives related to animal products, live animals, or vaccine / biotechnology.

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Academic Experience

- At my *alma mater* in Bogotá, Colombia, I was Instructor for a general veterinary pathology course.
- At the University of Nebraska, I was Assistant Professor, then tenured Associate Professor, responsible for teaching and advising students enrolled in both the pre-veterinary curriculum and animal science department. In addition, I had academic assignments through the Department of Veterinary Sciences and the Institute of Agriculture and Natural Resources (part of the University of Nebraska's Agriculture Experiment Station).

- At Cornell University's College of Veterinary Medicine, I had the opportunity, as Associate Professor, to be active in a variety of the College's committees, including search committees. I was also involved in a variety of international program activities of the College as well as of the University. I frequently lectured in graduate and undergraduate courses.

- While at USDA, I was actively teaching several aspects of foreign animal diseases. I lectured regularly at professional meeting seminars, and at colleges of veterinary medicine in the United States and abroad. I had major responsibility in organization and teaching of comprehensive courses on foreign animal diseases for federal, state, and military veterinarians, for professors of veterinary colleges, and for second-year veterinary students from all U.S. veterinary colleges (Smith-Kilborne Foreign Animal Disease Training). I taught courses on foreign animal diseases at centers in Spain, Argentina, and Colombia, and courses on livestock infectious diseases in many foreign countries.

- In my current work at Cornell University, I am involved in high-level academic administration while maintaining an active participation in lectures dealing with instruction on the awareness and recognition of foreign animal diseases and biosecurity.

Research Experience

- My research experience focused primarily on diseases (mostly viral) affecting poultry, cattle, swine, dogs, and cats, both at the bench level and on host and experimental animals. Researching the clinical pathology of horses and cattle at high altitude led to my D.V.M. degree. I conducted research on a viral disease of poultry for my M.S. degree. Research on a viral enteric disease of pigs was the basis of my Ph.D. project. My academic research experience included work on the pathogenesis (with extensive electron microscopy) and immune response studies of gnotobiotic piglets and calves against rotaviruses and coronaviruses of animal or human origin. I also worked under contract with the National Institutes of Health (NIH) to develop the gnotobiotic piglet as an animal model for human infant rotaviral diarrheas. I gained extensive experience on the use of the technologies required for the delivery and maintenance of germ-free and gnotobiotic calves and piglets. These academic research projects were funded by the Nebraska Agricultural Experiment Station, Cornell University, USDA, NIH, and the World Health Organization.

- At SmithKline Beecham Animal Health, my research activities were directed to the development or improvement of animal vaccines. I led 4 major projects, and supervised more than 25 additional projects related to the pathogenesis and immune response of dogs, cats, and cattle against a variety of infectious diseases.

- As Director of the Plum Island Animal Disease Center, I participated in a variety of research studies on exotic viral diseases of livestock, including aspects of classic pathology, virology, and immunology, as well as research projects involving genetic sequencing, gene cloning and

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expression, gene deletion, gene recombination, and gene reassortment experiments. Some of these activities led to technology transfer efforts from bench research observations to private companies interested in exploiting these findings for commercial purposes.

CURRENT MEMBERSHIP IN PROFESSIONAL SOCIETIES

- American Veterinary Medical Association
- American Association of Veterinary Laboratory Diagnosticians
- Conference of Research Workers in Animal Diseases
- United States Animal Health Association
- American Veterinary Epidemiology Society

MEMBERSHIP IN HONORARY SOCIETIES

- Gamma Sigma Delta - Honor society of agriculture
- Sigma Xi - The scientific society of North America
- Phi Zeta - Honor society of veterinary medicine

HONORS AND AWARDS

- Ralston Purina Award - 1968. Presented to the top ranking graduate of the College of Veterinary Medicine, National University of Colombia.

- National University of Colombia, Post-Graduate Fellowship 1968-1971. Full scholarship to undertake post-graduate studies at the MS level.

- United Nations, FAO Scholarship 1971-1973. Full scholarship to undertake post-graduate studies at the Ph.D. level.

- Academic Tenure granted by the Board of Regents of the University of Nebraska, July 1, 1982.

- Distinguished Alumni Award, given by the Faculty of Veterinary Medicine, National University of Colombia during the 25th class reunion, November 30, 1994.

- Appointed to the Senior Executive Service of the United States of America, September, 1996.

- Recipient of the "Hombre del Campo" (Man of the Field) Award, by the AMEZVELLANOS Veterinary Association, Bogotá, Colombia, March, 1998.

- Special Recognition Award presented by the Colombian Veterinary Medical Association, Bogotá, Colombia, March, 1998.

- Special Recognition Award presented by the Colombian Institute of Agriculture, Bogotá, Colombia, March, 1998.

- Recipient of the 1998 "Daniel E. Salmon" Award, presented by the Secretary of Agriculture, Washington, D.C., June, 1998

- Awarded an Honorary Diploma by the American Veterinary Epidemiology Society, Salt Lake City, UT. July 25, 2000

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Robert M. Wildzunas, Ph.D.

CURRICULUM VITAE

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Fort Detrick, MD 21702-5024

EDUCATIONAL HISTORY

University Of New Orleans / Louisiana State University at New Orleans

Major:	Applied Biopsychology	
Minor:	Mathematics Statistics	
Degree:	M.S. / Ph.D.	1992 / 1993
Thesis:	The effects of mental workload on time estimation.	1992
Dissertation:	Transient deficits in the magnocellular visual subsystem: A possible common etiology for specific reading disability and attention deficit disorder.	1993
Honors:	LSU Neuroscience Center, Research Excellence Award	1991
	Distinguished Graduate Research Fellowship	1989 - 1993
	National Dean's List	1989 - 1993

Auburn University

Dual Major:	Pre-Clinical Psychology and Experimental Psychology	
Dual Minor:	Biology and Anthropology	
Degree:	B.S. with Honors	1986
Honors:	Distinguished Psychology Senior	1986
	Outstanding Sciences Senior	1986
	Chancellor's Scholarship	1983 - 1986
	University Scholar	1983 - 1986
	Dean's List	1983 - 1986

Huntingdon College

Major:	Pre-Medical Studies (Biology concentration)	
Minor:	Psychology	
Honors:	Huntingdon Merit Scholarship	1982

PROFESSIONAL POSITIONS

Assistant Director, Directorate of Research Plans and Programs — 2002 - Present
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702

Deputy Research Area Director, Combat Casualty Care Research Program — 2000 - 2002
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702

Command Psychologist and — 1999 - 2000
Human Factors Psychology Consultant to the Director of Army Safety
Headquarters, Department of the Army, U.S. Army Safety Center, Fort Rucker, AL 36362

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Technical Staff Officer (MRMC-SARDA Pentagon Medical Intern Program) 1998
Office of the Deputy for Medical Systems, Assistant Secretary of the Army (Research, Development, and Acquisition)
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702
Headquarters, Department of the Army, Arlington, VA 22202

Deputy Director, Aircrew Health and Performance Division 1997 - 1999
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Chief, Visual Science Branch (concurrent position with above) 1997 - 1998
Aircrew Health and Performance Division
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Aviation Research Psychologist 1993 - 1997
Visual Sciences Branch, Aircrew Health and Performance Division
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Graduate Research Fellow 1989 - 1993
Department of Psychology, Visual Sciences Laboratory
University of New Orleans, New Orleans, LA 70148

Research Psychologist (ONR-ASEE Faculty Research Program) 1989 - 1991
Human Factors Division, Research Department
Naval Biodynamics Laboratory, NASA Michoud Facility, New Orleans, LA 70189

COMMITTEES and PROFESSIONAL ASSOCIATIONS

MRMC Patent Disclosure and Invention Evaluation Committee	2000 - 2002
American Board of Hypnotherapy	1999 - Present
Chairman, USAARL Human Use Committee, Institutional Review Board	1997 - 1999
Biological Safety Officer, USAARL Radiation Control and Biosafety Committee	1997 - 1999
The Technical Cooperation Program (TTCP)	1997 - 1999
NATO Subgroup U, UTP-7: Human Factors in Aircraft Environments	
U. S. Army Aviation Center, Night Vision Goggles Working Group	1997 - present
Aerospace Medical Association	1994 - present
Scientific Program Committee	1995 - present
Aerospace Human Factors Committee	1995 - present
Science and Technology Committee	1995 - present
Registration Committee (chair elect 1999)	1996 - present
Membership Committee	1997 - present
Army Aviation Association of America	1996 - present
Department of Defense Human Factors Engineering Technical Advisory Group	1994 - present
Chairman: Controls, Displays, and Voice Interactive Systems Working Group	1995 - 1998
Technology Base Executive Steering Committee: Soldier Systems Modeling Working Group	1994 - 1995
21st Century Air Warrior Technical Working Group (Air Warrior Task Force)	1994 - 1995
Association of Aviation Psychologists	1994 - present
Society of Aerospace Physiologists	1994 - present
Aerospace Human Factors Association	1994 - present

PUBLICATIONS, ABSTRACTS, and PRESENTATIONS

Attached Separately (upon request)

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MILITARY TRAINING

Joint Operations Medical Managers Course, Fort Sam Houston, TX
Aircraft Mishap Investigation and Prevention - Clinical Psychologist, Brooks AFB, TX
Combined Arms and Services Staff School (CAS3), 98-02, Fort Leavenworth, KS
Aviation Accident Prevention Management Course, 011 D2197, USAAVNC, Fort Rucker, AL
Combat Casualty Care Course, 97-006, Camp Bullis, TX
Army Medical Department, Officer Advanced Course, 97-001, Fort Sam Houston, TX
Medical Management of Chemical Casualties, December 1995, Aberdeen Proving Ground, MD
Medical Defense Against Biological Warfare Agents, December 1995, Fort Detrick, MD
MANPRINT Action Officer Course, 95-007, Fort Bragg, NC
Aviation Psychology Training Course, 94-001, Fort Rucker, AL
Army Medical Department, Officer Basic Course, 93-006, Fort Sam Houston, TX

MILITARY AWARDS and DECORATIONS

Order of Saint Michael (Bronze Award)
Army Aircrewmember Badge
Meritorious Service Medal (1 OLC)
Army Commendation Medal (3 OLC)
Army Achievement Medal (1OLC)
National Defense Service Medal (w/Bronze Service Star)
Army Service Ribbon

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Board Certified in Clinical Hypnotherapy, American Board of Hypnotherapy
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Reviewer, *Aviation Space and Environmental Medicine*
Reviewer, *Military Psychology*

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APPENDIX B
GOVERNMENT-FURNISHED INFORMATION

1. *ARS Manual 242.1*, "ARS Facilities Design Standards," Chapter 9

2. Final Report: *Task Force on Biocontainment Facilities for Foreign Animal Disease Research and Diagnostic Activities (ARS and APHIS)*, March 1994

3. Review Report on Plum Island dated December 9, 1998

4. Review Report, *The Animal Health Safeguarding Review: Results and Recommendations*, The National Association of State Departments of Agriculture Research Foundation, October 2001

5. Review Report, *Security Review of the U.S. Department of Agriculture Plum Island Animal Disease Center* (4th Draft), Sandia National Laboratories dated April 4, 2002 (Official Use Only)

6. Final Report, *Task Force on Biocontainment Facilities for Foreign Animal Disease Research and Diagnostic Activities (ARS and APHIS)* dated March 1994.

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UNITED STATES DEPARTMENT OF AGRICULTURE BIOCONTAINMENT FEASIBILITY STUDIES

STUDY REPORT:

PLUM ISLAND ANIMAL DISEASE CENTER

AUGUST 15, 2002

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EXECUTIVE SUMMARY

In response to contract number GS-23F-8006H, delivery order 53-3K06-2-0701 from the United States Department of Agriculture (USDA), Science Applications International Corporation (SAIC) conducted a feasibility study that considered the possibility of conducting research and diagnostics of exotic diseases on the U.S. mainland as well as operational and cost issues regarding the USDA's Plum Island Animal Diseases Center (PIADC). SAIC conducted this study concurrently with another feasibility study concerning a USDA Biosafety Level (BSL)-4 facility. The period of performance for both studies was May 9, 2002 - August 1, 2002.

The USDA tasks as stated in the statement of objectives for the PIADC study focused on providing an independent assessment for the following questions:

- Is it technically feasible to conduct exotic disease research and diagnostics, including foot and mouth disease and rinderpest, on the U.S. mainland with adequate biosafety and biosecurity to protect U.S. agriculture?
- If it is possible to move exotic-disease research and diagnostics to the U.S. mainland, what kind of location would provide optimal biosafety and biosecurity for the research facility? Are there sites already in use that would be sites for a joint program of research and diagnostics? How do potential mainland biosafety and biosecurity compare to that currently found at PIADC?
- What would be the cost and time required to replace the current facility: on PIADC? On the mainland at types of locations identified in bullet 2 above?
- What are the relative long-term costs for operation of a new BSL-3 facility on the mainland vs. on an island, including infrastructure and "cleanup" issues?
- What are the benefits/liabilities for joint research with universities or military researchers in a BSL-3 facility?
- Are there benefits/liabilities of collaborative research, i.e., is there a tangible benefit by having BSL-3 work accomplished in an atmosphere whereby other non-agricultural work may be ongoing?

The first question stems from the statutory requirement (Title 21 U.S. Code 113a) that all research and diagnostics of foot and mouth disease (FMD) must be conducted on an island that has no direct access (i.e., bridge or tunnel) to the U.S. mainland. Since the 1950s, work using the live FMD virus has been restricted to PIADC, on Plum Island, New York, located in Long Island Sound near the far eastern end of Long Island.

In addition to SAIC's in-house expertise, an independent, 14-member Executive Panel was formed to address the questions associated with the study. SAIC and the panel found that:

- Biocontainment technology allows safe research and diagnostics of exotic foreign animal diseases (FAD) on the U.S. mainland.
- Biosafety and biosecurity considerations are manageable at any site location. While biosafety may be addressed principally by facility design and practice considerations, biosecurity considerations are characterized principally as location issues that are site specific.
- If research and diagnosis of FMD are considered for the U.S. mainland, the USDA should institute additional procedures and practices beyond the current BSL-3 Ag capability that will further reduce the potential for human workforce vectoring of the disease through respiratory transmission.
- Under certain circumstances, some BSL-3 Ag FADs should be considered for BSL-4 containment.

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- Before any decision to move this work to the mainland, the USDA should consider convening an industry committee to explore a long-range mission and location for FAD research and diagnostics programs that are located on the mainland.
- Costs for building a PIADC-like facility on the mainland were estimated to be approximately 17% less than building on an island like Plum Island. However, specific mainland locations and availability of essential infrastructure would define actual differences and would likely increase the costs for construction at a mainland facility beyond that for the PIADC option.
- Similarly, operations and maintenance costs on the mainland are estimated to be approximately 13% less than on an island. Again, differences would be site specific.
- There are no schedule differences for construction on an island versus the mainland.

Because of the national importance of sustaining responsive FAD research and diagnostics programs and in light of the predicted difficulty in moving the research of any disease like FMD to the mainland, the Executive Panel and SAIC concluded that the USDA should sustain effective FMD research and diagnostic operations at PIADC until (if) the decision is made to move operations to the mainland, and a suitable facility is constructed, equipped, and staffed to accommodate this mission. This conclusion is important because the USDA should commit to continuing the upgrade of PIADC BSL-3 Ag facilities to sustain effective, efficient, and safe operations at this location until a suitable mainland facility is available. This conclusion was reached without consideration to the presidential proposal and legislative initiatives to include portions of the current PIADC operations in a newly established federal Department of Homeland Security.

The finding that some FADs should be considered for BSL-4 containment was reached by SAIC and a majority of the Executive Panel[1] by virtue of Centers for Disease Control and Prevention guidelines that call for BSL-4 containment when large amounts of pathogens normally associated with BSL-3 are required or when conducting operations that causes the aerosolation of these agents. In addition, BSL-4 containment of exotic FADs may be a consideration to gain the approval of the agricultural, political, and other stakeholder communities to move research and diagnosis of these diseases to the mainland.

Finally, to establish and maintain strong research and diagnostics programs, the USDA would need to (1) establish a strategic plan that integrates BSL-3 Ag and -4 operations, (2) locate this integrated facility at a large research/diagnostics campus, (3) assign a comprehensive mission to this facility, and (4) resource it to accomplish the strategic plan and mission.

[1] Three of the 14-member Executive Panel objected on the grounds that BSL-4 containment is only required for pathogens dangerous to humans. Not all FADs are dangerous to humans.

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1. INTRODUCTION

In response to contract number GS-23F-8006 H, delivery order 53-3K06-2-0701 from the United States Department of Agriculture (USDA), Agricultural Research Service (ARS), Science Applications International Corporation (SAIC) provided the management and professional support services necessary to prepare reports for two feasibility studies. These two studies address a number of considerations including national facility requirements, benefits, costs, and risks, as well as site selection implications of conducting agriculturally related biological research and diagnostic operations in Biosafety Level 3 Agriculture (BSL)-3 Ag and BSL-4 facilities.

Because of the timeframes involved, both studies were conducted concurrently during the period May 9 through August 1, 2002. This study report addresses the specific objective of determining the feasibility of conducting exotic disease research and diagnostics, including foot and mouth disease (FMD) and rinderpest, on the U.S. mainland as well as operational issues regarding the USDA Plum Island Animal Disease Center (PIADC). The report is organized by the USDA statement of objectives (SOO) and specific tasks.

2. SCOPE OF THE TASK AND GENERAL UNDERSTANDING

2.1. Scope of the Task

The scope of SAIC's review and findings regarding USDA's biocontainment program was defined in the USDA SOO. The scope of this study, Objective 2: PIADC Facility Study, was defined by the following tasks in the USDA SOO.

- Is it technically feasible to conduct exotic disease research and diagnostics, including foot and mouth disease and rinderpest, on the U.S. mainland with adequate biosafety and biosecurity to protect U.S. agriculture?
- If it is possible to move exotic-disease research and diagnostics to the U.S. mainland, what kind of location would provide optimal biosafety and biosecurity for the research facility? Are there sites already in use that would be sites for a joint program of research and diagnostics? How do potential mainland biosafety and biosecurity compare to that currently found at PIADC?
- What would be the cost and time required to replace the current facility: at PIADC? On the mainland at types of locations identified in bullet 2 above?
- What are the relative long-term costs for operation of a new BSL-3 facility on the mainland vs. on an island, including infrastructure and "cleanup" issues?
- What are the benefits/liabilities for joint research with universities or military researchers in a BSL-3 facility?
- Are there benefits/liabilities of collaborative research, i.e., is there a tangible benefit by having BSL-3 work accomplished in an atmosphere whereby other non-agricultural work may be ongoing?

The USDA requested an independent assessment of each task.

2.2. General Understanding

In addition to foreign animal disease (FAD) threats, the latest threat of bioterrorism has raised USDA concerns regarding additional diseases that pose a health risk to both livestock and humans; that is, zoonotic diseases. USDA has long-standing interest in zoonotic diseases and already has several facilities dedicated to this type of research. Of particular interest and concern is the potential of animal diseases being transmitted to the general human population, either as a natural course of disease or as a

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bioengineered instrument of bioterrorism. Also bearing on the problem is the fact that USDA has limited capability for housing large animals in BL-3 Ag containment for challenge studies that are vital to protecting U.S. livestock health as well as the population at large from zoonoses.

The Centers for Disease Control and Prevention (CDC) defines four biosafety levels of operation identified for laboratories involved with biomedical practices using infectious materials. These levels use laboratory technique, safety equipment, and facility design for containment and control of the hazards associated with infectious agents of humans. BSL-3 is a high-biocontainment category for operations that involve etiologic agents that present a risk of causing infections in humans. The purpose of the design, equipment, and safety procedures of a BSL-3 facility is to prevent release of an agent into the environment and protect the human researcher from exposure to the agent. As can be seen in Table 1, within a BSL-3 facility all work performed must be either within a Class II or III biological safety cabinet (BSC)—primary containment barrier—with working personnel wearing appropriate BSL-3 laboratory clothing and using respiratory protection as needed. In addition, there are special engineering and design features to prevent etiologic agents from release into the environment.

Table 1. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench-top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	Primary barriers = Class II or Class III BSCs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed[1]	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory

[1] There is a discrepancy in the BMBL where the descriptions on pages 52 and 75 (Tables) do not agree with the text of paragraph C4 on page 32. The more restrictive conditions are selected.

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Table 1. Summary of Recommended Biosafety Levels for Infectious Agents (cont.)

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
4	Dangerous/exotic agents that pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practice plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decon systems • Other requirements outlined in the CDC/NIH reference

PPE = Personal Protective Equipment
Source: Department of Health and Human Services, *Biosafety in Microbial and Biomedical Laboratories*, 4th edition, April 1999

The USDA, by virtue of its unique laboratory operational environment, has instituted an additional classification of biocontainment, BSL-3 Ag. In a BSL-3 Ag, the animal-holding areas become the primary containment barriers. A BSL-3 Ag facility is used with pathogens that present a risk of causing infections of animals and plants and causing great economic harm, FMD being the prime example. These facilities are similar to BSL-3, but also include many features associated with BSL-4, for instance [1]:

- Integral double-door steam and/or ethylene oxide sterilizers
- Lab contiguous with shower
- No windows recommended. If windows are present, breakage resistant and sealed
- High-efficiency particulate air (HEPA)-filtered supply and exhaust; HEPA supply and two in series HEPAs exhaust for high-risk areas
- Seamless work surfaces
- Decontamination of animal waste prior to disposal
- BSL-4 entry and exit practices (i.e., clothing exchange, shower at exit, and decontamination of all material upon exit)

Thus, BSL-3 Ag has many features associated with BSL-4. The major difference is that BSL-3 Ag does not require personal protection via a BSC or positive-pressure suit.

2.2.1. Research Conducted and Expertise Used

During the initial phase of this study, SAIC staff efforts were focused on gathering technical data for review and use by a panel of independent experts to assess the feasibility of conducting exotic (foreign animal) disease research and diagnostics, including FMD and rinderpest, on the mainland with adequate biosafety and biosecurity to protect U.S. agriculture. The panel consisted of 14 individuals with experience in animal health and agricultural sciences. The membership of the panel is provided in Table 2. Curriculum vitae for each member may be found at Appendix A. The panel met for 2 days, June 18–19, 2002, to discuss the issues, assess the feasibility of conducting exotic disease research and diagnostics requiring BSL-3 Ag biocontainment on the mainland, and develop their findings. This provided the basis of this report.

In addition to the Executive Panel, SAIC contracted for the services of a consultant, Dr. Richard O. Spertzel. Dr. Spertzel is recognized worldwide as an expert in matters related to bioterrorism and biological warfare (BW) defense. In this capacity, he served as the Head of the Biology Section and Senior Biologist for the United Nations Special Commission on Iraq (1994 – 1998) and has supported many U.S. Government agencies, to include the Department of Justice as an instructor in the Louisiana

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State University course "Emergency Response to Domestic Biological Incidences." While on active duty in the U.S. Army, Dr. Spertzel served in varied BW defense and infectious disease assignments, to include Deputy Commander and Deputy for Research of the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland. Dr. Spertzel contributed directly to the preparation of this report.

Table 2. Executive Panel Members

Name	Organization
Dr. Richard Breitmeyer	California Department of Food and Agriculture
Dr. Corrie Brown	University of Georgia
Dr. Jerry Callis	U.S. Department of Agriculture, Retired
Ms. Regina Kowalski	Defense Intelligence Agency
Dr. Thomas Ksiazek	Centers for Disease Control and Prevention
Dr. Linda Logan	Texas Animal Health Commission
Dr. N. James MacLachlan	University of California, Davis
Lieutenant Colonel John Morrill	U.S. Army Southwest Plains District Veterinary Command
Dr. Kenneth Olson	Independent Consultant
Dr. Jean Patterson	Southwest Foundation for Biomedical Research
Dr. Jonathan Richmond	Centers for Disease Control and Prevention
Dr. Reynolds Salerno	Sandia National Laboratories
Dr. Alfonso Torres	New York State Animal Health Diagnostics Laboratory at Cornell University
Major Robert Wildzunas	U.S. Army Medical Research and Materiel Command

2.2.2. USDA Participation in Panel Meeting

Additionally, during the second day of the panel's deliberations, four USDA personnel (Table 3) were available to respond to questions raised by panel members.

Table 3. USDA Representatives Made Available to Executive Panel

Name	Organization
Dr. Caird Rexroad	ARS
Dr. Thomas Walton	APHIS
Dr. Peter Fernandez	APHIS
Dr. Randall Levings	APHIS

2.2.3. Documentation and External Information Sources

In addition to the information derived from the Executive Panel meeting, several reports, manuals, and other documents from the USDA were supplied as Government-Furnished Information (GFI). These reports and documents were reviewed for relevancy and used to corroborate other fact-finding initiatives. These documents were posted on a secure, password-protected website for all SAIC personnel and Executive Panel members to review. A listing of GFI is included at Appendix B. Non-GFI documentation used during this study is identified in Table 4.

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Table 4. Non-GFI Document Sources

Document Title	Document Date
Biological Defense Safety Program, 32 *Code of Federal Regulations* (CFR) Parts 626 & 627	
Interstate Shipment of Etiologic Agents, 42 CFR Part 72	
Bioterrorism Preparedness and Response Act of 2002 (Agricultural Bioterrorism Protection Act), Public Law (PL) 107-188.	
Department of Health and Human Services Publication, *Biosafety in Microbial and Biomedical Laboratories*, 4th Edition	April 1999
U.S. Department of Agriculture Draft Departmental Manual, *USDA Security Policies and Procedures for Biosafety Level-3 and Other Facilities*	1 May 2002
J.S. McKenzie, Emerging Viral Diseases: An Australian Perspective, *Emerging Infectious Diseases*	1999
K.B. Chua, W.J. Bellini, P.A. Rota, et al., Nipah Virus: A Recently Emergent Deadly Paramyxovirus, *Science*	2000
Emerging Infections: Microbial Threats to Health in the United States, National Academy Press	1992
Control of Communicable Diseases Manual (CCDM), ASM Press, Washington, DC	1995
"Selected Examples of Emerging and Reemerging Infectious Diseases in Animals," in Public and Scientific Affairs Board, American Society for Microbiology, Congressional Briefing for the House Agriculture Committee	April 1996
Biological Control of Vertebrate Pests: The History of Myxomatosis – an Experiment in Evolution (BCVP), CABI Publishing, NY	1999
Emerging Infectious Diseases of Animals: An Overview, in *Emerging Diseases of Animals*, ASM Press	2000
U.S. Animal Health Association, *Foreign Animal Diseases Book*	Revised 1998
"Airborne Spread of Foot-and-Mouth Disease," Alex Donaldson, *Microbiology Today*, Volume 26	August 1999
"Biosecurity-Fact or Fiction," Dr. Sandra Amess, Pan Pacific Pork Exposition-Seminar Proceedings	2001
G. Cameron, J. Pate, and K.M. Vogel, Planting Fear: How Real is the Threat of Agricultural Terrorism?, *The Bulletin of the Atomic Scientists*, Vol. 57, No. 5, pp. 38-44.	September/ October 2001
R. Casagrande, Biological Terrorism Targeted at Agriculture: The Threat to U.S. National Security, *The Nonproliferation Review*, Fall/Winter 2000; P. Chalk, The U.S. Agricultural Sector: A New Target for Terrorism?, *Jane's Security*.	February 9, 2001
T.M. Wilson, L. Logan-Henfrey, R. Welley, B. Kellman, "Agroterrorism, Biological Crimes, and Biological Warfare Targeting Animal Agriculture" in *Emerging Diseases of Animals*, C. Brown and C. Bolin, ASM Press, Washington, DC, Chapter 3, p. 34..	2000

2.2.4. Present Siting Status

The PIADC is a unique high-biological containment facility designated by congressional mandate as the only place in the United States where FMD and other highly contagious diseases of livestock can be conducted for scientific and regulatory purposes. PIADC is shared by scientists from the ARS performing research, and the Animal and Plant Health Inspection Service (APHIS) performing diagnostic services and training for some of the most serious FADs, and working together to protect the livestock industry of the United States and their export markets from the catastrophic economic losses caused by foreign or emerging animal diseases. ARS is the lead agency.

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2.2.4.1. Plum Island Animal Disease Center

The PIADC mission is accomplished by (1) development of more sensitive and accurate methods of disease detection and identification; (2) the development of new strategies to control disease epidemics, including DNA vaccines, antiviral drugs, and transgenic, disease-resistant animals; (3) the assessment of risks involved in importation of animals and animal products from countries where FADs occur; (4) diagnostic investigation of suspect cases of some FADs; (5) tests of animal products to be imported into the United States to ensure the imports are free of FAD agents; (6) production and maintenance of reagents used in diagnostic tests and vaccines; and (7) training animal health professionals in the recognition and diagnosis of FADs.

The U.S. livestock population is susceptible to foreign diseases. Threats of outbreaks of these diseases in the United States with potential risks that they might become established in this country have increased in recent years as man and animals continue to move across international borders in shorter time frames and ever-increasing numbers.

PIADC's diagnostic and research efforts are conducted by a staff of scientists representing the fields of biochemistry, immunology, physiology, virology, bacteriology, pathology and veterinary medicine. They study many infectious diseases of cattle, swine, goats, horses, sheep and poultry.

PIADC is located on an island (Plum Island) northeast of Long Island, New York, just off Orient Point. The island occupies slightly more than 840 acres (1.3 square miles); it is 2.9 miles long and 1.7 miles wide at its western end. Its facilities consist of a Biosafety Level 3 Ag structural laboratory and animal-handling facilities, an attached science/administrative support building, and other outlying buildings such as the Motor Pool, Duty Officer's quarters, Fire House, Shop Building, and support facilities such as the Waste Water Treatment Plant, Utilities Buildings, electrical and telecommunication distribution systems, and Chiller Plant.

Support facilities located at Orient Point, Long Island, include an administrative building and a shipping/receiving warehouse complex. Both the PIADC and Orient Point facilities have harbors with passenger and freight ramps for ferries. In addition, a ferry operates from Saybrook, Connecticut.

Biological security and safety are primary concerns due to the nature of work conducted by the research and diagnostic staffs with highly infectious pathogens, which may infect humans. Controlled island access is paramount. All persons arriving at PIADC (and their activities while on the island) are to abide by the requirements established in the PIADC Safety Manual.

2.2.4.2. Foreign Precedence (Australia/Canada/United Kingdom)

Canada has constructed a multi-biosafety level facility near Winnipeg, Manitoba, for studying animal diseases. The Canadians plan to begin working with the FMD virus at this facility. Australia has constructed and been operating a BSL-4 animal disease facility at Geelong on a peninsula of the mainland, but they also have not conducted research with FMD virus at that location. The British government's Institute for Animal Health (Pirbright Laboratory) is designed as the world reference laboratory for FMD and has conducted FMD research on the British mainland near London for many years. Many other FMD-free countries also study FMD on their own mainland. Thus, precedence for locating a facility to study FADs on a mainland exists.

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2.2.5. Contingency Issues and Risk Factors

2.2.5.1. Political and Economic Considerations

Although extremely important, panel members were instructed to not allow political and economic considerations to influence their discussions or the findings contained in this report. Notwithstanding this unconstrained approach, the following are considerations in making a decision regarding any establishment on the mainland of a new BSL-3/BSL-3 Ag capability to conduct exotic animal disease research and diagnostics, including FMD and rinderpest.

- Economics of Agriculture. The economics of the U.S. livestock industry alone has been estimated to be worth $100 billion [2] with approximately 20% of this figure dedicated to export markets. The economic importance and magnitude of the livestock industry is an important consideration in any decision to establish a new BSL-3/BSL-3 Ag capability on the mainland.

- Influence of Agriculturally Related Associations (e.g., National Cattlemen's Beef Association, National Pork Producers Council, American Sheep Industry Association, and the American Association of Equine Practitioners). These groups have very real concerns regarding the research and diagnostic programs of the USDA that warrant consideration in any decision-making process regarding potential establishment and site selection of a new BSL-3/BSL-3 Ag capability.

- Congressional Liaison. As with the agriculture industry associations, the concerns of the U.S. Congress, state, and local elected officials should be considered in the decision-making process concerning a new BSL-3/BSL-3 Ag capability.

- Public Perception. Establishment of BSL-3/BSL-3 Ag facilities have been accepted by the public and successfully operated generally when outreach programs that keep the public fully informed have been established. Implementation of USDA plans for new BSL-3 Ag facilities would benefit by public involvement and outreach. Further, public confidence and trust in associated USDA animal disease programs would benefit from remaining open and transparent.

2.2.5.2. Other Considerations

- Competing Priorities. As part of any decision to enter into a collaborative research operations with other organizations, an important issue that surfaced is the competing priorities for research and diagnostic programs on FADs and/or zoonotic diseases with the objectives and priorities of other collaborative research programs. It is generally agreed that there are benefits from collaboration with exotic animal disease research and human and animal medical research. Success of such collaborative arrangements requires that provisions be established to ensure exotic animal disease research retains appropriate priority and support among the collaboration partners even though the respective research missions might vary. There was strong sentiment and agreement among the Executive Panel members that the USDA strategic plan should include a detailed and comprehensive plan to establish and sustain a strong USDA program so that animal disease (indigenous and exotic) work in a joint or collaborative setting would be adequately supported. This plan must include adequate resources to maintain the facility and fund the research program.

  The potential for collaborative investigations also exists for programs that are not collocated. For example, if animal health aspects of Nipah virus were to be investigated by the USDA, it would need to be conducted under BSL-4 containment and special practices because of the human health

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manifestation of this virus; collaboration would be most beneficial with organizations such as U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) or CDC whose interest would be the human health perspectives. This could be accomplished by collaborative exchange of scientists and development of a close working arrangement. Visiting National Research Council (NRC) scholars and postdoctoral work agreements could also provide a valuable adjunct to infusion of new ideas and fresh talent into the USDA FAD program.

- If additional biosafety measures must be established as a prerequisite to conducting some research and diagnostics on the U.S. mainland with exotic etiologic agents, currently studied under BSL-3 Ag rules at PIADC, then the frequency of operating under these measures must be considered. Unless a BSL-3 Ag facility is sustained at a working level, when it is needed, there could be a significant delay to be truly operational. Personnel need to maintain constant proficiency in augmented procedures and practices. Otherwise, physical and psychological adaptations are likely to be required. Without BSL-3 Ag work environment training and experience, the risk to personnel and environmental health increases. Similarly, if some FAD research and diagnostic operations require BSL-4 containment, provisions will need to be made to sustain BSL-4 operations on a regular basis.

2.2.5.3. Foot and Mouth Disease

FMD has historically received special consideration due to its potential impact on the agricultural economy. This disease is endemic to large areas of Asia, Africa, South America, and Eastern Europe. An important means of transmission of FMD is the introduction of infected livestock into herds. Research has demonstrated the airborne transmission of the disease.

Vigorous steps are necessary to control FMD outbreaks because FMD virus is the most infectious animal disease-causing viruses known—for certain strains, the dose required to infect cattle or sheep through inhalation has been determined to be about 10 organisms (10^1 $TCID_{50}$) [3]. Infected pigs produce immense amounts of airborne virus; that is, an infected pig exhales 400 million organisms per day ($10^{8.6}$ $TCID_{50}$) [3]. The sensitivity of cattle to infection and the high levels of airborne virus produced by infected pigs illustrate that airborne spread of infection is another important factor in FMD outbreaks. Under ideal conditions, airborne spread is probably restricted to 10 km. It has been suggested that plumes of virus contained within droplets exhaled by infected, asymptomatic animals, might be carried by the wind over long distances—up to 60 km (37 miles) over land and or 250 km (155 miles) over water. An atmospheric modeling study suggests that the 1981 outbreaks of FMD on Jersey and the Isle of Wight in the UK may have originated in an outbreak of FMD in Brittany, which was blown across the English Channel by prevailing winds [4].

The virulence of FMD and its severe economic and social consequences have restricted FMD research and diagnosis to only select facilities. These facilities must provide the highest levels of biosecurity and appropriate biocontainment. They must operate under stringent safety and personnel reliability regulations. The British government maintains the high-security laboratory at the Institute for Animal Health in Pirbright, Surrey, near London. This laboratory is the World Reference Laboratory for FMD and maintains a library of FMD virus isolates collected from around the world during the past 60 years. Another laboratory doing research with live FMD virus in an FMD-free country is the PIADC, near Point Orient, Long Island, New York.

Considering the infective nature of the FMD virus, and the disastrous consequences of an outbreak of FMD in the United States, it is reasonable to continue special provisions to minimize the risks of accidental or intentional infection of U.S. livestock. Such precautions should have a sound scientific basis and community support.

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3. IS IT TECHNICALLY FEASIBLE TO CONDUCT EXOTIC-DISEASE RESEARCH AND DIAGNOSIS, INCLUDING RESEARCH WITH LIVE FOOT AND MOUTH DISEASE VIRUS AND RINDERPEST VIRUS ON THE MAINLAND WITH ADEQUATE BIOSAFETY AND BIOSECURITY TO PROTECT U.S. AGRICULTURE?

3.1. General Considerations

The virulence of FMD and the severe economic consequences of an outbreak of disease by this virus have been discussed above. To determine whether it is technically feasible to perform research on the mainland with this highly infectious organism and other exotic threats to the livestock industry, it is necessary to consider the biosafety and biosecurity containment measures standard to microbiological laboratories, the microorganisms that are likely to be encountered in the laboratory, as well as the types of experiments and procedures that would be employed in the USDA research program.

In addition to the long-standing requirement of protecting American livestock from devasting animal diseases that are established abroad, the laboratories of the USDA will face new challenges from the continual emergence of new diseases and the possibility of the intentional employment of disease agents directed against livestock as an act of terrorism or other criminal act. The development of molecular biology has made it possible to investigate many aspects of disease prevention without utilizing whole, live infectious microorganisms. However, in light of the continuous emergence of novel diseases and the potential for employment of bioengineered agents directed with hostile intent against our agricultural economy, it will remain necessary for the USDA to retain the capability to safely perform experiments with live infectious organisms in livestock. Foreseeable occasions where experiments involving the live agent and infected livestock would include experiments directed toward an understanding of the means of transmission of disease, determination of the pathological effect of the microorganism upon livestock, tests of diagnostic procedures and reagents, as well as challenge studies to determine the effectiveness of vaccines or vaccine candidates in preventing infections.

BSL-3/BSL-3 Ag is a high-biocontainment category for operations that involve indigenous or exotic (foreign) etiologic agents that may cause serious or potentially lethal disease to livestock and possibly humans depending on the organism as a result of an aerosol exposure [5]. Aerosol-producing laboratory operations with dangerous human pathogens for which no medical countermeasures are available (immunizations or drugs) to protect personnel must be conducted under BSL-4 guidelines. In addition, some virulent FADs may require special consideration in terms of BSL requirements on the mainland, vis-a-vis current guidelines at PIADC, depending on location.

For the purposes of this report, the term "biosafety" is considered to address issues pertaining to the potential exposure of animals or humans to dangerous pathogens. This includes the escape of pathogens from a facility due to human error. The term "biosecurity" is considered to address the protection against the diversion of high-consequence pathogens and toxins, which could be used by someone with malicious intent. This includes the classic terrorist threats of an attack on a facility by a well-organized and motivated group of individuals and an insider(s) motivated to remove pathogens for illegal purposes.

3.2. Specific Considerations

Most infectious agents of interest to animal health do not require high levels of biocontainment for personnel safety because the majority of these infectious agents are highly host specific, that is, etiologic agents that cause disease in one species of animal generally do not cause a clinically significant infection in other species. High levels of biocontainment and special practices are employed in agricultural research and diagnostic laboratories primarily to prevent escape of agents into the environment and

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potential infection of domestic livestock [6]. Obviously, zoonotic diseases present the additional concern of potential infections in the human population.

3.3. Do BSL-3 Agents Need Enhanced Containment?

There are a number of infectious agents of considerable interest to agriculture that require BSL-3 biocontainment and special practices. Guidelines from the CDC [7] consider work on these etiologic agents, where the size of the culture is large or where procedures could result in the production of a significant risk for respiratory transmission, may require BSL-4 biocontainment if drugs for treatment of infection or vaccines for prevention of infection are not available (Venezuelan equine encephalitis (VEE) virus, Rift Valley fever virus, Japanese encephalitis virus, louping illness virus, Piry virus, and Wesselsbron disease virus) [8]. The CDC guideline for biosafety specifically states that where large quantities of agent material are involved or when laboratory activities may create aerosols, consideration should be given to raising the biosafety containment one level higher. Fortunately, the majority of BSL-4 viruses, such as Ebola virus and Marburg virus, are not threats to American agriculture. However, there are viruses in the BSL-3 category that are significant threats and cause considerable losses in livestock abroad. An example is Rift Valley fever, a mosquito-borne disease of cattle and sheep that causes substantial losses in the Rift Valley of Africa and in Egypt. The virus has recently caused epidemics in livestock in the Arabian peninsula [9]. No licensed vaccine for humans is available so research on this vaccine may likely have to be performed at BSL-4, particularly for research aimed at vaccine development. Other viruses in this category would include the arboviruses responsible for louping illness, VEE, Piry, and Wesselsbron virus. The USDA facilities in Ames, Iowa, and Plum Island, New York, conduct diagnostic tests for many BSL-3 agents, some of which are: Aino, Akabane, Getah, Ibaraki, Israel turkey meningioencephalomyelitis, Japanese encephalitis B, Rift Valley fever, and vesicular stomatitis. Elements of vaccine development programs (e.g., production of agent and animal challenge studies) for these disease agents could require BSL-4 containment.

3.3.1. BSL-3 Ag +

There are some FADs that have little or no effect on humans, but are so virulent in animals that they require containment beyond that associated with BSL-3 Ag, but short of BSL-4. FMD virus has been shown to be carried in the upper respiratory passages of workers for up to 36 hours. Consequently, addition of respiratory protection measures to BSL-3 Ag guidelines might be needed to prevent human vectoring of FMD. The infectivity (apparent and unapparent) of FMD virus to humans has caused additional biosafety policies to be imposed for workers exposed to FMD virus such as those currently in practice at PIADC. In addition to the usual BSL-3 biosafety practices, the following additional policies/practices are required:

- Before exiting the laboratory through the change room shower, blow nose in a tissue or paper towel
- Clear throat and expectorate to remove mucous material that may contain trapped particles inhaled while in the facility
- Clean underneath fingernails with nail files
- Scrub hands and arms with soap using a brush (particular attention to fingernails)
- Soak eyeglasses in decontamination solution

Additionally, restrictions are placed on any possible contact with ruminants and swine for 5 days after last possible exposure to FMD virus. Visits are prohibited to farms, sale farms, stockyards, animal laboratories, packinghouses, zoos, various menageries, and other animal exhibits such as fairs. Therefore, for FMD, additional respiratory protection measures beyond those afforded by BSL-3 Ag containment

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might be needed to prevent the human workforce from becoming vectors of the disease. Biocontainment of FMD need not be at the BSL-4 level.

3.3.2. BSL-4

If worker personnel are not immunized for diseases like Rift Valley fever, then appropriately tailored restrictions to animal contacts, including some pets, would also be required. If research on such agents were conducted at the BSL-4 level where the worker would not be directly exposed to the virus, then such restrictions of visitations and risk of unintentional animal exposure could be eliminated. Additionally, performance of research at a higher biosafety level could be an incentive and may be required to obtain the necessary clearances for location of such a facility and mission.

A minority of members (3 of 14) of the Executive Panel objected to the SAIC finding that under certain circumstances, some BSL-3 agents may need BSL-4 containment. Their objections are summarized by stating that doing so could mislead people unfamiliar with FADs into believing BSL-4 containment is required. They further state, and SAIC recognizes, that BSL-4 containment is only required for agents that cause severe illness or death in humans and for which no vaccine is available.

SAIC notes these objections but maintains that because of the extraordinary circumstances involved with the research and diagnostics of FADs on the mainland, BSL-4 containment is a reasonable consideration, but is NOT a requirement. SAIC also recognizes that because of the inherent dangers of working with or near large animals, the decision to do so in BSL-4 containments should not be taken lightly. Validated physical and procedural safeguards must be in place to protect the human researchers from injury.

3.4. Emerging and Reemerging Diseases

New diseases are constantly emerging or reemerging. This process is favored by the increasing encroachment of people and livestock into areas previously inhabited by only wildlife, allowing transmission of novel diseases into livestock. Many of these are caused by agents that were previously unknown in wildlife and were first reported in humans (i.e., HIV) [10]. Many are present in wildlife and "jump" across species lines to infect humans or livestock. Lyme disease [11] and West Nile fever [12] represent familiar examples. New diseases in humans seem to appear at a rate of about one per year. New diseases of livestock appear at a similar rate. Fortunately, only two BSL-4 agriculturally related agents have appeared in recent times, Hendra virus and Nipah virus [13,14]. Factors favoring the encroachment of agriculture into previously virgin habitat continue, and with the international trade in food, importation and smuggling of exotic animals, human migration, and tourism, the likelihood of the importation of foreign animal diseases into the United States can be expected to increase [15]. The recent experience of the United Kingdom and the European Union with outbreaks of FMD and of bovine spongiform encephalopathy (BSE, mad cow disease) provides salient examples of this rising global phenomenon.

There have been numerous examples in human history of pandemics of surprising lethality. Bubonic plague in Europe in the 14th century [16] and the global pandemic of Spanish influenza [17] of 1918-1920 provide examples of diseases normally endemic to animals that have crossed species barriers and spread through naïve populations with devastating effect. Influenza presents a continuing threat to fowl through the continuous genetic reassortment of the virus's virulence factors [18]. In this light, a human-adapted strain of the avian influenza virus has emerged as a candidate for BSL-4 containment.

Arthropod vector-borne diseases (diseases transmitted by blood-feeding arthropods such as mosquitoes and ticks) are an important class of disease in animals and humans. It is estimated that one previously unknown tick-borne infectious agent is discovered each decade [19]. These agents typically cause mild

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diseases in wildlife but may cause serious disease in species previously unexposed to them. A number of these diseases are exceptionally virulent. Central European tick-borne encephalitis, Kyasanur Forest disease, Crimean-Congo hemorrhagic fever, Omsk hemorrhagic fever, and Russian spring and summer encephalitis are all BSL-4 level viral agents [20,21]. Important agricultural and human mosquito-borne viral diseases requiring BSL-3 biocontainment and special practices include Japanese encephalitis, Wesselsbron disease, Rift Valley fever, West Nile fever, VEE, and St. Louis encephalitis [21]. Vesicular stomatitis (Alagoas), a BSL-3 agent, and Piry are transmitted by arthropods [20,21].

Because new diseases are continuously crossing species lines around the world, it is likely that arthropod diseases previously alien to us will appear in the United States. A recent example is the appearance and spread of West Nile fever, a mosquito-borne disease previously confined to Africa, which has spread throughout the Mediterranean basin and recently into the Eastern United States [12,22]. In Europe and Africa, this virus infects birds, in particular, but also people and domestic animals. In view of the ease with which West Nile fever is becoming established in the United States, it is reasonable to believe that similar viral encephalitic diseases such as Rift Valley fever could pose a threat of becoming established here as well. The spread of VEE into the United States and the subsequent epidemic in Texas and the Gulf Coast is a salutary example [23]. These cited examples suggest that new agents requiring high levels of containment are likely to appear eventually within—or be introduced into—the United States. Hence, research programs will likely have to be initiated to protect livestock from these potential serious threats.

Sometimes etiologic agents are encountered whose properties are unprecedented. The development over the past decades of our knowledge of prions as infectious agents demonstrates that there are still surprises to be encountered in biology of infection. Investigation of the rare human neurodegenerative diseases Kuru and new variant Creutzfeldt-Jacob disease suggested that an infectious agent caused the disease. However, the causative agents though filterable could not be cultured, and furthermore, it was possible to show that in animals with similar diseases, nucleic acid-free extracts from infected animals were capable of causing disease when introduced into disease-free hosts. The discovery of this new class of infectious agents, separate from the long familiar quartet of microbial pathogens—viruses, bacteria, fungi, and parasitic organisms—is an astounding event in biology. These agents cause the transmissible spongiform encephalopathies (TSEs) of animals: scrapie (sheep and goats); BSE; transmissible encephalopathy of mink; and chronic wasting disease (deer and other cervids) [24]. The agents are particularly resistant to chemicals commonly employed as microbiocides. Fortunately, the agents discovered to date are not easily transmissible and can be routinely investigated under BSL-2 conditions [25]. Nonetheless, the number of BSE cases in cattle in the UK exceeded 180,000 [26]. Statistical analysis indicates that more than 1 million cattle in the UK were infected with BSE, and that about 500,000 of these infected cattle entered the human food chain [27]. The pathological agent for BSE has been convincingly linked to new variant Creutzfeldt-Jacob disease in humans [26].

3.5. Intentionally Introduced Infections

The anthrax letter incidents demonstrate the susceptibility of civilization to seemingly easily accomplished acts of anonymous terrorism. The anthrax-laden letters caused unprecedented disruption to our postal system and government and business dependent on it. Fortunately, agro-bioterrorism and the susceptibility of the agricultural industry have not received widespread publicity. A search of the literature reveals few incidents of the intentional infection of animals. There have been government projects employing biological agents to control rabbits in Australia [28] and feral cats in South Africa [29], and two descriptions of individuals' efforts to control rabbit populations with viruses lethal to rabbits (in France in 1952 and more recently in New Zealand [30,31]). The rapidity of spread of highly lethal infections in these populations is indicative of the potential susceptibility of herds and flocks to any deliberately introduced infections. The ease with which this might be accomplished is illustrated by events in New Zealand where farmers used kitchen blenders to prepare baits from the carcasses of rabbits

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that had died from rabbit hemorrhagic disease in Australia and distributed them in bait for feral rabbits on their property in New Zealand [31]. Another compelling argument is the documentation that other nations (e.g., Iraq and South Africa) have conducted offensive biological warfare research [32,33].

As part of its Public Health Emergency Preparedness and Response effort, the CDC has categorized biological disease and etiologic agents into three priorities (see Table 5). Most of these diseases are animal diseases that are diagnosed at the Ames or PIADC facilities. Category A diseases/agents, the highest priority, include anthrax, botulism, plague, smallpox, tularemia, and virual hemorrhagic fevers. Smallpox and viral hemorrhagic fevers are the only two diseases/agents from this highest priority category not included in the Ames diagnostic repertory. Category B diseases/agents, the second highest priority, include brucellosis, *Clostridium perfringens*, food safety threat agents (salmonella, *Escherichia coli* O157:H7, and shigella), glanders, meliodosis, psittacosis (*Chlamydia psittaci*), Q-fever, ricin, staphylococcal enterotoxin B, typhus, viral encephalitis, and water safety threats such as vibriosis and cryptosporidium. The only Category B diseases/agents not diagnosed at Ames are typhus, SEB, and the plant toxin ricin. Category C includes emerging infectious disease threats such as Nipah and hantavirus. With emerging new diseases and the potential for bioengineered agents, some reprioritization of agents within the three categories may occur.

Table 5. Biological Diseases/Etiologic Agents Categorized by CDC

CDC Category	Description	Agent Examples
A	Highest priority agents that pose a risk to national security because of ease of dissemination, high mortality rates, impact on public, and special action for public health preparedness	Anthrax, Botulism, Plague, Smallpox, Tularemia, Virual Hemorrhagic Fevers
B	Second highest priority that include agents moderately easy to disseminate, moderate mortality rates, and require specific enhancements for diagnosis and surveillance	Brucellosis, *Clostridium perfringnes*, Salmonella, *E. coli*, Shigella, Glanders, *Meliodosis*, Psittacosis, Q-fever, Ricin, Staphylococcal enterotoxin B, Typhus, Viral encephalitis
C	Third highest priority that includes emerging pathogens that could be engineered for mass dissemination because of availability, ease of production/dissemination, potential for high mortality rates and major health impact	Nipah virus, hantavirus

Most diseases that deserve serious consideration as potential bioterrorism agents are caused by zoonotic etiologic agents that are of serious consequence to human health and the livestock industry. Thus an incident of bioterrorism directed against the American public may well have a serious impact on agriculture by causing epidemics in livestock. Bioterrorism directed at livestock is a major concern that may be considered a higher priority by the livestock and agricultural industries. It is possible that the initial cases of a bioterrorism incident will be diagnosed in a USDA facility. When agents applicable to bioterrorism are discussed, the possibility that bioengineered agents might be employed also must be considered. Properties that might be altered to make an agent more amenable to its role as a biological weapon are likely to include alterations that increase the agent's virulence and enhance its transmissibility, provide resistance to antibiotics or immunizations, as well as factors increasing the stability of the organism that allow it to persist in the environment. Live agents encountered in an incident of bioterrorism may require BSL-4 containment during the initial phases of their investigation, until their pathological properties are understood.

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3.6. Role in Homeland Security

The USDA SOO for this study is silent on bioterrorism and agroterrorism. The President's plans for homeland security, however, which were announced after award of this study, may impact any potential decision on a new BSL-3/BSL-3 Ag facility on the U.S. mainland and its potential linkage with a BSL-4 capability. Since the USDA operates a comprehensive national disease surveillance system, it is reasonable to assume that the Department would be expected to participate in the biosecurity of the nation, whether in animal health or the public health arena. The exact composition of a bioterror weapon cannot be predicted. A list of livestock and poultry pathogens that may be directed against U.S. agriculture has been developed [34] and is reflected in Table 6. As noted, biological weapons directed against the United States may be expected to have been bioengineered to enhance agent virulence, transmissibility, and ability to overcome medical protective countermeasures such as drugs and vaccines. A new USDA BSL-3/BSL-3 Ag capability on the mainland, along with a potential BSL-4 requirement, could be expected to play a significant role in the homeland response to a bioterror incident. In connection with the creation of the Department of Homeland Security, there are many issues that will require resolution.

Table 6. Anti-Livestock and Anti-Poultry Biological Weapons [34]

- Foot and mouth disease virus
- Classical swine fever virus
- African swine fever Virus
- Rinderpest virus
- Rift valley fever virus
- Avian influenza virus
- Exotic Newcastle disease virus
- Venezuelan equine encephalomyelitis virus
- Blue tongue virus
- Sheep and goat pox viruses
- Pseudorabies virus (Anjeszky's disease)
- Vesicular stomatitis virus
- Teschan disease virus (porcine enterovirus 1)
- Porcine enterovirus type 9
- Lumpy skin disease virus
- Porcine reproductive and respiratory syndrome virus
- African horse sickness virus
- *Bacillus anthracis* (anthrax)
- *Chlamydia psittaci* (psittacosis)
- *Cowdria ruminata* (heart water)
- Screwworm

3.7. Federal and State Regulatory Considerations

Determining the biosafety and biosecurity considerations for the location of a new BSL-3/BSL-3 Ag facility to conduct exotic-disease research and diagnostics, including FMD and rinderpest, on the mainland with adequate biosafety and biosecurity to protect U.S. agriculture began with a review of the relevant statutory and regulatory mandates. A thorough review of the federal and state statutes and regulations found that there are no location discriminators although the issue of where FMD virus work is located may arouse special congressional interest.

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21 United States Code (USC) 113a sets forth rather stringent locality restrictions for work with live virus of FMD as follows:

> "Provided, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States (except coastal islands separated therefrom by water navigable for deep-water navigation and which shall not be connected with the mainland by any tunnel)..."

21 USC 113a goes on to provide for a potential exception to these restrictions thus allowing for the possibility of such work on the mainland with this ensuing language:

> **"...unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York)...."**

The current regulations and statutes apply the same measures to all facilities, regardless of location. Federal materials that were reviewed and found to have universal applicability were the *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition, May 1999 (CDC) Guidelines; the *Agriculture Research Service Facility Design Standards*, ARS Manual 242.1; *Interstate Shipment of Etiologic Agents*, 42 CFR Part 72, and the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Agricultural Bioterrorism Protection Act), PL 107-188.

State laws and regulations vary, but only at the reporting level (see Table 7). States' enforcement of their rules and regulations at federal facilities also vary. If the facility was to be collocated with an academic institution, it would be necessary to ensure that the institution followed all state-level structure and reporting requirements, which generally consist of maintaining a biosafety committee and officer, and minor reporting considerations. None of the states surveyed have statutory restrictions regarding BSL-4 laboratories. State legislative initiatives are currently under way in 12 states for the creation of state-level Biological Agents Registry. The recent passage of PL 107-188 may alter the technicalities of the state legislation, but not to the extent that it would prove to be a location discriminator.

Table 7. State Legislation

State	Evolving Legislation
California	No legislation of note
Connecticut	S.B. 5288, for the creation of a state Biological Agents Registry, has been introduced
Iowa	No legislation of note
Maryland	H.B. 361, for the creation of a state Biological Agents Registry, has been passed and signed into law. Effective October 1, 2002
Minnesota	H.F. 2622, The Minnesota Anti-Terrorism Act of 2002, contains a section mandating the creation of a state Biological Agents Registry
New Jersey	A. 1968, for the creation of a state Biological Agents Registry, has been introduced
New York	No legislation of note
North Carolina	H.B. 1472, creating a state Biological Agents Registry, was passed and signed into law. Effective October 1, 2002
Oklahoma	No legislation of note
Pennsylvania	No legislation of note
Texas	No legislation of note
Wisconsin	S.B. 421, for the creation of a state Biological Agents Registry, failed to pass due to procedural issues

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3.8. Policy and Practice Considerations

When work is carried out on live exotic animal disease agents, particular attention must be paid to prevent the escape of the agent from the facility from where it may become established in the national herd. BSL-3 Ag physical containment provides barriers that are comparable to those found in BSL-4 facilities working on the most dangerous human pathogens. When exotic animal diseases are not human pathogens, BSL-3 Ag containment is utilized, which represents BSL-4 physical facilities without Category III BSC or personal safety suits with self-contained breathing. Since the only material not leaving the facility through an autoclave, incinerator, or HEPA filter is the laboratory worker, stringent personnel measures are utilized. To prevent microorganisms from leaving with the investigator, the PIADC requires investigators to shower out of the facility. Even eyeglasses must be decontaminated while showering out. Used laboratory clothing is left in the locker room on the facility side of the shower. Street clothes are in the locker room on the street side of the shower facility. These precautions are necessary because the ability of humans to spread infections, particularly FMD, between animals as a result of contaminated hands and clothing, has long been recognized [35]. Because some microorganisms infective to animals might persist for a time in the human body without causing human infection, people who have visited the PIADC BSL-3 Ag containment area must avoid contact with livestock, poultry, and wildlife for a period of 5 days following their visit to containment areas. This requires that the visitor or laboratory worker avoid places such as farms, sale barns, pet stores, animal fairs, and zoos. The policies of the Australian Animal Health Laboratory requires that visitors and staff of containment laboratories not have contact with livestock for 7 days. The origin of these "stand down" periods presumably derives from the observation that humans examining infected pigs may carry FMD virus for up to 28 hours [36], and that theoretically, humans exposed to high concentration of FMD virus aerosols, like in heavily infected pig farms, could spread the virus to susceptible animals in another location during contact or examination through sneezing, snorting, coughing, and breathing near the animals [37].

SAIC recognizes that there has never been a documented case of the human respiratory transmission of the FMD virus from infected to uninfected animals. However, our research of available literature suggests this vectoring is possible. Therefore, consideration of countermeasures in the form of additional respiratory protection for the workforce is a prudent and cost-effective precaution.

3.9. Panel Findings

The panel concluded that today's technology is adequate to contain any biosafety risks at any site; however, they also noted that biosafety is only as effective as the individual who practices it. It is recognized that there is a need for adequate medical assistance at any high-containment facility. Both USDA facilities at PIADC and Ames, Iowa meet this criterion. The panel noted that the U.S. limitation of FMD to PIADC is an exception since a number of countries conduct FMD research and diagnostics on the mainland. However, like the United States, Australia does not do FMD work in their mainland high-containment facilities. Canada plans to begin a live FMD virus research program in the near future in their Winnipeg, Manitoba facility.

With regard to biosecurity, the panel only considered the issue of a terrorist threat to the facility. As such, the panel felt that biosecurity was somewhat of a "moving target" that will impact, but not eliminate any site from consideration. That is, facility design considerations could mitigate the biosecurity-related differences for potential siting locations. To date, no biosecurity guidelines exist that are analogous to the *Biosafety in Microbiological and Biomedical Laboratories* [5] guidelines for biosafety. Entities such as the Biosecurity Subgroup of the DHHS Select Agent Group (established under PL 107-188) are in the process of creating biosecurity guidelines. However, the absence of established guidelines does not vacate the need to consider biosecurity issues in establishing and operating a facility that will be engaged in high-consequence biological agents research and diagnostics.

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Despite considerable discussion, because no concerns emerged, the record of panel deliberations did not capture the potential impact of location and lapse of safety measures on the community or nation as a whole. The panel deliberations also did not reflect the issues of security of the etiologic agent from workers and/or graduate students under any participating collaboration arrangement. High-containment biological laboratories require substantive personnel-screening policy and procedures. These additional considerations could also be mitigated by policy, infrastructure, and design factors.

4. IF IT IS POSSIBLE TO MOVE EXOTIC-DISEASE RESEARCH AND DIAGNOSTICS TO THE U.S. MAINLAND, WHAT KIND OF LOCATION WOULD PROVIDE OPTIMAL BIOSAFETY AND BIOSECURITY FOR THE RESEARCH FACILITY? ARE THERE SITES ALREADY IN USE THAT WOULD BE SITES FOR A JOINT PROGRAM OF RESEARCH AND DIAGNOSTICS? HOW DO POTENTIAL MAINLAND BIOSAFETY AND BIOSECURITY COMPARE TO PIADC?

4.1. General Considerations

In practical terms, site discriminators are more likely to be resource and geopolitical specific—e.g., does the site have access to an appropriate quantity of water, what are the natural disaster possibilities, and what is the attitude of the local community? For example, siting a BSL-3/BSL-3 Ag, along with a potential BSL-4 capability, in a high earthquake area could present a potential risk to the local human and animal community; the structural specifications of such a facility in that locale would need to consider earthquake-proofing the facility. Benefits of such a siting choice would have to be very substantial to justify the risk.

Many agricultural communities are likely to be less than enthusiastic about having a BSL-3/BSL-3 Ag facility studying FAD near their pigs, sheep, cattle, or horses. Any potential location for a new BSL-3/BSL-3 Ag facility will have its own unique set of terrorist and natural threats to the integrity of the facility that will need to be responsibly addressed.

Location of a BSL-3/BSL-3 Ag FAD facility in a community with a sizeable, susceptible animal population presents a unique set of potential risks in terms of lapses in biosafety practices that will require special consideration. Additionally, reliability of collaborating investigators, technicians, animal caretakers, and graduate students could pose additional personnel reliability risks as they relate to the ability of security agencies processing security clearance requests. Inherently, universities seek diversity among their student body and, to a lesser extent, their faculty, including those from many countries. It would be difficult to subject all such individuals to the degree of screening expeditiously to enable access to high-consequence biological agents as envisioned by present-day biosecurity concerns. Such concern takes on even greater importance if consideration is given to establishing a BSL-4 capability with a new BSL-3/BSL-3 Ag.

4.2. Domesticated Animal Populations

Domesticated animal populations that would be at risk to FADs vary from region to region within the United States and with the specific agent. For example, equine disease, would be of more importance to Kentucky and California than to New Hampshire, whereas sheep diseases would be of more importance to New Hampshire, Michigan, and Montana than to West Virginia. Similarly, poultry diseases would be of special interest to Delaware, Maryland, Virginia, and Georgia.

On April 21, 2000, a USDA briefing indicates that 2% of feedlots produce 78% of marketed cattle in the United States. Furthermore, 84% of feedlot cattle is centered in seven states; Iowa, Nebraska, Kansas, Colorado, Texas, Arizona, and California. This same briefing cites that 74% of swine are produced in

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nine contiguous states; South Dakota, Nebraska, Kansas, Minnesota, Iowa, Missouri, Illinois, Indiana, and Ohio.

The increased risk of these higher density domestic animals to release or escape of FDA agents must be considered in siting a facility to research and diagnose FADs.

4.3. Special Interest Groups and Terrorism

There has been an increase of incidences where special interest groups such as animal rights organizations have resorted to violence to foster their ideals. For example, the Animal Liberation Front (ALF) advocates that no animal should be used in research. This loosely knit group communicates through chat rooms and allows specific actions to individuals or local smaller groups to utilize their own ingenuity to foster the ALF ideals. There has been violence including the use of explosive devices and guns. Additional perimeter security could be required for a mainland-based facility to assure no escape of agent from the facility. Consideration would include the provision for armed guards to protect the facility.

4.4. Bioterrorism

The increased threat of bioterrorism directed against humans or animals (as well as plants) is generating new ways of looking at biosecurity at laboratories engaged in disease research and diagnostics related to high-consequence biological agents. High consequence may be illness and death of humans and animals but may also be economic with relatively low incidence of death or disease.

A terrorist act resulting in a major biological event could come about by (1) physical damage to the facility by explosives, missile (auto, plane, etc.), rupture of facility, etc., (2) intentional disruption of secondary barriers by an individual with access to the facility, and (3) intentional removal of "seed" agent material that could then be used in a bioterrorist event potentially remote from the facility.

The risk of physical damage to a facility by a terrorist can be mitigated by physical security considerations such as structural and facility design. While the physical security issues may be location specific, such issues should be able to be mitigated by appropriate measures at any location.

Intentional disruption of secondary barriers or intentional removal of "seed" agent material are personnel reliability issues discussed in paragraph 4.7. With appropriate personnel screening and access control, these risks can also be minimized.

The location of the facility could play a role in the consequence of intentional release of agents dependent on the local susceptible population.

4.5. Location Considerations

Biosafety needs for a BSL-3 Ag facility can be met at any location provided the appropriate containment facility and biosafety operating practices are met. As such, biosafety is not considered to be a facility location discriminator. Different degrees of biosecurity can be anticipated for the various locations. Three locations discussed by the panel are considered: Ames, Iowa; Plum Island, New York; and DoD (Fort Detrick at Frederick, Maryland). These examples should not be construed as recommendations for location of a BSL-3 Ag facility.

In general, any facility could be constructed to withstand the highest consequence national disaster, but this must be specifically considered for each locale. Similarly, additional protection from terrorist breach

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of facility could be obtained at any location, but again would need to be specifically considered. The three locations cited in this section are to illustrate three different environments for discussion of the issues and not to signify a preference for one location over another. Additionally, it is expected that the audience for this report is familiar with these three locations, and it will facilitate their understanding of the issues.

4.6. Biosafety

Biosafety addresses issues pertaining to the unintentional exposure of animals or humans and the escape of pathogens from a facility due to natural phenomenon.

Ames is located in a high-risk tornado area and, although the risk may be low, the risk cannot be ignored when research on FADs such as Nipah virus or FMD virus is conducted in a high animal-populated community. Additionally, the present Ames facility is more easily accessed by the public than PIADC and Fort Detrick. PIADC is subject to Atlantic hurricanes but in its history, none have resulted in a breach of the containment area. Thus its risk from natural disasters is considered minimal. Fort Detrick is located in a very low tornado/earthquake risk area.

There are two main considerations pertaining to release of agent from a facility: (1) lapse in biosafety practices resulting in release of agent and (2) intentional removal by someone with access to the facility; e.g., staff, visiting scientists, and graduate students. Unintentional lapse in biosafety practices, if unintentional, is an issue common to all facilities and locations that can be mitigated by personnel biosafety education and training. There may also be a personnel reliability issue related to individuals behavioral characteristics. Intentional lapse in biosafety practices and intentional removal from a facility are biosecurity issues and are discussed under biosecurity.

Biosafety lapses at any facility location likely have an equal risk of occurrence. Thus, the impact of such a release becomes a more dominant consideration. In this respect, not all locations can be considered equal; that is, facilities located where significant animal populations exist that are susceptible to agents under investigation have a greater degree of risk.

Ames has a high degree of risk when consideration is given to the severity of impact should release of a FAD agent occur and infect the surrounding animal population. Fort Detrick was considered to have lesser risk because of a decreasing farm population immediately surrounding the facility. PIADC was considered to have the lowest risk should accidental release of agent from the facility occur in part because of its island location, but mainly due to the lack of commercial livestock farming in Long Island and the surrounding areas.

4.7. Biosecurity

Biosecurity addresses the diversion/release of high-consequence biological agents from the facility for bioterrorism or biocriminal purposes. The release from the facility to expose animals or humans in the local community could come about by physical penetration of the facility by explosives or missile penetration (car, planes) or by intentional lapse in biosafety practice. Diversion (removal of "seed" material) is an intentional act for personal motivational reasons by individual(s) with access to the facility and agents.

One of the inherent complexities of PIADC's island location is that by isolating the facility to reduce the impacts and concerns of agent release you may actually increase the biosecurity risk. Although physical location may deter casual or unsophisticated acts of terrorism, facilities located long distances from police, emergency personnel, and response teams pose greater biosecurity risks due to their isolation.

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Fort Detrick is a DoD military facility with limited access. Since September 11, two photo identifications are required for entry. Thus, it is expected this would provide a degree of antiterrorist security. Employees with access to a high-containment facility could be motivated (financially or loyally to a terrorist group) to violate good safety practices to allow "natural escape" of agent from the laboratory into the human or animal community. Such intentional "lapses" in biosafety would be difficult to prove and would be unpredictable in occurrence, making it attractive to some terrorist group.

The risk level of intentional removal/release of agent is largely dependent on the screening that is given to all personnel with access to the facility. This becomes particularly important when consideration is given to academic collocation/integration and access by facility and graduate students.

At Ames, integration of a BSL-3 Ag facility with an academic center (e.g., university) that enables access to the facility by students and others carries the increased potential risk of release. For Fort Detrick, it is expected that access to the facility, while still permitting visiting scientists and graduate students, would be more restrictive than if it were closely integrated with academics. Like the Fort Detrick consideration, PIADC's academic faculty and student access is unlikely to be a close integrated relationship and thus, while permitted and encouraged, could be more selective.

Although several examples of possible sites for BSL-3 Ag facility have been discussed, including pros and cons, they should not be interpreted as a recommendation for facility location.

5. WHAT WOULD BE THE COST AND TIME REQUIRED TO REPLACE THE CURRENT FACILITY AT PIADC AND ON THE MAINLAND AT TYPES OF LOCATIONS PREVIOUSLY IDENTIFIED?

5.1. Cost and Schedule Data Collection Approach

The proposed approach to data collection required by this task was to conduct a request for information/sources sought (RFI/SS) through the Federal Business Opportunities (FBO) website. However, the USDA disapproved this approach since using a public forum like FBO was not in keeping with the non-disclosure constraints placed upon the conduct of this study.

In lieu of the RFI/SS approach, SAIC pursued a parametric analysis utilizing existing public data and GFI. A number of government laboratories and academic institutions were contacted through a data call for cost and schedule information. At the conclusion of the data call, it became apparent that the most viable approach would be to obtain as many applicable data points as possible to range the costs and schedules associated with the design, construction, operations and maintenance, and eventual decontamination and decommissioning of BSL-3 and BSL-3 Ag facilities. Table 8 shows the academic institutions and laboratories that were contacted.

The following definitions are provided for clarification:

Net Square Footage (nsf)
Net square footage is the total usable square footage of a facility as measured from the inside wall surface of each room. Included in this figure are nonassignable areas such as mechanical rooms and common corridors.

Gross Square Footage (gsf)
The total square footage for a facility measured from the outside wall surfaces of the building.

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Current Year (CY) Dollars
Reflect the total funds required to procure goods or services at the time expenditures are made. Dollars can be increased by an inflation factor to determine what goods or services cost in later years, and for purposes of this report are reflected as CY 2001.

Table 8. Contacted Academic Institutions and Laboratories

Facility Name	Function	Containment	Comments
National Animal Disease Center Modernization Program Ames, Iowa	Caged animal facility, Large animal TSE wing, Prion work	BSL-3 Ag	PIADC mainland construction figures were applied to the Ames facility
Centers for Disease Control and Prevention	Not specified	BSL-3 and BSL-4	No information was received from this facility
Health Canada/Canadian Food Inspection Agency (CFIA)	Research on contagious disease-causing agents on both animal and humans	BSL-2, 3 and 4	Information provided from this facility was used in the analysis
Kansas State University	Not specified	Not specified	No information was received from this facility
Louisiana State University	Research and Teaching	BSLs-1, 2, and 3	Original construction costs were dated (1970s) with numerous renovations. Specific operations and maintenance (O&M) costs not available
Michigan State University	Pathogenesis, immunization, efficacy studies	BSL-2 with BSL-3 being planned	Some information provided but was too general for comparison to other facilities
Plum Island Animal Disease Center	Responsible for research and diagnostics to protect the U.S. animal industries and exports against catastrophic losses caused by FADs introduced into the United States	BSL-3 Ag	GFI provided from this facility was used in the analysis
Southwest Foundation for Biomedical Research	Infectious disease studies using nonhuman primates and other studies requiring singly-caged nonhuman primates	BSL-3 Ag and BSL-4 laboratory space	Information provided from this facility was used in the analysis

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Table 8. Contacted Academic Institutions and Laboratories (cont.)

Facility Name	Function	Containment	Comments
U.S. Army Medical Research Institute of Infectious Diseases	Research on pathogenesis, diagnosis, prophylaxis, treatment, and epidemiology of infectious diseases. Development of vaccines, therapies, diagnostics, and information to protect the U.S. military.	BSL-3 and BSL-4	Information provided from this facility was used in the analysis
University of California, Davis Western National Center for Biodefense and Emerging Diseases (WNCBED)	Research, advanced training, and public service programs in response to new, emerging, and re-emerging infectious disease threats	BSL-3 and BSL-4	Information provided from this facility was used in the analysis
University of Georgia – Animal Health Research Center (AHRC)	Research infectious animal diseases; vaccine development; Eminent Scholar in Vaccinology Program to be housed in this facility	BSL-3 and BSL-3 Ag	Specific data unavailable due to contracting actions
University of Nebraska	Mostly infectious disease and animal challenge studies. Studies of viral diseases of poultry and livestock	BSL-2 and potential for BSL-3	Construction costs were dated (1976-77) with numerous renovations. Specific O&M costs not available. University is examining the feasibility of expanding to BSL-3, however, feasibility studies have not begun.
University of Texas Medical Branch (UTMB)	Tropical disease and HIV research; environmental containment and chemical warfare lab	BSL-3, small BSL-4 facility under construction	Information provided from this facility was used in the analysis
Utah State University	Not specified	Not specified	Not a good candidate for evaluation because of numerous renovations over last 30 years. Detailed data regarding square footage costs is not available.

After assessing the cost and schedule data available from these facilities, data from the operating and planned institutions and laboratories shown in Table 9 were used in this analysis. It should be noted that Health Canada/CFIA, the current PIADC facility, and the Southwest Foundation for Biomedical Research are operational facilities. USAMRIID-expanded mission, the PIADC upgrade, University of California (UC) Davis, University of Georgia, and the University of Texas Medical Branch are considered to be in

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some stage of "facilities planning" and development. As a result, some facilities were able to provide more detailed information based on historical data, and other facilities provided information based on preliminary planning figures.

Additionally, average unit costs from related federal projects are shown for comparison purposes. Specifically, the "Oak Ridge National Laboratory Strategic Facilities Plan for Making ORNL a 21st Century Laboratory," October 2000, is referenced. This facility plan encompasses the revitalization of the nation's largest and most diverse energy research and development institution in the United States. This study applied a number of cost planning factors to a wide variety of buildings and equipment, including specialized experimental laboratories, user facilities, a large complement of office space, and associated utility systems. Also referenced are two recent Department of Defense demolition projects [38].

Table 9. Data Sources Used in Analysis

Operational Facilities	Planned Facilities
Health Canada/CFIA	Plum Island Animal Disease Center – Upgrade
Plum Island Animal Disease Center (PIADC) – Current Facility	University of California, Davis (WNCBED)
Southwest Foundation for Biomedical Research	University of Texas Medical Branch
	USAMRIID-expanded mission

5.2. Baseline Costs and Schedules: PIADC versus Mainland Site Locations

In May 2000, the Kling-Lindquist Architecture, Engineering and Interior Design (KL) firm submitted to the USDA a draft Strategic Facility and Utility Investigative Report of the Building No. 101 renovation/expansion at the PIADC. This report considered six reconstruction options and one new construction option.

The organizational concept selected from seven proposed in the draft Investigative Report was Option 6A, the new construction option. As a result, in May 2001, KL submitted a second Strategic Facility and Utility Investigative Report, which detailed the new construction option. The Executive Panel was also in agreement that new construction was likely to be more cost effective and expeditious than renovations to the existing facility.

As a result, the costs and schedules presented below are for the PIADC upgrade and are taken directly from the KL May 2001 draft Investigative Report. It should be noted that the construction portion of the report assumes a 15% markup to account for the "island" factor. This accounts for factors that will affect construction costs such as hauling construction materials, transporting workers, locating storage and waste sites, and importing or eliminating excess material. This "island" factor was applied to the design and construction estimates; it is not assumed to affect the schedule.

While awaiting other government and academic data requests solicited in Task 5, the KL May 2001 draft Investigative Report was adjusted in an attempt to remove the "island" factor from the design and construction estimates. The reductions that were realized from the PIADC facility include:

- An approximate 15% reduction in the cost of the overall construction based on the "island" factor mentioned above
- Because of the lower construction costs, a 6% reduction was realized in the design cost
- Demolition costs of $18,700,000 were removed so it would not skew the comparison with other construction-only based costs

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A comparison of the PIADC new construction versus mainland, "non-island," construction approaches is presented in Table 10. It must be recognized that the apparent savings in non-island construction are a function of the actual site selected and the availability of existing infrastructure (see paragraph 5.3) that is essential for safe operations of a new facility.

Table 10. PIADC Construction - BSL-3 Ag

Construction - BSL-3 Ag gsf = 180,829				
	PIADC		Non-Island	
Category	**Cost ($)**	**Duration (Months)**	**Cost ($)**	**Duration (Months)**
Design	6,648,809	12	5,398,964	12
Construction	134,003,450	35	114,985,087	35
Total	**140,652,259**	**47**	**120,384,051**	**47**

5.3. Excursions: Mainland Sites with and without Support Infrastructure

The cost impacts of a decision to move PIADC operations to the mainland must be addressed. These impacts are not addressed in detail in this report but must be considered as part of any cost analysis.

Cost estimates for any mainland location must consider the following trade-offs:

- The costs required to sustain PIADC while a new facility is constructed. These costs will include both operating and maintenance costs for the construction duration as well as necessary repairs and/or renovations necessary to ensure safe operating conditions. It should be noted that the commissioning of some containment facilities has taken longer than estimated, or in the case of the University of Georgia, is still pending. As shown in paragrah 5.2, this duration is estimated to be at least 4 years.
- The costs associated with the decommissioning of PIADC. These costs will include the decommissioning of both the USDA facility and the remaining military infrastructure on the island. As discussed during the panel session, when the USDA inherited Plum Island, it assumed responsibility for cleanup of the U.S. Army garrison that had been operating on the island. This will include compliance with the myriad of administrative and environmental requirements that may be applicable, to include the National Historic Preservation Act, Housing and Urban Development, General Services Administration, National Environmental Policy Act (NEPA), and Environmental Protection Agency regulations.
- Staff and personnel relocation costs that might be incurred during facility transition.
- Salvage value or equipment transfer to the new facility.

PIADC has existing infrastructure that may not be available at a mainland location. Specifically, PIADC has recently constructed a 60,000 nsf administration building and has an existing utilities plant. The infrastructures and associated estimates are:

- $18M for the construction of a 60,000 nsf office building
- $12M for construction and installation of a utilities plant that includes
  - $3M for chiller plant and cooling tower
  - $2.5M boiler plant
  - $0.5M utilities distribution system
  - $2.0M emergency generators

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These estimates assume that an adequate water supply, wastewater treatment, and sewage treatment exist at the mainland candidate site.

To further analyze the mainland option, cost and schedule information from government and academic agencies that have recently built or plan to construct BSL-3, BSL-3 Ag, and/or BSL-4 facilities was compiled. Again, it should be noted that in most cases, projects are in the requirements definition stage and that only very preliminary cost, schedule, and sizing information is available. Table 11 outlines the design, construction and commissioning schedules for each facility.

Table 11. Schedules (Months)

Description/Facility	Health Canada	PIADC	Southwest	USAMRIID	UC Davis Fast-Track	UC Davis Conventional	UTMB
Design/Bid and Award	22	17	5	18	20	27	
Construction	60	66	13	33	33	36	14
Commissioning			1	6	3	3	
Subtotal	**82**	**83**	**19**	**57**	**56**	**66**	**14**
Overlap Design/Const	0	5	0	6	7	0	0
Overlap Const/Comm	0	31	0	3	1	0	0
Total	**82**	**47**	**19**	**48**	**48**	**66**	**14**
nsf	Not Available	89,237	5,868	Not Available	120,323	120,323	Not Available
gsf	304,812	246,489	Not Available	1,150,200	243,280	243,280	12,000

The dollars in Table 12 are reflected in current year (CY) 2001. The Canadian (1998) dollars were converted to U.S. dollars and inflated to 2001 dollars. The Canadian conversions were performed on the Bank of Canada web page at: http://www.bankofcanada.ca/en/exchform.htm and reflect an exchange rate of $0.6345 Canadian for $1.00 U.S.

Table 12. Construction and Average Square Foot Costs and for Each Facility

Description/Facility	Health Canada	PIADC Mainland	PIADC	Southwest	USAMRIID	UC Davis Fast-Track	UC Davis Conventional	UTMB
Total Construction Cost	$118,623,913	$143,376,087	$140,652,259	$1,513,518	$1,006,223,221	$180,161,880	$189,620,378	$13,000,000
nsf		149,237	89,237	5,868		120,323	120,323	
gsf	304,812	336,489	246,489		1,150,200	243,280	243,280	12,000
Average $/sf - Net	Not Available	$961	$1,576	$258	Not Available	$1,497	$1,576	Not Available
Average $/sf - Gross	$389	$426	$571	Not Available	$875	$741	$779	$1,083

In Table 12, the PIADC mainland column includes the cost of the infrastructure upgrades described in paragraph 5.2. It should be noted that the Health Canada facility includes 2,788 gsf of BSL-4 space, which is less than 1% of the total space allocation. Detailed data were not available to deduct the BSL-4 construction costs from the total costs. The construction cost for UTMB is high when compared to other facilities. According to the UTMB Safety Director, the events of September 11, 2001, resulted in

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extremely inflated containment construction bids. Further negotiation is required to align these bids with the other construction costs shown. The construction estimates for UC Davis include some BSL-4 space, and the construction costs were presented as combined BSL-3Ag and BSL-4. However, the BSL-3 Ag and BSL-4 areas were both estimated using the same cost per square foot.

The space requirements at USAMRIID are considerably larger than the other facilities. In addition to standard laboratory rooms, additional space is required to support production of vaccines for eventual licensure. The new facility will also require a medical branch containing areas for clinical trials (inpatient ward) and a contaminated patient care isolation unit.

The figures for UC-Davis WNCBED include BSL-3 Ag and BSL-4 laboratory, aerobiology and pathology space totaling 15,700 nsf which is approximately 13% of the total space allocation. The WNCBED conceptual layout for high-containment laboratories allows operations at either the BSL-3 or BSL-4 level to maximize operational efficiency.

5.4. Net Present Value (NPV) Analysis

Net present value (NPV) is defined as the present value of all future cash flo[illegible] an investment, less the initial cost of the investment. The base for present v[illegible] future cash flows. The rationale for those estimates must be documente[illegible] cost estimate. Discount factors depend on the discount rate and the timing of the [illegible]sh flow.

The Office of Management and Budget suggests the use of NPV analysis in a[illegible] government decisions to initiate, renew, or expand programs or projects [illegible] measurable benefits or costs extending for 3 or more years into the futu[illegible]ples [illegible] acq[illegible]ion decisions that involve such analyses include (1) lease-purchase analyses, (2) analysis of different lease alternatives, (3) life cycle cost analyses, and (4) trade-off analyses considering a[illegible]isition costs and energy-utilitization costs of operation.

While examples 1 and 2 do not apply, NPV would be a useful tool when actual facility site a[illegible] ves are being assessed. At that point, cash flow values and cash flow timing information can be su[illegible] ted and documented. However, any NPV analysis requires site-specific data and information makin[illegible] the estimating error substantial. For these reasons, the utility of performing such analysis was determin[illegible] be of very little value for the purposes of this study and report. Consequently, a NPV analysis [illegible] conducted.

5.5. Discussion

As shown from construction schedule and cost survey, construction costs for an approximately 250,000-300,000 gsf facility are estimated to range from $400-$800/gsf and will take 4 years to construct and commission. UTMB costs approach $1,000/gsf, but the higher cost is most likely due to the smaller size of the facility (12,000 versus 240,000 gsf), combined with the impacts of the September 11, 2001, terrorist attack, which apparently caused extremely inflated construction bids for this project.

In addition to the other considerations discussed earlier in the report, mainland candidate site selection analysis would also include the following. These costs are site specific but could easily erode any differences between PIADC and mainland costs:

- Wages and salaries (professional, craft, labor)
- PIADC staff relocation and disposition
- Materials

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- Transportation (incoming materials, outgoing products, other)
- Utilities and fuel (fuel, electric power, water, waste treatment)
- Amortization of facility (land and building, equipment and machinery, financing)
- Taxes (state, local)
- Site survey and environmental documentation (i.e., NEPA Compliance; disposition of archeological or historical matters; wetlands protection)

6. WHAT ARE THE RELATIVE LONG-TERM COSTS FOR OPERATION OF A NEW BSL-3 FACILITY ON THE MAINLAND VERSUS AT PIADC, INCLUDING INFRASTRUCTURE AND "CLEANUP" ISSUES?

6.1. Operations and Maintenance (O&M) Costs

The basis of estimate for the operating and maintenance costs presented in Table 13 for the PIADC upgrade are annual O&M costs incurred. The assumptions in O&M costs that were made include:

- Current staffing is assumed to remain constant
- Utility usage will remain constant
- All other island-specific costs will remain constant

As with the design and construction costs, the current O&M costs were adjusted in an attempt to remove the "island" factor from the design and construction estimates. The $1.3M reduction was primarily realized in the marine transportation arena, to include boat maintenance and repairs, dock facilities, and utilities.

A comparison of the two O&M approaches is presented in Table 13.

Table 13. Annual O&M Costs ($FY01)

Category	PIADC	Mainland
Research Salary	2,711,052	2,711,052
Research Other	1,247,034	1,247,034
Total Research	3,958,086	3,958,086
Indirect Salary	2,238,789	2,238,789
Indirect Utilities	1,933,200	1,674,000
Indirect Other	652,950	652,950
Contractor Salary	5,214,594	4,898,594
Contractor Other	1,206,375	1,101,303
Total O&M	11,245,908	9,917,429

Most operational facilities were unable to provide operations and maintenance estimates because the specific containment buildings performing the operations are part of a larger campus. As a result, the accounting systems do not capture individual containment building O&M costs. The facilities that were able to provide annualized O&M information are shown in Table 14.

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Table 14. Comparison of O&M Costs

Category	PIADC (Actuals)	Mainland with Infrastructure Upgrades (Estimates)	Mainland without Infrastructure Upgrades (Estimates)	Health Canada (Actuals)	UTMB (Planned) (Estimates)
Operations and Maintenance Costs	$11,245,908	$9,917,429	$9,917,429	$10,483,043	$750,000
nsf	89,237	149,237	89,237	120,323	
gsf	246,489	336,489	246,489	243,280	12,000
Avg $/nsf	$126	$66	$111	$87	
Avg $/gsf	$46	$29	$40	$43	$63

The information from Health Canada was based on the 1998 Report of the Auditor General of Canada but inflated to 2001. SAIC has contacted the Health Canada facility for updated costs but had not received any additional information as of the date of this report.

6.2. Decontamination and Demolition Costs

A number of sources were used to research Decontamination and Demolition (D&D) costs. Table 15 lists those cost factors for estimating D&D costs by structure type. These unit costs include decontamination, demolition, site work, and removal of demolished materials, rubbish, and site debris to a landfill.

Table 15. Cost Factors for Estimating D&D Costs

Building Description	D&D Costs - $/nsf
Office [39]	12
DoD Base Realignment and Closure (BRAC) [40]	30-40
Light Laboratory [39]	45
Hazardous/Nuclear Facility [39]	225

The Kling Lindquist USDA Investigative Report dated May 25, 2001 estimates the following demolition costs (Table 16):

Table 16. Kling-Lindquist Report Demolition Costs (May 2001)

Building Description	Demolition Costs - $/nsf
Administrative space	10
Laboratory space	97

The demolition costs of a mainland PIADC facility are within industry averages. However, the Plum Island demolition costs do not include internal building decontamination efforts. An allowance of approximately $50/nsf should be applied to the containment area.

Office, laboratory, and holding space, construction, operations, and clean-up costs at a mainland PIADC facility were compared to the ORNL information. This comparison is reflected in Table 17.

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Table 17. ORNL [39] vs. Mainland Costs

Cost Description	ORNL Avg $/nsf	Mainland Avg $/gsf
D&D Costs (Light Lab/Haz/Nuclear)	45-225	100
Construction (Light Laboratory)	200-400	400-1,000
Lease/operating (Light Laboratory)	15-25	40-60

6.3. Discussion

6.3.1. O&M

The data call did not provide many O&M data points for comparison. However, PIADC provided very detailed O&M costs for the facility, which were based on the FY02 actual operating budget. When the PIADC-specific marine operation costs were eliminated, the O&M costs decrease approximately 35%, or $16/gsf. However, this estimate will be impacted by the regional factors of candidate locations, once they are determined. Any savings due to mainland O&M costs could conceivably be eliminated over the life cycle due to these regional factors.

As stated earlier, the Health Canada O&M costs were taken from a 1998 Auditor's Report. Current actual costs were not available for this study. The Canadian O&M costs include incremental resources for scientific programs and grants in lieu of taxes. Clarification for these items was requested but has not yet been received. The UTMB O&M costs are based on projections for the new BSL-4 laboratory only. This estimate includes six to eight research scientists supported by one advanced laboratory technician. As shown in the data presented, O&M costs range from $29-$63/gsf with current PIADC O&M falling within this range at $46/gsf.

6.3.2. Decontamination and Demolition

The D&D costs will be a function of the type of square footage demolished. Industry averages researched range from $10-$15/sf for an administrative building to $45-$225/sf for light laboratory (low end) to hazardous/nuclear containment structures (high end) decontamination and demolition. The PIADC estimates of $10/sf for administrative buildings and $100/sf for containment structures are within these industry averages; however, decontamination is not included. An allowance of approximately 50% should be included for decontamination of containment structures. Applying this allowance results in decontamination and demolition costs of an estimated $10/gsf for uncontaminated administrative space to $150/gsf for contaminated space.

As with construction, cleanup of a mainland location is estimated to cost somewhat less than cleanup of the island location. However, any apparent savings would have to be validated by site-specific comparisons.

7. WHAT ARE THE BENEFITS/LIABILITIES FOR JOINT RESEARCH WITH UNIVERSITIES OR MILITARY RESEARCHES IN A BSL-3 FACILITY?

In most important programmatic areas, the benefits and liabilities of conducting joint research with universities or military in a BSL-3 facility will depend on the scientific and personnel relations between the programs and are subject to potential competition for resources. Collocation with a scientifically active human health program, particularly at a university setting, would expose the agricultural research effort to graduate students and university professors who would not ordinarily consider health issues of livestock and thus serve to broaden the intellectual resources and scientific techniques applied against

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agricultural research problems. Similarly, location at a university with a strong animal health program would provide an environment conducive to successful research. These include links to vigorous collaborative research efforts, access to the university library and information specialists, computer facilities, visiting scientists, and research efforts in the sciences allied to animal health.

The concerns for intentional clandestine acquisition of bioterrorism agents from government laboratories has increased in recent years and particularly since 2001. Microbial agents and toxins cannot presently be identified by currently available stand-off detection technology that would enable the prevention of intentional removal of micro quantities of disease agents sufficient for "seed" culture. Thus, security against the insider threat will depend on the integrity of the individuals who have access to the high-consequence pathogens. Eliminating or minimizing the "insider threat" requires substantive screening policies and procedures that may be difficult with close, integrated collaboration between a BSL-3/BSL-3 Ag FAD facility and an academic institution.

An additional governmental option is collocation at a military or other federal agency facility. The Defense Department has a BSL-3 and BSL-4 facility at Fort Detrick and the scientists at Fort Detrick and PIADC have worked on collaborative projects of mutual interest in the past. The Department of Health and Human Services operates BSL-3 facilities at the Frederick Cancer Research Center, Fort Detrick, Maryland, as well as BSL-3 and BSL-4 facilities at the National Institutes of Health in Bethesda, Maryland, and those at the CDC in Atlanta, Georgia. The intense human health focus of these laboratories on priority national defense and homeland security issues makes it unlikely that serious collaborative effort and facility sharing will be favorably entertained before sufficient capacity to meet the bioterrorism threat is available. Further, these facilities cannot accommodate large animals.

The Executive Panel recognized the invigorating scientific benefits of strong collaborations. Their major concern was that, sustaining a strong USDA animal program at the hosting institution will be essential to ensure agricultural research receives the resources and priorities envisioned in the conception of the program. Research performed in a BSL-3 Ag facility should not suffer from the competition of human health research with agricultural research because the host and guest programs derive from the same culture.

8. ARE THERE BENEFITS/LIABILITIES OF COLLABORATIVE RESEARCH, I.E., IS THERE TANGIBLE BENEFIT BY HAVING BSL-3 AG WORK ACCOMPLISHED IN AN ATMOSPHERE WHEREBY OTHER NON-AGRICULTURAL WORK MAY BE ONGOING?

The benefits expected to derive from joint or collaborative work in a BSL-3 Ag facility where non-agricultural work is ongoing result from alignment of common programmatic interests and shared infrastructure. With joint and collaborative research agreements and assuming adequate capacity, facilities become available to the USDA immediately upon ratification of the agreement—there is no delay for design and construction of the facility. Furthermore, productivity of both the host and guest programs benefit because the facility is used more extensively, decreasing the cost per investigator. An increase in the numbers of scientists sharing the facility reduces program risks associated with temporary funding shortfalls. The likelihood that scientific tools (reagents, equipment, and facilities) will be useful to both host and guest is high where the program objectives of the two groups are similar in terms of animals, pathogens, and technical approach. The USDA program would benefit greatly in access to a vibrant university community and academic faculty and staff in all of the sciences allied to animal health, visiting scientists, seminars, technical support (DNA, RNA, and peptide synthesis services and monoclonal antibody production), clinical laboratory support, and academic support.

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The Executive Panel found that liabilities of the host–guest relationship derive principally from conflicts over access to resources. Whose experiments will obtain priority for scarce resources? Will the facility be available when the USDA requires it? This could be a major concern if the facility is envisioned as playing a role in homeland defense. These issues should be foreseen and addressed in the negotiation of the agreement. There may be scientific incompatibilities that preclude the use of certain agents or animals in the facility while a study is being performed due to the potential for cross contamination.

9. FINDINGS AND RATIONALE

9.1. Findings

- It is technically feasible to conduct exotic (FAD) disease research and diagnostics, including FMD and rinderpest, on the U.S. mainland with adequate biosafety and biosecurity to protect U.S. agriculture.

- Biosafety is generally not so much a location issue as it is facility design (appropriate high-containment) and biosafety operational practices. Biosecurity, securing pathogens from national (e.g., terrorist) threats and preventing pathogens release (intentional biosafety lapse or removal) from the facility are important considerations that have site-specific consequences. Thus, these would need to be addressed individually when site locations are considered.

- Adequate biosafety and biosecurity can be achieved at any site location but would require more stringent operational and control measures than now exist and seemingly considered by the panel. The USDA should consider conducting work with some BSL-3 agents at BSL-4 containment, depending on the nature of the work and facility location. A minority of Executive Panel members (3 of 14) objected to this conclusion.

- Although not a serious human infection, humans have been shown to carry the FMD virus for short periods of time. Because FMD is recognized to be transmissible from humans to animals, additional respiratory protective measures for the workforce beyond that associated with BSL-3 Ag containment may be required to prevent human vectoring of the disease.

- BSL-4 containment of FMD is not considered necessary.

- A USDA strategic plan detailing programs in all BSL-3 Ag and -4 facilities will contribute to the mid- to long-term viability of these programs.

- PIADC operations will need to be maintained for the foreseeable future (5 – 10 years) by upgrading current PIADC BSL-3 Ag facilities as necessary to maintain integrity of current research and diagnostic missions and those missions determined as part of the strategic plan.

- FMD research and diagnosis will need to be sustained at PIADC pending development of a USDA strategic plan and any mainland site alternatives.

- If a new BSL-3/BSL-3 Ag facility is built on the U.S. mainland, consideration should be given to building and operating it as part of a consolidated BSL-3 Ag/BSL-4 facility. This facility should have the capability to transfer to and from BSL-3 Ag and BSL-4 operations seamlessly.

- The costs of replacing the current facility at PIADC is estimated to be approximately 17% greater ($140.7M versus $120.4M) than to replace it on the mainland at a location having comparable infrastructure to that already present on PIADC. The construction schedules are

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comparable. As an excursion on the basic question, if this alternative involved closure and decommissioning of PIADC and relocation of its functions to the mainland, the mainland alternative would be more expensive with the actual differences dependent on site-specific costs. This is especially true if the mainland location requires construction of substantial and new infrastructure.

- Similarly, O&M costs for PIADC are estimated to be approximately 13% higher than for comparable operations at a mainland location. As with construction, site-specific information is needed and might erode the estimated savings. Clean-up costs are in line with other estimates. PIADC is estimated to be more costly than mainland cleanup, but site-specific data are necessary to improve our confidence in these estimates.

- A proactive program of joint research with universities or military researchers in a BSL-3 facility would foster the dynamic scientific atmosphere required to attain a leading-edge scientific program. This program could include visiting scientists, and NRC fellow or postdoctoral arrangements. Such a program would be independent of facility location, but would be subject to biosecurity considerations. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

- A proactive program of collaborative research provides an additional venue for promoting a leading-edge scientific program. Such collaborative research could be established with academic and military medical programs of similar scope and designs. As with a joint program, this could include visiting scientists, NRC fellows or postdoctoral arrangements. Such a program would be independent of facility location, but would be subject to biosecurity considerations. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

9.2. Rationale

While it is technically feasible to relocate the research and diagnostics on the mainland, there are inherent, but manageable, risks for doing so. Mistakes in the laboratory (lapse in biosafety practices) or breach in containment (mechanical failure or security issues) could be devastating to the economy of not only the immediate area, but the entire United States.

Canada and Australia operate BSL-4 animal disease research and diagnostics facilities on the mainland, and Canada plans to do research with live FMD virus in their Winnipeg facility. Furthermore, Australia's facility is located on a narrow peninsula that facilitates biosafety and biosecurity. Britain has conducted FMD research at its Pirbright Laboratory near London for many years. Spain, Switzerland, The Netherlands, Germany, France, Italy, and South Africa also conduct FMD research on their mainlands.

There are issues to be resolved related to biosecurity from the viewpoint of risk to physical breach due to terrorism as well as personnel-driven escape of agents from the facility (safety lapse or intentional removal).

Some panelists queried whether it would be "smart" to have all diagnostics and research at the same location. Consolidation might improve efficiency and economy but carries a risk associated with any "all or none" operations. Such issues need to be intensively studied and clarified before a decision should be made to move PIADC operations to a mainland location. A strategic plan is required for all BSL-3/BSL-3 Ag and BSL-4 facilities including a consideration for an altered operational status of some present

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BSL-3 Ag agents such as FMD virus if work should be transferred from an island location with sparse surrounding livestock to a mainland livestock-rich environment.

Relocating FAD diagnostics and research to the mainland requires augmented BSL-3 Ag practices and, under certain circumstances, may more closely approximate BSL-4 practices. It will certainly require scientifically sound biosafety and biosecurity practices that have community acceptance. At present, there are three infectious agents that are significant to agriculture and require BSL-4 containment (avian influenza virus, Hendra virus, and Nipah virus). Although these agents do not appear to pose a significant threat at present to American agriculture, there are presently no active research programs under way at USDA on these agents. Additionally, there is a high probability that the USDA program will include the diagnosis and study of unknown pathogens for which there is no information regarding risks to animals or humans. Additionally, if FMD virus work is moved to a mainland facility, serious consideration should be given for this work to be in a BSL-3 Ag biocontainment facility enhanced with respirators to prevent human vectoring.

Construction costs and schedules were derived from the May 2001 Kling-Lindquist Investigative Report and from parametric estimates from similar construction projects, completed and planned. Given the time for the study, SAIC was not in a position to thoroughly validate the KL data and relied on their study results. Estimates based on these data fall within ranges for similar projects. Removing the "island-factor" from PIADC estimates supports the estimates that construction, operations, and cleanup on a mainland location having equivalent existing infrastructure to PIADC is somewhat less costly than for PIADC construction, operations, and cleanup. If PIADC is closed, the costs to relocate the workforce and decommission the site would make the mainland alternative more costly than the island alternative. Site-specific costs may be substantial and could quickly erode savings of mainland operations.

A proactive program of joint research with universities or military research is needed to create and retain the dynamic scientific atmosphere and will be required to attain a leading-edge scientific program. This program could include visiting scientists, and NRC fellow or postdoctoral arrangements. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

A proactive program of collaborative research provides an additional venue for promoting a leading-edge scientific program. Such collaborative research should be established with academic and military medical programs of similar scope and designs. As with a joint program, this could include visiting scientists, and NRC fellow or postdoctoral arrangements. All personnel with access to high-consequence agents would need diligent screening including not only the facility staff, but also visiting scientists, students, and other program participants.

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37. R.F. Sellers, K.A.J. Herniman, and J.A. Man, Transfer of foot and mouth disease virus in the nose of man from infected to non-infected animals, *Veterinary Record*, 89, 447-449 (1971)
38. Department of Defense and Infrastructure Demolition, John Daly, *Wavelengths*, June 2001 Excerpt.
39. Oak Ridge National Laboratory web page http://www..ornl.gov/~dmsi/strategic_plan/table61.htm
40. June 2001 excerpt of *Wavelengths* at http://www.dt.navy.mil/pao/excerpts%20pages/2001/DoDdemolition6_01.html

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APPENDIX A
CURRICULUM VITAE OF EXECUTIVE PANEL MEMBERS

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CURRICULUM VITAE

Richard E. Breitmeyer, D.V.M., M.P.V.M.
State Veterinarian and Director, Animal Health and Food Safety Services
California Department of Food and Agriculture
1220 N Street, Room A-114
Sacramento, CA 95814

EDUCATION

California Polytechnic State University, San Luis Obispo
Animal Science - 1972 - 1976

University of California, Davis, School of Veterinary Medicine
Doctor of Veterinary Medicine - 1980

University of California, Davis, School of Veterinary Medicine
Master of Preventive Veterinary Medicine - 1990

LICENSED TO PRACTICE VETERINARY MEDICINE

California

PROFESSIONAL ASSOCIATIONS

American Veterinary Medical Association
California Veterinary Medical Association (Member Agriculture Committee)
United States Animal Health Association (Chairman of Food Safety Committee, Member of Brucellosis, Tuberculosis, Foreign Animal Diseases, Government Relations and Professional Oversight Committees)
National Assembly of Chief Livestock Health Officials
Western States Livestock Health Association (Past President)
American Association of Food Hygiene Veterinarians
National Institute for Animal Agriculture (Executive Committee, Past Chairman - Food Safety Assurance Committee)
United States Department of Agriculture Secretary's Advisory Committee for Foreign Animal and Poultry Diseases (Past Chairman)

EXPERIENCE

1993 - Present
Director, Animal Health and Food Safety Services, California Department of Food and Agriculture and State Veterinarian, California

As Director, responsibilities include oversight of the Animal Health Branch, the Milk and Dairy Foods Control Branch, the Meat and Poultry Inspection Branch and the Livestock Identification Branch; responsible for oversight of the contract with the California Animal Health and Food Safety Laboratory

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1992 – 1993
Chief, Animal Health Branch, California Department of Food and Agriculture

1989 - 1992
Veterinary Medical Officer IV - Staff Veterinarian - Emergency Diseases Program, California Department of Food and Agriculture

1989 - 1992 (simultaneous with Emergency Diseases Program responsibilities above)
Designated Epidemiologist - Brucellosis Task Force

1988 - 1989
Staff Veterinarian - Equine Programs, California Department of Food and Agriculture

1988 - Present
Foreign Animal Disease Diagnostician - United States Department of Agriculture Training Course, Ames, Iowa and Plum Island, New York

1984 - 1987
Veterinary Medical Officer - Range A/B, California Department of Food and Agriculture

1983 - 1984
Arroyo Grande Veterinary Clinic
Mixed animal veterinary practitioner (50% large and 50% small animal)

1980 - 1983
Arcata Animal Clinic
Large animal veterinary practitioner

HONORS AND AWARDS

1994 **Superior Accomplishment Award**, California Department of Food and Agriculture, for role as Designated Epidemiologist in the successful Critical Area Brucellosis Task Force.

1998 **Hammer Award**, Office of the Vice President, for efforts implementing the California Egg Quality Assurance Plan, recognized as a national partnership for reinventing government.

1998 **Honor Award**, National Association of State Departments of Agriculture, for outstanding accomplishment in service.

1999 **Alumni Achievement Award**, School of Veterinary Medicine, University of California, Davis, for contribution to animal health and food safety locally, nationally and internationally.

2000 **Pacific Egg and Poultry Association**, Scientist of the Year, for contribution to poultry science in California

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CURRICULUM VITAE

Corrie Brown
Department of Veterinary Pathology
College of Veterinary Medicine
The University of Georgia
Athens, Georgia 30602-7388

Educational History:

Doctor of Philosophy (Comparative Pathology) - University of California, Davis, 1986
Residency (Veterinary Pathology) -University of California, Davis (program combined with Ph.D.)
Doctor of Veterinary Medicine - Ontario Veterinary College, University of Guelph, 1981
Bachelor of Science - McGill University, 1973

Academic and Professional Positions Held:

2001 – present	Professor, Department of Pathology Coordinator of International Activities College of Veterinary Medicine, University of Georgia
1996 - 2000	Professor and Head, Department of Pathology, College of Veterinary Medicine, University of Georgia
1989 - 1995	Head, Pathology Section, Foreign Animal Disease Diagnostic Laboratory, Plum Island, U.S. Department of Agriculture
1988 - 1989	Veterinary Medical Officer, Pathology Section, Foreign Animal Disease Diagnostic Laboratory, U.S. Department of Agriculture
1987 - 1988	Research Scientist, Pathobiology, Agricultural Research Service, Plum Island, U.S. Department of Agriculture
1986 - 1987	Assistant Professor, Department of Veterinary Pathology, School of Veterinary Medicine, Louisiana State University
1981 - 1986	Postgraduate Researcher, University of California at Davis
1981	Clinical Veterinarian, Westfield Veterinary Hospital, Westfield, New York

Professional Organizations:

American College of Veterinary Pathologists (1986)
American Veterinary Medical Association
United States Animal Health Association
American Association of Veterinary Laboratory Diagnosticians
American Association of Avian Pathologists
American Society for Microbiology

Honor Societies, Awards, Special Recognitions:

Toronto Humane Society Award for Proficiency in Small Animal Medicine, 1981
Phi Zeta Veterinary Honor Society
USDA Certificate of Merit, 1991, 1992, 1993
USDA Women's History Award, 1993
Phi Beta Delta International Honor Society, 1999
Faculty Recognition Award (Excellence in Teaching, from Class of 2001), 1999
Faculty Recognition Award (Excellence in Teaching, from Class of 2001), 2000
Faculty Recognition Award (Excellence in Teaching, from Class of 2002), 2000
Norden Award for Teaching Excellence, 2000

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Faculty Recognition Award (Excellence in Teaching, from Class of 2002), 2001
Faculty of Discussants, C.L. Davis Foundation, 2001
Outstanding Lecturer, C.L. Davis Course on Gross and Morbid Anatomy, 2002
National SAVMA Excellence in Teaching Award, 2002

Reviews, Panels, Advisory Boards:
Extramural:

Editorial Board, *Veterinary Pathology*, 1995-1998
Ad Hoc Reviewer for: *Journal of Veterinary Diagnostic Investigation, Journal of Wildlife Diseases, Virus Research, Journal of Virology, Emerging Infectious Diseases*
USDA National Research Initiative Grants Program
Ad Hoc reviewer, 1997, 1998, 1999
American College of Veterinary Pathologists
Infectious Diseases Specialty Group, Co-Chair 1992; Chair 1993
Standing Education Committee, 1995-2000; Meeting organizer, 1999; Chair, 2000
Young Investigator Award Committee, 1994-1996
External Regulations Committee, 1992-1996
Councilor, 2000-2003
United States Animal Health Association Foreign Animal Disease Committee
Member 1990-present; Vice-Chair, 1999-2004
American Association of Veterinary Medical Colleges
International Affairs Committee, 1997-present
International Safety Advisory Board on Xenotransplantation, Novartis, Cambridge, England, 1997-1999
International Conference on Emerging Diseases, Atlanta, March 1998, Chair, Zoonoses Section
Armed Forces Institute of Pathology Wednesday Slide Conference Moderator, March 1999, March 2000, March 2001, February 2002
External Review, Department of Pathobiology, University of Pennsylvania, December 1996
USDA Foreign Agricultural Service Scientific Exchange, Kunming, China, April 1997
Faculty Exchange, Kitasato University, Towada, Japan, January 1999
Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases, 1999-present
External Review, Department of Pathobiology, University of Connecticut, October 1999
Panel Member on Agro-Terrorism, Senate Armed Services Subcommittee, October 1999
Team member, Development of Biological Weapons Convention Inspection Guidelines, Henry L. Stimson Center, Washington, DC, 2000-2001
USAID Middle East Regional Cooperation Grants Program, External Review, February 2000
Scientific Advisory Board, Armed Forces Institute of Pathology, 2000-present
National Institute for Animal Agriculture
Emerging Diseases Committee, 2000-present
Panel Member, Development of Guidelines to Safeguard Animal Health, National Association of State Departments of Agriculture, 2001
Co-Chair, International Conference, *Preparing the Veterinary Profession for Corporate and Trade Issues in the Americas*, Santiago, Chile, May 2001
Chair, Review Panel, USDA ARS Animal Health - Virology, May 2001
Rapporteur, General Session, Office International des Epizooties, May 2001
Moderator, National Academies of Sciences Workshop, Emerging Animal Diseases, January 2002
Member, Technical Advisory Committee, United States – Israel Binational Agricultural Research and Development Fund, 2002-2005
USDA Executive Panel on Biocontainment Feasibility, June 2002

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Intramural:

University:

Creative Research Medal Panel, Office of the Vice President for Research, 1996
Graduate Faculty Review Committee, Health Sciences Division, 1996-present
Search Committee for assistant professor, Center for Tropical and Emerging Global Diseases, 1999
State-of-the-Art Conference and Study in a Second Discipline committee, member 1999-2000, chair 2000-2001
Search Committee, Executive Director for Office of International Education, 2002
Member, Agroterror Task Force, 2002
Search Committee, Eminent Scholar in Emerging Diseases, Center for Tropical and Emerging Global Diseases, 2002

College:

Ad Hoc Search Committee for Associate Dean for Academic Affairs, College of Veterinary Medicine, Chair, 1996
Animal Health Research Center Steering Committee, Chair, 1996-present
Scholarship and Appeals Committee, member, 1996-present
Ad Hoc Committee for Development of New Awards, Chair, 1997
Ad Hoc Committee for Review of Assignment of Time, member, 1998-1999
Chair, Organizing Committee, International State-of-the-Art Conference on Emerging Diseases, August 1999 (funded by a competitive $11,000 grant from UGA Office of the Provost)
Ad Hoc International Affairs Committee, chair, 1999
Coordinator, International Activities, 2000-present
Faculty Advisor, Patheads Club, 1998-present
Faculty Advisor, Student Association for Global Awareness, 2000-present

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CURRICULUM VITAE

Jerry Callis

Education Auburn University, D.V.M., 1947
Purdue University, M.S., 1949

Work Experience

Entire professional career was with United States Department of Agriculture (USDA), 1947 through 1988
1947-1949, Work/Study, Purdue University
1949-1951, Work/Study, Veterinary Laboratory, Amsterdam
1952-1988, USDA laboratory at Plum Island

At this laboratory I held positions of investigator to in-charge of research, to Assistant Director to Director (1963-1986). The last 2 years, I was senior scientific advisor. As director of Plum Island (1963-1986), I was responsible for scientific and administrative direction for USDA program of diagnosis and research on animal diseases not present in the United States. As senior scientific advisor, I was responsible for advising two agencies of USDA, Agricultural Research Service and Animal and Plant Health Inspection Service, on several animal health programs including those at the international level.

Membership in Professional Organizations

American Veterinary Medical Association
U.S. Animal Health Association
American Association for the Advancement of Science
American College of Veterinary Microbiologists (Diplomate)

Committees Served

Pan-American Health Organization, Scientific Advisor
International Exchange of Fellows, Fulbright, 1972-1975
National Academy of Sciences, Institution of Laboratory Animal Resources
Board of Governors, American Association of Veterinary Lab. D.
Editorial Board, Elsevier Press, Dr. of Veterinary Microbiology
Rockefeller Foundation, Advisor, Tropical Animal Diseases
New York State Veterinary College, Cornell University Board of Advisors
IICA, RDNA Advisory Committee
FAO, Several advisory groups, the most recent being Survey Animal Health Vaccines in China

Honors

Doctor of Science, Purdue University, 1979
Doctor of Science, Long Island University, 1980
Distinguished Service Award, USDA, 1988
AVMA-XII, International Veterinary Congress Award

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Civic Contributions

Boy Scouts, Cub Master, 1964-1967
Board of Trustees, Eastern Long Island Hospital, 1968-1978

Scientific Contributions

Numerous (approx. 100) contributions to Journals, Annuals, and Books

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CURRICULUM VITAE

Ms. Regina Kowalski
Defense Intelligence Agency

CV Not Available.

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NAME: Thomas G. Ksiazek

BUSINESS ADDRESS:

Chief, Disease Assessment Section
Special Pathogens Branch, G14
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

EDUCATION:

1964-1969	B.S., Biological Sciences Kansas State University, Manhattan, Kansas
1966-1970	D.V.M., Kansas State University, Manhattan, Kansas
1974-1976	M.S., Virology, University of Wisconsin, Madison, Wisconsin
1980-1983	Ph.D., Epidemiology/Virology, University of California, Berkeley, California

PROFESSIONAL EXPERIENCE:

1970	Associate Veterinarian, Adirondack Animal Hospital, Glensfalls, New York
1971	Base Veterinarian, Sheppard Air Force Base, Texas
1971-1974	Chief, Veterinary Services, Royal Air Force Chicksands, United Kingdom
1974-1976	Air Force Institute of Technology, Civilian Institution Graduate Program, University of Wisconsin, Madison, Wisconsin
1976-1978	Head, Virology Division, Department of Microbiology, U.S. Naval Medical Research Unit No. 2, Taipei, Taiwan, Republic of China
1978-1980	Head, Zoonoses Department, U.S. Naval Medical Research Unit No. 2, Jakarta Detachment, Jakarta, Republic of Indonesia
1980-1983	Air Force Institute of Technology, Civilian Institutions Graduate Program, University of California, Berkeley, California
1983-1984	Veterinary Microbiologist, USAMRIID, Fort Detrick, Maryland
1984-1986	Deputy Head, Virology Department, U.S. Naval Medical Research Unit No. 3, Cairo, Arab Republic of Egypt
1986-1988	Veterinary Microbiologist, Disease Assessment Division, USAMRIID, Fort Detrick, Maryland

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1988-1991	Chief, Rapid Diagnosis Section, Department of Epidemiology, Disease Assessment Division, USAMRIID, Fort Detrick, Maryland
1991-present	Chief, Disease Assessment Section, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia
Aug 2000-present	Acting Chief, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia

MEMBERSHIP IN ACADEMIC AND PROFESSIONAL SOCIETIES:

American Society of Tropical Medicine and Hygiene
American Society for Microbiology
American Association for the Advancement of Science
Phi Zeta
American Veterinary Medical Association
Society of Tropical Veterinary Medicine

SERVICE AND CONSULTING:

1987	BOSTID Program, National Science Foundation: Epidemiology and Diagnosis of Arthropod-borne Viruses, Bangkok, Thailand
1990	APHIS, USDA: Equine Encephalitis in the Americas
1991	CDC, Atlanta: Crimean-Congo Hemorrhagic Fever diagnostic techniques
1994	ASM, ICAAC, Workshop on Hantavirus Diagnosis
1995	Australian Animal Health Laboratory, Biosafety Level-4 familiarization and training, Geelong, Australia
1995	Filovirus Investigation Planning, Ivory Coast, WHO, Geneva
1993-1996	Chairman, American Committee on Arthropod-borne Viruses
1997	*Ad hoc* editor, *Biosafety in Microbiological and Biomedical Laboratories* (CDC NIH Safety manual)
1999	Member, Review Panel, National Wildlife Health Center (USGS), Madison, WI
1998-2000	Member, Peer Review Panel, Military Infectious Diseases Research Program (Virology)
1999-2000	Member, Advisory Committee, Design of new BSL-4 laboratory, University of Texas Medical Branch, Galveston, Texas

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2000-	Member, USDA (ARS/APHIS) Biocontainment Advisory Committee
2000-	Member, Interagency Working Group on Biosecurity (USDA, DOD, HHS, DOJ).

HONORS AND ACCOMPLISHMENTS:

1970	High score, National Veterinary Board
1971	Veterinary Officer Basic Course (Honor Graduate)
1974	Squadron Officer School, Air University, Maxwell Air Force Base, Alabama (Distinguished Graduate)
1983	The Margaret Beattie Award for Excellence in Laboratory Science, School of Public Health, University of California, Berkeley, 3 June 1983
1990	The Army Surgeon General's Award of an "A" skill identifier for Veterinary Microbiologists
1990	Department of the Army Research and Development Achievement Award for Technical Achievement.
1992	Pekka Halonen Award for Diagnostic Virology, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention
1995	Founders Lector, American College of Veterinary Preventive Medicine
1996	Stitt Lecture, Association of Military Surgeons of the United States
1997	Senior Biological Research Service, CDC, USPHS

LICENSES:

Veterinary Medicine: Colorado

RESEARCH INTERESTS:

Epidemiology and ecology of the viral zoonoses
Diagnosis of viral diseases

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CURRICULUM VITAE

Name: Linda L. Logan

Office Address: Texas Animal Health Commission
2105 Kramer Lane
Austin, TX 78758

EDUCATIONAL BACKGROUND

1987	Doctor of Philosophy, Comparative Pathology, University of California, Davis, California
1983-1986	Postdoctoral Research, USDA, Plum Island Animal Disease Center, Cooperative Agreement with the University of California, Davis, California
1980-1982	Postdoctoral Fellowship, National Cancer Institute, Veterinary Pathology, University of California, Davis, California
1973-1976	Doctor of Veterinary Medicine, Texas A&M University, College Station, Texas
1972-1973	Master of Science, Veterinary Parasitology, University of Georgia, Athens, Georgia
1967-1971	Bachelor of Science, Zoology, Texas Tech University, Lubbock, Texas
1967	Diploma, American Community School, Addis Ababa, Ethiopia

WORKING RESEARCH EXPERIENCE

September 2000 - Present	Executive Director Texas Animal Health Commission Austin, Texas
January 1996 - September 2000	National Program Leader for Animal Health, National Program Staff U.S. Department of Agriculture, Agricultural Research Service, Beltsville, Maryland
February 1994 - December 1995	Program Area Leader, Host Resistance and Immunity, Trypanosomiasis Program, International Laboratory for Animal Disease Research (ILRAD), Nairobi, Kenya.
November 1991 - December 1995	Project Leader, Mechanisms of Anemia, Trypanosomiasis Program, ILRAD
February 1994 - December 1995	"Acting" Project Leader, The Role of T-cells and B-cells in Resistance to Bovine Trypanosomiasis, Trypanosomiasis Program, ILRAD

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April 1987 - November 1995	Scientist, Veterinary Pathology, ILRAD, Nairobi, Kenya
January 1983 - December 1986	Postdoctoral Research, USDA - ARS Plum Island Animal Disease Center, Greenport, New York
September 1978 - August 1980	Assistant Professor, Texas Agricultural Experiment Station, College Station, Texas
April 1977 - April 1980	Veterinary Parasitologist, Texas A&M University Contract, Tsetse Trypanosomiasis Research and Training Project, Bamako, Mali
September 1976 - April 1977	Research Associate, Institute of Tropical Veterinary Medicine, Texas A&M University, College Station, Texas
September 1974 - April 1976	Laboratory Assistant, Department of Veterinary Parasitology, College of Veterinary Medicine, Texas A&M University, College Station, Texas
January 1972 - August 1973	Graduate Research Assistantship, Department of Veterinary Parasitology, College of Veterinary Medicine, University of Georgia, Athens, Georgia
September - December 1971	Teaching eighth grade mathematics and science to my sister in Zaria, Nigeria
June - September 1971	Voluntary work and research in the Department of Veterinary Parasitology, College of Veterinary Medicine, Ahmadu Bello University, Zaria, Nigeria

APPOINTMENTS

Chair, Texas Foreign Animal Disease Working Group, Texas Emergency Management Council
Adjunct Professor, Department of Pathobiology, College of Veterinary Medicine, TAMU
TVMA Research Committee
TVMA Emergency Preparedness Committee
Member of USDA APHIS Veterinary Services Safeguarding Animal Health Review Team 2001-Present
ARS National Program Leader of Animal Health, 1996-2000
Team Member of ARS National Programs:
- Animal Health
- Animal Genome, Germplasm, Reproduction and Development
- Arthropod Pests of Animals and Humans
- Animal Well-Belling and Stress Control Systems
- Aquiculture
- Food Safety

National Animal Health Emergency Management Steering Committee
Member of the U.S. Delegation to the O.I.E. (World Animal Health Organization), May 15-21, 1999, Paris, France.
Co-Chair USDA Liaison Committee to the Animal Agriculture Coalition on Biocontainment, 1997-2000
Chair, Industry-Agency Scrapie/BSE Consultants Working Group, 1996-2000
Co-Chair of the Research Committee, National Working Group on Johne's Disease, 1996-2000
Member, USAHA Blue Ribbon Task Force for Vesicular Stomatitis, 1996-present

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Adjunct Professor, Department of Pathology, Virginia Maryland Regional College of Veterinary Medicine, Virginia Tech, Blacksburg, Virginia, 1993 - 1997
Chairman of the ILRAD Executive Staff Council 1994 -1995

ARS HONORS and AWARDS

Certificate of Merit, 2000: For excellent communication with stakeholders and customers of National Program 103.
Certificate of Appreciation, 2000: Communicating Animal Health Research Needs.
Certificate of Merit, 1999: For excellence in communicating with customers and stakeholders of the national program on animal health.
Certificate of Appreciation 1999: For extra effort and teamwork displayed working on the National Animal Health Monitoring System Review. APHIS, December 1999.
"Spot Award" 1999: North Atlantic Area Director for organization of an external review for the Plum Island Animal Disease Center and support to the program.
Certificate of Merit, 1998: For extra effort in developing the extensive network of communication that has enhanced the relationship of ARS with the agencies it supports and with its customers.
Time Off Award, 1998: 16 hours
Certificate of Merit, 1997: In recognition of excellence in communicating the priorities of ARS animal disease research.
Time Off Award, 1997: 32 hours
Certificate of Merit, 1996: In recognition of unique contribution in establishing an international symposium on bovine spongiform encephalopathy and scrapie, identifying the status and improving communications among regulatory agencies and commodity groups.

TEXAS A&M UNIVERSITY 1973-1976

Chairman, Honor Code Committee (1974 - 1975, 1975 - 1976)
Class Rep. to Student-Faculty Relations Committee (1974 - 1975, 1976)
Cum laude graduate, College of Veterinary Medicine, TAMU (1976)
AVMA Women's Auxiliary, Outstanding Achievement Award, Texas (1976)
Judge Marvin Jones Loan and Scholarship
Distinguished Student

TEXAS TECH UNIVERSITY 1967-1971

Dean's List
Alpha Chi Omega, Most Valuable Active (1971)
Beta Beta Beta (Biological Society Honorary Organization)
Student Union: Trophy Award (1970), Life Past Award (1971)
All University Recognition for Leadership (1969 - 1970, 1970 - 1971)
Who's Who in American Colleges and Universities (1970 - 1971)

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ASSOCIATION MEMBERSHIP

American Association of Veterinary Diagnosticians
American Association of Veterinary Immunologists
American Association of Veterinary Parasitologists
American Society of Rickettsiology
American Society of Tropical Medicine and Hygiene
American Veterinary Medical Association
American Association for the Advancement of Science
American Association of Bovine Practitioners
California Veterinary License
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary
...and Comparative Pathology 1987-1999
International Society of Animal Clinical Biochemistry
Kenya Veterinary Association 1987-1995
Society for Tropical Veterinary Medicine
Texas Veterinary License
Texas Veterinary Medical Association
U.S. Animal Health Association, Committee for Foreign Animal Diseases and
Committee for Sheep and Goats
Assembly of State Veterinarians

REVIEW PANELS

USDA APHIS Veterinary Services Animal Health Safeguarding Review, Exclusion Committee

Review all the ARS Animal Health Research Project Proposals on a 5-year cycle and provide comments and final approval.

Serve as a reviewer for ARS scientists performance as part of the Research Peer Evaluation System (RPES) used as a basis for grade promotion.

Plum Island Facilities Review Panel, meets twice a year.

ARS reviewer for a number of field research programs nationally and internationally in animal health, arthropod pests, animal production, and food safety.

Manuscript reviewer for *Journal of Wildlife Diseases*, *Journal of the American Society of Tropical Medicine and Hygiene*, *Theriogenology*, *Acta Tropica*, and *Journal of Clinical Immunology*.

Review of manuscripts for ARS scientists for subject matters classified as sensitive issues.

Chaired the peer review panel for animal and plant health proposals submitted to the Foreign Agriculture Service (FAS), USDA Scientific Cooperative Program, 1996.

Ad hoc reviewer for the National Research Initiative, Animal Health, Cooperative State Research and Extension Service (CSREES), USDA grants, 1998, 1999 and FAS grant proposals.

Panel participant for several programs within the USDA Animal Plant and Health Inspection (APHIS) on emerging disease and exotic animal disease issues such as BSE, scrapie, classical swine fever and vesicular stomatitis.

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Review Panel of the USDA APHIS national epidemiological surveillance program, i.e. National Animal Health Monitoring System (NAHMS) of APHIS.

Chair - Workshop on Cytokine and Cytokine Receptor Assays. International Symposium: Cytokines and the Type I, Type II Paradigm, Cairns, Australia, October 25-30, 1996.

Chair, External review team for the United Nations International Atomic Energy Agency, Vienna, October, 1997. Reviewed and declared the success of the IAEA tsetse fly sterile male release program on Zanzibar, Tanzania. Recommendations were made for continued parasitological and tsetse monitoring and surveillance for 2 years after sterile tsetse fly release discontinuation.

Chair for the Pre-harvest Food Safety Review Sessions on "Immunological Approaches to Pathogen Control and Preharvest Intervention Strategies." 19th Annual USDA Food Safety Research Planning Meeting, Athens, Georgia, December 1-3, 1998.

One of the three ARS scientists sent to Russia in September 1998 with representatives from the Department of State and Department of Defense representatives to initiate a new program of research between ARS scientists and Russian scientists formerly engaged in bioweapons development. This program of research has grown to $7,550,000 in FY2000 and will require several more trips to Russia and former states of the Soviet Union such as Kazahkstan. Second trip to Russia in October 1999. Eight projects in Animal Health identified for collaboration.

Chair for the session on *E. coli* O157:H7 on the farm. ARS Cattle Food Safety Pathogen Workshop. U.S. Meat Animal Research Center, Clay Center, Nebraska, June 17-18, 1998.

Chair, USAID External Peer Review Panel of the safety of release of the double recombinant vaccinia-rinderpest vaccine, June 2-4, 1999.

Chair, Workshop on Comparative Erythropoiesis, Gordon Research Conference, August, 1999.

Organized and hosted the National Animal Health Research Workshop for the Agricultural Research Service -USDA, September 21-24, 1999.

Organized and hosted an Animal Immunology Workshop for ARS scientists, March 27, 28, 2000.

Chaired Disease Session at World Buiatrics Congress, December, 2000, Punta del Este, Uruguay.

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CURRICULUM VITAE

Dr. N. James MacLachlan

NAME	POSITION TITLE
N. James MacLachlan	Professor and Chair

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
Massey University, New Zealand	BVSc	1976	Veterinary Medicine
University of Missouri, Columbia	MS	1979	Veterinary Virology
University of California, Davis	Dip ACVP	1982	Anatomic Pathology
University of California, Davis	PhD	1983	Comparative Pathology

RESEARCH AND PROFESSIONAL EXPERIENCE

1976 – 1977	Junior Lecturer, Department of Veterinary Pathology, Faculty of Veterinary Science, Massey University
1977 - 1979	Teaching Associate, Department of Microbiology, School of Veterinary Medicine, University of Missouri
1979 - 1982	Research Associate, Department of Pathology, School of Veterinary Medicine, University of California
1982 - 1988	Assistant/Associate Professor, Department of Microbiology, Pathology, and Parasitology, College of Veterinary Medicine, North Carolina State University
1989	Panel member USDA Special Research Grants Program
1991	Panel Manager, Molecular and Cellular Basis of Disease, USDA Competitive Grants Program
1992	Chair of the Faculty, School of Veterinary Medicine, University of California
1993	Norden Distinguished Teaching Award, School of Veterinary Medicine, University of California
1995, 1998	Panel member, Molecular and Cellular Basis of Disease (Virology), USDA Competitive Grants Program
1996, 97, 98	Scientific advisor to U.S. Trade Negotiating Teams in Agriculture with the People's Republic of China
1997	Panel member, Livestock/Aquaculture panel, Fund for Rural America
1998	President, American College of Veterinary Pathologists
1988 – present	Associate/Full Professor of Veterinary Pathology, School of Veterinary Medicine, University of California
1993 - present	Chair, Department of Pathology, Microbiology & Immunology, University of California (Acting 91,93,94)

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CURRICULUM VITAE

NAME: John Charles Morrill
LTC, U.S. Army
Veterinary Corps

Area of Interest: Virology

BUSINESS ADDRESS: Commander
South Plains District Veterinary Command
Attn: MCVS-GPP-C
80th & Engineer Dr., Bldg 4905
Fort Hood, TX 76544-4752

EDUCATION:

1964-1968 Texas A&M University, College Station, Texas,
College of Science, B.S., Animal Science

1968-1971 Texas A&M University, College Station, Texas,
College of Veterinary Medicine, D.V.M.

1980-1983 Texas A&M University, College Station, Texas,
College of Veterinary Medicine,
Ph.D., Veterinary Microbiology

PROFESSIONAL EXPERIENCE:
1999-Present

Commander
South Plains District Veterinary Command
Attn: MCVS-GPP-C
80th & Engineer Dr., Bldg 4905
Fort Hood, TX 76544-4752

Serves as Commander of the South Plains District Veterinary Command. Supervises approximately 62 military and 30 civilian personnel who provide veterinary services for Army, Navy, and Air Force installations located in 4 states. Manages food safety, animal medicine, veterinary preventive medicine programs, and human-animal bond programs throughout the District. Coordinates with federal, state, and local health and regulatory agencies on health-related issues. Provides administrative support to 3 District Branch offices and 6 Section offices. Serves as Veterinary Staff Officer for III Corps and Fort Hood and as Foreign Animal Disease Diagnostician member of Great Plains Regional Veterinary Command Special Medical Augmentation Response Team-Veterinary.

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1995-1999

Chief, Diagnostics Section
DoD Veterinary Laboratory
Attn: MCVS SCL
2472 Schofield Rd. Bldg. 2632
Fort Sam Houston, TX 78234-6232

Serves as Deputy Laboratory Director and Chief, Diagnostics Section, supervising 5 civilian laboratory supervisors and technicians. Responsible for diagnostic and serologic assays for zoonotic diseases to include rabies, Q-fever, brucellosis, leptospirosis, and toxoplasmosis. Assays are also performed for the detection of antibodies to babesia, ehrlichia, equine infectious anemia, rocky mountain spotted fever, bluetongue virus, Borrelia, and typhus. Performs fluorescent antibody virus neutralization test (FAVN) in support of Hawaii's modified rabies quarantine program. Responsible for the implementation of molecular biologic techniques, where practical and applicable, to enhance diagnostic capabilities. Implemented electronic data capture to increase efficiency of data handling and security. Serves as a consultant to the Military Working Dog Medical Records and Gulf War Projects. Advisor to Operation Baker Lifeline in support of the U.S. Army PACOM's Expanding Relations Program with the PDR Laos. Foreign Animal Disease Diagnostician (FADD).

1992-1995

Chief, Applied Research Division
U.S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21702-5011

Served as Chief of a medical research division composed of 64 civilian and military professional, technical, and support staff assigned to five branches (Rapid Diagnosis, Preventive Medicine, Epidemiology, Aerobiology, and Clinical Immunology), with an annual budget of $2.6 million. Implemented the Biological Defense Research Program by developing field-deployable rapid diagnosis tests, determining aerosol transmission characteristics of threat agents, defining risk of endemic diseases, and developing vaccination strategies. Successfully applied remote sensing and Geographical Information Systems (GIS) to field investigations of viral disease outbreaks in Florida and eastern Africa. Directed investigations, managed budget, supervised and evaluated senior staff, allocated resources, reported progress, and served as a technical expert for the United States Army Medical Research and Development Command. Served as WHO Consultant to Eastern Mediterranean Regional Office on Rift Valley fever during the RVF outbreak in Egypt in 1993. Member of WHO Working Group on Rift Valley fever virus.

1988-1992

Department of Pathogenesis and Immunology
Disease Assessment Division
U.S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21702-5011

Served as research virologist responsible for development and testing of vaccines against high hazard viral agents of military relevance. Responsible for all preclinical testing of a mutagen-attenuated Rift Valley fever vaccine for use in humans. Wrote and assembled investigational new drug application (IND) that was approved and allowed Phase I/II clinical testing of the mutagen-

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attenuated Rift Valley fever vaccine. Conducted epidemiologic studies on Marburg virus outbreak in western Kenya. Conducted virologic and serologic surveys of bats, wild rodents, and birds that included trapping or mist netting, identifying, and collecting blood and selected tissues.

1986-1988

Head, Virology Department,
U.S. Naval Medical Research Unit #3,
Cairo, Egypt

Served as Head of Virology Department, which consisted of two other senior American scientists, three senior and four junior Egyptian scientists, and a technical staff of eight Egyptian Nationals and one Navy corpsman. Responsible for country-wide epidemiologic studies on HIV and arboviral infections in Egypt. Conducted virologic and serologic surveillance for arboviral and rickettsial agents in Egypt, Sudan, Somalia, Djibouti, and Kenya. Studies in[illegible]ved trapping, netting, identifying, data recording, bleeding, and collecting tissues from birds [illegible] wild mammals. Conducted annual week-long training seminar on HIV diagnostics for northeastern African nations. While under my direction the Virology Laboratory was recognized [illegible] the Egyptian Ministry of Health for its outstanding contributions [illegible] rch and [illegible] World Health Organization as a "WHO Reference Center for HIV [illegible] dle East region.

1983-1986

Department of Pathogenesis and Immunology
Disease Assessment Division
U. S. Army Medical Research Institute of Infectious Diseases
Fort Detrick, MD 21701

Planned, organized, and conducted studies on the epidemiology [illegible]ogene[illegible] [illegible]laxis treatment of Rift Valley fever virus (RVFV) infections. Devel[illegible] [illegible]oph[illegible] [illegible]ue regimens for the use of recombinant human interferons in Rift [illegible] [illegible]s infec[illegible] Evaluated novel RVFV vaccines (i.e., mutagen-attenuated virus vaccines [illegible]d vaccinia recombinant vaccines). Responsibilities included training of technical staff; co[illegible]ting, processing, and assaying specimens for virus, viral antigen, antibody, and in[illegible]; collecting, analyzing, interpreting, presenting, and publishing research data; BSL-3 level containment laboratory supervisor; acquisition of computer workstations and training of technical staff in their use.

1980-1983

U. S. Army-sponsored graduate student
Texas A&M University
Department of Veterinary Microbiology
Ph.D. Thesis: Pathogenesis of Quadritypic Bluetongue
Virus Infection in Cattle (1984)

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1978-1980

Deputy for Veterinary Activities and Officer-in-Charge
Food Hygiene Safety Quality Assurance Branch
U. S. Army Medical Department Activity
Fort Hood, Texas

Managed zoonotic disease surveillance and prevention program, responsible for rabies control program, conducted epidemiologic investigations of food-borne illnesses, and managed food safety and quality assurance program in support of a troop population of approximately 45,000 active duty personnel.

1975-1978

Owned and operated private veterinary hospital in Gatesville, Texas

Veterinary practice in rural central Texas included livestock and pets. Special emphasis on herd health programs for dairy cattle, beef cattle, dairy goats, sheep, swine, and brood mare operations.

1973-1975

Officer-in-Charge
Animal Care Branch
U. S. Army Medical Department Activity
Fort Hood, Texas

Managed rabies control and zoonotic disease prevention and surveillance programs. Duties included public education on prevention of zoonotic disease and food-borne illnesses, plague surveillance in cooperation with the Texas Department of Public Health, and arthropod-borne viral disease surveillance in collaboration with the Centers for Disease Control, Fort Collins, Colorado.

1971-1973

Officer-in-Charge
Veterinary Food Inspection Service
Kansas City, Missouri

Supervised inspection of government-owned subsistence and sanitation practices in U. S. government regional food storage warehouses in and around the Kansas City area. Responsibilities included food and sanitation inspections of more than 100 food-processing plants located throughout western Missouri and eastern Kansas.

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PROFESSIONAL ORGANIZATIONS:

American Veterinary Medical Association
American Society of Tropical Medicine and Hygiene
American Society of Tropical Veterinary Medicine
Phi Zeta
Phi Sigma
U.S. Animal Health Association

AWARDS AND HONORS:

Navy and Marine Corps Medal for Heroism
Meritorious Service Medal (5)
Army Commendation Medal (2)
Army Achievement Medal (2)
Army Superior Unit Award
Outstanding Volunteer Service Medal
National Defense Service Ribbon (2)
Humanitarian Service Medal
Army Service Ribbon
Overseas Service Ribbon
Expert Field Medical Badge
Army Science Conference award, West Point, New York, 1986
"A" proficiency designator - Microbiology
Fort Detrick Outstanding Man of the Year Award – 1994
Order of Military Medical Merit - 1998

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CURRICULUM VITAE

Kenneth E. Olson, Ph.D., PAS

EDUCATION:

University of Wisconsin-Madison
Ph.D. in Dairy Science (Dairy Cattle Breeding) 1976
Minors in Genetics and Statistics
M.S. in Dairy Science 1972
University of Wisconsin-River Falls
B.S. in Animal Science (Dairy Option) 1969
Minor in Mathematics

HONORARY SOCIETY MEMBERSHIP:

Alpha Zeta (Agriculture)
Kappa Mu Epsilon (Mathematics)

COMMUNITY SERVICE:

Member of Lord of Life Lutheran Church
Member of Church Council (2 terms) - President (4 years)
Co-Chair Capital Fund Appeal - 2001
Chairman of Computer Committee, Lord of Life
Delegate to Metro-Chicago Synod Convention - 3 years
Metro Chicago Synod Nominating Committee
Elected as voting member from Metro Chicago Synod to 2003 National Assembly
Past Treasurer, Board of Directors for the Resource Office for Social Ministry, Lexington, KY
Schaumburg Township District 54 PTA -Scholarship Committee
Schaumburg Township District 54 - Reporting to Parents Committee
Conant High School Booster Club - Member of Audit Committee

WORK EXPERIENCE:

Employment:

April 2001 – Present Principal - KEO Consulting (Dairy & Animal Health)
Project Leader for FASS/ARPAS Animal Care Project, served as member of Response Committee for the APHIS Safeguarding Review, analysis of dairy policy options for the Farm Bill, project coordination for publication of "Understanding Forage Quality," development of Johne's CD and industry communication on animal disease emergencies.

1989-April 2001 Dairy and Animal Health Specialist - AFBF
I served as the Dairy and Animal Health Specialist in the Public Policy Division of the American Farm Bureau Federation. I also worked in the areas of Animal Welfare, Agricultural Research, Food Safety (Animal issues) Biotechnology, and Hay and Forage. I served as the primary national resource person for the organization in these areas. In this role I provided information to state Farm Bureaus on these issues, developed comments and testimony as needed and served as a liaison with industry groups and governmental agencies.

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Employment (continued):

1987-89	Ext. Professor - Univ. of Kentucky
1981-87	Associate Ext. Prof. - Univ. of Kentucky
1977-81	Assistant Ext. Prof.- Univ. of Kentucky

Extension: I was employed as an extension dairy specialist with the Cooperative Extension Service, University of Kentucky from January 1977 through January 1989. My major emphasis was the Dairy Herd Improvement (DHI) program. I had responsibility for educational aspects of the program and served as an advisor to the state board of directors. I assisted in hiring of the management and laboratory personnel. I also had responsibilities for extension work in dairy cattle breeding and work with microcomputer applications.

Teaching: While I had no teaching component in my appointment, I did assist in teaching two courses; providing lectures on genetics and dairy sire selection for ASC 462 Artificial Insemination and Fertility of Farm Animals, and microcomputer use in ASC 420 Dairy Cattle Science.

Research Areas:

- Effect of days open on persistency in dairy cattle
- Effect of DHI management factors on production
- Effect of shipment on DHI milk samples
- Relationship of somatic cell counts to production
- Estimation of genetic trend in Wisconsin Holsteins from 1952 to 1972 using DHI records
- Estimation of the effect of two levels of nutrition, two genetic groups and two reproductive management systems on production and efficiency in dairy cattle

MEMBERSHIP AND ACTIVITIES:

National: National Institute for Animal Agriculture (formerly the Livestock Conservation Institute (LCI))

- Chairman, Board of Directors
- Vice-Chair of the Board of Directors
- Secretary of the Board of Directors

National Livestock Ethics Council

- Member of the Board of Directors

National Coalition for Food and Agricultural Research (N-CFAR)

- Member of Operations Committee

U.S. Animal Health Association

- Member of the Board of Directors
- Vice-chair District at Large

National Johne's Working Group

- Chair of Economics Subcommittee
- Treasurer for Working Group
- Chair Industry Implementation Committee

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MEMBERSHIP AND ACTIVITIES: (continued)

National Animal Health Emergency Management (NAHEM) Steering Committee
- Member of Education and Meetings Committees
- Member of the U.S. delegation for the "Tripartite Exercise 2000" on Foot and Mouth Disease

Dairy Quality Assurance Program
- Chair of the Board of Trustees
- Editor of Dairy Care Materials

Agricultural Databases for Decision Support (ADDS)
- Member Board of Directors (1999 - present)
- Editor - Genetics section of National Dairy Database

Member of McDonald's Animal Welfare Council
- This group advises McDonald's Corporation on animal welfare issues.

Member U.S. Dairy Forage Research Center Stakeholder Advisory Committee

Member of the Response Committee of the National Association of State Department of Agriculture's Animal Safeguarding Review

Member of USDA review panels for the U.S. Dairy Forage Research Center and the National Animal Health Monitoring System (NAHMS) of the Animal and Plant Health Inspection Service (APHIS) and selection committee for the director of the Center for Epidemiology and Animal Health (CEAH)

Executive Planning Committee for Food Animal Integrated Research (FAIR) 2002

Member American Dairy Science Association
- Member of Animal Care Committee (1996 - 1999)
- Chairman ADSA Microcomputer Subcommittee (1983-1985)
- Vice Chairman ADSA Microcomputer Subcommittee (1982-1983)
- Secretary ADSA Microcomputer Subcommittee (1987-88)

Member of:
- American Registry of Professional Animal Scientists
- Council for Agricultural Science and Technology (CAST)
- National Mastitis Council
- American Forage and Grassland Council
- Dairy Shrine

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CURRICULUM VITAE

Jean L. Patterson

EDUCATION:	Degree	Year	Major
Miami University, Oxford, Ohio	B.A.	1975	Zoology
University of Notre Dame, Notre Dame, Indiana	Ph.D.	1979	Biology

POSTDOCTORAL TRAINING:

1979 - 1980	NIH Postdoctoral Trainee, Department of Biochemistry, University of Wisconsin, Madison, Wisconsin
1980 - 1981	NIH Postdoctoral Fellow, Department of Biochemistry, University of Wisconsin, Madison, Wisconsin
1981 - 1984	Research Associate, Department of Microbiology, University of Geneva Medical School, Geneva, Switzerland

PRESENT POSITIONS:

1996 - present	Chairman, Department of Virology and Immunology, Southwest Foundation for Biomedical Research, San Antonio, Texas
1996 - present	E.M. Stevens Chair for Biomedical Research, San Antonio, Texas
1996 - present	Adjunct Professor, Department of Microbiology, The University of Texas Health Science Center at San Antonio, San Antonio, Texas
2000 - present	Member, Technology Area Review and Assessment (TARA), Department of Defense
2000 - present	Member, Graduate Faculty at University of Texas Health Science Center, Department of Microbiology
2000 – present	Member, NIH COBRE (Center of Biomedical Research Excellence)
2000 – present	Member, Biomedical Review Panel, Department of Defense

PREVIOUS POSITIONS:

1984 - 1986	Instructor, Department of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts
1986 - 1991	Assistant Professor of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts
1984 - 1996	Scientific Associate, Department of Medicine (Infectious Diseases), Children's Hospital, Boston, Massachusetts
1991 - 1996	Associate Professor, Department of Microbiology and Molecular Genetics, Harvard Medical School, Boston, Massachusetts

PROFESSIONAL SOCIETIES:

1976 Society of Sigma Xi
1986 American Society for Virology (ASV)
1989 American Society of Tropical Medicine and Hygiene (ASTMH)
1990 International Society for Antiviral Research

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1990 American Society for Biochemistry and Molecular Biology (ASBMB)
1993 American Society for Microbiology (ASM)
1997 American Association for the Advancement of Science (AAAS)
1997 Society for the Advancement of Chicanos and Native Americans in Science (SACNAS)

NATIONAL AND INTERNATIONAL COMMITTEE ASSIGNMENTS:

1988 - 1986	NIH Ad Hoc Study Section for AIDS Program Projects Currently a reviewer for: Journal of Virology, Virology, Journal of General Virology, Molecular and Biochemical Parasitology, Experimental Parasitology, Antiviral Research, American Institute for Biological Sciences
1991 - 1993	Chairman of the Study Group on Protozoal Viruses of the International Committee on Taxonomy of Viruses (ICTV) NIH Special Reviews: Tuberculosis Vaccine Development and Basic Biology and Pathogenesis of Human Tuberculosis
1995 - 1997	Program Steering Committee, American Society of Tropical Medicine and Hygiene NIH Ad HOC Study Sections: NINDS, NIAID

LOCAL COMMITTEE ASSIGNMENTS:

1985 - 1987	Subcommittee on Recombinant DNA, Harvard Medical School, Boston, Massachusetts
1987 - 1996	Committee on Biological Safety, Harvard Medical School, Boston, Massachusetts
1989 - 1990	Committee on Virology Seminar Series, Harvard Medical School, Boston Massachusetts
1989 - 1992	Programs and Admissions, Division of Medical Sciences, Harvard Medical School, Boston, Massachusetts
1990 - 1994	Chairman, Committee on Virology Graduate Admissions, Harvard Medical School, Boston, Massachusetts
1990 - 1993	Chairman, Virology Graduate Advisory Committee, Harvard Medical School, Boston, Massachusetts
1991	Graduate Program Re-evaluation Committee, Harvard Medical School, Boston, Massachusetts
1991 - 1996	Committee on Virology Steering Committee, Harvard Medical School, Boston, Massachusetts

TEACHING EXPERIENCE:

1976 - 1977	Lecturer in Comparative Anatomy and General Biology, University of Notre Dame, Notre Dame, Indiana
1977 - 1979	Lecturer in General Physiology and Comparative Physiology, University of Notre Dame, Notre Dame, Indiana
1985	Lecturer and lab instructor in Pathophysiology of Infectious Diseases Lab, Microbiology 701, Harvard Medical School, Boston, Massachusetts
1986	Lecturer in Seminar in Animal Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1986	Lecturer in Principles of Animal Virology, Virology 101, Harvard Medical School, Boston, Massachusetts
1987	Course Director of Principles of Animal Virology, Virology 101, Harvard Medical School, Boston, Massachusetts

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1988	Lecturer in Molecular Genetics of Neurotropic Viruses, Genetics 710, Harvard Medical School, Boston, Massachusetts
1989	Lecturer in Seminar in Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1990 - 1991	Course Co-Director of Animal Virology, Virology 200, Harvard Medical School, Boston, Massachusetts
1991 - 1993	Course Co-director of Seminar in Virology, Virology 201, Harvard Medical School, Boston, Massachusetts
1992 - 1995	Lecturer in Animal Virology, Virology 200, Harvard Medical School, Boston, Massachusetts
1993	Discussion Leader in Critical Thinking and Proposal Writing/Presentation, Genetics 330, Harvard Medical School, Boston, Massachusetts
1993 - 1995	Chairman, Responsible Conduct of Science Curriculum, Harvard Medical School, Boston, Massachusetts
1994	Lecturer in Basic Mechanisms of Microbiology Pathogenesis, HST 040, Harvard Medical School, Boston, Massachusetts
1996 - 1998	Lecturer in Microbial Pathogenesis, MICR 5031, UTHSC-SA
1997 - 1998	Lecturer in Medical Microbiology, MICR 1005, UTHSC-SA
1999	Lecturer in Virology, MICR 5041, UTHSC-SA

MAJOR RESEARCH INTERESTS:

1. Molecular biology of viruses infecting protozoan parasites
2. Transcription of bunyaviruses
3. Mechanisms of action of anti-viral agents

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CURRICULUM VITAE

Jonathan Y. Richmond, Ph.D.

Education:

1967, Ph.D., Genetics, Hahnemann University, Philadelphia, PA
1964, MS, Genetics, University of Connecticut, Storrs, CT
1962, BA, University of Connecticut, Storrs, CT

Employment:

1990-present: Director, Office of Health and Safety, Centers for Disease Control and Prevention, Atlanta, GA
1990-present: Director, WHO Collaborating Center for Applied Biosafety and Training, CDC, Atlanta, GA
1983-1990: Chief, Safety Operations Section, Occupational Safety and Health Branch, NIH Division of Safety, Bethesda, MD
1979-1983: Biological Safety Officer, Plum Island Animal Disease Center, USDA, Greenport, NY
1969-1979: Research Microbiologist, PIADC, USDA, ARS, Greenport, NY
1967-1969: Post-Doctoral Resident Research Fellow, PIADC, Greenport, NY

Professional Interests:

Biological Safety; General Occupational Safety and Health, including Animal (Bio) Safety; Communication and Training; HIV/AIDS Education (Director of HIV/AIDS Workplace Education, CDC/ATSDR)

Professional Affiliations:

American Biological Safety Association (ABSA)
President 1986-1987; Chesapeake Area Chapter, President 1989-1990; *Anthology* editor
American Society for Microbiology (ASM)
Coordinator Biosafety Workshops (1986, 89, 94, 98, 99)
Member Lab Safety Committee (1993-present)
Chairperson, CDC's National Symposium on Biosafety (1992, 94, 96, 98, 00, 02)

International Consultations:

Laboratory Design Project, San Juan, Puerto Rico: Consult on the design of a BSL-3 laboratory for work with *M. tuberculosis*, 1993-present.

Project RETRO-CI, Abidjan, Côte d=Ivoire, Africa: Design and certification of BSL-3 laboratories for work with *M. tuberculosis*, HIV, and other bloodborne pathogens, 1994.

Plasma-derived Hepatitis B Vaccine Project, Bulandshar, Uttar Pradesh, India: Conduct biosafety evaluation of a new HBV vaccine production facility, an Indo-U.S. vaccine action program, 1994.

Viral Diagnostic Laboratory, Toronto, Canada: Review and public discussion of safety matters associated with a BSL-4 laboratory (glove box line) for work with exotic human pathogens, 1995.

International Center for Diarrheal Disease Research, Dhaka, Bangladesh: Biosafety review, training, containment certification, 1996, 1997.

HIV/AIDS Program, Bangkok, Thailand: Biosafety review, training, containment certification, 1997.

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National Institute of Biologics, New Delhi, India: Biosafety training, new facility review, 1997.

National Institute of Infectious Diseases, Tokyo, Japan: Biosafety facility and program review, training, 1997.

National Laboratories for Human and Animal Health, Winnipeg, Canada: Biosafety facility and program revier, Tier 2 Commissioning phase, 1997.

Selected Honors:

Elected **Fellow**, American Academy of Microbiology (1980).

Presented the **Arnold G. Wedum Distinguished Achievement Award**, the highest honor of the American Biological Safety Association, in recognition of outstanding contributions to biological safety accomplished through teaching, service and leadership (1999).

Selected **Distinguished Fellow**, Centers for Disease Control and Prevention, 2000.

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CURRICULUM VITAE

Reynolds M. Salerno

International Security Center
Sandia National Laboratories
PO Box 5800, Mail Stop 1373
Albuquerque, NM 87185

CURRENT PROFESSIONAL POSITION

Senior Member of the Technical Staff, International Security Center, Sandia National Laboratories, Albuquerque, New Mexico. Since June 1999.

- Program Manager, Biosecurity and Biodefense Initiative
  - Vulnerability analyses, conceptual designs, security systems implementation, security policy and standards development for U.S. Department of Agriculture and U.S. Department of Defense
  - Policy and standards development for international arms control and nonproliferation applications for U.S. Department of Energy
- Member of U.S. Interagency Working Group on Biosecurity

SELECT SANDIA PUBLICATIONS

"Analysis of U.S. Bioterrorism Legislation," Prepared for Office of Nonproliferation Policy, U.S. National Nuclear Security Administration, SAND 2002-forthcoming, July 2002.

"U.S. Laboratory Biosecurity Policy Paper," Prepared for U.S. Office of Homeland Security, SAND 2002-1068P, February 2002.

"Biological Laboratory and Transportation Security and the Biological Weapons Convention," Prepared for U.S. Delegation to the BWC, U.S. Department of State, SAND 2002-1067P, February 2002.

"Enhancing the Security of Dangerous Pathogens: A Workshop Report," Prepared for Office of the Secretary of Defense, U.S. Department of Defense, SAND 2001-0289P, January 2002.

"Mitigating the Threat of Biological Weapons and Novel Infectious Diseases: Real-time Syndromic and Epidemiological Surveillance," Prepared for U.S. Defense Threat Reduction Agency, SAND 2001-2014, July 2001.

"Enhancing the U.S. Response to the Bioterrorist Threat," SAND2000-0076, January 2000.

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EDUCATION

Yale University, Ph.D. in History, 1997; MPhil, 1994; MA, 1992

Middlebury College, BA in History, 1989

SELECT SCHOLARLY PUBLICATIONS

Vital Crossroads: Mediterranean Origins of the Second World War, 1935-1940 (Ithaca, NY: Cornell University Press, 2002).

"Britain, France and the emerging Italian threat in the Mediterranean, 1935-38," in William Philpott and Martin Alexander, eds. *Anglo-French Defence Relations Between the Wars* (London: Palgrave, 2002).

"Italy's pirate submarine campaign of 1937," in Greg Kennedy and Keith Neilson, eds. *Butterfly Wings: Incidents and International Relations, 1795-1940* (New York: Praeger, 2001).

"Global independence versus regional interdependence: France and Italy in the Mediterranean since 1945," in John Hattendorf, ed. *Naval Policy and Strategy in the Mediterranean Sea, Past, Present and Future* (London: Frank Cass, 2000).

"Naval strategy and the origins of the Second World War in the Mediterranean, 1938-40," in William McBride, ed. *New Interpretations in Naval History: Selected Papers from the Thirteenth Naval History Symposium* (Annapolis, MD: NIP, 1998).

"The French navy and the appeasement of Italy, 1937-39," *The English Historical Review* cxii:445 (February 1997).

"Multilateral strategy and diplomacy: The Anglo-German naval agreement and the Mediterranean crisis, 1935-36," *Journal of Strategic Studies* xvii:2 (June 1994).

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Name: Alfonso Torres

Work Address: NYS Animal Health Diagnostic Laboratory
College of Veterinary Medicine
Cornell University
Upper Tower Road
Ithaca, NY 14853

EDUCATION

Academic Degree	Year	Institution
D.V.M.	1968	National University of Colombia Bogota - Colombia **Major:** Veterinary Medicine
M.S.	1971	University of Nebraska-Lincoln Lincoln, NE **Major:** Veterinary Pathology
Ph.D.	1973	University of Nebraska Medical Center Omaha, NE **Major:** Medical Microbiology (Virology)

PROFESSIONAL EXPERIENCE

Title	Dates	Institution
Associate Dean for Veterinary Public Policy, and Director, New York State Animal Health Diagnostic Laboratory	Feb. 2002 to Present	College of Veterinary Medicine Cornell University Ithaca, NY
Deputy Administrator for Veterinary Services and Chief Veterinary Officer	Jan. 1999 to Feb. 2002	U.S. Department of Agriculture Animal and Plant Health Inspection Service Washington, DC
Director, Plum Island Animal Disease Center	Sep. 1996 to Jan. 1999	U.S. Department of Agriculture Agricultural Research Service Plum Island Animal Disease Center Plum Island, NY.
Acting Director, Plum Island Animal Disease Center	March 1996 to Sep. 1996	U.S. Department of Agriculture Agricultural Research Service Plum Island Animal Disease Center Plum Island, NY

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Chief Foreign Animal Disease Diagnostic Laboratory	Oct. 1995 to Sep. 1996	U.S. Department of Agriculture Animal and Plant Health Inspection National Veterinary Services Laboratories Foreign Animal Disease Diagnostic Laboratory Plum Island, NY
Head Diagnostic Services Section	April 1991 to Oct. 1995	U.S. Department of Agriculture Animal and Plant Health Inspection National Veterinary Services Laboratories Foreign Animal Disease Diagnostic Laboratory Plum Island, NY
Manager Virology Development	Dec. 1987 to March 1991	SmithKline Beecham Animal Health (Former Norden Labs) Lincoln, NE
Associate Professor	Oct. 1983 to Dec. 1987	New York State College of Veterinary Medicine Veterinary Diagnostic Laboratory Cornell University, Ithaca, NY
Assistant /Associate Professor	Feb. 1978 to Oct. 1983	Department of Veterinary Science University of Nebraska-Lincoln Lincoln, NE
New Products Manager for Latin America	Apr. 1976 to Jan. 1978	Ames, Company Division of Miles Laboratories, Inc. Cali, Colombia
Assistant Professor	Dec. 1973 to Oct. 1975	Department of Veterinary Science University of Nebraska-Lincoln Lincoln, NE
Graduate Student Fellow	Sep. 1971 to Dec. 1973	Department of Veterinary Science University of Nebraska Lincoln, NE
Instructor (On academic leave)	Jul. 1969 to Aug. 1971	College of Veterinary Medicine & Zootecnics National University of Colombia Bogotá, Colombia
Instructor	Jan. 1969 to Jun. 1969	College of Veterinary Medicine & Zootecnics National University of Colombia Bogotá, Colombia

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OTHER APPOINTMENTS

Adjunct Professor Dec. 1987 to Feb. 2002	New York State College of Veterinary Medicine Cornell University Ithaca, NY
Adjunct Professor Aug. 1989 to Aug. 1997 Lincoln, NE	Department of Veterinary Science University of Nebraska-Lincoln

DESCRIPTION OF PROFESSIONAL EXPERIENCES

Administrative Experience

Private industry

- During my employment with Miles Laboratories, I managed the marketing activities for human diagnostic products throughout Latin America, including preparation of technical information, implementation of marketing plans, and support for sales personnel in 19 countries.

- As a Manager at SmithKline Beecham Animal Health (and its predecessor Norden Laboratories), I coordinated all regulatory licensing of the company's veterinary biologics in the United States and in several European countries. Later, I managed and supervised research and development teams involved in projects dealing with new or improved vaccines for viral and bacterial diseases of domestic animals and livestock.

Academia

- During my years of service at the University of Nebraska, I supervised and managed my own virology and electron microscopy research laboratory. I served the Nebraska Agricultural Experiment Station on several academic committees related to teaching, research, and international programs.

- As faculty at Cornell's College of Veterinary Medicine, I had joint responsibility for the administration of the diagnostic virology services, and financed and managed my own research laboratory. I served on administrative committees of the Diagnostic Laboratory and College, and the search committees for department heads and a dean.

- Serving currently as Associate Dean for Veterinary Public Policy and Director, New York State Animal Health Diagnostic Laboratory, College of Veterinary Medicine at Cornell University.

Public Service

- I managed the USDA's Foreign Animal Disease Diagnostic Laboratory, the leading laboratory in the United States responsible for the diagnosis of exotic animal diseases.

- As Director of the Plum Island Animal Disease Center (PIADC), I was responsible for the administration of an annual budget of approximately $15 million dollars, and 160 employees. PIADC is a complex research, diagnostic, and training center, the premier high security bio-containment laboratory in the United States. While at PIADC, I gained extensive experience on

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the design, operation, and maintenance of high biocontainment (BL-2, BL-3 and BL-3 Ag) facilities. Due to the nature of the mission of PIADC, and its joint operations involving the USDA Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS), I have strong connections with the veterinary diagnostic community and the biomedical research community of the United States, and all major commodity groups representing the U.S. animal industries. I have also cultivated cooperative programs with similar high security animal research centers around the world.

- In my immediate past position as APHIS' Deputy Administrator of Veterinary Services, I was responsible for all aspects related to the animal health safeguarding programs for the U.S. Department of Agriculture. The APHIS Veterinary Services programs under my leadership included approximately 1,400 employees (with over 400 veterinarians) in all 50 states and U.S. possessions, with an annual budget of about $130 million dollars per year. Reporting to me were six units:

  i. Animal Health Programs, a headquarters staff responsible for domestic and foreign animal disease prevention, control, and eradication activities, as well as regulatory oversight of international trade of animals and animal products.
  ii. Field Veterinary Service Programs, organized in two Regional Centers and some 44 state offices, responsible for coordination and management of all field activities in the U.S. and overseas possessions.
  iii. Management and Support Services, a headquarters staff responsible for budget preparation and monitoring, and communications.
  iv. The Centers for Epidemiology and Animal Health at Fort Collins, Colorado, responsible for monitoring the health of the U.S. animal population, the epidemiologic and information systems in support of domestic animal health programs, and for the monitoring and evaluation of emerging animal health issues.
  v. The Center for Veterinary Biologics at Ames, Iowa., responsible for the licensing and other regulatory aspects of all animal biologics and diagnostics marketed in the United States; and
  vi. The National Veterinary Services Laboratories at Ames, Iowa, and Plum Island, New York, responsible for providing diagnostic services for all domestic and foreign animal diseases.

- I served as the Chief Veterinary Officer of the United States before the International Office of Epizootics (OIE) in Paris, France. The World Trade Organization has delegated to the OIE the leadership for the development of international animal health standards for trade in animals and animal products.

For these reasons, I have wide experience in multilateral and bilateral trade negotiations, development of international standards, harmonization activities, and other aspects of international cooperation. As the head of the main regulatory agency for animal health in the United States, I handled multiple complex issues which affect national and international animal health and veterinary practices. I enjoyed effective communication and interaction with domestic and international academic and professional organizations, state government representatives, commodity groups, and industry representatives related to animal products, live animals, or vaccine / biotechnology.

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Academic Experience

- At my *alma mater* in Bogotá, Colombia, I was Instructor for a general veterinary pathology course.
- At the University of Nebraska, I was Assistant Professor, then tenured Associate Professor, responsible for teaching and advising students enrolled in both the pre-veterinary curriculum and animal science department. In addition, I had academic assignments through the Department of Veterinary Sciences and the Institute of Agriculture and Natural Resources (part of the University of Nebraska's Agriculture Experiment Station).

- At Cornell University's College of Veterinary Medicine, I had the opportunity, as Associate Professor, to be active in a variety of the College's committees, including search committees. I was also involved in a variety of international program activities of the College as well as of the University. I frequently lectured in graduate and undergraduate courses.

- While at USDA, I was actively teaching several aspects of foreign animal diseases. I lectured regularly at professional meeting seminars, and at colleges of veterinary medicine in the United States and abroad. I had major responsibility in organization and teaching of comprehensive courses on foreign animal diseases for federal, state, and military veterinarians, for professors of veterinary colleges, and for second-year veterinary students from all U.S. veterinary colleges (Smith-Kilborne Foreign Animal Disease Training). I taught courses on foreign animal diseases at centers in Spain, Argentina, and Colombia, and courses on livestock infectious diseases in many foreign countries.

- In my current work at Cornell University, I am involved in high-level academic administration while maintaining an active participation in lectures dealing with instruction on the awareness and recognition of foreign animal diseases and biosecurity.

Research Experience

- My research experience focused primarily on diseases (mostly viral) affecting poultry, cattle, swine, dogs, and cats, both at the bench level and on host and experimental animals. Researching the clinical pathology of horses and cattle at high altitude led to my D.V.M. degree. I conducted research on a viral disease of poultry for my M.S. degree. Research on a viral enteric disease of pigs was the basis of my Ph.D. project. My academic research experience included work on the pathogenesis (with extensive electron microscopy) and immune response studies of gnotobiotic piglets and calves against rotaviruses and coronaviruses of animal or human origin. I also worked under contract with the National Institutes of Health (NIH) to develop the gnotobiotic piglet as an animal model for human infant rotaviral diarrheas. I gained extensive experience on the use of the technologies required for the delivery and maintenance of germ-free and gnotobiotic calves and piglets. These academic research projects were funded by the Nebraska Agricultural Experiment Station, Cornell University, USDA, NIH, and the World Health Organization.

- At SmithKline Beecham Animal Health, my research activities were directed to the development or improvement of animal vaccines. I led 4 major projects, and supervised more than 25 additional projects related to the pathogenesis and immune response of dogs, cats, and cattle against a variety of infectious diseases.

- As Director of the Plum Island Animal Disease Center, I participated in a variety of research studies on exotic viral diseases of livestock, including aspects of classic pathology, virology, and immunology, as well as research projects involving genetic sequencing, gene cloning and

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expression, gene deletion, gene recombination, and gene reassortment experiments. Some of these activities led to technology transfer efforts from bench research observations to private companies interested in exploiting these findings for commercial purposes.

CURRENT MEMBERSHIP IN PROFESSIONAL SOCIETIES

- American Veterinary Medical Association
- American Association of Veterinary Laboratory Diagnosticians
- Conference of Research Workers in Animal Diseases
- United States Animal Health Association
- American Veterinary Epidemiology Society

MEMBERSHIP IN HONORARY SOCIETIES

- Gamma Sigma Delta - Honor society of agriculture
- Sigma Xi - The scientific society of North America
- Phi Zeta - Honor society of veterinary medicine

HONORS AND AWARDS

- Ralston Purina Award - 1968. Presented to the top ranking graduate of the College of Veterinary Medicine, National University of Colombia.

- National University of Colombia, Post-Graduate Fellowship 1968-1971. Full scholarship to undertake post-graduate studies at the MS level.

- United Nations, FAO Scholarship 1971-1973. Full scholarship to undertake post-graduate studies at the Ph.D. level.

- Academic Tenure granted by the Board of Regents of the University of Nebraska, July 1, 1982.

- Distinguished Alumni Award, given by the Faculty of Veterinary Medicine, National University of Colombia during the 25th class reunion, November 30, 1994.

- Appointed to the Senior Executive Service of the United States of America, September, 1996.

- Recipient of the "Hombre del Campo" (Man of the Field) Award, by the AMEZVELLANOS Veterinary Association, Bogotá, Colombia, March, 1998.

- Special Recognition Award presented by the Colombian Veterinary Medical Association, Bogotá, Colombia, March, 1998.

- Special Recognition Award presented by the Colombian Institute of Agriculture, Bogotá, Colombia, March, 1998.

- Recipient of the 1998 "Daniel E. Salmon" Award, presented by the Secretary of Agriculture, Washington, D.C., June, 1998

- Awarded an Honorary Diploma by the American Veterinary Epidemiology Society, Salt Lake City, UT. July 25, 2000

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FOR OFFICIAL USE ONLY

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Robert M. Wildzunas, Ph.D.

CURRICULUM VITAE

CONTACT INFORMATION

Address:	HQ, U.S. Army Medical Research and Materiel Command Research Plans and Programs (MCMR-PR) 504 Scott Street Fort Detrick, MD 21702-5024

EDUCATIONAL HISTORY

University Of New Orleans / Louisiana State University at New Orleans

Major:	Applied Biopsychology	
Minor:	Mathematics Statistics	
Degree:	M.S. / Ph.D.	1992 / 1993
Thesis:	The effects of mental workload on time estimation.	1992
Dissertation:	Transient deficits in the magnocellular visual subsystem: A possible common etiology for specific reading disability and attention deficit disorder.	1993
Honors:	LSU Neuroscience Center, Research Excellence Award	1991
	Distinguished Graduate Research Fellowship	1989 - 1993
	National Dean's List	1989 - 1993

Auburn University

Dual Major:	Pre-Clinical Psychology and Experimental Psychology	
Dual Minor:	Biology and Anthropology	
Degree:	B.S. with Honors	1986
Honors:	Distinguished Psychology Senior	1986
	Outstanding Sciences Senior	1986
	Chancellor's Scholarship	1983 - 1986
	University Scholar	1983 - 1986
	Dean's List	1983 - 1986

Huntingdon College

Major:	Pre-Medical Studies (Biology concentration)	
Minor:	Psychology	
Honors:	Huntingdon Merit Scholarship	1982

PROFESSIONAL POSITIONS

Assistant Director, Directorate of Research Plans and Programs — 2002 - Present
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702

Deputy Research Area Director, Combat Casualty Care Research Program — 2000 - 2002
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702

Command Psychologist and — 1999 - 2000
Human Factors Psychology Consultant to the Director of Army Safety
Headquarters, Department of the Army, U.S. Army Safety Center, Fort Rucker, AL 36362

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Technical Staff Officer (MRMC-SARDA Pentagon Medical Intern Program) 1998
Office of the Deputy for Medical Systems, Assistant Secretary of the Army (Research, Development, and Acquisition)
Headquarters, Medical Research and Materiel Command, Fort Detrick, MD 21702
Headquarters, Department of the Army, Arlington, VA 22202

Deputy Director, Aircrew Health and Performance Division 1997 - 1999
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Chief, Visual Science Branch (concurrent position with above) 1997 - 1998
Aircrew Health and Performance Division
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Aviation Research Psychologist 1993 - 1997
Visual Sciences Branch, Aircrew Health and Performance Division
U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362

Graduate Research Fellow 1989 - 1993
Department of Psychology, Visual Sciences Laboratory
University of New Orleans, New Orleans, LA 70148

Research Psychologist (ONR-ASEE Faculty Research Program) 1989 - 1991
Human Factors Division, Research Department
Naval Biodynamics Laboratory, NASA Michoud Facility, New Orleans, LA 70189

COMMITTEES and PROFESSIONAL ASSOCIATIONS

MRMC Patent Disclosure and Invention Evaluation Committee	2000 - 2002
American Board of Hypnotherapy	1999 - Present
Chairman, USAARL Human Use Committee, Institutional Review Board	1997 - 1999
Biological Safety Officer, USAARL Radiation Control and Biosafety Committee	1997 - 1999
The Technical Cooperation Program (TTCP)	1997 - 1999
NATO Subgroup U, UTP-7: Human Factors in Aircraft Environments	
U. S. Army Aviation Center, Night Vision Goggles Working Group	1997 - present
Aerospace Medical Association	1994 - present
Scientific Program Committee	1995 - present
Aerospace Human Factors Committee	1995 - present
Science and Technology Committee	1995 - present
Registration Committee (chair elect 1999)	1996 - present
Membership Committee	1997 - present
Army Aviation Association of America	1996 - present
Department of Defense Human Factors Engineering Technical Advisory Group	1994 - present
Chairman: Controls, Displays, and Voice Interactive Systems Working Group	1995 - 1998
Technology Base Executive Steering Committee: Soldier Systems Modeling Working Group	1994 - 1995
21st Century Air Warrior Technical Working Group (Air Warrior Task Force)	1994 - 1995
Association of Aviation Psychologists	1994 - present
Society of Aerospace Physiologists	1994 - present
Aerospace Human Factors Association	1994 - present

PUBLICATIONS, ABSTRACTS, and PRESENTATIONS

Attached Separately (upon request)

This document reflects the opinions of SAIC and the independent Executive Panel and should not be construed as the official position of the USDA.

MILITARY TRAINING

Joint Operations Medical Managers Course, Fort Sam Houston, TX
Aircraft Mishap Investigation and Prevention - Clinical Psychologist, Brooks AFB, TX
Combined Arms and Services Staff School (CAS3), 98-02, Fort Leavenworth, KS
Aviation Accident Prevention Management Course, 011 D2197, USAAVNC, Fort Rucker, AL
Combat Casualty Care Course, 97-006, Camp Bullis, TX
Army Medical Department, Officer Advanced Course, 97-001, Fort Sam Houston, TX
Medical Management of Chemical Casualties, December 1995, Aberdeen Proving Ground, MD
Medical Defense Against Biological Warfare Agents, December 1995, Fort Detrick, MD
MANPRINT Action Officer Course, 95-007, Fort Bragg, NC
Aviation Psychology Training Course, 94-001, Fort Rucker, AL
Army Medical Department, Officer Basic Course, 93-006, Fort Sam Houston, TX

MILITARY AWARDS and DECORATIONS

Order of Saint Michael (Bronze Award)
Army Aircrewmember Badge
Meritorious Service Medal (1 OLC)
Army Commendation Medal (3 OLC)
Army Achievement Medal (1OLC)
National Defense Service Medal (w/Bronze Service Star)
Army Service Ribbon

MISCELLANEOUS

Board Certified in Clinical Hypnotherapy, American Board of Hypnotherapy
Adjunct Professor of Psychology, Troy State University (currently inactive)
Reviewer, *Aviation Space and Environmental Medicine*
Reviewer, *Military Psychology*

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APPENDIX B
GOVERNMENT-FURNISHED INFORMATION

1. Spreadsheet with information from the RCRA/CERCLA studies

2. *ARS Manual 242.1*, "ARS Facilities Design Standards."

3. Final Study Report, *Strategic Facility and Utility Investigative Report, Building No. 101 Renovation/Expansion, Plum Island Animal Disease Center at Greenport, NY,* Kling-Lindquist dated May 25, 2001

4. Draft Study Report, *Strategic Facility and Utility Investigative Report, Building No. 101 Renovation/Expansion, Plum Island Animal Disease Center at Greenport, NY,* Kling-Lindquist Report dated May 23, 2000

5. *Final Report: Task Force on Biocontainment Facilities for Foreign Animal Disease Research and Diagnostic Activities (ARS and APHIS)* dated March 1994

6. Review Report on PIADC dated December 9, 1998

7. Websites for laws and regulations governing disposal of real property

8. Review Report, The Animal Health Safeguarding Review: Results and Recommendations, The National Association of State Departments of Agriculture Research Foundation, October 2001

9. Review Report, Security Review of the U.S. Department of Agriculture Plum Island Animal Disease Center (4th Draft), Sandia National Laboratories dated April 4,2002 (official use only)

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Survey of Livestock Associations

Should Foot-and-Mouth Disease Be Transferred from Plum Island to the Mainland United States?

YES	NO	Undecided
American Veal Association (need risk assessment for all prospective sites)	American Farmers and Ranchers	Illinois Pork Producers Assn (USDA should be in charge; need risk assessment for all prospective sites)
Kansas Livestock Association	Missouri Cattlemen's Association	Iowa Pork Producers Assn (USDA should be in charge; need risk assessment for all prospective sites)
National Cattlemen's Beef Association	National Milk Producers Federation	Mississippi Pork Producers Assn (USDA should be in charge; need risk assessment for all prospective sites)
South Dakota Cattlemen's Association (identical to NCBA)	North Dakota Stockman's Association	National Pork Board (USDA should be in charge; need risk assessment for all prospective sites)
	Oregon Cattlemen's Association	National Pork Producers Council (USDA should be in charge; need risk assessment for all prospective sites)
	South Carolina Cattlemen's Association	New York Pork Producers Inc. (USDA should be in charge; need risk assessment for all prospective sites)
	Wyoming Stock Growers Association	Pennsylvania Pork Producers Council (USDA should be in charge; need risk assessment for all prospective sites)
		Texas Livestock Associations (7 Texas livestock assns) (need cost-benefit analysis)
		Wisconsin Pork Association (USDA should be in charge; need risk assessment for all prospective sites)

Responses received as of May 7, 2008.

From: Arlington, John
Sent: Wednesday, February 27, 2008 10:01 AM
To: Arlington, John
Subject: FW: American Veal Association - Foot and Mouth

From: Bryan Scott [mailto:calfdoc1@msn.com]
Sent: Tuesday, February 26, 2008 7:32 PM
To: Guerrieri, Sarah
Cc: calfdoc1@msn.com; Steve Kraut
Subject: American Veal Association - Foot and Mouth

February 26, 2007

Mr. John Arlington
Senior Investigative Counsel
Committee on Energy and Commerce

John:

This is in response to the Committee's letter, dated February 21, to Mr. Steven Kraut. Mr. Kraut left the AVA in October of 2006, but I am happy to respond to your questions in his place.

The American Veal Association supports a thorough and comprehensive risk analysis of potential sites for a new biological research facility. We certainly believe that today's technology would allow for a center on the U.S. mainland, as long as certain precautions, like buffer zones between the facility and livestock are established.

If we were to encounter an outbreak, we understand the current limitations of the USDA in tracking and isolating affected animals due to the voluntary nature of animal ID, however, state authorities have shown great competence in isolating Bovine TB and other highly contagious animal diseases, and we believe the same methodologies could be used in a Foot and Mouth outbreak.

Because of the very regional nature of our production facilities, the cost of an outbreak would very dramatically. An outbreak in California would have almost no impact on our producers, their facilities, herds, or future operations. However, an outbreak in certain counties in Wisconsin, Indiana, Ohio, or Pennsylvania could cost our producers in excess of $20,000,000.00.

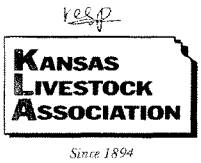
The American Veal Association certainly has a continued interest in this issue, and would happy to work with the Committee as events unfold or circumstances warrant. Thank you for considering our producers in this very critical issue, and feel free to contact me at any time.

My regards,

Bryan Scott
Executive Vice President
Legislative & Regulatory Affairs
American Veal Association

bryanscott@americanveal.com
708-227-3210

resp



Arlington, Ky 66
MAR 19 2008

Tuesday, March 11, 2008

The Honorable John Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

On behalf of the Kansas Livestock Association (KLA), I appreciate the opportunity to respond to your inquiry regarding KLA's position on the proposed National Bio and Agro-Defense Facility (NBAF). As you know, the United States Department of Agriculture and the Department of Homeland Security have been discussing the need for a state-of-the-art foreign animal disease research center for several years now. NBAF will greatly enhance the research and foreign animal disease diagnostic facility currently at the Plum Island Animal Disease Center. KLA has been involved in efforts in Kansas to locate the proposed facility at a site on the campus of Kansas State University in Manhattan.

1. **"Does your organization support moving foot-and-mouth disease from Plum Island to a research facility on the mainland United States?"**

Yes, the KLA supports the NBAF as a critical national priority intended to research biological threats involving foreign animal and zoonotic (i.e., transmitted from animals to humans) and diseases. KLA and our members understand our nation's agricultural and food infrastructure is potentially susceptible to the intentional and unintentional introduction of foreign disease-causing microorganisms. In addition to the devastating impacts of such an incident on the economy, some animal diseases could potentially be transmitted to humans. Kansans embrace the NBAF as a unique and vital agricultural component of the urgently needed effort to modernize homeland security facilities and research to ensure public health and the safety and security of our state's and nation's food supply.

NBAF will be a modern, high-containment facility that will enhance our nation's capacity to assess potential threats to animals and wildlife as well as humans and develop countermeasures to them. It will incorporate design and operational characteristics to maximize safety and security.

2. **"What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?"**

An outbreak of foot-and-mouth disease in the United States could devastate the Kansas cattle industry. It is estimated that a domestic outbreak would result in losses of $934 million to Kansas livestock. This figure is a result of production losses, export losses, control costs (de-population, disposal, vaccination, disinfection, surveillance), and allied industry losses (feed suppliers, banks, veterinarians, equipment dealers). The 2001 foot-and-mouth disease outbreak in the United Kingdom cost $6 billion and resulted in almost 6.5 million animals being destroyed. Many of our members could immediately be put out of business, and the beef industry, which we have worked so hard to develop, could be crippled.

6031 SW 37th Street • Topeka, KS 66614-5129 • (785) 273-5115 • Fax (785) 273-3399 • E-mail: kla@kla.org • www.kla.org

3. **"Does your organization believe modern technology is adequate to prevent the accidental release of foot and mouth disease – or other contagious diseases affecting livestock – from a research facility located on the mainland United States?"**

Today's state-of-the-art biocontainment technology is fully adequate to protect our agriculture industry and to allow for safe research and diagnostics on the mainland. The multiple layers of protection found in modern BSL-3 and BSL-4 labs will protect the workforce and the surrounding environment from accidental releases. In fact, the precedent for locating BSL-3/BSL-4 laboratories dedicated to containing high consequence foreign animal disease causing agents, including the foot-and-mouth disease virus, on the mainland has been established with facilities such as Canada's National Center for Foreign Animal Disease in Winnipeg. The fact that there has never been any loss of containment of agent at this facility on the mainland is a testament that the animal and human population can be protected with full confidence. Moreover, many of the most dangerous human infectious disease agents have been studied safely for decades in BSL-3/BSL-4 laboratories in the midst of major population centers. These include the CDC in Atlanta, Georgia and USAMRIID in Frederick, Maryland.

4. **"If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?"**

Because of the incredible impact this disease could have on the cattle industry, KLA and Kansas has long at the forefront of public and private efforts with respect to early detection, rapid response, and recovery in case of an incursion of any cattle disease, including foot-and-mouth disease. Clearly, prevention is the primary goal. NBAF is intended to support licensure of vaccine and other countermeasures to protect the health of the American people and our nation's agriculture industry.

In summary, regardless of where the NBAF is located, we must ensure safety protocols are in place to prevent the introduction of the very diseases being researched. Please find enclosed a copy of the testimony we provided to the Department of Homeland Security last August. Thank you for the opportunity to address your concerns, and we look forward to working with your Committee in the future.

Regards,

Rich McKee
Senior Vice President

RM:s

Encls.

COMMENTS OF THE KANSAS LIVESTOCK ASSOCIATION
With regard to:
National Bio and Agro-Defense Facility Environmental Impact Statement
DEPARTMENT OF HOMELAND SECURITY
Presented by
Rich McKee
Senior Vice President

August 28, 2007

The Kansas Livestock Association (KLA), formed in 1894, is a trade association representing approximately 6,000 members on legislative and regulatory issues. KLA members are involved in many aspects of livestock production, including cow-calf/stocker enterprises, cattle feeding, seedstock production and diversified farming operations. Kansas ranked third nationally with 6.4 million cattle on ranches and in feedyards as of January 1, 2007. The state's beef industry consumes 72% of the corn, 16% of the soybeans, and 60% of the hay grown in Kansas. Cattle sales typically generate nearly two-thirds of all annual agricultural receipts, generating over $6.25 billion in cash receipts during 2006.

Thank you for the opportunity to provide comments with regard to the proposed National Bio and Agro-Defense Facility (NBAF). In general, we have three points for your consideration.

1. It is imperative that, as a nation, we conduct the research necessary to protect agriculture and public health from high-consequence biological threats involving human, zoonotic, and foreign animal diseases. Our national security, from the perspectives of human health and food security, demands this type of research. We must have the proper facilities to conduct this field of research.
2. Regardless of where the NBAF is located, the Department of Homeland Security must absolutely ensure safety protocols are in place to prevent the introduction of the very diseases being researched. The safety protocols must address measures to prevent both the unintentional and intentional (e.g. bio-terrorism) release of

6031 SW 37th Street * Topeka, KS 66614-5129 * (785) 273-5115 * Fax (785) 273-3399 * E-mail: kla@kla.org * www.kla.org

diseases. It is safe to say none of the six proposed sites would want NBAF if this assurance could not be obtained.

3. The proposed site in Manhattan, Kansas, is an excellent choice for the NBAF. There are several unique aspects that make the Kansas site distinctively qualified.
    a. The Biosecurity Research Institute already located at Kansas State University would complement the research to be conducted at NBAF. The synergy that would be generated from these two sites would provide exciting opportunities.
    b. Locating NBAF in Manhattan, Kansas, would place it within the existing animal health corridor that includes the headquarters for more than 100 animal health companies. In addition, the Midwest Research Institute, the University of Kansas Medical Center, the Stowers Institute for Medical Research and the Kansas City Area Life Sciences Institute are located within this corridor.
    c. A broad coalition of public and private organizations supports Manhattan, Kansas, as the NBAF site. One of the key members of this coalition is Kansas State University. The university administration and scientists have earned a great deal of respect and trust from the agriculture community for staying on the cutting edge of research. Kansas State University is fully committed to serving the needs of the livestock and farming industries.

We appreciate the opportunity to provide these comments for your consideration. Should you have any questions, please do not hesitate to contact us.

NATIONAL CATTLEMEN'S BEEF ASSOCIATION
1301 Pennsylvania Ave., NW, Suite #300 • Washington, DC 20004 • 202-347-0228 • Fax 202-638-0607

February 29, 2008

The Honorable John Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

On behalf of the more than 247,000 members represented by the National Cattlemen's Beef Association (NCBA), and our state and breed affiliates, I appreciate the opportunity to respond to your letter of inquiry into NCBA's position on the proposed National Bio and Agro-Defense Facility (NBAF). As you know, the United States Department of Agriculture and the Department of Homeland Security have been discussing the need for a state-of-the-art foreign animal disease research center for several years now. NBAF will replace the research and foreign animal disease diagnostic facility currently at the Plum Island Animal Disease Center. NCBA has been involved with the committees of jurisdiction and with the Administration to offer input and feedback on this new facility.

Foot-and-mouth disease is the most contagious animal disease known and represents a worst-case scenario for livestock diseases because of the variety of the species involved (cattle, sheep, swine, and wildlife such as deer), the rapid spread of the disease, and the difficulty in controlling outbreaks. The need for research and the development of effective counter-measures are critical to the health and welfare of the domestic cattle herd and cattle producers across this country. As such, we have compiled the following responses to the questions you posed in your letter.

1. *"Does your organization support moving foot-and-mouth disease from Plum Island to a research facility on the mainland United States?"*

   Yes, NCBA supports the NBAF regardless of where it is located. NCBA has more 100 years of experience working closely with local, state, and Federal animal health officials, veterinarians, and animal scientists to control and eradicate animal diseases, and to prevent the introduction of foreign animal diseases into the United States. With the help of facilities such as Plum Island, we have created a series of formidable barriers to the introduction of foreign animal diseases, and we have been successful at eradicating many diseases that were at one time present in our domestic herd. It is because of this work that the United States has been free from foot-and-mouth disease for more than 70 years.

   However, Plum Island is an old facility whose infrastructure has not kept up with today's technology, nor does it meet the demands of today's research needs. It is critical that the United States have an adequate large animal biosecurity level 3 and 4 (BSL-3/BSL-4) laboratory to conduct research on all of the diseases that could destroy or sicken the food animal population.

2. *"What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?"*

   An outbreak of foot-and-mouth disease in the United States could devastate the cattle industry. Foot-and-mouth is a viral disease that is spread via contact and fomites, with inhalation and ingestion being the routes of infection. Airborne transmission (virus can be spread by the wind and is influenced by weather conditions) has been reported, and cattle may be more susceptible to this route of infection. It is estimated that a domestic outbreak would result in losses of $10 to 34 billion. This figure is a result of production losses, export losses, control costs (de-population, disposal, vaccination, disinfection, surveillance), and

allied industry losses (feed suppliers, banks, veterinarians, equipment dealers). The 2001 foot-and-mouth disease outbreak in the United Kingdom cost $6 billion and resulted in almost 6.5 million animals being destroyed. Many of our members could immediately be put out of business, and the beef industry, which we have worked so hard to develop, could be crippled.

3. *"Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease – or other contagious diseases affecting livestock – from a research facility located on the mainland United States?"*

   Yes, NCBA believes that modern biocontainment technology is adequate to protect our industry and to allow for safe research and diagnostics on the mainland. The multiple layers of protection found in today's BSL- 3 and BSL-4 labs will protect from accidental releases as long as the Administration and Congress commit to appropriate funding of the facility to make sure it is continuously and properly maintained and upgraded. In fact, the precedent for locating BSL-3/BSL-4 laboratories in populated urban centers has been set with such facilities as Canada's National Center for Foreign Animal Disease in Winnipeg. There have been no accidental releases at this facility, which is a testament that the population can be protected.

   Today's technology has markedly improved over the technology available when the animal buildings were constructed at Plum Island more than 50 years ago. Throughout the years, funding has not been timely or adequate enough to constantly improve the Plum Island facilities. Increased construction and operating costs of an island location has been a challenge. In addition, Plum Island is not the "fortress" some people may contend. The island has long had a problem with wildlife swimming over from the mainland at low tide, and there have been numerous reports of how close boaters can get to the island without any warning or consequences. Regardless of its location, new and modern technology must be utilized to protect our food animal herd.

4. *"If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?"*

   Because of the incredible impact this disease could have on the U.S. cattle industry, NCBA has long taken proactive measures to work with industry and government to address the response to an outbreak. NCBA has sponsored summits and has participated in training exercises to work with first responders, government officials, and others in the cattle and livestock industries to identify what does and does not work, and to try to find ways to improve the response. Additionally, both USDA and NCBA have worked with foreign governments and industries, including those in Canada and Mexico, in response planning. Prevention is the primary goal, but we have been and will continue to be aggressive in our work with all of our partners to be ready with early detection, rapid response, and recovery in case of an incursion of any cattle disease, including foot-and-mouth disease.

As you can see, our industry has given much thought to the closing of Plum Island and the construction of NBAF. A disease this detrimental to our industry has to be taken seriously, and we believe that Congress and the Administration have given thorough and careful consideration to this issue. We continue to monitor the progress of this facility and will weigh in with our comments and concerns. In the meantime, we feel it is the role of Congress to ensure that this facility is properly supported financially and that the jurisdiction of USDA and DHS be properly outlined and supported so that we maximize the use of this facility without wasting taxpayer dollars with overlapping activities. NCBA takes the health of our animals seriously. Foreign animal disease research, diagnostics, and control are complex and multi-faceted. We would be happy to discuss in further detail if needed.

Thank you for the opportunity to respond to your concerns, and we look forward to working with your Committee in the future.

Sincerely,

Jay H. Truitt
Vice President – Government Affairs

www.sdcattlemen.org

March 11, 2008

The Honorable John Dingell
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight & Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

On behalf of the South Dakota Cattlemen's Association (SDCA) and our 1,000 members, thanks for the opportunity to respond to your letter of inquiry into SDCA's position on the proposed National Bio and Agro-Defense Facility (NBAF).

As you know, the United States Department of Agriculture and the Department of Homeland Security have been discussing the need for a state-of-the-art foreign animal disease research center for several years now. NBAF will replace the research and foreign animal disease diagnostic facility currently at the Plum Island Animal Disease Center. SDCA supports these efforts to modernize animal research facilities and safeguard our domestic livestock herd from foreign diseases.

Foot-and-mouth disease is the most contagious animal disease known and represents a worst-case scenario for livestock diseases because of the variety of the species involved (cattle, sheep, swine, and wildlife such as deer), the rapid spread of the disease, and the difficulty in controlling outbreaks. The need for research and the development of effective counter-measures are critical to the health and welfare of the domestic cattle herd and cattlemen across South Dakota and the U.S. As such, we offer the following feedback to the questions outlined in your letter.

1. *"Does your organization support moving foot-and-mouth disease from Plum Island to a research facility on the mainland United States?"*

SDCA supports upgrading and modernizing animal disease research facilities regardless of where they are located. Our experience working with local, state, and Federal animal health officials, veterinarians, and animal scientists to control and eradicate animal diseases, and to prevent the introduction of foreign animal diseases into the United States demonstrates an ongoing commitment to ensuring the health of our domestic livestock herd. With the help of facilities such as Plum Island, we have created a series of formidable barriers to the introduction of foreign animal diseases, and we have been successful at eradicating many diseases that were at one time present in our domestic herd. It is because of this work that the United States has been free from foot-and-mouth disease for more than 70 years.

However, Plum Island is an aging facility whose infrastructure has not kept up with current technology, nor does it meet the demands of today's research needs. It is critical that the United States have an adequate large animal biosecurity level 3 and 4 (BSL-3/BSL-4) laboratory to conduct research on all of the diseases that could destroy or sicken the food animal population.

2. *"What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?"*

An outbreak of foot-and-mouth disease in the United States could devastate the cattle industry, which is the single largest segment of South Dakota's ag economy. Foot-and-mouth is a viral disease that is spread via contact and fomites, with inhalation and ingestion being the routes of infection. Airborne transmission (virus can be spread by

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the wind and is influenced by weather conditions) has been reported, and cattle may be more susceptible to this route of infection. It is estimated that a domestic outbreak would result in losses of $10 to $34 billion. This figure is a result of production losses, export losses, control costs (de-population, disposal, vaccination, disinfection, surveillance), and allied industry losses (feed suppliers, banks, veterinarians, equipment dealers). The 2001 foot-and-mouth disease outbreak in the United Kingdom cost $6 billion and resulted in almost 6.5 million animals being destroyed. Many of our members could immediately be put out of business, and the beef industry, which we have worked so hard to develop, could be crippled.

3. *"Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease – or other contagious diseases affecting livestock – from a research facility located on the mainland United States?"*

Yes, SDCA believes that, with proper management, modern biocontainment technology is adequate to protect our industry and to allow for safe research and diagnostics on the mainland. The multiple layers of protection found in today's BSL-3 and BSL-4 labs will protect from accidental releases as long as the Administration and Congress commit to appropriate funding of the facility to make sure it is continuously and properly maintained and upgraded. In fact, the precedent for locating BSL-3/BSL-4 laboratories in populated urban centers has been set with such facilities as Canada's National Center for Foreign Animal Disease in Winnipeg. There have been no accidental releases at this facility, which is a testament that the population can be protected. Today's technology has markedly improved over the technology available when the animal buildings were constructed at Plum Island more than 50 years ago. Throughout the years, funding has not been timely or adequate enough to constantly improve the Plum Island facilities. Increased construction and operating costs of an island location has been a challenge. In addition, Plum Island is not the "fortress" some people may contend. The island has long had a problem with wildlife swimming over from the mainland at low tide, and there have been numerous reports of how close boaters can get to the island without any warning or consequences. Regardless of its location, new and modern technology must be utilized to protect our food animal herd.

4. *"If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?"*

Because of the incredible impact this disease could have on the U.S. cattle industry, SDCA has worked diligently with our state and national industry and regulatory partners to proactively address the response to an outbreak. However, due to the lack of a modern animal identification and traceback system in the U.S. and the fact that brucellosis has essentially been eradicated in our domestic cattle herd, we are not currently bangs vaccinating very many cattle. This results in a smaller pool of cattle identified through the official vaccination program and means we are at greater risk of not being able to identify and track the source of an outbreak of foot-and-mouth disease in the earliest stages. SDCA supports a mandatory identification program for *breeding age* livestock so animal health authorities will have the necessary tools to combat animal diseases. And we urge Congress to carefully consider all programs and tools that enhance the ability of animal health officials to monitor, track, and eradicate animal diseases. Prevention should remain the primary goal, but the industry has been and will continue to be aggressive in our work to be ready with early detection, rapid response, and recovery in case of an incursion of any cattle disease, including foot-and-mouth disease.

As you can see, we take the health of our domestic livestock herd seriously. Foreign animal disease research, diagnostics, and control are complex and multi-faceted. We urge Congress to ensure that all efforts to ensure the safety of our domestic food animals are properly supported financially, including efforts to modernize and upgrade research facilities.

Thank you for the opportunity to respond to your concerns. Please contact our office at 605.945.2333 or executive@sdcattlemen.org if we can be of further assistance on this important issue.

Regards,

Scott Jones

Scott Jones, President

American Farmers & Ranchers

RAY L. WULF, President & CEO
TERRY DETRICK, Vice Pres.
ROYCE MEEK, Secretary

March 11, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C.

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight & Investigations
U.S. House of Representatives
Washington, D.C.

Dear Chairman Dingell and Chairman Stupak:

On behalf of American Farmers & Ranchers (AFR) we thank you for the opportunity to comment on the Department of Homeland Security's (DHS) recent proposal to close the Plum Island Animal Disease Center (PIADC) and move it's biological research laboratory, including research on foot-and-mouth disease, to a new location on the mainland United States. This is an issue that is of particular interest and concern to our membership.

As a general farm organization that has been representing family farmers, ranchers and rural Americans since 1905, AFR is ***opposed*** to the movement of the foot-and-mouth disease research facility from Plum Island to a research facility on the mainland U.S. There are simply too many possibilities for error, either by negligence or accident that could pose extreme economic impacts on U.S. producers and consumers. Foot-and-mouth disease can be carried accidentally on clothing, skin and even through nasal passages. The current location or one with similar natural barriers should continue to be the site for research and diagnostic activities that protect our nation's food supply.

Specifically foot-and-mouth disease creates the most serious threat to the U.S. livestock industry as well as the U.S. economy. A GAO report released December of 2005 stated that nationally recognized animal disease experts were interviewed and agreed that foot-and-mouth disease constitutes the greatest threat to American livestock. Furthermore GAO provided a letter on December 17, 2007 stating that some of the pathogens maintained at Plum Island, such as foot-and-mouth disease, are highly contagious to livestock and could cause catastrophic economic losses in the agricultural sector if they are released outside of the facility.

Plum Island's research and diagnostic activities work to accomplish an important mission to protect U.S. animal industries and exports from deliberate or accidental introductions of foreign animal diseases. Although steps have been taken to implement better security measures at Plum Island, an outbreak is not out of the question. The U.S. should take note of the most recent U.K. outbreak in August of 2007. Investigations determined that the U.K. outbreak was caused by a strain of virus used for vaccine research at laboratories associated with the institute for Animal Health at Pirbright.

800 North Harvey • Oklahoma City, OK 73102 • 1-800-324-7771 • Mailing Address: P.O. Box 24000, Oklahoma City, OK 73124

The possibility of an outbreak is magnified by the efficiencies in the U.S. infrastructure and the transportation industry, which allows livestock to move rapidly across the U.S. In one week cattle traded from the Oklahoma City National Livestock Market are transported to 39 states. Within a matter of days livestock can be transported hundreds to thousands of miles away and intermingled with other livestock. Our U.S. efficiencies accelerate the movement of any animal disease outbreak.

The economic impacts to AFR members would no doubt be severe and devastating and reach far beyond the livestock industry. Quarantines affecting large areas would be established stopping all incoming and outgoing commerce in the quarantined area. The impact would not only be felt by the producer but also the local community, region and nation and could cause irreparable damage to the financial community. In addition the U.S. could expect severe consequences in the global market. Many studies have attempted to assess the economic implications of an outbreak of foot and mouth disease. Results can vary but at the same time all point out the significant economic losses as a result of a foot and mouth outbreak

Dr. Clem Ward of Oklahoma State University outlines how estimating the effects is difficult to gauge:

- First, the effects would depend upon how isolated or widespread the incidence was and how quickly it was contained.
- Second, the effects would depend upon the type of livestock operations that were infected and how frequently or recently animals have moved from the sites.
- Third, impacts would depend on how the media handles the news reporting of the outbreak.
- And fourth, markets would likely react immediately to the news, and how long it would take them to rebound to a more normal level would depend on the first three factors mentioned.

Dr. Ward also looked at two studies that estimate the economic impacts of a foot-and-mouth outbreak based on a given set of wide ranging scenarios.

1) A 1979 study with impacts adjusted to 2000; estimated economic impacts from $2.4 billion to $27.6 billion (McCauley, et al.).
2) A 1999 study estimated the impacts for California alone at $8.5 billion to $13.5 billion (Ekboir).

In 2005, producers in Kansas marketed the largest number of fed cattle in the nation at 5.3 million head. Kansas and neighboring states represent roughly 80% of fed cattle marketing's in the U.S. with 40% of the cattle on feed concentrated in the Oklahoma and Texas panhandles and southwest Kansas. Therefore, introduction of a contagious disease such as foot-and-mouth disease in this region would not only have significant regional affects but the entire U.S. and world. Therefore, to better understand the effects of a foot-and-mouth disease outbreak in the U.S., one study in this report estimates the effects of a hypothetical outbreak of foot-and-mouth disease in southwest Kansas.

Kansas State University agricultural economists reported on three different scenarios of a foot-and-mouth outbreak. The study stated total impacts estimated to accrue to southwestern Kansas associated with a foot-and-mouth disease outbreak originating in a cow-calf, medium-size feedlot, and five large feedlots. Scenarios were estimated to be $32 million, $193 million, and $942 million, respectively. The combined overall impact for the State of Kansas for the cow-calf, medium-size feedlot, and five large feedlots scenarios were estimated to be losses of $51 million, $284 million, and $1.3 billion, respectively. Again it is extremely hard to measure the collateral damage a quarantine would have on the entire economy.

Another report titled "Potential Revenue Impact of an Outbreak of foot-and-mouth disease in the United Sates" by Paarlbwerg, Lee, and Seitzinger was published in the Journal of American Veterinary Medical Association in April of 2002. The report stated an outbreak similar to that which occurred in the U.K. during 2001, would cause an estimated U.S. farm income losses of $14 billion. *Note*: this is only the effect on farm income.

AFR does not believe that there are adequate technologies and safety precautions that can assure U.S. producers and consumers that there would not be an accidental or intentional release of foot-and mouth disease or for that fact any other contagious disease affecting livestock from a research facility located on the mainland U.S.

Although Federal, State and local authorities continue to try to prepare themselves for a foreign animal disease outbreak, AFR believes there are entirely too many unknown variables that would hinder a successful containment of the disease.

In addition, USDA has been pursuing implementation of an effective animal identification system since the BSE discovery in a U.S. cow in 2003 and the U.S. has yet to establish a workable I.D. program, making it even more difficult to control any kind of animal disease outbreak. Until traceability is mandatory and in place moving the PIADC to the mainland should ***not*** be considered and even then it should be reviewed carefully and any consideration should be focused on a remote area with little or no livestock or wild game habitation.

AFR believes the U.S. should not risk bringing highly contagious animal disease research to the mainland with so many variables that could wreak havoc on the U.S. livestock industry and the U.S. economy.

We applaud your efforts to investigate this issue and appreciate the opportunity to comment.

Sincerely,

Ray L. Wulf
President & CEO
American Farmers & Ranchers

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Missouri Cattlemen's Association

Serving Missouri's Cattle Industry Since 1911

3-11-08

U.S. House of Representatives
Committee on Energy and Commerce
Washington D.C. 20515-6115
John D. Dingell, Michigan, Chairman

Dear Chairman Dingell:

Thank you and your committee for soliciting comments from the Missouri Cattlemen's Association regarding the issue of closing Plum Island and potentially moving the research to the mainland. As you are aware, the Missouri Cattlemen's Association represents all 68,000 beef producers in Missouri. Therefore, it is incumbent upon us to protect the health of the animal industry and the livelihoods of the beef producers of Missouri. The beef industry is a $1.5 billion dollar industry to the state. Because, of the substantial investment of our industry, we are very concerned of moving the infrastructure of this facility to the mainland.

Many of our producers make their entire livelihood from the production of beef. Missouri is the second leading state in terms of cow numbers and the leading state in the production of registered cattle. Our investment in the nation's beef industry is undeniably one of the largest of any state. Therefore, if a disease outbreak were to occur on the mainland, would be devastating to our producers, the economy and to supplying food to the nation's consumers!

The Plum Island facility has served us very well for over 50 years. Given the recent outbreaks in the U.K., we believe accidents can and will happen regardless of technologies. Foot and Mouth Disease is one of the most deadly and contagious diseases known to the beef industry. We believe it would be a mistake to relocate these facilities to the mainland and risk an outbreak! The impacts of an outbreak on the mainland could have a devastating outcome to our producers and cause a severe disruption in the marketing of our livestock.

In summary, the Missouri Cattlemen's Association fully supports locating the Plum Island Animal Disease Center on Plum Island. Recognizing technology has improved, we also realize accidental breaches can occur due to human error can and do occur. We believe authorities are making strides towards improving their preparedness, however, until an outbreak occurs, we will not fully know to what extent a disease such as Foot and Mouth Disease can be controlled.

We appreciate the opportunity to respond to your questions and voice our concerns on such an important issue!

Sincerely,

Jeff Windett
Executive Vice President
Missouri Cattlemen's Association

2306 Bluff Creek Drive, Suite 100 • Columbia, MO 65201 • (573) 499-9162 • FAX (573) 499-9167

National Milk Producers Federation

National Milk Producers Federation • 2101 Wilson Blvd., Arlington, VA 22201 • 703-243-6111 FAX 703-841-9328

Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers, Inc.
Case-Clay Creamery, Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Assn.
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Dairylea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
Humboldt Creamery
est Jersey cooperative, Inc.
Land O'Lakes, Inc.
Lone Star Milk Producers, Inc.
Manitowoc Milk Producers Coop.
MD & VA Milk Producers Cooperative Association, Inc.
Michigan Milk Producers Assn.
Mid-West Dairymen's Company
Northwest Dairy Association
Prairie Farms Dairy, Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
Southeast Milk, Inc.
Swiss Valley Farms, Co.
Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers

March 4, 2008

The Honorable John Dingell
Chairman
House Committee on Energy
And Commerce
2125 Rayburn House Office Bldg.
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight
and Investigations
2125 Rayburn House Office Bldg.
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

The National Milk Producers Federation appreciates the opportunity to provide input to the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations investigation into the Department of Homeland Security's recent proposal to close the Plum Island Animal Disease Center and move its biological research laboratory to a new location on the mainland United States. The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well being of dairy producers and the cooperatives they own. The members of NMPF's 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of nearly 50,000 dairy producers on Capitol Hill and with government agencies.

NMPF has worked with the United States Department of Agriculture (USDA) and the Department of Homeland Security (DHS) for years on the need for a world class foreign animal disease research center. They have identified the proposed National Bio and Agro-Defense Facility (NBAF) as this center for the future and have proposed that it be located on the mainland U.S. Obviously, with a disease that is as contagious and potentially devastating as foot-and-mouth disease, every precaution must be taken to ensure that risks are minimized. We offer the following comments to the questions in your letter dated February 21, 2008.

- Does your organization support moving the foot-and-mouth disease from Plum Island to a research facility on the mainland United States?

  NMPF's primary concern is that the NBAF be a facility that has adequate protection so that no accidental release of a disease such as foot-and-mouth disease could occur. As such, no matter where it is located, the

facility needs to have a large animal biosecurity level 3 and 4 laboratory so that research can be conducted on diseases such as foot-and-mouth disease.

The current location on Plum Island has served this purpose and has not resulted in any release of foot-and-mouth disease to the domestic animal population since its existence. While the facility is rather dated, it certainly has the advantage of being isolated by water from the mainland as an added precaution against unintentional introduction of foot-and-mouth disease into the U.S. animal population. This demonstrated advantage is something that can be taken advantage of by upgrading the existing facility or building a new facility on Plum Island.

- What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?

  The cost to the dairy industry of an outbreak of foot-and-mouth disease in the U.S. would vary, depending upon how quickly it spreads and the effectiveness of the response. However, recent epidemiological studies conclude that any outbreak in any region with a concentration of livestock production would likely be quite serious. A 1999 University of California at Davis study estimated that a foot-and-mouth disease outbreak optimistically limited to California's South Valley would result in the destruction of 20% to 100% of the region's dairy herds. Resulting losses of milk production plus the containment and depopulation costs are conservatively estimated at $325 million to $1.75 billion, adjusted for 2007 prices. A 2007 study published in the *Journal of the American Veterinary Medical Association* demonstrated that an outbreak spread through a sale barn or state fair could be multiplied by 10- or 20-fold, as would the dairy industry's cost, to as much as $30 billion or more.

  Finally, even a quickly contained foot-and-mouth disease outbreak could close overseas markets to U.S. dairy export sales. These were worth over $3 billion in 2007, and the loss of these sales would have an additional, disastrous impact on U.S. milk prices.

- Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease--or other contagious diseases affecting livestock--from a research facility located on the mainland United States?

  NMPF believes that modern technology exists to secure facilities so that release of contagious diseases such as foot-and-mouth disease does not occur. As indicated earlier, a facility that has biosecurity level 3

and 4 laboratories has adequate protection to enable the necessary research to be conducted while protecting against accidental releases. One key component of these facilities is that they are adequately funded to remain up-to-date with modern technologies that evolve to ensure that they continue to provide the necessary security against a release of harmful microorganisms.

The location of the laboratory is independent of the technology that exists. Physical barriers such as water around an island can provide an added level of protection as the experience with current facilities at Plum Island has demonstrated.

We believe that the experience in the United Kingdom last summer is instructive with regard to the potential hazards in working with highly-contagious microorganisms. Due to plumbing control problems at its Pirbright facility, the foot-and-mouth disease virus was inadvertently released into the environment, where it infected commercial farms before it was ultimately contained. This incident should be a cautionary tale of what can happen, even accidentally, when biohazards exist in too close a proximity to concentrations of humans and animals.

- If an outbreak of foot-and-mouth disease were to occur on the mainland United States, does your organization believe that Federal, State, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?

  NMPF has worked with Federal, State, and local authorities as well as industry representatives for many years to develop preparedness plans and continuity of business plans in the event of a disease outbreak such as foot-and-mouth disease. NMPF believes preventing an outbreak is the first line of defense. However, in the unlikely event of an accidental release that results in an outbreak, the quick response by authorities and industry will be the key to minimizing the spread and, therefore, economic impact.

  NMPF supports continued funding and work in the area of emergency preparedness and continuity of business so that none of the entities involved in limiting an outbreak, including Federal, State, and local authorities, as well as industry, get complacent. In addition, exercises to test the system and identify areas that need attention should be conducted on a regular basis. Lastly, more work and research is needed on technologies that will allow for milk movement from farms in infected zones and on vaccination possibilities for infected farms.

In summary, an outbreak of foot-and-mouth disease, from either an intentional or unintentional release of the virus, would have a catastrophic

impact on the U.S. dairy industry. The potential for such an occurrence must be minimized through any means possible. Therefore, all available resources necessary to prevent an outbreak must be provided to ensure that facilities are up-to-date with the latest modern technologies and that research can be conducted to enable government and industry representatives to contain any outbreak that should occur. NMPF prefers to maintain an upgraded or new Plum Island research facility as the new NBAF site.

Thank you again for the opportunity to provide input to this important decision. If you have any questions or need additional information, please contact me.

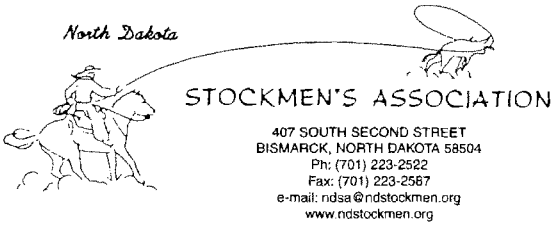
Sincerely,

Jerry Kozak

Jerry Kozak, President & CEO

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations



March 6, 2008

The Honorable John Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell,

Thank you for contacting the North Dakota Stockmen's Association concerning the potential relocation of the National Bio and Agro-Defense Facility (NBAF). Ever since 911, our industry has had concerns over a terrorist threat that would impact our industry. The discussion of that threat always surrounds the concerns about exposing our industry to the Foot-and-Mouth disease and how easy that could happen.

Our response to your questions are as follows:

1. "Does your organization support moving Foot-and-Mouth disease from Plum Island to a research facility on the mainland United States?"

No. Because of potential terrorist activity, we do not feel that a facility could be adequately protected from terrorists if it was on the mainland. We also feel that any facility placed on the mainland would probably be in a less populated area which means in agriculture's backyard. Our suggestion would be to upgrade and modernize at the current Plum Island facility.

2. "What would be the estimated cost to your membership of an outbreak of Foot-and-Mouth disease in the United States?"

It is impossible for us to put a dollar value on our way of life and business. Our questions would be, "What would be the chances of any producer, being wiped out the Foot-and-Mouth disease, ever being able to restart and continue in the business?" and "What are the consequences to other businesses that would be impacted by the loss of animal agriculture in a region?"

3. "Does your organization believe modern technology is adequate to prevent the accidental release of Foot-and-Mouth disease or any other contagious diseases affecting livestock from a research facility located on the mainland United States?

We think that accidental release is not the issue. Terrorist activities would cause far more concern.

4. "If an outbreak of Foot-and-Mouth disease were to occur on the mainland United States, does your organization believe that federal, state and local authorities are prepared to identify, isolate and halt the spread of such an outbreak before it caused significant damage?"

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Although we have a lot of confidence in the authorities' ability to handle many disease situations, we have had experience that questions their ability to communicate with each other and resolve issues in a quick and decisive manner.

We realize that the Plum Island facility is old and in need of upgrading, which is expensive. But Plum Island was chosen years ago for a good reason and that reason is still good today.

Thanks again for the opportunity to express our concerns.

Sincerely,

Wade Moser

Wade Moser
Executive Vice President

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MAR 24 2008

March 13, 2008

The Honorable John Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

Thank you for the opportunity to provide our views on the Department of Homeland Security's (DHS) recent proposal to close the Plum Island Animal Disease Center (PIADC) and move its biological research laboratory, including its research on foot-and-mouth disease, to a new location on the mainland United States.

The Oregon Cattlemen's Association has serious concerns about this proposal and request the PIADC be kept off shore to keep the water barrier intact. Cattle production is the largest food commodity in Oregon with gross sales over $710 million in 2007. Cattle ranches and farms make up nearly a third of all Oregon farms, utilizing the highest number of agricultural acres (over 10 million acres or almost 60%). A foot-and-mouth outbreak would devastate Oregon's cattle industry and cripple the State of Oregon's economy.

We do not believe modern technology alone is adequate to prevent the accidental release of contagious diseases affecting livestock from a research facility. England's foot-and-mouth outbreak from a research laboratory, just last year, gives incredible cause to pause and scrutinize safety precautions. It is of the utmost importance the level of security currently provided by PIADC, due to water separation and distance, be preserved and the protective barrier not be reduced.

While there is a plan, it remains undetermined how effective Federal, State and local authorities would be in preventing significant damage from an outbreak. There is no justifiable basis to jeopardize an entire livestock industry by relocating the biological research laboratory at the PIADC.

Respectfully,

Kay Teisl
Executive Director

~ Voice of the Oregon Cattle Industry Since 1913 ~

S.C. CATTLEMEN'S ASSOCIATION

P.O. Box 11280 · Columbia, S.C. 29211 · TL: (803) 734-9807 · TOLL FREE: (877) 859-9121 · FAX: (803) 734-9808

March 4, 2008

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115
Attn: John D. Dingell, Michigan, Chairman

Dear Mr. Chairman,

On behalf of the South Carolina Cattlemen's Association, we did receive your letter concerning the Oversight and Investigations of (DHS) wanting to close the Plum Island Animal Disease Center, and moving the operation to the mainlands.

We have great concern with this research being performed on the mainland. If an outbreak of foot-and-mouth disease would reach the states it would be devastating to the US beef supply. We want to encourage that the research stay on Plum Island. We believe and have to upmost confidence in our system that if, such an issue, was to come into the states, that the problem would be contained, however, if we can prevent this from happening by keeping the research on Plum Island, let's do so.

Sincerely,

Peter M. Wilkins

Peter Wilkins
Executive Director
South Carolina Cattlemen's Association

Affiliated with
National Cattlemen's Beef Association

Mar. 7. 2008 9:02AM Wyoming Stock Growers Assn. No. 1048 P. 2

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113 East 20th Street

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President- Jon Kirkbride, *Cheyenne*
Region I Vice President- Ogden Driskill, *Devils Tower*
Region III Vice President- Garret Falkenburg, *Douglas*
Region V Vice President- Rob Hellyer, *Lander*
First Vice President- Frank Shepperson, *Midwest*
Region II Vice President- Rodger Schroeder, *Chugwater*
Region IV Vice President- Niels Hansen, *Rawlins*
Executive Vice President- Jim Magagna, *Cheyenne*

March 7, 2008

Representative John Dingell
Chairman
Committee on Energy & Commerce
House of Representatives
Washington, DC 20515-6115

Representative Bart Stupak
Chairman
Subcommittee on Oversight & Investigations
House of Representatives

Dear Chairmen Dingell and Stupak:

The Wyoming Stock Growers Association (WSGA) appreciates the opportunity to provide input regarding the proposal by the Department of Homeland Security (DHS) to close the Plum Island Animal Disease Center (PIADC) and to relocate its research laboratory. We are pleased that your committee and subcommittee have chosen to address this issue.

WSGA opposes moving research on foot and mouth disease and similarly highly contagious diseases to a research facility on the mainland. It is our position that the necessary upgrading or reconstruction of the biological research facility should be undertaken at the present location. The concerns that influenced the original decision to locate this facility away from the U.S mainland have only increased in today's climate of easy global movement of both humans and products as well as increased threats of terrorist activities.

While new technologies have enhanced our ability to prevent accidental release of foot and mouth disease, the risk of human error remains. We must add to this the growing threat of intentional release. While these risks are not totally eliminated at the Plum Island facility, they are greatly reduced by the physical separation of the facility from the mainland.

The costs to Wyoming's cattle industry from a FMD outbreak are difficult to project. The impacts would be dependent on the location of the outbreak and the ability of government authorities to isolate and halt its spread. If an outbreak were to occur during the fall marketing season for Wyoming cattle, even a halt in the movement of livestock for a single day could cost our nearly one billion dollar Wyoming cattle industry several million dollars. In addition, although FMD is not a consumer health hazard, consumer perception could lead to a long-term decrease in beef consumption.

The outbreak of FMD in Great Britain has motivated U. S. authorities at all levels to enhance preparedness to respond to an outbreak. Our industry has also devoted significant resources

Representative John Dingell
Page 2

toward preparedness. WSGA has participated in these efforts. Nevertheless, our ability to identify, isolate and halt the spread of FMD is untested. It remains imperative that our country make every effort to minimize the risk of an outbreak. Maintaining the Plum Island biological research facility is a critical step in this effort. Because USDA ha a long history of managing PIADC without incident while conducting valuable research on FMD and similar diseases, WSGA would further urge that consideration be given to transferring the facility back to USDA jurisdiction.

Please feel free to contact us if you need further information.

Sincerely,

Jim Magagna

Jim Magagna
Executive Vice President

Cc: Representative Barbara Cubin

RSP

John
Arlington
Kyle

ILLINOIS PORK PRODUCERS
ASSOCIATION

MAR 19 2008

March 11, 2008

The Honorable John Dingell
Member of Congress
Committee on Energy and Commerce
Washington. DC 20515-6115

Dear Congressman Dingell:

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment, which is estimated to be at least 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

Our industry believes there is an urgent need to construct the National Bio and Agro-Defense facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF. The present process appears to be driven more by economics and the growth interest of universities than bio-security. Several universities and their supporting cities/counties located in major livestock producing areas have put forth proposals to be considered by DHS.

We know from the experience of other countries, such as the United Kingdom, that the costs of a Foot and Mouth Disease Outbreak (FMD) in the U.S. would be enormous. We do know that the immediate loss of our export markets is estimated to be $4.8 billion. Kansas estimates that an outbreak of FMD would cost their state alone $945 million. These costs could be significantly reduced if the United States Department of Agriculture

6411 S. 6TH ST. RD. SPRINGFIELD, IL 62712-6817 (217) 529-3100 FAX (217) 529-1771 www.ilpork.com

(USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals, which allows authorities to more quickly gain control of the outbreak.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our industry strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risks associated with disease spread to susceptible livestock and wildlife populations. A risk assessment of the six remaining sites should be conducted as part of the final site selection process.

USDA's current mission at the PIADC is to develop diagnostics, treatments, and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated!

Thank you for the opportunity to share our views.

Sincerely,

Phil Borgic
President

CC: The Honorable Joe Barton
The Honorable John Shimkus

March 11, 2008

Representative John D. Dingell
U.S. House of Representatives
Committee on Energy and Commerce
Washington, D.C. 20515-6115

Dear Congressman Dingell,

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share the Iowa Pork Producers Association's (IPPA) point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and pork producers specifically. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, it is our understanding that the decision was made to construct a new facility on the mainland due to the cost of operation. It has been reported that the increased cost of operating in an island environment is estimated to be at least 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics, and training; and the increased costs associated with the added security of an island environment.

IPPA leaders believe there is an urgent need to construct the National Bio and Agro-Defense facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF.

We know from the experience of other countries, such as the United Kingdom, that the costs of a Foot and Mouth Disease Outbreak (FMD) in the U.S. would be enormous. We do know that the immediate loss of U.S. pork export market is estimated to be $4.8 billion. Iowa's livestock inventory consists of 18.2 million head of swine, 3.95 million head of cattle (includes dairy), and 235,000 head of sheep. The State of Iowa also has a free-range deer population in excess of 300,000 head providing a difficult to control means of carrying FMD throughout the state. The IPPA has assisted in drafting a FMD Response and Recovery Plan for the State of Iowa. The IPPA has participated in a State of Iowa FMD exercise to test the plan. Additionally, the IPPA was part of a Vulnerability Assessment Exercise for the pork industry.

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The substantial cost of a major disease outbreak could be significantly reduced if the United States Department of Agriculture (USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals, which allows authorities to more quickly gain control of an outbreak.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is remarkable. However, application of all technology does have a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our association strongly supports having the USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risks associated with disease spread to susceptible livestock and wildlife populations.

USDA's current mission at the PIADC is to develop diagnostics, treatments, and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance.

The association's leaders take the issue of a foreign animal disease outbreak very seriously. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated.

Thank you for this opportunity to share our views.

Sincerely,

Dave Moody

Dave Moody
President

Mississippi Pork Producers Association, Inc.
Box 9815
Mississippi State, Mississippi 39762
Phone: (662) 325-3516

MAR 2 4 2008

U.S. House of Representatives
Committee on Energy and Commerce
Honorable John Dingell, Chairman
Washington, DC 20515-6115

Dear Congressman Dingell,

The Mississippi Pork Producers Association appreciates your interest and concerns regarding the relocation of the Plum Island Animal Disease Center (PIADC) and your request for our Association's view on the relocation to a mainland site.

Our Association believes it is important that the research and diagnostic work at PIADC be continued and it is critical to our national interest that US Producers and Farmers provide our citizens a safe and wholesome supply of food. It is our understanding the current facility needs to be replaced and moving the facility to the mainland has been determined to be the best option for enhancing research and diagnostic capabilities of a (NBAF). The Mississippi Pork Producers Association supports the construction of a new National Bio and Agro-Defense facility. If the new facility is to be located on the mainland, we believe the Department of Homeland Security (DHS) needs to choose the location after careful consideration of the potential risks associated with disease spread to susceptible livestock and wildlife populations.

As pointed out in your correspondence, the outbreak of Foot and Mouth Disease (FMD) in the U.K. in 2001 had serious economic consequences for the livestock producers in the U.K. and the 2007 outbreak of FMD in the U.K. resulting from the bio-security breakdown at England's Pirbright laboratory raises concerns about re-location for the NBAF. We understand the enormous economic impact of a Foot and Mouth Disease Outbreak (FMD) in the U.S. would have on our economy and the pork industry of Mississippi. Although Mississippi is considered a small pork producing State, we have a gate value of about $50 million annually and this is important to the Pork Producers in Mississippi and related agribusiness industries.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated. This human risk component is a serious concern regardless of where the facility is located.

We support the United States Department of Agriculture (USDA) making premises registration mandatory under the National Animal Identification System (NAIS). This would result in a more rapid response to contain the outbreak and prevent movement of animals within the outbreak zone which allows authorities to more quickly control an outbreak and limit the impact of an outbreak.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our Association strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

USDA's current mission at the PIADC is to develop diagnostics, treatments, and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated!

Thank you for your consideration of our views.

Respectively:

Mr. Charles R. Power
President, Mississippi Pork Producers Association

pork checkoff
www.pork.org the Pork Checkoff Service Center @ 800-456-PORK
National Pork Board 1776 NW 114th Street • Des Moines, Iowa 50325 • Phone: 515-223-2600 • Fax: 515-223-2646

March 10, 2008

The Honorable John D. Dingell
House of Representatives
Committee of Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Dingell:

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment, which is estimated to be at least 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

Our industry believes there is an urgent need to construct the National Bio and Agro-Defense facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF. The present process appears to be driven more by economics and the growth interest of universities than bio-security. Several universities and their supporting cities/counties located in major livestock producing areas have put forth proposals to be considered by DHS.

It has been estimated that an outbreak of Foot and Mouth Disease (FMD) would cost American agriculture between $40 and $60 billion. A foreign animal disease outbreak affecting swine would result in the immediate loss of our export markets, costing the U.S. pork industry an estimated $4.8 billion. Kansas estimates that an outbreak of FMD would cost their state alone $945 million. These costs could be significantly reduced if the United States Department of Agriculture (USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals, which allows authorities to more quickly gain control of the outbreak.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our industry strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risks associated with disease spread to susceptible livestock and wildlife populations. A risk assessment of the six remaining sites should be conducted as part of the final site selection process.

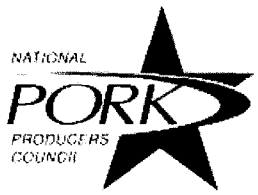
USDA's current mission at the PIADC is to develop diagnostics, treatments and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated!

Thank you for the opportunity to share our views.

Sincerely,

Lynn E. Harrison

Lynn E. Harrison
President
National Pork Board



March 11, 2008

The Honorable John D. Dingell
Chairman, House Committee on Energy and Commerce
2328 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joe Barton
Ranking Member, House Committee on Energy and Commerce
2109 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bart Stupak
Chairman, Subcommittee on Oversight and Investigations
2352 Rayburn House Office Building
Washington, D.C. 20515

The Honorable John M. Shimkus
Ranking Member, Subcommittee on Oversight and Investigations
2452 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Dingell, Ranking Member Barton, Subcommittee Chairman Stupak and Subcommittee Ranking Member Shimkus:

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment which is estimated to be at least 25 percent more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

Our industry believes there is an urgent need to construct the National Bio and Agro-Defense Facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF. The present process appears to be driven more by economics and the growth interest of universities than bio-security. Several universities and their supporting cities/counties located in major livestock producing areas have put forth proposals to be considered by DHS.

It has been estimated that an outbreak of Foot and Mouth Disease (FMD) would cost American agriculture between $40 and $60 billion. A foreign animal disease outbreak affecting swine would result in the immediate loss of our export markets, costing the U.S. pork industry an estimated $4.8 billion. Kansas estimates that an outbreak of FMD would cost their state alone $945 million. These costs could be significantly reduced if the United States Department of Agriculture (USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals which allows authorities to more quickly gain control of the outbreak.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represent serious challenges that need to be overcome. Our industry strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risk associated with disease spread to susceptible livestock and wildlife populations. A risk assessment of the six remaining sites should be conducted as part of the final site selection process.

USDA's current mission at the PIADC is to develop diagnostics, treatments and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, another concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated.

Thank you for the opportunity to share our views.

Sincerely,

Jill Appell
Immediate Past President
National Pork Producers Council

NEW YORK
PORK PRODUCERS INC.

4124 MacDougall Road, Waterloo, NY 13165
Phone 315-585-6276 Fax 315-585-6278

Monday, March 10th, 2008

Dear Congressman Dingell,

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment, which is estimated to be at least 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

Our industry believes there is an urgent need to construct the National Bio and Agro-Defense facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF. The present process appears to be driven more by economics and the growth interest of universities than bio-security. Several universities and their supporting cities/counties located in major livestock producing areas have put forth proposals to be considered by DHS.

We know from the experience of other countries, such as the United Kingdom, that the costs of a Foot and Mouth Disease Outbreak (FMD) in the U.S. would be enormous. We do know that the immediate loss of our export markets is estimated to be $4.8 billion. Kansas estimates that an outbreak of FMD would cost their state alone $945 million. These costs could be significantly reduced if the United States Department of Agriculture (USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals, which allows authorities to more quickly gain control of the outbreak.

NEW YORK
PORK PRODUCERS INC.

4124 MacDougall Road, Waterloo, NY 13165
Phone 315-585-6276 Fax 315-585-6278

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our industry strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risks associated with disease spread to susceptible livestock and wildlife populations. A risk assessment of the six remaining sites should be conducted as part of the final site selection process.

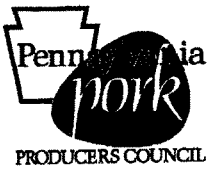
USDA's current mission at the PIADC is to develop diagnostics, treatments, and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the DHS's focus on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated!

Thank you for the opportunity to share our views.

Sincerely,

Jamie L. Mesmer
Executive Secretary/State Contact
New York State Pork Producers Co-op, Inc.
(315) 585-6276
amsinc@wildblue.net
www.NewYorkPork.org

John Arungh
Kyle C.



HERBERT SCHICK, Secretary-Treasurer
1631 Grim Road, Kutztown, PA 19530 Phone 610-285-8519

March 11, 2008

Congressman John D. Dingell
2328 Rayburn House Office Bldg.
Washington D.C. 20515

Dear Congressman Dingell:

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment, which is estimated to be at 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

Our industry believes there is an urgent need to construct the National Bio and Agro Defense Facility (NBAF). If the facility is to be located on the mainland, we believe the DHS needs to take a careful approach in choosing the location. The outbreak resulting from the bio-security breakdown at England's Pirbright laboratory has raised serious concerns about the site for NBAF. The present process appears to be driven more by economics and the growth interest of universities than bio-security. Several universities and their supporting cities/counties located in major livestock producing areas have put forth proposals to be considered by DHS.

We know from the experience of other countries, such as the United Kingdom, that the costs of a Foot and Mouth Disease Outbreak (FMD) in the U.S. would be enormous. We do know that the immediate loss of our export markets is estimated to be $4.8 billion.

Kansas estimates that an outbreak of FMD would cost their state alone $945 million. These costs could be significantly reduced if the United States Department of Agriculture (USDA) would make premises registration mandatory under the National Animal Identification System (NAIS). This would result in quicker tracing of diseased and exposed animals, which allows authorities to more quickly gain control of the outbreak.

We have confidence in the technology supporting the bio-security of our U.S. laboratories, and their record of success is rather remarkable. However, application of all technology has a human component. In spite of all the safeguards that can be built into the system, the risk of releasing a disease organism cannot be entirely eliminated.

We are very concerned regarding Federal, State and Local authorities' ability to detect and mitigate highly contagious foreign animal diseases, such as FMD. The absence of a mandatory NAIS, inadequate funding of animal disease surveillance programs and low priority on disease disaster preparedness represents serious challenges that need to be overcome. Our industry strongly supports USDA as the lead agency to manage a foreign animal disease emergency because of their experience, numbers of trained personnel and familiarity with animal agriculture. We also recognize the importance of DHS in their support role to USDA during these events, and we encourage USDA and DHS to strengthen this relationship through national test exercises.

We strongly support the immediate construction of the NBAF facility. Its location should be determined based on a thorough assessment of the potential risks associated with disease spread to susceptible livestock and wildlife populations. A risk assessment of the six remaining sites should be conducted as part of the final site selection process.

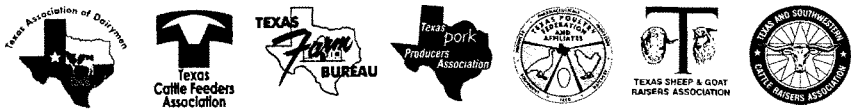
USDA's current mission at the PIADC is to develop diagnostics, treatments, and vaccines and to conduct training to address animal agriculture issues associated with the introduction of a foreign animal disease. In addition to the location of the facility, our larger concern is that once the facility is completed this mission will be overshadowed by the focus of the DHS on the human health component of its mission resulting in livestock concerns being viewed with less importance. The contribution of this facility to the livestock industry and its impact on the global food supply cannot be overstated!

Thank you for the opportunity to share our views.

Sincerely,

PA PORK PRODUCERS COUNCIL

Herbert K. Schick
State Executive



March 11, 2008

The Honorable John Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell and Chairman Stupak:

The livestock organizations in Texas appreciate the opportunity to respond to your letter of inquiry about locating the proposed National Bio and Agro-Defense Facility (NBAF) on the mainland of the United States. As you know, the United States Department of Agriculture and the Department of Homeland Security have been discussing the need for a state-of-the-art foreign animal and zoonotic disease research center for several years now. NBAF will replace the research and foreign animal disease diagnostic facility currently at the Plum Island Animal Disease Center. Several of us have been engaged—individually and through our national organizations—with the committees of jurisdiction and with the Administration to offer input and feedback on this new facility.

Foot-and-mouth disease (FMD) is a highly contagious animal disease and represents a worst-case scenario for livestock diseases due to the number of susceptible species (cattle, sheep, swine, and wildlife such as deer), its rapid spread, and the difficulty in controlling outbreaks. We appreciate your recognition of the severity of this disease and the need for adequate safeguards to protect domestic livestock production. Additional research and the development of effective counter-measures are sorely needed to further protect animal agriculture from accidental and intentional FMD contamination, and we would appreciate your continued support.

We have compiled the following responses to the questions you posed in your letter:

1. Does your organization support moving foot-and-mouth disease form Plum Island to a research facility on the mainland United States?

None of the organizations in Texas have specific policy opposing the relocation of FMD research from Plum Island to the mainland. However, we all have policy supporting animal health and disease prevention research. We are all aware of the negatives for performing FMD research on the mainland, but there are also several benefits including: improved recruitment and retention of qualified staff, collaboration and training opportunities with university research facilities, and accessibility—while Plum Island's remote location provides an additional layer of bio-security, it also makes it difficult to recruit and maintain staff and often hampers fast diagnosis because of the difficulty in delivering suspect samples to the lab, especially on nights and week ends. There may also be a fiscal savings by closing Plum Island and moving its research responsibilities to a new facility on the mainland. Our organizations would be interested in seeing an analysis of the costs to upgrade and modernize Plum Island, build a new facility on Plum Island, and build a new facility on the mainland.

2. What would be the estimated cost to your membership of an outbreak of foot-and-mouth disease in the United States?

The actual costs to Texas livestock producers and related industries as a result of an FMD outbreak are immeasurable. Texas is home to 149,000 cattle operations with 10.5 million head of beef cattle. Of this number, 5.3 million are mother cows valued at $1,200 per head and 2.9 million fat cattle valued at $1,100 per head. There are also 655 dairy operations in our state with 400,000 head each valued at $2,000. The Texas sheep industry totals 7,000 operations with 1.07 million sheep valued at $135 per head. There are approximately 5,000 goat operations in Texas with 1.3 million animals valued at $90 per head. Texas also has 400 swine operations with 1.2 million hogs valued at $100 per head. Also, about 10% of the Texas labor force is directly or indirectly employed by the livestock industry, jobs that would be lost if livestock operations and service providers went out of business due to an FMD outbreak. Additionally, our trading partners would halt imports and close their borders to our products costing the livestock industry billions of dollars.

3. Does your organization believe modern technology is adequate to prevent the accidental release of foot-and-mouth disease - or other contagious diseases affecting livestock - from a research facility located on the mainland United States?

Modern technology is probably more than adequate to prevent the accidental release of FMD, but locating this research on an island obviously adds an extra layer of security—especially given the propensity for human error. The United States is the only country that prohibited FMD research on the mainland. Canada recently built an FMD research facility just north of the border, and there are a number of Bio-level 3 and 4 labs that deal with human diseases located in populous cities like Atlanta, Houston, and San Antonio.

4. If an outbreak of foot-and-mouth disease were to occur on the mainland United States , does your organization believe that federal, state, and local authorities are prepared to identify, isolate, and halt the spread of such an outbreak before it caused significant damage?

The Texas livestock organizations along with local, state, and federal officials have exercised several emergency response scenarios and procedures to an FMD outbreak. We have developed a strong working relationship and have addressed several important issues; however, more work remains and additional education and research are very much needed. The literal "wild card" that may hamper our ability to contain an FMD outbreak quickly is the spread of the disease through wildlife—especially if it were to infiltrate the feral swine and deer populations in Texas. Another area of great concern is the lack of bio-security awareness and planning by some small producers and hobby farmers.

Thank you again for your concern for livestock producers and the recognition that an FMD outbreak—be it accidental or intentional—will have severe consequences for producers and a dramatic, long-lasting effect on our economy. We look forward to continuing this dialogue and working with you to build awareness, support research, and develop additional safeguards to protect domestic livestock production from this and other highly contagious, easily transmissible foreign animal and zoonotic diseases.

Respectfully,

Texas Association of Dairymen
Texas Farm Bureau
Texas Poultry Federation
Texas & Southwestern Cattle Raisers Association
Texas Cattle Feeders Association
Texas Pork Producers Association
Texas Sheep & Goat Raisers Association

WISCONSIN pork ASSOCIATION

P.O. Box 327, Lancaster, WI 53813 • 608-723-7551 • Fax: 608-723-7553 • e-mail: wppa@wppa.org

March 13, 2008

Dear Congressman Dingell,

Thank you for your interest in relocation of the Plum Island Animal Disease Center (PIADC) and the opportunity to share our industry's point of view on its transfer to a mainland location.

The research and diagnostic work carried out at the PIADC is invaluable to the swine industry and the broader livestock industry. There has been an open debate for years about whether the research and diagnostic work done at PIADC should continue on the island or be moved to a new, modern facility on the mainland. With the Department of Homeland Security (DHS) taking ownership of the deteriorating facility, the decision was made to construct a new facility on the mainland. The driving force for a mainland location has been the increased cost of operating in an island environment, which is estimated to be at least 25% more than a mainland location. These increased costs reduce the amount of funds available for the research and diagnostic work conducted at the facility. It is difficult to choose between diminished resources for research, diagnostics and training and the increased costs associated with the added security of an island environment.

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Thank you for the opportunity to share our views.

Sincerely,

John Lader
Co-Chair
WPA Legislative Committee

Bill Gnatzig
Co-Chair
WPA Legislative Committee

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, Jr., NEW JERSEY
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DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

April 29, 2008

The Honorable Collin C. Peterson
Chairman
Committee on Agriculture
U.S. House of Representative
Washington, D.C. 20515

The Honorable Bob Goodlatte
Ranking Member
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Peterson and Ranking Member Goodlatte:

We understand that the House-Senate Joint Conference Committee on H.R. 2419 (the Farm bill) may be close to agreement on the major provisions of this important legislation. Among the unresolved issues, however, are provisions contained in Section 11016 of the Senate version of the bill and in Section 7108 of the House version that would provide for the transfer of live virus of foot-and-mouth disease from the animal disease research laboratory on Plum Island, N.Y., to the mainland United States. These proposals are highly controversial, yet neither has been the subject of hearings nor open debate.[1] Decisions on these issues could have grave implications for the livestock industry and for the national economy. It is for this reason that we write to urge you to drop both the House and the Senate provisions until such time as these matters can be fully examined and debated.

By way of background, for more than 50 years the Federal Government has conducted animal disease research on Plum Island under the U.S. Department of Agriculture (USDA). In 2003, Plum Island was transferred from USDA to the Department of Homeland Security (DHS), while the research staff continued to be employed by USDA. *The majority of the research at Plum Island is concentrated on foot-and-mouth disease, one of the most contagious animal viruses in the world.*

The lab was originally sited on Plum Island to isolate foot-and-mouth disease from the mainland. Our investigation shows that this has been a very successful strategy, as foot-and-mouth disease has never escaped from the island, despite at least one instance in which it was accidentally released from the laboratory building.

[1] Although an administration bill addressing similar issues, H.R. 1717, was considered in markup last year by the House Committee on Homeland Security, no committee report has ever been filed, and the single hearing held on the bill featured only Administration witnesses.

The isolation of foot-and-mouth disease on Plum Island was further ensured by a Federal statute enacted many years ago, which prohibits research on foot-and-mouth anywhere in the U.S. except on Plum Island, unless the Secretary of Agriculture finds it is both necessary and in the public interest to move it elsewhere (21 U.S.C. 113a).

DHS now wants to eliminate this protection and take over research on foot-and-mouth disease and other dangerous animal and zoonotic diseases. To accomplish this, Section 11016 of the Senate version of the bill *directs* the Secretary of Agriculture to do what no previous Secretary has ever done—issue a permit to DHS at its own discretion to transfer foot-and-mouth disease from Plum Island to the mainland United States.

DHS intends to transfer foot-and-mouth disease to a new lab it proposes to build on the mainland U.S., to be called the National Bio and Agro-Defense Facility (NBAF). The NBAF would be the world's largest animal disease research center, and include the world's largest Biosafety Level–4 laboratory (BSL–4). BSL–4 labs handle the most deadly diseases for which there is no cure.

There is a serious question as to whether DHS has the expertise, understanding, and technical capability for conducting animal disease research, especially on this scale. The stakes are not small—as you are aware, foot-and-mouth disease is among the most highly contagious animal diseases in the world. The 2001 outbreak of foot-and-mouth disease in the United Kingdom caused at least $16 billion in damage, devastated the economy, and nearly brought down the government. Experts in the U.S. estimate that a similar release in the U.S. would be even more destructive.

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating these and related issues as part of a series of hearings on the proliferation of bio-research laboratories. The Subcommittee is holding a hearing on May 22, 2008, to examine these and related issues:

- Has DHS given adequate consideration to the hazards of shutting down Plum Island and transferring foot-and-mouth disease to the mainland?

- Can foot-and-mouth disease and other exotic animal disease research be carried out safely in bio containment facilities on the mainland?

- What are the views of the livestock industry about the plan to transfer foot-and-mouth disease research to the mainland?

- Have the direct and indirect costs of shutting down Plum Island and building the NBAF on the U.S. mainland been fully considered?

- Is there an agricultural need for a BSL–4 lab at the NBAF?
- Is the NBAF site-selection process being conducted fairly?
- Does DHS have adequate experience and expertise to lead Federal research on dangerous animal diseases, or should that responsibility more properly reside with USDA?

We believe these issues should be thoroughly examined before the proposal to transfer foot-and-mouth disease to the mainland is permitted. As part of our investigation, we have sent detailed requests for information and records pertaining to this matter to DHS and USDA. Moreover, we have sent letters to more than 100 livestock associations asking for their views on the issue of transferring foot-and-mouth disease research to the mainland, along with research on other animal diseases.

We recommend that you reject provisions in H.R. 2419 that would require the transfer of foot-and-mouth disease to the mainland until such time that DHS and USDA, at a minimum, have performed the necessary risk and consequence assessments, explained why it is necessary and in the public interest to move foot-and-mouth disease and other dangerous animal viruses to the mainland, and performed the necessary environmental impact studies.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

All House conferees to H.R. 2419

110TH CONGRESS
1ST SESSION

H. R. 1717

To amend the Homeland Security Act of 2002 to establish a National Bio and Agro-defense Facility.

IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2007

Mr. MCCAUL of Texas (for himself, Mr. PICKERING, Mr. LANGEVIN, Mr. THOMPSON of Mississippi, Mr. ETHERIDGE, and Ms. JACKSON-LEE of Texas) introduced the following bill; which was referred to the Committee on Homeland Security, and in addition to the Committees on Agriculture and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Homeland Security Act of 2002 to establish a National Bio and Agro-defense Facility.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. NATIONAL BIO AND AGRO-DEFENSE FACILITY.

(a) IN GENERAL.—Title III of the Homeland Security Act of 2002 (6. U.S.C. 181 et seq.) is amended by adding at the end the following new section:

1 **"SEC. 316. NATIONAL BIO AND AGRO-DEFENSE FACILITY.**

2 "(a) ESTABLISHMENT.—There is in the Department
3 a National Bio and Agro-defense Facility (referred to in
4 this section as the 'NBAF'), which shall be headed by a
5 Director who shall be appointed by the Secretary.

6 "(b) PURPOSES.—

7 "(1) IN GENERAL.—The NBAF shall be an in-
8 tegrated human, foreign-animal, and zoonotic dis-
9 ease research, development, testing, and evaluation
10 facility with the purpose of supporting the com-
11 plementary missions of the Department, the Depart-
12 ment of Agriculture, and the Department of Health
13 and Human Services in defending against the threat
14 of potential acts of agroterrorism and natural-occur-
15 ring incidents related to agriculture with the poten-
16 tial to adversely impact public health, animal health,
17 and the economy, or may otherwise impact homeland
18 security.

19 "(2) KNOWLEDGE PRODUCTION AND SHAR-
20 ING.—The NBAF shall produce and share knowl-
21 edge and technology for the purpose of reducing eco-
22 nomic losses caused by foreign-animal, zoonotic, and,
23 as appropriate, other endemic animal diseases of
24 livestock and poultry and preventing human suf-
25 fering and death caused by diseases existing or
26 emerging in the agricultural sector.

1 "(c) RESPONSIBILITIES OF DIRECTOR.—The Sec-
2 retary shall vest in the Director primary responsibility for
3 each of the following:
4 "(1) Directing basic, applied, and advanced re-
5 search, development, testing, and evaluation relating
6 to foreign-animal, zoonotic, and, as appropriate,
7 other endemic animal diseases, including foot and
8 mouth disease, and performing related activities, in-
9 cluding—
10 "(A) developing countermeasures for for-
11 eign-animal, zoonotic, and, as appropriate,
12 other endemic animal diseases, including
13 diagnostics, vaccines and therapeutics;
14 "(B) providing advanced test and evalua-
15 tion capability for threat detection, vulner-
16 ability, and countermeasure assessment for for-
17 eign-animal, zoonotic, and, as appropriate,
18 other endemic animal diseases;
19 "(C) conducting nonclinical, animal model
20 testing and evaluation under the Food and
21 Drug Administration's Animal Rule as defined
22 in parts 314 and 601 of title 22, Code of Fed-
23 eral Regulations, to support the development of
24 human medical countermeasures by the Depart-

1 ment of Human Services under the Public
2 Health Service Act (42 U.S.C. 201 et seq);
3 "(D) establishing NBAF information-shar-
4 ing mechanisms to share information with rel-
5 evant stakeholders, including the National Ani-
6 mal Health Laboratory Network; and
7 "(E) identifying and promoting uniform
8 national standards for animal disease
9 diagnostics.
10 "(2) Facilitating the coordination of Federal,
11 State, and local governmental research and develop-
12 ment efforts and resources relating to protecting
13 public health and animal health from foreign-animal,
14 zoonotic, and, as appropriate, other endemic animal
15 diseases.
16 "(3) Ensuring public safety during an emer-
17 gency by developing an emergency response plan
18 under which emergency response providers in the
19 community are sufficiently prepared or trained to re-
20 spond effectively and given sufficient notice to allow
21 for an effective response.
22 "(4) Ensuring NBAF site and facility security.
23 "(5) Providing training to develop skilled re-
24 search and technical staff with the needed expertise

in operations conducted at biological and agricultural research facilities.

"(6) Leveraging the expertise of academic institutions, industry, the Department of Energy National Laboratories, State and local governmental resources, and professional organizations involved in veterinary, medical and public health, and agriculture issues to carry out functions describes in (1) and (2).

"(d) REQUIREMENTS.—The Secretary, in designing and constructing the NBAF, shall ensure that the facility meets the following requirements:

"(1) The NBAF shall consist of state-of-the-art biocontainment laboratories capable of performing research and activities at Biosafety Level 3 and 4, as designated by the Centers for Disease Control and Prevention and the National Institutes of Health.

"(2) The NBAF facility shall be located on a site of at least 30 acres that can be readily secured by physical measure.

"(3) The NBAF facility shall be at least 500,000 square feet with a capacity of housing a minimum of 80 large animals for research, testing and evaluation.

"(4) The NBAF shall be located at a site with a preexisting utility infrastructure, or a utility infrastructure that can be easily built.

"(5) The NBAF shall be located at a site that has been subject to an Environmental Impact Statement under the National Environmental Policy Act of 1969.

"(6) The NBAF shall be located within a reasonable proximity to a national or regional airport and to major roadways.

"(e) AUTHORIZATION TO PROCURE REAL PROPERTY AND ACCEPT IN KIND DONATIONS FOR THE NBAF SITE.—The Secretary may accept and use donations of real property for the NBAF site and may accept and use in-kind donations of real property, personal property, laboratory and office space, utility services, and infrastructure upgrades for the purpose of assisting the Director in carrying out the responsibilities of the Director under this section.

"(f) APPLICABILITY OF OTHER LAWS.—

"(1) PUBLIC BUILDINGS ACT.—The NBAF shall not be considered a "public building" for purposes of the Public Buildings Act of 1959 (40 U.S.C. 3301 et seq.).

"(2) LIVE VIRUS OF FOOT AND MOUTH DISEASE RESEARCH.—The Secretary shall enable the study of live virus of foot and mouth disease at the NBAF, wherever it is sited, notwithstanding section 113a of title 21, United States Code.

"(g) COORDINATION.—

"(1) INTERAGENCY AGREEMENTS.—

"(A) IN GENERAL.—The Secretary shall enter into understandings or agreements with the heads of appropriate Federal departments and agencies, including the Secretary of Agriculture and the Secretary of Health and Human Services, to define the respective roles and responsibilities of each Department in carrying out foreign-animal, zoonotic, and other endemic animal disease research and development at the NBAF to protect public health and animal health.

"(B) DEPARTMENT OF AGRICULTURE.—The understanding or agreement entered into with the Secretary of Agriculture shall include a provision describing research programs and functions of the Department of Agriculture and the Department of Homeland Security, including those research programs and functions car-

1 ried out at the Plum Island Animal Disease
2 Center and those research programs and func-
3 tions that will be transferred to the NBAF.
4 "(C) DEPARTMENT OF HEALTH AND
5 HUMAN SERVICES.—The understanding or
6 agreement entered into with the Department of
7 Health and Human Services shall describe re-
8 search programs of the Department of Health
9 and Human Services that may relate to work
10 conducted at NBAF.
11 "(2) COOPERATIVE RELATIONSHIPS.—The Di-
12 rector shall form cooperative relationships with the
13 National Animal Health Laboratory Network and
14 American Association of Veterinary Laboratory Di-
15 agnosticians to connect with the network of Federal
16 and State resources intended to enable an inte-
17 grated, rapid, and sufficient response to animal
18 health emergencies.".
19 (b) CLERICAL AMENDMENT.—The table of contents
20 in section 1(b) of such Act is amended by adding at the
21 end of the items relating to title III the following:

"Sec. 316. National Bio and Agro-defense Facility.".

○

From the U.S. Code Online via GPO Access
[wais.access.gpo.gov]
[Laws in effect as of January 3, 2006]
[**CITE: 21USC113a**]

TITLE 21--FOOD AND DRUGS

CHAPTER 4--ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

SUBCHAPTER III--PREVENTION OF INTRODUCTION AND SPREAD OF CONTAGION

Sec. 113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases; research contracts; employment of technicians and scientists; appropriations

The Secretary of Agriculture is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and also the making of research contracts under the authority contained in section 427i(a) of title 7, for research and study, in the United States or elsewhere, of foot-and-mouth disease and other animal diseases which in the opinion of the Secretary constitute a threat to the livestock industry of the United States: Provided, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States (except coastal islands separated therefrom by water navigable for deep-water navigation and which shall not be connected with the mainland by any tunnel) unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York) and issues a permit under such rules as the Secretary shall promulgate to protect animal health, except that the Secretary of Agriculture may transport said virus in the original package across the mainland under adequate safeguards, and except further, that in the event of outbreak of foot-and-mouth disease in this country, the Secretary of Agriculture may, at his discretion, permit said virus to be brought into the United States under adequate safeguards. To carry out the provisions of this section, the Secretary is authorized to employ technical experts or scientists: Provided, That the number so employed shall not exceed five and that the maximum compensation for each shall not exceed the highest rate of grade 18 of the General Schedule. There is authorized to be appropriated such sums as Congress may deem necessary; in addition, the Secretary is authorized to utilize in carrying out this section, funds otherwise available for the control or eradication of such diseases.

(May 29, 1884, ch. 60, Sec. 12, as added Apr. 24, 1948, ch. 229, 62 Stat. 198; amended July 31, 1956, ch. 804, title I, Sec. 119, 70 Stat. 742; Pub. L. 85-573, July 31, 1958, 72 Stat. 454; Pub. L. 87-793, Sec. 1001(e), Oct. 11, 1962, 76 Stat. 864; Pub. L. 88-426, title III, Sec. 305(1), Aug. 14, 1964, 78 Stat. 422; Pub. L. 101-624, title XVI, Sec. 1618(b), Nov. 28, 1990, 104 Stat. 3733.)

Codification

Provisions that authorized the Secretary to employ technical experts and scientists ``without regard to the Classification Act'', meaning the Classification Act of 1923, were omitted as obsolete. Sections 1202 and 1204 of the Classification Act of 1949, 63 Stat. 972, 973, repealed the 1923 Act and all laws or parts of laws inconsistent with the 1949 Act. While section 1106(a) of the 1949 Act provided that references in other

laws to the 1923 Act should be held and considered to mean the 1949 Act, it did not have the effect of continuing the exception contained in this section because of section 1106(b) which provided that the application of the 1949 Act to any position, officer, or employee shall not be affected by section 1106(a). The Classification Act of 1949 was repealed by Pub. L. 89-554, Sept. 6, 1966, Sec. 8(a), 80 Stat. 632 (the first section of which revised and enacted Title 5, Government Organization and Employees, into law). Section 5102 of Title 5 contains the applicability provisions of the 1949 Act, and section 5103 of Title 5 authorizes the Office of Personnel Management to determine the applicability to specific positions and employees.

Amendments

1990--Pub. L. 101-624 substituted ``United States (except'' for ``United States except'' and ``tunnel) unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York) and issues a permit under such rules as the Secretary shall promulgate to protect animal health,'' for ``tunnel, and''.

1962--Pub. L. 87-793 substituted ``shall not exceed the highest rate of grade 18 of the General Schedule'' for ``shall not exceed $19,000 per annum''.

1958--Pub. L. 85-573 inserted in proviso clause of first sentence the exception clause respecting transportation of virus in original package across mainland under adequate safeguards.

Effective Date of 1962 Amendment

Amendment by Pub. L. 87-793 effective on first day of first pay period which begins on or after Oct. 11, 1962.

Repeals

Act July 31, 1956, ch. 804, title I, Sec. 119, 70 Stat. 742, which increased the maximum compensation of technical experts or scientists, was repealed by Pub. L. 88-426, title III, Sec. 305(1), Aug. 14, 1964, 78 Stat. 422.

References in Other Laws to GS-16, 17, or 18 Pay Rates

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, Sec. 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SEC. 7524. LIVE VIRUS FOOT AND MOUTH DISEASE RESEARCH.

(a) *In General*.--The Secretary shall issue a permit required under section 12 of the Act of May 29, 1884 (21 U.S.C. 113a) to the Secretary of Homeland Security for work on the live virus of foot and mouth disease at any facility that is a successor to the Plum Island Animal Disease Center and charged with researching high-consequence biological threats involving zoonotic and foreign animal diseases (referred to in this section as the ``successor facility'').

(b) *Limitation to Single Facility*.--Not more than 1 facility shall be issued a permit under subsection (a).

(c) *Limitation on Validity*.--The permit issued under this section shall be valid unless the Secretary determines that the study of live foot and mouth disease virus at the successor facility is not being carried out in accordance with the regulations promulgated by the Secretary pursuant to the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401 et seq.).

(d) *Authority*.--The suspension, revocation, or other impairment of the permit issued under this section--

(1) shall be made by the Secretary; and

(2) is a nondelegable function.

HHS COMMENTS ON
HR 1717 - NATIONAL BIO AND AGRO-DEFENSE FACILITY

- H.R. 1717 is essentially identical to a section of the DHS Authorization bill (sec. 606 of H.R. 1684) as reported in the House that was struck before House passage.

- H.R. 17171 would unnecessarily duplicate statutory responsibilities at the Department of Health and Human Services and the Department of Defense with regard to human countermeasure and human health research and development activities.

1. Human Countermeasures:

A Statement on Administration Policy (SAP) on H.R.1684 indicates that the Administration supports provisions to authorize the National Bio and Agro-Defense Facility (NBAF). However, the Administration clearly indicates concerns with provisions in the bill on human countermeasures research and development:

> "Principal responsibility for research and development activities relating to human countermeasures lies with HHS for the civilian populations and the Department of Defense (DOD) for the military. The bill should be revised to avoid any duplication or confusion of missions."

(see <http://www.whitehouse.gov/omb/legislative/sap/110-1/hr1684sap-h.pdf>, p.3).

2. Human Health:

We are remained concerned that the bill language places more emphasis on human health, rather than animal health. The primary focus of NBAF is to address animal health issues related to agriculture. Human health issues are primarily the responsibility of HHS (and DOD for the military). The bill language should clearly delineate this distinction.

STATEMENT FOR THE RECORD

of

Dr. John Vitko, Jr.
Head, Chemical and Biological Division
Science & Technology Directorate
Department of Homeland Security

Regarding a Hearing Entitled

"Reducing Threats to Our Nation's Agriculture: Authorizing the National Bio and Agro-defense Facility (NBAF)"

Before the
U.S. House of Representatives
Committee on Homeland Security
Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology

May 23, 2007

INTRODUCTION

Good afternoon, Chairman Langevin, Ranking Member McCaul, and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the Nation's critical need for the Department of Homeland Security's National Bio and Agro Defense Facility.

There is a need for a secure, state-of-the-art agriculture biocontainment facility that researches and diagnoses foreign animal and zoonotic diseases. Currently, there is only a limited research laboratory capacity in the Nation for large animal BioSafety Level -3 (BSL-3Ag) studies, and there is no BSL-4 research space for the study of threat agents that infect both large animals and humans. If the United States is to have the proper capability to rapidly identify and control outbreaks of high-threat foreign animal and zoonotic disease agents, whether natural or intentional, it must begin investing in additional biocontainment capacity and capability.

Numerous infectious animal diseases are present throughout the world that threaten the nation's public health, agriculture and economy. For example, recall the foot-and-mouth disease outbreak in the U.K. in 2001 and the catastrophic losses that this outbreak caused that nation, and from which it is still recovering now six years later. The economic loss was well into the billions, affecting agricultural industries but having a wider impact on other industries including tourism. The impact would be far greater in the U.S, with its much larger livestock population, larger herds, and extensive shipment across the country.

As evidenced by recent examples, including West Nile Fever and Avian Influenza, existing and emerging foreign animal and zoonotic diseases pose an immediate threat not only to our agricultural industry but also to our public health.

Realizing this threat, the President issued Homeland Security Presidential Directive 9: *Defense of the U.S. Agriculture and Food.* HSPD-9 requires the Secretaries of Agriculture and Homeland Security , Health and Human Services, and the Administrator of the Environmental Protection Agency to "develop a plan to provide safe, secure and state-of-the-art agricultural biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases" and further states that "The Secretaries of Homeland Security, Agriculture ... will accelerate and expand development of current and new countermeasures against intentional introduction or natural occurrence of catastrophic animal, plant and zoonotic diseases." As will be elaborated in the following sections, NBAF fulfills a critical role in meeting both these requirements and ensuring that the nation's public health, food and agriculture are protected for the next 50 years.

In pursuing NBAF, DHS will work closely with its partners in the United States Department of Agriculture under the same terms and spirit as it currently does at the Plum Island Animal Disease Center.

The Need for NBAF

For more than 50 years, the Plum Island Animal Disease Center (PIADC) has served as the nation's first defense against foreign animal diseases. However, the threats to the Nation's agriculture and public health have changed dramatically since the time of PIADC's establishment. These changes include the globalization of travel and trade, the broadened size and scope of U.S. livestock and agricultural industry, and now the threat of agro-terrorism. PIADC's research and diagnostic activities stem from its mission to protect U.S. animal industries and exports from deliberate or accidental introduction of foreign animal diseases. PIADC has been a leader in researching foreign animal diseases, developing diagnostics and vaccines to prevent and contain them, and training foreign animal disease diagnosticians to detect them. The Homeland Security Act of 2002 transferred the operations of PIADC to DHS. Since that time, the DHS Science & Technology Directorate has been working jointly with the United States Department of Agriculture's Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS) to meet the island's shared mission objectives.

However, despite significant investments in the facility's infrastructure, Plum Island Animal Disease Center is unable to fully meet the research and diagnostic capabilities required to address the threat of agro-terrorism. The available laboratory space at PIADC, especially the large animal holding laboratory space, is limiting the pace at which we can develop improved veterinary countermeasures. The joint USDA-DHS team has made significant progress in developing next-generation vaccines for foot-and-mouth disease. The path forward for such state-of-the art vaccines includes taking these discoveries through developmental and testing phases for licensure necessary for inclusion in the National Veterinary Stockpile and for eventual use by first responders. However, the limited animal testing space at PIADC is limiting the number of vaccine trials that can be conducted and drastically extending the time frame to complete these studies. Additionally, because of capacity and biocontainment constraints, PIADC concentrates on research and diagnostic activities for only a subset of the highest-consequence foreign animal diseases and cannot facilitate expanded research into other high priority foreign animal disease and emerging threats of concern.

Additionally, BSL-4 work cannot be done at PIADC. Thus, the nation lacks a facility to adequately address high-consequence zoonotic diseases that infect both large animals and humans. The impact of disease agents, such as Rift Valley Fever, Nipah, and Hendra, underscore the growing threat posed by emerging zoonotic diseases and the need to establish better facilities to study them.

To address these limitations, the planned NBAF will provide the infrastructure necessary to research and develop diagnostics for, and countermeasures to, high-consequence biological threats involving foreign animal and zoonotic diseases by:

- Providing state-of-the art biocontainment laboratories for development, test and evaluation of countermeasures for foreign animal and zoonotic diseases to support their inclusion in the National Veterinary Stockpile;
- Integrating those aspects of animal and public health research that are key to fulfilling that mission;
- Continuing to meet evolving needs in defending against agro-terrorism threats over the next five decades.

Plum Island Animal Disease Center's capability is a critical national asset and essential to protecting the U.S. agriculture economy and food supply. No other facility now exists in this country to perform this research. However, due to its age, location and outdated design, PIADC does not meet all of the nation's current needs. The planned NBAF will enable us to fully meet the challenges of intentional or unintentional introduction of a foreign animal disease that could threaten public health and the food supply over the next 50 years.

The Scope of NBAF

NBAF is being designed to provide the Nation with the "safe, secure, and state-of-the-art agriculture biocontainment laboratories" (HSPD-9) needed to develop countermeasures to current, emerging and future foreign animal and zoonotic diseases. The facility design will enable concurrent development of multiple priority vaccine candidates. It will also meet the shared interagency mission objectives of a successful agro-defense strategy, including:

- basic research on how an organism infects an animal and how the disease is transmitted from animal to animal;
- identification of 'lead candidates' for new vaccines and antivirals and novel delivery systems to better facilitate response actions;
- pilot lot production and proof-of-concept testing of those lead candidates;
- the development of molecular diagnostics to characterize the efficacy of the new countermeasures;
- clinical testing and evaluation of the countermeasures to support licensure by the USDA Center for Veterinary Biologics and inclusion in the National Veterinary Stockpile;
- maintain a vaccine bank that contains a secure inventory of antigens that would be used to formulate a vaccine in the event of an outbreak;
- develop and test diagnostics to rapidly identify, characterize, and control outbreaks;
- train veterinarians, giving them first hand experience in recognizing and diagnosing high consequence foreign animal diseases and thereby establishing a clinical capability for rapid response throughout the U.S.

DHS, in close coordination with USDA, is actively engaged in the definition of these program areas and the conceptual design of facility aspects to best support them. Additionally, USDA personnel are active participants in the NBAF site selection process. The conceptual design is independent of the site selected and will ensure that the NBAF's research requirements will be met. Such a state-of-the-art facility will synergize with existing veterinary, medical and public health, and agriculture programs and will help attract, train and retain future generations of researchers, technicians, diagnosticians, veterinary and medical personnel.

DHS has begun taking the steps to make this vision a reality. In January of 2006 DHS issued a notice of request for Expressions of Interest (EOI) for potential sites for the NBAF in the Federal Register and received 29 submissions from consortia in 21 states. An interagency review committee (DHS, USDA, HHS and DoD) evaluated the site proposals using four major sets of criteria which had been published in the EOI notice of request:

- Site proximity to Research Capabilities that can be linked to NBAF mission requirements
- Site proximity to a skilled Workforce to support NBAF mission requirements
- Acquisition/Construction/Operations; and
- Community Acceptance

Based on this initial evaluation, 12 consortia in 11 states were asked to submit additional information on 17 sites. That information is currently under review. In addition, the review team and the DHS Under Secretary for Science and Technology are visiting each of the sites for further evaluation. Following the site visits, a small number of sites will be selected for inclusion in the Environmental Impact Statement (EIS). This selection will be completed by June 2007. The final site selection will be determined following completion of the EIS.

Key milestones and anticipated dates in this process are summarized below:

• Additional information due	February, 2007
• Conduct reviews	March, 2007
• Site visits	April- May, 2007
• Issue Notice of Intent (NOI) announcing sites selected for evaluation in the EIS	June, 2007
• Begin EIS	July, 2007
• Complete EIS; announce site selection	October, 2008
• Begin detailed design	November, 2008
• Begin construction	2010
• Facility operational	2013 – 2014

Conclusion

In summary, the planned NBAF will play a crucial role in protecting the Nation against current and future foreign animal and zoonotic diseases, whether naturally or intentionally introduced. The list of such high priority diseases is already long and growing. Plum Island has been doing an excellent job in the defense against foreign animal disease threats – but the age of its facilities and its limited capacity is pacing the development of needed countermeasures. Further, there are no facilities in the Nation to fully address those zoonotic diseases that affect both large animals and humans and attract the scientists, technicians, researchers, veterinarians and medical personnel needed to defend against current and future threats for the next 30-50 years. Therefore, DHS is committed to making the planned NBAF, as the next generation capability to support our partners in ARS and APHIS, a reality.

SUPPLEMENTAL SHEET – FOLLOW-UP ADDRESS:

Dr. John Vitko, Jr.
Head, Chemical and Biological Division
U.S. Department of Homeland Security
Science and Technology
Washington, D.C. 20528

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STATEMENT OF DR. EDWARD KNIPLING
ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE
UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON HOMELAND SECURITY
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY
ON
THE ESTABLISHMENT OF THE NATIONAL BIO AND AGRO-DEFENSE FACILITY.

MAY 23, 2007

Mr. Chairman, Ranking Member McCaul, and Members of the Subcommittee, I am Dr. Edward Knipling, Administrator of the Agricultural Research Service (ARS). Accompanying me is Mr. Kevin Shea, Associate Administrator of the Animal and Plant Health Inspection Service (APHIS). ARS is the primary intramural science research agency of USDA, operating a network of over 100 research laboratories across the nation on all aspects of agricultural science. APHIS is responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

Thank you for the opportunity to appear before the Subcommittee today to present the Department's views on the establishment of the National Bio and Agro-Defense Facility (NBAF).

Mr. Chairman, the need to establish this facility is basically two fold: First, it is needed to replace the aging foreign animal disease research, diagnostic and training facility at Plum Island; and, second, it is needed to provide additional space and capability for animal borne diseases that can be transmitted to humans. Homeland Security Presidential Directive No. 9 (HSPD-9) identifies the need for "safe, secure, and state-of-the-art agricultural biocontainment facilities to research and develop diagnostic capabilities for foreign animal and zoonotic diseases." Current limitations at existing facilities result in a backlog of needed space for important experiments, diagnostics, and training efforts.

Despite the planned replacement of the Plum Island Animal Disease Center (PIADC) with NBAF, the PIADC must continue to operate during NBAF construction and beyond to allow adequate transition to the new facility and eventual facility decommissioning at Plum Island. It is estimated that PIADC facilities must operate for about the next 7-10 years. The highest priority for facility upgrade includes the construction of additional animal holding (experiment) facilities (10,000 ft2) and expansion of the necropsy room capacity. The additional capacity is needed to

address the coordinated USDA-DHS vaccine development program over the next 7-10 years.

The upgrade and expansion of the necropsy facility will also improve our current educational facility for the foreign animal disease (FAD) training schools carried out by APHIS at PIADC. APHIS conducts these training schools on Plum Island to ensure that our Nation's corps of foreign animal disease diagnosticians—those specially trained veterinarians immediately dispatched by APHIS to investigate and, if necessary, respond to possible introductions of exotic animal diseases into the United States—have the latest scientific and technical information and skills necessary to carry out their work. APHIS also conducts its confirmatory testing for extremely contagious foreign animal diseases, such as foot-and-mouth disease (FMD), at the PIADC. In addition, the Agency houses the North American Foot-and-Mouth Disease vaccine bank on PIADC. The bank ensures that if FMD were to be found in North America and vaccination was to be used as a tool in the ensuing control and eradication program, adequate supply of vaccine would be quickly available to animal health officials.

Under Section 310(a) of the Homeland Security Act of 2002, the Secretary of Agriculture transferred PIADC to the Secretary of Homeland Security, including the assets and liabilities of PIADC. Section 310(b) of the Act required the Secretary of Homeland Security and the Secretary of Agriculture to enter into an agreement upon such transfer **to ensure that USDA is able to carry out research, diagnostic, and other activities of USDA at PIADC.** USDA-ARS, USDA-APHIS and DHS-S&T entered into an Interagency Agreement dated June 1, 2003, ("the FY03 Agreement) which together with successor agreements sets forth the Parties' agreements regarding the management, administration, and operations of PIADC, and the Parties' respective rights and responsibilities for research, diagnostic, and development activities at PIADC. According to this agreement, a Board of Directors (BOD) is composed of the Directors or Administrators of APHIS, ARS and DHS-S&T Directorate. A Senior Leadership Group (SLG), composed of the senior administrators of each agency at PIADC, executes the FY03 Agreement, implements policies, coordinates at the local level and reports to the BOD.

DHS's work currently focuses primarily on FMD; whereas ARS, in addition to FMD, also addresses other diseases, specifically classical swine fever and vesicular stomatitis. A FMD countermeasure roadmap was prepared in 2004 to coordinate DHS and ARS activities. According to this document, ARS would maintain responsibility for basic research, and DHS would focus on product development. A high priority disease diagnostic roadmap was prepared in 2006 to coordinate DHS, ARS, and APHIS activities in this area.

Mr. Chairman this concludes my remarks. We would be happy to answer any questions at this time.

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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September 20, 2007

The Honorable Charles F. Conner
Acting Secretary
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dear Acting Secretary Conner:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the management, operation, and activities of the Department of Homeland Security's (DHS's) Plum Island Animal Disease Center (PIADC), including the recent proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agro-Defense Facility (NBAF). The Committee has jurisdiction over interstate and foreign commerce generally, public health and quarantine, biomedical programs and health protection in general, food safety, drug safety, environmental protection, and the homeland security-related aspects of the foregoing.

The Plum Island research facility has been in operation for more than 50 years, the majority of that time owned and managed by the U.S. Department of Agriculture (USDA). In June 2003, operational responsibility for the PIADC was transferred to DHS, while the research staff continued to be employed by USDA. It is the Committee's understanding that the majority of the research at Plum Island has been concentrated on foot-and-mouth disease (FMD), which, as you know, is highly contagious. Research has also been conducted on classical swine fever, African swine fever, and other diseases.

The PIADC was originally sited on Plum Island due to concerns that an accidental release of the extraordinarily hazardous viruses and other diseases handled at that facility would pose a serious threat to animal health and, in some cases, human health and the environment. The natural barrier of water surrounding the island, along with its remoteness at the far end of Long Island, New York, were perceived as, and have apparently been successful over the last 50 years,

an effective buffer zone between Plum Island research and farming activities in the rest of the country.

There is no doubt that a release of FMD or swine fever could be devastating to the livestock industry in the United States. The 2001 outbreak of FMD in the United Kingdom resulted in the destruction of millions of cattle and sheep and cost more than $16 billion. The 2007 U.K. outbreak was identified and isolated almost immediately, so its economic effects were limited. This incident, however, illustrates how easily the disease can spread from a government research facility located in a farming community on the mainland of England.

We are concerned that inadequate consideration may have been given to the hazards of shutting down the Plum Island PIADC and transferring its operations—and the live virus stored there—to the interior of the United States. We are also concerned that the direct and indirect costs of this proposal may have not have been fully considered.

To aid in our investigation, please provide the following information and records:

1. Does USDA agree with the DHS proposal to close the Plum Island PIADC and transfer its operations elsewhere?

2. Please provide copies of all records, including memoranda, reports, studies, etc., dated January 1, 2002, or later, whether draft or final, discussing whether Plum Island should be closed and/or relocated.

3. Has an assessment been conducted that reviewed the need for the closure, expansion, or replacement of the PIADC? If so, please provide a copy.

4. Plum Island covers some 840 acres of land. If there is a need to expand the PIADC facilities at Plum Island, is there enough room at Plum Island to accommodate that expansion?

5. Please provide a detailed description of USDA's role in the planning, construction, and operation of the proposed NBAF.

6. The scientific research conducted at the Plum Island PIADC typically requires highly trained professionals. Please provide a list of researchers employed at the PIADC, with names omitted, showing the education level, field of expertise, and pay grade/compensation rate for each.

7. Closing the PIADC and transferring its functions to the new NBAF would require the transfer of the current research staff to the new location. Experience at other government laboratories shows that a large number of such personnel would be unable

or unwilling to relocate, thus causing a substantial loss in expertise and continuity of operations. Has USDA estimated the number of researchers who would be likely to refuse a transfer from Plum Island? Please provide copies of any such analysis.

8. Please provide copies of all records pertaining to the need for and cost of environmental cleanup at Plum Island.

9. How many people are employed by USDA at Plum Island?

10. Have any outside contractors been involved in proposing, analyzing, or planning the closing of the Plum Island PIADC or the establishment of the NBAF? If so, please provide their names and roles.

11. Please provide a description of all renovations and new construction carried out at Plum Island in the past 10 years. Please provide detailed cost data by year for each of the past 10 years on the cost of such renovations and new construction.

12. Classical swine fever and African swine fever could be devastating to the swine populations of the United States. Yet, apparently, swine fever research at Plum Island has been severely curtailed in recent years. Why has swine fever research at Plum Island been virtually eliminated? Please provide copies of all records since January 1, 1997, regarding the decision to reduce swine fever research at Plum Island.

13. Has USDA been contacted by members of the agricultural and livestock industries regarding the proposal to close Plum Island and transfer FMD and other livestock disease research to another facility in the United States? If so, please provide copies of all records pertaining to such contacts.

14. Under Federal law (7 USC 113a), no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States without the express permission of the Secretary of Agriculture, who must find that it is both necessary and in the public interest. Has the Secretary granted such permission at any time in the last 10 years? If so, please provide a list of all such instances.

15. Do you intend to grant permission for the transfer of live virus of foot-and-mouth disease from the PIADC to a new location on the mainland United States, if the PIADC is closed?

16. The PIADC includes a biosafety level 3 (BSL–3) laboratory. Please identify the types of research currently being performed in this BSL–3 laboratory and which have been performed at any time since January 1, 1997.

17. It is our understanding that DHS plans to construct a BSL-4 laboratory as part of the new NBAF. In your opinion, is a BSL-4 laboratory needed at either Plum Island or at the proposed NBAF to conduct research on plant and animal disease? Please provide copies of any analysis that has been performed on this issue.

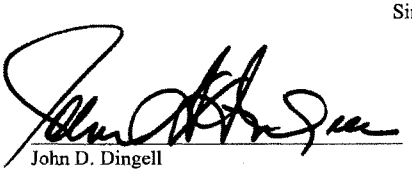
Please deliver the requested information and records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, room 316 Ford House Office Building, no later than the close of business on October 2, 2007.

In responding to this request, please be advised that the terms "records" and "relating to" are defined in the attachment to this letter.

If you elect to assert a privilege or objection to the production of the foregoing records or information, please provide a privilege log fully identifying each record withheld and the legal basis asserted for withholding the record from a congressional committee of competent jurisdiction.

If you have any questions regarding this request, please contact us or have your staff contact John Arlington, Senior Investigative Counsel with the Committee on Energy and Commerce staff, at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

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GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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February 21, 2008

The Honorable Michael Chertoff
Secretary
U.S. Department of Homeland Security
Washington, DC 20528

Dear Secretary Chertoff:

As you are aware, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the management, operation, and activities of the Department of Homeland Security's (DHS) Plum Island Animal Disease Center (PIADC), and the proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agrodefense Facility (NBAF). In a letter to you dated September 20, 2007, we requested records and information to aid our investigation of these matters.

Your failure to make a complete response to our records request is troubling. Despite assurances of cooperation from Under Secretary Jay Cohen in a letter to this Committee dated October 25, 2007, we continue to discover the existence of records directly related to our request, but which were not included in your response. For example, it was in the course of a visit to Plum Island by committee investigators in November that we became aware that DHS possessed two studies performed by SAIC analyzing Plum Island and NBAF issues. Similarly, it was only as a result of Committee staff interviews of certain DHS officials that we became aware of a study on Plum Island performed by the Homeland Security Institute (HSI) in 2007. The SAIC studies have now been provided, but despite staff requests, the HSI study has yet to be produced.

It is unclear what has caused this failure to fully comply with our initial request. Whatever the cause may be, we are continuing our investigation of this matter. The recent discovery of additional records requires further exploration of these issues. Therefore, please provide the following information and records:

1. Section 11016 of the farm bill (H.R. 2419) as passed by the Senate, would *require* the Secretary of Agriculture to issue a permit to the Secretary of Homeland Security to move live virus of foot-and-mouth disease from Plum Island to the mainland United States. A similar provision is contained in H.R. 1717. Under 21 U.S.C. 113a, the Secretary of Agriculture already has the authority to issue such a permit. Do you believe it is

necessary to override the Secretary of Agriculture's statutory discretion in this matter by requiring that the Secretary issue a permit for transfer of live virus of foot-and-mouth disease to the proposed NBAF? If so, why?

2. Please provide copies of all records, including copies of all testimony, comments, memoranda, letters, notes, e-mails, talking points, or communications between DHS and any other party, including the U.S. Congress, pertaining to: (a) the authority of the Secretary of Agriculture to issue a permit under 21 U.S.C. 113a to transfer live virus of foot-and-mouth disease to the mainland United States; and (b) legislation pertaining to such authority.

3. Following initial interviews of DHS employees, Committee staff requested a copy of the original draft April 27, 2007 study prepared for DHS by the Homeland Security Institute titled, "DHS Agrosecurity Science and Technology – Plum Island and Beyond." In an attachment to his letter of November 30, 2007, Under Secretary Cohen stated that this study "is still in draft form and changes are being worked with HSI. A copy of this draft is not being supplied at this time." No reason was offered by Under Secretary Cohen for withholding a copy of this study and we are aware of no valid reason under which this study may be withheld from this Committee. Please provide a copy of the April 27 draft of this study and all subsequent drafts, whether final or not.

4. Please provide copies of all records DHS may have on the economic effects of an outbreak of foot-and-mouth disease in the United States.

5. Please provide copies of all records which model, demonstrate, and/or analyze the spread of foot-and-mouth disease in the United States.

6. Please provide copies of all reports and analyses of the Crimson Sky simulation.

7. As an attachment to his November 30, 2007, letter, Under Secretary Cohen provided copies of travel authorizations for himself for eight NBAF site visits. Please provide copies of all other travel records for Under Secretary Cohen from August 10, 2006, to December 31, 2007.

8. As an attachment to his November 30, 2007, letter, Under Secretary Cohen provided copies of travel authorizations for Dr. Tam Garland for six NBAF public scoping meetings. Please provide copies of all other travel records for Dr. Tam Garland from July 1, 2006, to December 31, 2007.

9. DHS received 29 expressions of interest for the NBAF. Please provide copies of all such expressions of interest.

10. Under the "Selection Plan" for the first round evaluation of the expressions of interest, the "Individual Committees" were required to generate reports for the "Steering Committee," evaluating each expression of interest. Please provide copies of all such reports.

11. Under the "Selection Plan" for the first round evaluation of the expressions of interest, the Steering Committee was required to provide a "draft Selection Document" to the "Selection Authority," who was then required to "document the basis for his/her decision on final site(s) selection in a final Selection Document." Please provide a copy of the draft Selection Document and the final Selection Document, and all associated documents, including letters and memoranda of transmittal.

12. Under the "Selection Plan" for the first round evaluation of the expressions of interest, the Selection Authority was to make the first round selection. In the event, did any other DHS officials, including the Secretary of Homeland Security and the Deputy Secretary of Homeland Security, have any role in the first round selection? If so, please identify all such officials and provide copies of all records pertaining to such participation.

13. Please list all DHS personnel, including contractors, detailees, agents, representatives, or others, who participated in searching for and/or selecting the current director of the PIADC and identify their affiliations.

14. Please provide a list of the dates and attendees at all meetings that you, Deputy Secretary Jackson, and Under Secretary Cohen may have had with representatives or members of the consortia that filed expressions of interest in the NBAF process.

15. Please provide copies of all records pertaining to the development and submission of the DHS proposed budget for Plum Island and the NBAF for FY2006, FY2007, FY2008, and FY2009.

16. In the attachment to his November 30, 2007, letter, Under Secretary Cohen stated that a copy of the after action report on the 1978 accidental release of foot-and-mouth disease on Plum Island was marked "FOUO" and could not be distributed or duplicated without clearance from the U.S. Department of Agriculture. A mark of "FOUO" on a document is not a valid reason for withholding it from a Congressional committee, nor are restrictions placed on its duplication or distribution by another agency. Please provide a copy of the after action report.

17. Under Item 14 of the attachment to his November 30, 2007, letter, Under Secretary Cohen provided a list of members of the agricultural and livestock industries that had contacted DHS regarding the proposal to close Plum Island and transfer foot-and-mouth disease research to a new facility on the mainland United States. No supporting documentation of these contacts was provided, however. Please provide copies of all records pertaining to these contacts.

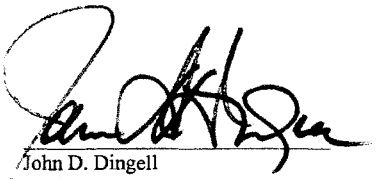
18. Please provide copies of all records pertaining to the internal S&T "tasker" coordinating the response to the Committee on Energy and Commerce September 20, 2007, letter.

Please deliver the requested information and records to the Subcommittee on Oversight and Investigations, room 316 Ford House Office Building, no later than the close of business on Tuesday, February 26, 2008. In responding to this request, please be advised that the terms "records" and "relating to" are defined in the attachment to this letter.

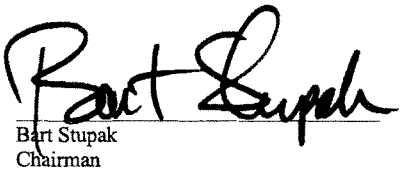
If you elect to assert a privilege or objection to the production of the foregoing records or information, please provide a privilege log fully identifying each record withheld and the legal basis asserted for withholding the record from a Congressional committee of competent jurisdiction.

If you have any questions regarding this request, please contact us or have your staff contact John Arlington with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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MARSHA BLACKBURN, TENNESSEE

April 3, 2008

The Honorable Michael Chertoff
Secretary
U.S. Department of Homeland Security
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20229

Dear Secretary Chertoff:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the management, operation, and activities of the Department of Homeland Security's (DHS) Plum Island Animal Disease Center (PIADC), and the proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agrodefense Facility (NBAF). In letters to you dated September 20, 2007, and February 21, 2008, we requested records and information to assist our investigation of these matters.

Despite the detailed requests in these letters, your agency is still withholding records requested by the Committee. Specifically, in his most recent response to us on your behalf, Under Secretary Jay M. Cohen refused to provide copies of the following:

- A draft report prepared by the Homeland Security Institute (HSI) dated April 27, 2007, titled, "*DHS Agrosecurity Science and Technology Plum Island and Beyond.*" Our February 21, 2008, letter requested this draft report "and copies of all subsequent drafts, whether final or not";

- Copies of all reports and analyses of the Crimson Sky simulation. Any documents in the possession of DHS regarding the Crimson Sky simulation are covered by this request, whether authored by DHS or not; and

- A copy of the after-action report on the 1978 accidental release of foot-and-mouth disease on Plum Island.[1]

In addition, the Committee staff requested a copy of the "ground rules" for Under Secretary Cohen's NBAF site visits prepared by the Science and Technology Office of General Counsel.[2] DHS has failed to provide a copy of this document as well.

Under Secretary Cohen has not proffered any valid reason for withholding the foregoing documents, nor has he denied that DHS possesses these records. We must therefore insist that the requested copies be delivered to us no later than 4:00 p.m. on Friday, April 11, 2008. Should these records not be delivered by that time, we will be forced to convene a meeting of the Subcommittee the following week to issue a subpoena to compel production.

Moreover, in the course of our investigation, we have learned that there may have been at least two releases of foot-and-mouth disease at Plum Island in addition to the 1978 incident referenced above. Please provide a list of all releases of foot-and-mouth disease that have occurred at Plum Island since 1954, including the dates, circumstances, and other relevant information, and all reports and studies of such incidents that may be in the possession of DHS.

In addition to the matter of records, we understand that representatives from the Government Accountability Office (GAO), who are conducting an investigation of related issues at our request, have encountered difficulties in obtaining access to the PIADC and to the PIADC Director, Dr. Larry Barrett. GAO is authorized by statute to conduct such investigations and to obtain access to all Government records and personnel.

We hereby request that you personally ensure the full cooperation of DHS with GAO's requests and facilitate their investigation, particularly with respect to the Plum Island and NBAF inquiries. By Friday, April 4, 2008, please provide a written explanation from Under Secretary Cohen regarding his reasons for delaying GAO's access to Plum Island and PIADC personnel, as well as an open invitation to GAO to visit the island and conduct such interviews as they may deem necessary.

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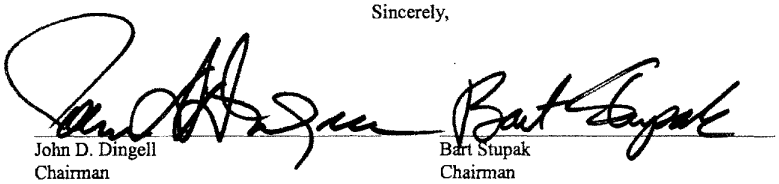
[1] We have since learned that there were two after-action reports on this incident, one that was published externally, and one that was internal. We are hereby requesting copies of both reports.

[2] The existence of these ground rules was revealed in the course of a staff interview of DHS personnel on November 16, 2007, and the request acknowledged in an e-mail from DHS on that date.

If you have any questions regarding this request, please contact us or have your staff contact John Arlington of the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

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