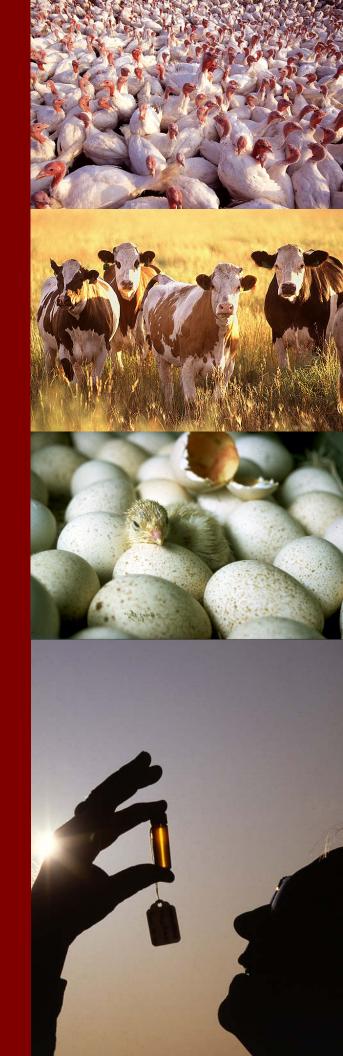
Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012



A document prepared by the Subcommittee on Foreign Animal Disease Threats, Committee on Homeland and National Security, National Science and Technology Council



EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20502

January 22, 2007

Dear Colleague:

America's agricultural system is vital to our well being. It accounts for approximately 12 percent of our Gross Domestic Product, and ensures that we can feed our Nation without depending on other countries. Recognizing this importance, the President has designated the Nation's agriculture and food systems as a critical infrastructure and on January 30, 2004, signed Homeland Security Presidential Directive 9 (HSPD-9) to establish a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies.

In response to HSPD-9, which calls for 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, the Subcommittee on Foreign Animal Disease Threats (FADT) of the President's National Science and Technology Council, has brought together leading agro-defense experts and decision makers from eight federal agencies to identify the key technological tools needed to protect our agricultural system as well as the supporting research needed to develop those tools. The FADT Subcommittee focused on those agricultural threats with the greatest potential economic or public health impacts, and limited its scope to the research and development needed to inform policy decisions and provide the key tools to mitigate the impacts of a natural or intentional agricultural outbreak.

The result is the attached document "Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012," which describes research needs in four major areas: (1) the development of models to predict the spread and economic impact of diseases in order to enable decision makers to guide policy and formulate requirements; (2) the development of diagnostics and vaccines to rapidly characterize and protect against diseases; (3) the development of decontamination and carcass disposal methods to stop the further transmission of disease; and (4) the conduct of basic research to better understand disease spread and infection and to train the next generation of researchers.

I am pleased to transmit this report, which provides a roadmap that will help enable the research community to develop a flexible 'toolbox' aimed at enhancing our ability to prepare for major agricultural outbreaks.

Sincerely,

John H. Marburger, III

Director















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Veterinary Countermeasures Diagnostics: Vaccines; * Immunomodulators Modeling **Decontamination &** Intervention Disposal strategies: Agent fate & transport Countermeasure data: requirements Affordable, acceptable disposal technologies **Basic Research** * How a pathogen interacts with its host and is spread; How a pathogen exists in nature and in wildlife reservoirs

Figure 1. This R&D plan consists of four closely coupled elements. For example, one intervention strategy can be to vaccinate animals "to live" thus reducing the need to dispose of animals. All these rely on basic research providing a basic understanding of how the pathogen attacks the host and survives in the environment.

Introduction and Current Efforts

According to the Homeland Security Office of the United States Department of Agriculture (USDA), agriculture accounts for \$1.24 trillion, or 12.3 percent of the Gross Domestic Product (GDP). This translates to 16.7 percent of the national workforce, or one out of every 6 jobs. In addition to the importance of the existing agriculture system, the U.S. Fish and Wildlife Service estimates the economic value of wildlife at 1.1 percent or \$129 billion of the GDP.

Clearly, domestic agriculture and food production systems are vital to the economic success of the United States. Any deliberate or natural disruptions would have enormous economic and public health impacts, and would present a serious threat not only to the national economy and society, but also to national strategic credibility and position. The remarkable success of these systems provides the country with subsistence independence, which is a significant strategic advantage over most countries of the world.

A foreign animal disease (FAD) is a transmissible disease that infects livestock (farm-raised animals), poultry, or wildlife, and is not present in the U.S. and its territories. FADs are a national threat when they significantly affect human health or animal production, or when there is a potential for appreciable cost associated with disease control and eradication. The identification and control of FADs is critical to the protection of long-term health and profitability of U.S. agriculture and food systems. At this time, the most effective disease control measure is rapid depopulation of all infected or exposed animals, even when specific disposal plans are not predetermined and surge

capacity for the resulting carcass disposal is not available. In many cases, this is a sub-optimal solution. The practicality of this approach is questionable in many situations, such as when the disease becomes widespread in free-ranging wildlife.

In addition to the economic losses associated with disease eradication, FAD outbreaks impair the ability of the United States to export its animal products, costing industry billions of dollars annually. The goal of this plan is to promote research and development (R&D) efforts most likely to identify, control, and eradicate the FADs that pose the greatest risk to the U.S. economy. Modelers at USDA estimate that a U.S. Foot and Mouth Disease (FMD) outbreak similar to one in the United Kingdom in 2001 would have the greatest potential economic impact in export markets from trade restrictions, and in the domestic market from consumer fear. These elements combine for tens of billions of dollars in losses in U.S. farm income from pork, beef, milk, lamb and sheep meat, live animals, forage, and soybean meal. These declines in farm income do not include the substantial costs estimated for disease containment, eradication, disposal, or other downstream effects.

The Nation has been hard at work defending against foreign animal diseases. In 2003, the Office of Science and Technology Policy (OSTP), Executive Office of the President, convened a Blue Ribbon Panel of experts to identify research and development (R&D) gaps and priorities to mitigate potential foreign animal disease threats. The foundation of this meeting was based on previous reports from a number of federal government working groups and non-governmental organizations that identified requirements, research and development gaps, and priorities for national agricultural and food biosecurity, and have clarified the roles and responsibilities of respective federal agencies. The proceedings of this meeting are available at http://www.ostp.gov/html/STPI.pdf and identified three key areas that need enhanced R&D funding:

- Infectious disease epidemiology;
- Vaccination and protection technologies; and
- Detection, diagnostic, and forensic capabilities

The Foreign Animal Disease Threats Subcommittee

Has identified key technologies needed to protect our agricultural system; the supporting research to develop these technologies; and recommendations for strategic investments in FY 2008-2012. This document summarizes the interagency plan focusing on four key areas: epidemiological and economic modeling; veterinary countermeasures; decontamination and disposal; and basic research.

With input from the National Veterinary Stockpile (NVS) and the National Animal Health Laboratory Network (NAHLN), the Subcommittee identified four diseases as high priority threats: Highly Pathogenic Avian Influenza (HPAI); Foot and Mouth Disease (FMD); Rift Valley Fever (RVF); and Exotic Newcastle Disease (END). Although these are the four diseases discussed in this document, the long-term goal of this R&D plan is to develop defensive strategies and veterinary countermeasures that can crosscut multiple foreign animal and zoonotic diseases.

The Blue Ribbon Panel

In December 2003, the White House Office of Science and Technology Policy (OSTP) convened an international panel with representatives from National, state and local governments, academia, and industry. OSTP tasked the panel with assessing the likelihood and potential consequences of biological terrorism directed against U.S. agricultural livestock, and recommending priorities for a federal defense research and development agenda.

The panel broke into four areas of focus and made recommendations in the following areas:

- Surveillance Capabilities;
- Epidemiology;
- Vaccination and Protection Technologies;
- Detection, Diagnosis, and Forensics

The proceedings were published in April 2004 and are available at http://www.ostp.gov/html/STPI.pdf

Two recent Homeland Security Presidential Directives (HSPD), "Critical Infrastructure Identification. Prioritization, and Protection" (HSPD-7) and "Protection" of U.S. Agriculture and Food" (HSPD-9), designate the U.S. agriculture and food systems as critical infrastructure and establish a national policy to defend these systems against terrorist attacks, natural disasters, and other emergencies. In response to paragraph 23 of HSPD-9, in July 2005 the National Science and Technology Council (NSTC) brought together leading agro-defense experts and decision makers from 13 federal agencies and established the Foreign Animal Disease Threats (FADT) Subcommittee. This paragraph calls for an interagency effort to accelerate and expand development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases.

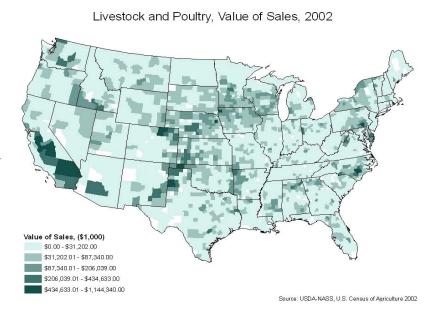
One of the primary beneficiaries of this effort is the National Veterinary Stockpile (NVS), established by the USDA to provide the best possible protection against a national disaster affecting animal agriculture and the food system, which could have adverse public or animal health, and environmental or economic effects. The NVS is responsible for the development of plans to stockpile and disperse vaccines, diagnostic tests and reagents, therapeutics, and equipment for use during disease outbreaks. Defense against FADs requires a well-coordinated program of multidisciplinary R&D activities involving human health, agriculture, environmental and wildlife interests. Many diseases of concern can involve wildlife populations as pathways of introduction or disease reservoirs.

There are other major ongoing projects, including the National Animal Health Laboratory Network (NAHLN), that play a role in validating diagnostics, and the National Biological Information Infrastructure (NBII) Wildlife Disease Information Node for data acquisition and management, as well as information dissemination. In addition, ongoing basic science in infectious disease processes can help guide the development of next-generation countermeasures.

An indicator of the success of these efforts is the proposal to establish the Joint Agroterror Defense Office (JADO), which will provide a dedicated interagency staff to enhance the coordination of strategic planning for FADs.

This document focuses on the proposed R&D requirements and priorities for the FADs considered the greatest economic threat to the United States, rather than on operational activities. When implemented, this R&D plan will provide the Nation and its decision makers with a flexible toolbox for preventing and mitigating major agricultural outbreaks.

Figure 2. Agriculture accounts for \$1.24 trillion, or 12.3 percent, of the Gross Domestic Product (GDP). This translates to 16.7 percent of the national workforce, or one out of every six jobs in the United States. The remarkable success of these systems provides the country with subsistence independence, which is a significant strategic advantage over most countries of the world.



Top Priority Diseases

Foot and Mouth Disease (FMD)

affects cloven-hoofed animals, such as cattle, swine, and deer, and is characterized by blisters on the mouth



Figure 3. Foot and Mouth Disease causes painful blisters in the mouths and on the feet of cattle, pigs and other clovenhoofed animals. Introduction of this disease could cause major economic disruptions to beef, dairy and pork markets.

and feet. These painful lesions often result in decreased appetite which in turn leads to weight loss and a decrease in milk production. This is a high priority disease due to ease of access to the virus, its rapid spread, the impact on international trade, and potentially severe economic and social consequences. Commonly found in many countries around the world, the accidental or intentional introduction of FMD to the U.S. is a major concern. An incursion of FMD within U.S. borders could result in severe disruption of the dairy, cattle, and swine industries and allied sectors, the loss of export markets, and stop movement restrictions that would create significant disruption to the national economy (including transportation systems, travel, and consumer confidence). It is extremely rare for FMD to infect

humans and there is no evidence of human-to-human transmission, or of transmission through the consumption of FMD-infected meat.

Rift Valley Fever (RVF)

is a mosquito-borne disease which has caused outbreaks in animals and humans in sub-Saharan Africa and the Middle East. As seen with West Nile Fever, an outbreak of RVF in the United States could potentially impact public health, livestock, and wildlife, and thus the national economy as well as those of neighboring countries. The establishment of the virus in a widespread reservoir following an incursion would cause the disease to become both endemic in livestock and a persistent threat to human health. In livestock, RVF causes severe disease and abortion in mature cattle, sheep, and goats, with greater than 70 percent mortality in young animals. In humans, symptoms may include retinitis, encephalitis, and hemorrhagic fever. According to the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), the mortality rate approximates 1 percent in the infected human population.

Highly Pathogenic Avian Influenza (HPAI)

causes a range of clinical signs from mild or subclinical infection to an acute and fatal disease of domestic poultry (chickens, turkeys), migratory waterfowl, and other avian species. HPAI can result in up to 100 percent mortality in infected flocks and impact international export markets. An outbreak of HPAI in the U.S. would place the domestic poultry industry at risk and restrict the availability of poultry meat and eggs. It is currently of major worldwide concern in the public health, agricultural and wildlife communities. The HPAI virus can evolve rapidly in nature and has the potential through genetic mutation or reassortment to become a disease easily transmissible from human to human.

Exotic Newcastle Disease (END)

is a contagious and fatal viral disease affecting all species of birds and is one of the most infectious diseases of poultry worldwide. END is so virulent that many birds die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. Considered a major agroterrorism threat agent, this infectious disease poses a threat to animal health on an international scale. Classified as a notifiable disease based on its potential for rapid spread, serious economic consequence, and impact on the international trade of poultry and poultry products, introductions of END are a continual threat and of great economic significance to the U.S. poultry industry and the Nation's wild bird populations. Of the 15 Office International des Épizooties (OIE) transboundary diseases reported through 2003, only the number of FMD virus outbreaks exceeds the number of END outbreaks worldwide.

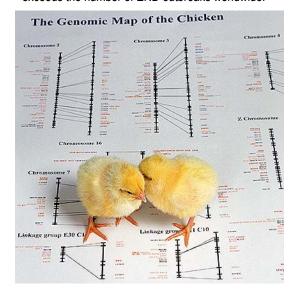


Figure 4. Chicks stand on a genomic map of a chicken. Further basic research, such as in genomics and immunology, is needed to defend against Exotic Newcastle Disease (END), Highly Pathogenic Avian Influenza (HPAI) and other foreign animal diseases.

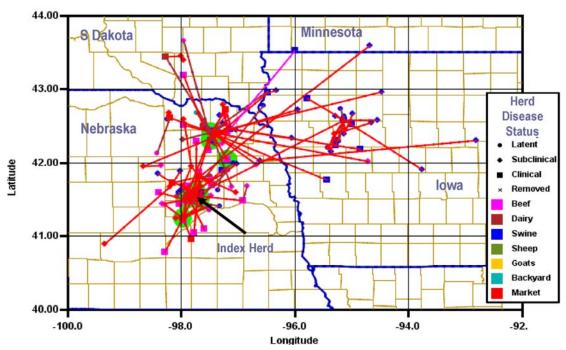


Figure 5. Modeling experts can use computers to simulate the initial stages of a Foot and Mouth Disease epidemic, thereby giving guidance on where to invest in research and how to deploy the most effective emergency response tools.

Modeling: Forecasting Future Needs

Modeling is a critical resource in both the management of disease and in the determination of priorities for critical countermeasures.

Epidemiological and economic modeling software programs are frequently used to develop and improve response plans, inform policy decisions, compare and exercise effects of control measures under different scenarios, train response personnel, and educate industry professionals. A small number of universities, national laboratories, and federal centers provide animal disease modeling expertise. However, these current efforts are limited and insufficient to produce the information needed for national planning efforts.

Considering the increasing number of international foreign animal and zoonotic disease events, there has never been a greater need for the United States to have the capability to model the spread of both livestock and wildlife diseases to provide threat awareness, to enhance prevention and protection, to enable surveillance and detection, and to test measures for response and recovery.

A Modeling Infrastructure

There are currently several R&D modeling efforts underway, but there are limited commitments for sustained funding. Modeling experts have continued

their work in disparate pockets at university and research centers around the world. As a highly multi-disciplinary endeavor, it has been a challenge to engage all parties with subject matter expertise. For example, 70 percent of emerging diseases have a connection to wildlife, yet oversight responsibility for monitoring wildlife disease is not clear. This leaves wildlife events often undocumented and unanalyzed. Wildlife play many important roles in FAD issues, including as potential vectors and sentinels for diseases. West Nile and Ebola viruses were both detected in wildlife prior to humans, providing time for public health intervention.

A modeling infrastructure that will promote FAD eradication would include three essential elements:

- Establishing a Modeling Operations Center to coordinate data acquisition and developing and maintaining operational models for livestock and wildlife disease spread;
- Establishing an Modeling Research Center for developing next generation models and stimulating basic research in disease modeling; and
- Funding modeling research, training, and education

A Modeling Operations Center

The first major element of the Modeling Infrastructure is the establishment of a Modeling Operations Center. The Nation needs a better understanding of how to use disease spread and economic impact models in policy formulation, preparedness and response planning, and requirements setting. There is an interaction between modeling, operations, and R&D. Establishment of a Modeling Operations Center will use well-defined, stable models to develop and test various strategies for containing outbreaks, and guide both operational and R&D activities. It will also constantly work to improve these models, both drawing on and stimulating advances in the research community.

Policy developers could use the Modeling Operations Center to input a new threat or hazard and generate potential strategic approaches to:

- Mitigate introduction (e.g., prevention);
- Respond with minimal impact on the United States or North American animal production community for pre-defined scenario settings (i.e., response plan);
- Understand the direct and indirect economic impacts of various intervention strategies to better guide response and recovery actions; and
- Provide recommendations on how to update the National Veterinary Stockpile inventory

Local planners and researchers would be able to use this Modeling Operations Center to:

- Provide realistic simulation scenarios to train and exercise animal health professionals or responders;
- Generate hypotheses that require further research; and
- Test hypotheses without requiring a "real" outbreak

In addition to the current operational models, the Modeling Operations Center will also make use of the leading research models to provide further insights into FAD strategies and to identify capabilities and approaches for future upgrades to the operational models. This activity will likely be patterned after the highly successful Models of Infectious Disease Study (MIDAS) established by the National Institutes of Health (NIH). MIDAS funds several world-class groups of investigators using epidemiological and mathematical models to address high priority infectious diseases of public health concern. MIDAS has already had a profound impact on the Nation's understanding of pandemic influenza, including its transmission, the effectiveness of various strategies for mitigating its spread, and the required amounts of vaccines and antivirals. By similarly creating an international community



Models of Infectious Disease Agent Study

Figure 6. The Models of Infectious Agent Disease Study has been successful in bringing together modeling experts to address high priority infectious diseases of public health importance. The MIDAS experience provides an excellent example of the impact a strategic investment in several key groups can make.

of leading FAD modelers focused on key intervention strategies for foreign animal diseases, we will provide new insights into the strategies and requirements for containing FAD outbreaks.

A Modeling Research Center

The second major element of the Modeling Infrastructure is a Modeling Research Center. Increasing our national modeling capacity would require a center where basic research in animal disease modeling for livestock and wildlife would occur, generating and testing new ideas. A Modeling Research Center could bring together scientists from academia, the federal government, and private industry to form new types of partnerships. A very successful example of this in the ecological community is the National Center for Ecological Analysis and Synthesis (NCEAS) established by the National Science Foundation (NSF) in 1995. NCEAS provides the intellectual atmosphere, facilities, equipment, and staff support to promote the analysis and synthesis of ecological information, and has had a catalytic and transforming effect in building a more cohesive community. About two-thirds of the members of the international ecological community have spent time at NCEAS during the past decade. Thus, NCEAS provides a well-established and extremely successful model for the FAD community to emulate. While ecological modelers focus on modeling the effects of a stimulus on a defined ecology, FAD modelers are specifically needed for their expertise in the spread or impact of these disease agents through production and wild animal populations. Investment in a Modeling Research Center would cultivate and grow the modeling community in these areas of national importance. Like NCEAS, the Modeling Research Center would provide not only a venue for experts to work together, generate, and test new ideas, but also a way to attract and train the next generation of modelers.

Training the Next Generation of Modelers

The third major element of the Modeling Infrastructure is training. As infectious disease modeling is an emerging discipline which requires highly interdisciplinary approaches (e.g., mathematics, statistics, probability, epidemiology, and computer science), there is need for significant investment to attract and nurture the next generation of young scientists into the field. Unfortunately, there are currently very limited undergraduate, graduate, or postgraduate programs in the United States and the rest of North America for educating and training animal disease modelers. These limited programs are insufficient to produce the needed national capacity. Future national needs require a dedicated multidisciplinary and interdisciplinary program designed to generate and sustain animal disease and pest

modelers capable of interacting with the veterinary, public health, infectious disease, epidemiology, bioinformatic, information technology, sociological, and economic communities. A Young Investigators Program (YIP) focused on animal disease modeling would address this need by providing incentives for talented individuals to pursue research in these areas. The NSF runs a similar undergraduate training program for young mathematician-biologists. Based on this experience, the NSF estimates that 80 undergraduates and 40 graduate students could be educated nationally each year under curricula designed to prepare them for careers in animal disease modeling. Such efforts will also attract well-qualified modelers currently working in other disciplines and integrate them into animal disease modeling.

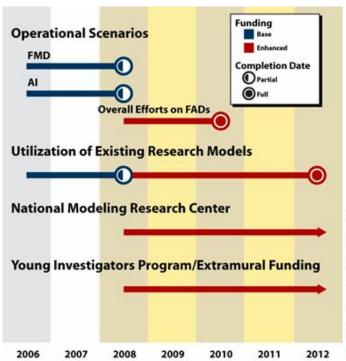


Figure 1. Preparations have begun for the new modeling infrastructure. Relationships are developing to synchronize current FMD and HPAI models. Partnerships for data inputs are being formed between epidemiologists and industry groups. Further coordination with human and wildlife components are underway.

Timetable for the Modeling Infrastructure

Numerous steps have already been taken to build a foundation for these new initiatives. Both USDA and the Department of Homeland Security (DHS) are establishing relationships to synchronize the two organization's current FMD and HPAI models. Partnerships for data inputs are being formed with USDA - National Agricultural Statistics Service; USDA - Centers for Epidemiology and Animal Health; and Industry. Further coordination with human (Department of Health and Human Service, DHHS) and wildlife (Department of Interior, DOI) components are underway. Major deliverables by end of FY 2007 from the Modeling Infrastructure include between four and ten HPAI and FMD scenarios and analysis; updates to the NVS; modeling outputs to guide decontamination

and disposal; modeling outputs for economic modelers; and establishment of data archives.

The President's budget request for 2007 includes funding to establish the Joint Agroterror Defense Office (JADO), which will provide a dedicated interagency staff to enhance the coordination of strategic planning for FADs. NSF and DHS have initiated planning discussions to collaborate on an NCEAS-like National Modeling Research Center, for FADs and plan to develop the requirements so that a request for proposals may be issued in 2008. Intramural and extramural modeling programs will be launched in 2008, as well as calls for proposals, competitions, and initial awards to encourage students and other young investigators to enter modeling-related fields.



Figure 7. USDA veterinarian observes cultured cells that are infected with an animal virus for use in experimental vaccines. Research using live foot and mouth disease is currently performed at the Plum Island Animal Disease Center. With limited space at the facility, project completion could be delayed.

Veterinary Countermeasures

Modeling is only one of the critical pieces needed for preparedness. Better, more effective vaccines, biologicals and diagnostics will allow us to detect and respond to disease more quickly and to more effectively stop or slow the course of a disease.

Historically, the eradication of a FAD relied solely upon the establishment of quarantines and large-scale depopulation. More recently, technological developments are providing complementary or alternative mechanisms for disease control and eradication. Despite this, the most common approach to recent outbreaks of high-consequence FADs are depopulation policies, which result in major financial losses to agriculture and allied businesses, and secondary impacts such as a reduction in tourism. Clearly, the development of better tools to control and eradicate FADs would benefit these control efforts.

Initial efforts for FAD countermeasure discovery and development focused on the highest and most significant threats, including FMD, HPAI, and END. In 2006, DHS and USDA expanded their joint efforts to include RVF. As the veterinary countermeasures program continues its expansion to include additional disease agents, increased resources are required to

accelerate research, development, test and evaluation (RDT&E) to meet operational goals.

Current Support for Veterinary Countermeasures

The U.S. Government currently supports the development and refinement of veterinary countermeasures, including vaccine and diagnostic technologies, for use in FAD prevention and mitigation. HSPD-9 "Defense of U.S. Agriculture and Food," lays out requirements for the development and deployment of these tools to foster preventative and response actions needed for either an unintentional or an intentional domestic introduction of a high-consequence agricultural or zoonotic agent.

In 2004, participants in the OSTP Blue Ribbon Panel provided specific recommendations to further RDT&E for "vaccination and protection technologies" and "detection, diagnosis and forensics," with specific guidance for certain diseases, including the four high consequence FADs identified in this report. The findings of the Blue Ribbon panel, and other similar working groups, underscore the need for tools for early and accurate diagnosis and rapid intervention to effectively control and eradicate an outbreak of such FADs.

Future development of veterinary countermeasures

An array of next-generation technologies for diagnostics, detection, and prophylaxis are under development to supplement traditional serological tests and vaccine preparations. A program to develop robust countermeasures for high priority FADs must include a cooperative plan using assets of multiple agencies, primarily DHS and USDA, to foster rapid development, validation, and deployment. Broadly, the program entails efforts in three major areas of RDT&E:

- Diagnostic technologies to provide tools for detection and surveillance and surge capacity during response and recovery;
- Vaccines and immunomodulators needed for an effective response to an incursion of the disease; and
- Basic research on disease epidemiology and disease pathogenesis to provide a greater understanding of disease spread and countermeasure potentials

This research would allow for the development and the implementation of next generation diagnostics at National Veterinary Services Laboratories (NVSL), the National Wildlife Health Center (NWHC), and in the National Animal Health Laboratory Network (NAHLN), and provide well-characterized current generation and next generation vaccines and immunomodulators available for acquisition by the NVS.

Measures needed to aid veterinary countermeasure development

The establishment of a robust countermeasure development/implementation program will require the investment of additional resources and continued interagency coordination. This program must encompass a number of requirements:

- Meet the diagnostic needs of the NVSL, the NWHC, the NAHLN, and bioforensics which include surveillance, confirmation, surge capacity, response, and recovery;
- Better characterization and improvement of onset of immunity and application for the current inactivated North American FMD Vaccine Bank (NAFMDB) vaccines;
- Development of new vaccines and immunomodulators for FADs that may serve as next generation countermeasures in the NVS;
- The basic and applied research necessary not only to complete deployment of countermeasures currently under development, but also to foster future countermeasure development

Diagnostics

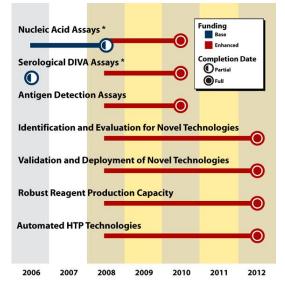


Figure 8. Timetable for Diagnostic Technologies. Presently, there are many areas of diagnostic development remaining to be explored. Enhanced funding would result in the establishment of a state of the art diagnostic capability for U.S. agriculture.

A comprehensive diagnostic plan which addresses many of the interagency consensus, critical diagnostic gaps in FAD diagnostics would include:

- Validated single and multiplexed, high-throughput (HTP) differential diagnostics for use in surveillance, confirmation, response, and recovery;
- Validated HTP diagnostics to differentiate infected vs. vaccinated animals (DIVA) during the recovery phase;
- Capabilities for validation and technology transfer of these assays to NVSL and the NAHLN;
- An enduring basic discovery, development, validation, and technology transfer program for continued identification and movement of new and emerging technologies to NVSL and the NAHLN; and
- A robust reagent production program to ensure a reliable source of reagents (produced in the U.S.) needed to proficiency test, train, validate and perform assays in the NVSL and NAHLN laboratories

Development of these capabilities will ensure that the U.S. maintains a state-of-the-art diagnostic capability and is prepared to detect, respond to and recover from an FAD outbreak. In addition, establishment of a robust reagent production capability will allow the U.S. to be independent in performing or validating FAD diagnostic tools.

In addition to addressing critical diagnostic gaps, a successful program must provide for technology transfer into the hands of the end users at the laboratories. Technologies must be available for active FAD surveillance programs or for situations requiring additional surge capability.

A comprehensive program would address development, validation, and deployment to the NVSL and NAHLN of the following:

 A single and multiplexed HTP nucleic acid technology, applicable to multiple sample matrices, for use in FAD surveillance, response, recovery and confirmation;

- A single and multiplexed, HTP serological assay capable of differentiating vaccinated versus non-vaccinated infected animals (DIVA assay);
- HTP antigen detection assays, applicable to multiple sample matrices for use in FAD response, recovery and confirmatory diagnosis;
- Enduring capability for identification/evaluation and deployment of novel (new and emerging) diagnostic technologies and assay controls;
- Enduring capacity for validation and deployment of newly developed technologies to the NVSL and NAHLN:
- Enduring reliable, robust reagent production capacity for standardized reagents needed for diagnostic assay development, validation and proficiency testing;
- Enhanced, automated HTP technologies for use in NVSL and NAHLN

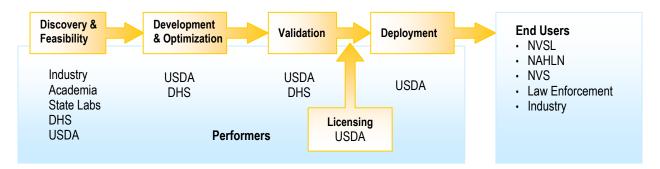


Figure 9. Diagnostics are a crucial component of a veterinary countermeasure strategy. As the primary stakeholder for FAD Diagnostic Development, USDA sets requirements for new technologies and determines deployment policy. The end users include the National Veterinary Services Laboratories, National Animal Health Laboratory Network, National Veterinary Stockpile, law enforcement and industry. Although diagnostic methodologies do not need licensing, licensing is required for commercial diagnostics kits.

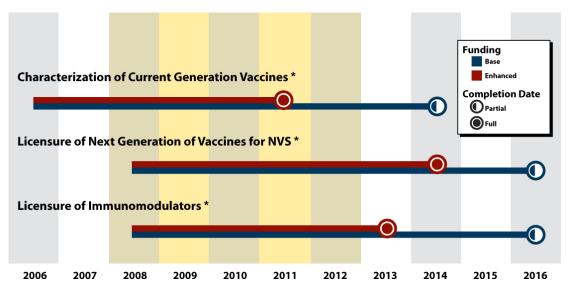


Figure 10. Timetable for Countermeasure Technologies. The R&D plan recommends a strategy to decrease the amount of time required to complete these projects from 8-10 years to 5-8 years. The National Veterinary Stockpile (NVS) stores only commercially available product for emergency use and many of these projects are still in development stages.

Vaccines and Immunomodulators

Current control strategies for FADs include quarantine, stop movement orders, and culling of infected herds, often with vaccination employed when disease spreads more quickly than depopulation can occur and facilities can be disinfected. Because current vaccine technologies sometimes do not elicit a timely protective response, the exploration of promising immunomodulating technologies to stimulate the immune system could fill the gap between vaccine administration and protection.

To address the threat of a FAD or zoonosis adequately. additional investments are required to support the transition from basic research and discovery to applied research and product development activities. Technology Readiness Levels (TRL) measure the maturity of new technologies. New technologies undergo experimentation, refinement, and increasingly realistic testing. A TRL program would leverage research by USDA Agricultural Research Service, leading FAD academic labs, USDA Cooperative State Research, Education and Extension Service (CSREES), DOD laboratories, and private industry. Industry conducts the final product development of promising candidates with clinical development study support from federal partners. Close coordination with USDA Animal and Plant Health Inspection Service (APHIS) and Center for Animal Health and Emergency Programs on both requirements and budget would facilitate the inclusion of final USDA-licensed or conditionally licensed products into the NVS.

The two most critical R&D needs of a vaccine countermeasure program are:

- Increased knowledge on the speed and efficacy at which current vaccines protect against infection and disease spread, and
- Development and licensure of new generation, DIVA vaccines that can provide both rapid and long-term protection and can be safely manufactured and stored in the United States

The Future of the Vaccine Program

Critical objectives necessary to attain next generation countermeasures include:

Characterization of current generation and late-stage experimental vaccines that needed in vaccine production using stored inactivated antigens in the North American FMD Vaccine Bank (NAFMDVB). These antigens must be safety-tested and evaluated for efficacy in the international standard 21-day post-vaccination challenge model. Only three antigens have been adequately characterized for onset of protection (e.g., seven days post-vaccination) or protection against direct contact (e.g., aerosolized) challenge in cattle. Acceleration of this program would enable more of the antigens to be characterized for use in an emergency response situation;

- Development of next generation FAD vaccines for inclusion into the NVS, and the identification of one or a limited number of crosscutting vaccine platforms. A vaccine platform is a technology that can produce a large number of different vaccine products, each specific for a particular FAD. A common, unifying plan of the FAD next generation countermeasure program is the identification of one or a limited number of vaccine platforms that can meet surveillance and response needs. This would significantly reduce the development time and cost of the overall FAD countermeasure program by applying scientific findings in research for one disease to many. Additional funding would allow the current lead vaccine platform for FMD (recombinant replication-deficient adenovirus) to be tested using immunoprotective antigens from HPAI. END or RVF;
- Licensure of immunomodulators to complement next generation vaccines. It is likely that next generation FAD vaccines will not be able to provide very rapid onset of protection (i.e., 18 hours to 96 hours) following vaccination. Thus, it is necessary to identify immunomodulators that can induce a short-lived protective innate immune response to fill the gap. As many viruses are susceptible to the same innate immune responses, one immunomodulator may be effective against several FADs. Additional funding would allow some of the current immunomodulators being tested in the FMD countermeasure program to be tested in animal models for use with other FADs

The ideal vaccine -

The desired characteristics of an ideal vaccine are as follows:

- Compatible with 'vaccinate-to-live' strategy, which would allow the animal to remain in the production cycle;
- Differentiates between infected and vaccinated animals:
- Rapid onset of innate and adaptive immunity;
- Prevents or greatly reduces virus spreading and shedding;
- Prevents carrier state in host animals (a carrier animal is one which is infected but shows no symptoms);
- New delivery platforms for rapidly inoculating masses of animals;
- One dose application and compatible with mass delivery;
- Economical;
- Able to be produced domestically;
- Readily deployable and shelf stable for long-term storage;
- Multivalency (provides cross-serotype protection)

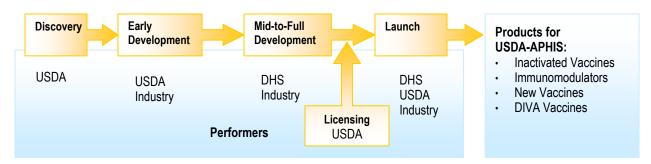


Figure 11. While USDA sets requirements for technology discovery, DHS facilitates the development in concert with industry partners. USDA Animal and Plant Health Inspection Service is the end user. DIVA vaccines are those that differentiate infected from vaccinated and non-infected animals.



Figure 12. Burning of carcasses during the Foot-and-Mouth Disease outbreak in Europe created air quality problems. Large scale culling requires better disposal technologies.

Decontamination and Disposal

Current disease containment strategies involve humanely euthanizing infected animals, disposing of the carcasses, and decontaminating affected farm premises and equipment. Typically, decontamination involves thoroughly scrubbing and washing the affected area/items with a detergent solution, followed by application of a disinfectant registered by EPA for that site and the specific pathogen. If a registered product is not available, then the states or the USDA may obtain exemptions from EPA on an expedited basis for use of unregistered disinfectants that have been shown to be effective. In general, disposal is a much bigger challenge. Even as additional countermeasures are considered (e.g., vaccination), euthanasia will remain an important element of the national response. The high concentration of animals in domestic livestock production facilities makes it highly likely that a FAD outbreak would result in thousands or millions of animal carcasses for disposal. In addition to carcasses. animal products such as wool, meat, and milk also may require disposal in mass quantities. Current response strategies rely on humane animal euthanasia to control and eradicate disease spread. Thus, large-scale

Research Needs for Decontamination and Disposal

There is a large gap in knowledge about this component of FAD event preparedness and response. Substantial new funds are needed to address these issues.

- Disease agent persistence, fate and transport;
- * Disposal method cost/benefit analysis;
- * Ecological and human health risk assessment;
- * Surrogate equivalency;
- Disinfectant efficacy and registration

outbreaks are likely to overwhelm the national capacity to dispose of carcasses on this scale.

Priorities for R&D, which address critical data gaps, include:

- Disease agent fate and transport in composting, rendering, open pit burial, landfill burial, and incineration, etc.;
- Disease agent fate and transport in carcasses of multiple species (e.g., cattle, swine, sheep, poultry, ducks, etc.);
- Cost/benefit analysis of available disposal technologies;
- Ecological and human health risk assessment data for carcass disposal technologies;
- Surrogate agent identification, to facilitate research without using the actual FAD agent;
- Efficacy data for the purpose of Environmental Protection Agency (EPA) registration of common household disinfectants that would be effective against FAD agents

The efficacy and registration data would allow emergency responders from industry, government, and the NVS to stockpile disinfectants that are inexpensive, readily available, easy to use, and environmentally sound. The collection of product efficacy data for registration requires coordination among industry, EPA, and USDA. This effort will also benefit from identification of FAD agent surrogates.

Policy issues related to carcass disposal:

- How will carcass disposal operations be coordinated nationally, regionally, and locally?
- Which state/federal entities need to approve carcass disposal decisions?
- How will local decision-makers weigh and choose disposal options for the protection of public, animal, or environmental health to achieve timely carcass disposal under sitespecific circumstances?



Figure 13. Direct burial of carcasses is inexpensive, quick, and does not require transport. However, it is site-dependent, seasonally dependent, and often there are legal restrictions to consider.

Currently, the United States lacks a standard operations system for carcass disposal. Carcass disposal is typically handled on an incident-specific basis where routine mortalities are managed by the owner/operator. As emphasized in the National Response Plan, federal agency resources are utilized in support of local and state resources. This is also true for carcass disposal support when USDA APHIS is the lead coordinating federal agency. The ease with which federal resources integrate into a response hinges predominantly on incident organization at the local and state levels. A well-organized local or state response can more easily and quickly utilize additional resources. Rules governing federal authority for carcass disposal lack consistency in national disposal operations; identification of primary end user for research and development data; recycling of lessons learned from site-specific experiences; and a multiple, parallel efforts across the federal government single unified effort.

Key issues include:

- Which technologies will be relied upon for surge capacity?
- How will technologies used for routine mortalities be adapted to address surge capacity?
- · Who will bear the cost of surge capacity?

- How will state/federal entities communicate with owner/operator/industry regarding carcass disposal decisions?
- How can we improve joint planning and coordination among responders in communities, counties, and States?
- Who will be responsible for addressing public, animal, and environmental health concerns associated with disposal decisions?

The desired goal is a disposal operations system utilized by industry and owner/operations on a daily basis, by state and federal government entities responding to a natural disaster, and by USDA-APHIS in response to outbreaks of FAD agents. There should be no disposal methods that are used only for surge capacity. The most effective technologies in an emergency response are typically adapted from technologies in practice every day. Any plan that deploys a new technology needs a well-understood system, tried and tested through routine use. A system that is used and practiced frequently for routine mortalities will have potential to adapt to surge capacity resulting from a FAD outbreak or a large-scale natural disaster. The establishment of such a system is the top priority for the future of safe, effective, large animal carcass disposal. Without this system, the lessons learned will continue to be under-utilized in improving our response to large animal mortalities; research will be unable to benefit the end user (an end user who has largely been undefined to date); and guidance will continue to come out of multiple departments and agencies without standardization. Currently, DHHS has pet disposal guidance, U.S. Geological Survey (USGS) has wildlife disposal guidance, EPA provides general carcass disposal guidance, and USDA has multiple guidance disposal documents. Most importantly, those federal programs that recognize the gap in disposal preparedness will continue to waste time and resources along parallel tracks without benefiting from coordinated and efficient utilization of the current fiscal and temporal investments.

In general, there is a lack of knowledge and awareness of decontamination and disposal authorities, and roles and responsibilities, among the local, state, and federal authorities that will be engaged in a national FAD incident. While a document recently produced outlines the federal roles and responsibilities, "Federal Roles and Responsibilities for Food and Agriculture Decontamination and Disposal" the significant effort to engage industry, states, and local authorities is still ahead. In addition, there is a lack of understanding of decontamination and disposal issues by the public sector. This can be remedied by improved communication and coordination, which will expedite carcass disposal at a local level with assistance from regulatory agencies so that highly contagious diseases can be stopped as quickly as possible.

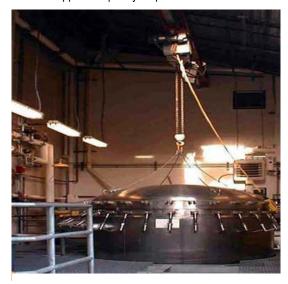


Figure 14. Alkaline Hydrolysis as a carcass disposal method can be made mobile, and destroys most FAD agents at the same time. However, capacity is limited and there are environmental health issues.

Decontamination and Disposal: Federal Roles and Responsibilities

Most decontamination and disposal actions are handled at the local level, not by the federal government. Local and state emergency operations plans should contain an animal emergency response annex addressing such issues as carcass disposal. The USDA's Animal and Plant Health Inspection Service (APHIS) has carcass disposal guidance as part of the National Animal Health Emergency Management System. The Environmental Protection Agency (EPA) Office of Solid Waste has also developed guidance for assisting state and local decision makers. Federal agencies may assume a primary role, even in "small" incidents, when foreign animal diseases are involved.

- USDA-APHIS is the lead for federal oversight regarding disposal of carcasses;
- In a catastrophic event, the National Response Plan would be activated and bring to bear the full authority and resources of the federal government;
- For animal and food incidents, EPA provides technical assistance;
- The Department of Interior (DOI) has authority for wildlife carcass disposal;
- The Food and Drug Administration (FDA) has authority over animal feeds and should be consulted regarding the reuse of rendered material
- Additionally, the United States Army Corps of Engineers (USACE) and USDA's Natural Resources Conservation Service (NRCS) have handled mortalities resulting from natural disasters, such as hurricanes or floods

Appropriate decontamination and disposal decisions and resulting operations involve multidisciplinary expertise and teamwork. In addition, strong communication and resource sharing are critical to efficient and effective response actions so that multi-disciplinary technical resources are accessible from anywhere and by all government levels of the emergency response community in a timely manner.

Table: Summary of Carcass Disposal Methods currently in use. There is no best method that is suitable for every situation. Each event is different and requires consideration of capacity, biosecurity, environmental health, cost, public perception, and legal issues.

Technology	Capacity (Tons/day or TPD)	Advantages	Disadvantages
Land filling	Variable ≈ 200 TPD	Commercially limitedLarge capacityWide availability	 Expensive Fate/transport Owner/operator concerns (e.g. economic and legal restrictions) Public perception Response worker highly exposed Time intensive Virus spread during transport
Composting (above ground burial)	Site dependent	DisinfectsInexpensiveLarge capacityOn-site	Environmental health issues Scavenging vectors
Direct Burial	Site dependent	FastInexpensiveLarge capacityOn-site	 Equipment availability Owner/operator concerns (e.g. economic and legal restrictions) Public perception Response worker highly exposed Seasonally dependent Site dependent
Mobile Incinerators	Variable	DisinfectsFastModerate capacityOn-site	Air quality issuesAvailability and capacity of unitsExpensePublic perception
Air Curtain Incinerators	Variable	DisinfectsFastInexpensiveOn-site	Environmental health issuesEquipment availabilityExpenseSite dependent
Alkaline Hydrolysis	≈ Limited (5 TPD)	DisinfectsMobileOn site	 Environmental health issues Limited capacity Virus spread during transport
Rendering ¹	Large (≈ 1000 TPD)	DisinfectsFacility is often nearbyLarge capacity	 Indemnification Industry disruption (routine rendering flow needs to be redirected) Public perception of rendered product Virus spread during transport Virus spread through crosscontamination at rendering facilities
Combustion in Incinerators	Varies: 200 TPD (Municipal Waste Incinerators) 20 TPD (Med Waste Incinerators) 50 TPD (Hazardous waste incinerators)	 Disinfects 	 Expensive Indemnification Permit considerations Public perception Virus spread during transport
Combustion in industrial processes such as cement kilns	Varies (50 TPD)	DisinfectsPre-event contracts are possible	Facility availabilityPermit considerationsPublic perceptionVirus spread during transport

¹ The Food and Drug Administration (FDA) should be consulted regarding the reuse of rendered materials.



Figure 15. A microbiologist inoculates a 10-day old embryonated hen's eggs with a specimen containing an H5N1 avian influenza virus inside a biological safety cabinet (BSC) within the Biosafety Level 3-enhanced laboratory. This experiment was part of a study to investigate the pathogenicity and transmissibility of newly emerging H5N1 viruses. Airflow within the BSC prevents any airborne virus from escaping the confines of the cabinet.

Basic Research

In addition to the targeted R&D efforts summarized above, interagency discussions clearly recognized the need for a basic research effort to provide the foundation for the future of FAD countermeasures, i.e., research directed at developing a broad understanding of the principles behind disease action and spread rather than surveillance or mitigation of immediate threats. USDA, DHHS, DHS, DOI, NSF and other agencies continue to invest in these research activities. It might focus on disease organisms that are not of major concern but which serve as useful models for discovering and testing basic processes. While mitigation of threats may occur as part of these projects, such mitigation would not be the focus. An extramural, peer-reviewed funding mechanism is recommended for this type of research program.

Diseases introduced into naïve healthy populations always present a threat to animal health. In order to respond to a disease incursion, research must provide tools for accurate and continuous surveillance programs. The research program must include studies

on how disease agents survive outside of the host, how the organism moves between susceptible hosts, and basic pathogenesis studies that define host-pathogen interactions. To counter an animal disease, research programs must include ways to manipulate immunological resistance to infection through vaccines and genetic selection. Research on common pathways of agent-host infection will have the most benefit, as it is difficult to create and/or stockpile specific vaccines for every individual disease threat. To ensure a return to full production as quickly as possible, research must provide means to prove that animals are free of the disease and thus eligible for international markets.

In the context of foreign animal diseases and their pathogens, the recommendations for basic R&D focus on two areas: the ecology and evolution of infectious disease, and animal immunological function.

Ecology and Evolution of Infectious Disease

The scientific community has clearly recognized that significant progress on mitigation strategies for emerging infectious diseases requires a greater understanding of the biology and environmental context of disease emergence and pathogen transmission. Such understanding is needed to anticipate and respond quickly to the effects of environmental changes on animal and environmental health. As the pace of anthropogenic change continues to accelerate, basic research will be essential to anticipating impacts and potential management or policy interventions. Whether the relevant questions concern long-range impacts of global health, more effective control of familiar pandemic diseases with animal vectors and reservoirs, the persistence of disease agents in the environment, or securing our food supply against the increasing threat of bioterrorism, the ecological dimensions of infectious disease are fundamental and poorly understood.

Despite increasing recognition for the need for a robust understanding of the ecology of infectious diseases, research funding in this area remains scarce. In part, the lack of funding opportunities is likely due to the inherently interdisciplinary nature of the research. Many infectious disease processes are best understood when studied in their natural setting where factors that may impede or accelerate their spread within an environment can be understood. There are well-developed principles from ecology that can provide a framework for the understanding of the interaction of pathogens and their hosts.

For example, understanding and mitigating the threat of HPAI requires knowledge of bird migration patterns. interactions between individual birds and bird populations, the prevalence of influenza in wild populations, the time course of infection in wild birds, the molecular evolution of influenza, responses of farmers to mitigation efforts, and the effects of outbreaks on poultry consumption. This knowledge spans multiple scientific disciplines and requires a long time to develop. The major migration routes are known as the result of a century of research, yet little is known about the daily movement patterns of many wild bird species. Basic information regarding the role of wildlife populations in maintaining and spreading FADs will be essential to the creation of integrated biological, economic, and social models.

While there will always be the need for 'fire engine' response to cope with outbreaks; we are beginning to develop better predictive tools and the knowledge to minimize their severity or even to prevent outbreaks before they occur. When integrated with research on vaccines, therapeutics, and environmental interventions, ecological studies may yield very powerful disease management tools.

Major Unanswered Questions in Basic Research

- How do ecological and evolutionary processes interact in determining disease dynamics?
- What is the role of within-host ecology, including hostpathogen interactions and interactions among multiple pathogens?
- How does innate immunity function and how does this function vary among animal species?
- · How does stress affect immune response?
- Can we develop predictive models that incorporate complex immunological, ecological, spatial and temporal relationships and processes?
- What are the target sites and mechanisms of infection, replication and dissemination of disease agents?
- What is the molecular basis of antigenic structure, antigenic stability, and ability of vaccines to rapidly induce widely protective immune responses?

Additional challenges in these areas

- The need to develop information management tools and data centers to facilitate data sharing and analyses;
- The need to cultivate multidisciplinary teams that encompass medical, veterinary, ecological and social scientists; and
- The need to translate research results into animal safety practice

Animal Immunological Function

Innate immunity is an evolutionarily ancient component of the disease defense system. The innate immune system is responsible for the body's decision whether to respond to a particular 'foreign' invader and thus constitutes the first line of defense. The innate immune response is critical to the resolution of many primary infections, and yet is poorly understood. In contrast, the adaptive immune system of vertebrates has received much attention because of its importance in vaccine development for humans and animals. More investigative attention needs to focus on basic research on a diversity of invertebrates and lower vertebrates to understand the evolution and mechanisms of the innate immune system, since it could potentially reveal novel or universal recognition and effector mechanisms conserved in evolution. More comparative and evolutionary studies may also help us understand interactions between host and pathogen, the movement of pathogens between species and classes. and requirements for stopping such movement.

Because of the focus on human medicine, immunologists have only begun to investigate the immune systems of other animals, including livestock and other commercially important species such as fish and shellfish. Basic research in non-mammalian vertebrates has been fundamental to many important discoveries in immunology. For example, invertebrates share the innate immune system with vertebrates, and there is some evidence to suggest that they may also have multiple different ways to achieve the kind of 'memory' typical of the acquired or adaptive immune system in vertebrates.

Stress can compromise the immune system, rendering organisms more susceptible to pathogens. We need to know more about the nature of the interactions between stress and the immune system and the various potentially relevant stresses for organisms as they encounter environmental changes. In addition, we need a greater understanding of recognition proteins that mediate anti-viral, anti-bacterial, anti-fungal and anti-parasitic immune responses. What can we learn from studies in reptiles and birds that provide insight into the evolution of vertebrate immune systems and how pathogens can move from one vertebrate to another?

These efforts would be complementary and supportive of a more focused research effort on vaccine development for HPAI, FMD, RVF, and END. The broader effort described here will provide important knowledge about immunological function applicable to a wide variety of animals and diseases. Such crosscutting research will both speed up vaccine development for these identified threats and improve our ability to respond to other emerging threats.

Next Steps

A high priority identified by the working groups is the critical need for risk and threat assessments for foreign animal and zoonotic disease pathogens beyond the top four discussed in this document. This would facilitate further prioritization of R&D programs for veterinary countermeasures. As mandated in Homeland Security Presidential Directive-10 'Biodefense for the 21st Century', such assessments of public health concern are currently in progress, and efforts to expedite the assessment of pathogens of concern for foreign animal and zoonotic disease are currently under consideration. These assessments will inform and guide subsequent strategic planning for identified priority diseases.

To capitalize on the high level of interagency coordination in this area, the President's proposed budget for FY 2007 includes funding for the creation of an interagency office within the DHS Science and Technology Directorate. The Joint Agroterror Defense Office will facilitate continued interagency planning for R&D programs required for foreign animal and zoonotic diseases.



Glossary of Terms

APHIS • Animal and Plant Health Inspection Service of the USDA

ARS • Agricultural Research Service of the USDA

CDC • Centers for Disease Control and Prevention

CSREES ■ Cooperative State Research, Education and Extension Service of the USDA

DHHS • U.S. Department of Health and Human Services

DHS • U.S. Department of Homeland Security

DIVA • a vaccine that differentiates infected from vaccinated animals

DOI • U.S. Department of Interior

END • Exotic Newcastle Disease

EPA • U.S. Environmental Protection Agency

FAD • Foreign Animal Disease

FADDL • Foreign Animal Disease Diagnostic Laboratories

FMD • Foot and Mouth Disease

GDP • Gross Domestic Product

HPAI • Highly Pathogenic Avian Influenza

HTP • High-throughput (as in high-throughput diagnostics)

Immunomodulators ● Biological agents or processes capable of modifying or influencing the immune system

JADO • Joint Agroterror Defense Office

Long-term goals ● for Fiscal Years 2010-2012

MIDAS ● Models of Infectious Disease Agent Study

Mid-term goals • for Fiscal Years 2008-2009

NAFMDVB ● North American FMD Vaccine Bank

NAHLN ● National Animal Health Laboratory Network

NBII • National Biological Information Infrastructure

NCEAS • National Center for Ecological Analysis and Synthesis

Near-term goals ● for Fiscal Years 2006-2007

NIH • National Institutes of Health

NRCS • Natural Resources Conservation Service of the USDA

NSF • National Science Foundation

NSTC • National Science and Technology Council

NVS • National Veterinary Stockpile for vaccines, therapeutics, and equipment for use in during disease outbreaks

NVSL • National Veterinary Services Laboratories

NWHC • National Wildlife Health Center

OIE ● Office International des Épizooties, or World Organization for Animal Health

OSTP • Office of Science and Technology Policy

PIADC • Plum Island Animal Disease Center

R&D • Research and Development

RDT&E ● Research and Development, Testing and Evaluation

Reservoir • An organism that harbors an infectious agent which can be transmitted to other hosts

RVF • Rift Valley Fever

SARS • Severe Acute Respiratory Syndrome

SEPRL • Southeast Poultry Research Laboratory of the USDA

TRL • Technology Readiness Levels

USACE ● U.S. Army Corps of Engineers

USDA • U.S. Department of Agriculture

USGS • U.S. Geological Survey of the DOI

Vector ● An organism, such as a mosquito or tick, which spreads infection by transferring an infectious disease agent from one host to another

WHO . World Health Organization

Zoonotic Disease • A disease that can be transmitted from animals to humans

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Cover photo, turkey flock, Scott Bauer, ARS-USDA. Cover photo, 4 steer, Keith Weller, ARS-USDA. Cover photo, turkey chick, photographer unknown, USDA.

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Fig. 1 NASS-USDA.

Fig. 2 DHS.

Fig. 3 Pam Hullinger, Lawrence Livermore National Laboratory (LLNL).

Fig. 4 Peggy Greb, ARS-USDA.

Fig. 5 Lawrence Livermore National Laboratory.

Fig. 6 Models of Infectious Disease Agent Study, NIH.

Fig. 7 DHS.

Fig. 8 Keith Weller, ARS-USDA.

Fig. 9 DHS.

Fig. 10 DHS.

Fig. 11 DHS.

Fig. 12 DHS.

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Fig. 17 CDC.

Next steps image, Scott Bauer, ARS-USDA. [note: credits format may change, depending on agency preferences]

Additional Reading

Biodefense for the 21st Century

http://www.whitehouse.gov/homeland/20040430.html

Critical Infrastructure Identification, Prioritization, and Protection (HSPD-7)

http://www.whitehouse.gov/news/releases/2003/12/20031217-5 html

Federal Roles and Responsibilities for Food and Agriculture Decontamination and Disposal

http://www.epa.gov/homelandsecurity/htm/ohs-food.htm

OSTP Blue Ribbon Panel on Agroterrorism http://www.ostp.gov/html/STPI.pdf

Potential revenue impact of an outbreak of Foot and Mouth Disease in the United States

http://avmajournals.avma.org/doi/abs/10.2460/javma.2002.220.988? prevSearch=allfield%3A%28fmd%29

Protection of U.S. Agriculture and Food (HSPD-9)

http://www.whitehouse.gov/news/releases/2004/02/20040203-2.html

Report from the Weapons of Mass Destruction Countermeasures Working Group

 $\label{lem:http://www.ars.usda.gov/research/programs/programs.htm?np_code = $103\&docid=5815$$

Wildlife Disease Information Node http://wildlifedisease.nbii.gov/

More Information

About the NSTC

The National Science and Technology Council (NSTC) was established by Executive Order on November 23, 1993. This Cabinet-level Council is the principal means within the executive branch to coordinate science and technology policy across the diverse entities that make up the federal research and development enterprise. Chaired by the President, the membership of the NSTC includes the Vice President, the Director of the Office of Science and Technology Policy, Cabinet Secretaries and Agency Heads with significant science and technology responsibilities, and other White House officials.

A primary objective of the NSTC is the establishment of clear national goals for federal science and technology investments in a broad array of areas spanning virtually all the mission areas of the executive branch. The Council prepares research and development strategies that are coordinated across federal agencies to form investment packages aimed at accomplishing multiple national goals. The work of the NSTC falls under four primary committees: Science, Technology, Environment and Natural Resources and Homeland and National Security. Each of these committees oversees subcommittees and working groups focused on different aspects of science and technology and working to coordinate across the federal government.

About the Foreign Animal Disease Subcommittee

The National Science and Technology Council's (NSTC) Foreign Animal Disease Threats
Subcommittee and its designated interagency working groups are chartered by the Committee on Homeland and National Security of the NSTC, as part of the response to taskings outlined in "Protection of U.S. Agriculture and Food" (HSPD-9). This subcommittee addresses both immediate and long-term action items related to foreign animal disease threats including data needs and coordination of modeling efforts; requirements and priorities for diagnostics and medical countermeasures; and requirements for Decontamination and Disposa technologies.

About OSTP

Congress established The Office of Science and Technology Policy (OSTP) in 1976 with a broad mandate to advise the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs. It grew out of the Office of Science and Technology formed in 1961 by President Kennedy. The 1976 Act also authorizes OSTP to lead an interagency effort to develop and to implement sound science and technology policies and budgets and to work with the private sector, state and local governments, the science and higher education communities, and other nations toward this end.

National Science and Technology Council www.ostp.gov/nstc