

# Federal Research and Development for Agricultural Biodefense

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*Federal Research and Development for Agricultural Biodefense*

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Before the Committee on Science, Space, and Technology  
Subcommittee on Research and Technology  
United States House of Representatives

November 2, 2017

**G**ood morning Chairman Comstock, Ranking Member Lipinski, and distinguished members of the subcommittee. I thank you for the opportunity to testify about Federal Research and Development for Agricultural Biodefense.

## Introduction

Since the establishment of the Department of Homeland Security (DHS) in 2003, the department has served a central role in agricultural biodefense, particularly in research and development (R&D). During my service as the Under Secretary (Acting) and Deputy Under Secretary of DHS's Science and Technology Directorate from 2011 to 2014, my duties included oversight and support for U.S. agricultural biodefense R&D, including the work at the Plum Island Animal Disease Center (PIADC), several academic centers of excellence related to agricultural biodefense, and tens of millions of annual R&D spending. It was also during this period when DHS, led by the S&T Directorate, developed the justification and secured funding for the National Bio & Agro-Defense Facility (NBAF) at Manhattan, Kansas, as the replacement facility for PIADC. My testimony today will largely draw on these experiences.

In my remarks today, I would like to place federal R&D efforts for agricultural biodefense efforts in context. To do this, I will develop several themes. First, federal agriculture research must be considered within a broad spectrum of global biological threats, from emerging infectious disease to the deliberate use of biological pathogens. Second, agriculture security is an issue of both national and economic security. Third, U.S. laws, policies, and regulations are part

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<sup>2</sup> The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

of a larger international system of disease monitoring and reporting framework. Finally, robust, well-coordinated biodefense research and development is an essential component of maintaining a healthy and vibrant agricultural sector.

Biodefense R&D serves as a hedge against the wide variety of growing threats to the agricultural sector. It should be thought of as a necessary, yet costly, insurance policy to protect this vital industry. Funding the \$1.2 billion NBAF was an important step in protecting the agricultural sector.<sup>3</sup> However, disparities still exist between the federal funding provided for human health versus agricultural biodefense R&D.<sup>4</sup>

## Global Biological Threats

The agriculture and food sectors of the U.S. economy accounted for almost \$1 trillion dollars—5.5 percent of the U.S. gross domestic product (GDP) in 2015. Agriculture and related industries<sup>5</sup> account for approximately 11 percent of U.S. employment. Farms directly contributed \$136.7 billion, or slightly less than 1 percent, of the U.S. GDP and accounted for 2.6 million jobs.<sup>6</sup>

The range of biological threats facing the agricultural industry continues to grow. Emerging infectious diseases (EID)<sup>7</sup> have continued to spread across the globe, and the number of diseases becoming endemic in the United States has continued to increase. At the same time, concerns about deliberate threats to the agriculture sector remain and in some cases, continue to grow.

“Socio-economic, environmental and ecological factors” have fueled the spread of EID. In a study analyzing 335 EID events between 1940 and 2004, such events were determined to be “significantly” increasing. Of great importance to the agricultural sector, 60.3 percent of these diseases are zoonotic—diseases with a nonhuman animal source—and 71.8 percent originated in wildlife. These statistics combine to imply that the U.S. agricultural sector is very much at risk; controlling the spread of these diseases could be very challenging.<sup>8</sup>

Global travel and an increasingly mobile population (both human and livestock) highlight the potential for foreign animal disease to rapidly spread, spreading diseases that have never been in or have been eradicated in the United States. Foot and Mouth Disease (FMD), eradicated in the United States in 1929, is endemic in parts of Asia, most of Africa, and the Middle East. It also

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<sup>3</sup> The \$1.2 billion estimate was for the construction and commissioning of NBAF.

<sup>4</sup> Tammy Beckham, “American Agriculture and Our National Security,” testimony before the House Committee on Agriculture, Washington, D.C., November 4, 2015.

<sup>5</sup> Food-related industries include forestry, fishing, and related activities; food, beverages, and tobacco products; textiles, apparel, and leather products; food and beverage stores; and food service, eating and drinking places.

<sup>6</sup> U.S. Department of Agriculture (USDA), “Ag and Food Sectors and the Economy,” last updated October 17, 2017.

<sup>7</sup> Centers for Disease Control and Prevention (CDC), “EID Journal Background and Goals,” last updated May 30, 2014.

<sup>8</sup> Kate E. Jones, Nikkita G. Patel, Marc A. Levy, Adam Storeygard, Deborah Balk, John L. Gittleman, and Peter Daszak, “Global Trends in Emerging Infectious Diseases,” *Nature*, Vol. 451, February 21, 2008, pp. 990–993.

occurs in Latin America, but is largely controlled by zoning.<sup>9</sup> Introduction of FMD in the United States would paralyze our exports of agricultural products, require a massive culling of potentially infected animals, and mandate a vaccination program to prevent further spread of the virus.

African Swine Fever (ASF) is a viral hemorrhagic fever; some strains are considered to have a 100-percent mortality rate. ASF has occurred in Europe, South America, and the Caribbean. Some of the outbreaks have been halted, while others continue to plague livestock in these areas. Some countries have managed to eradicate ASF, but the time and cost have been significant. For example, in Spain and Portugal, eradication took 30 years. Complete depopulation was required to rid Malta and Dominican Republic of the ASF virus. The virus is currently moving across Eastern Europe with alarming speed, with outbreaks in Georgia, Russia, and Ukraine. As of 2015, there were also reports of infection in Lithuania, Latvia, and Poland. The disease has spread when migrating wild boars infect domestic livestock populations.

A host of other zoonotic diseases are of concern to the agriculture sector and bear scrutiny. Highly Pathogenic Avian Influenza (HPAI) infections in 2014 and 2015 resulted in 223 cases of HPAI in domestic flocks in 15 states and the culling of 48 million chickens, turkeys, and other poultry to halt the spread of the disease.<sup>10</sup> The Ebola outbreak from 2014 to 2016 affected ten countries (including the United States). It caused 11,325 deaths out of 28,652 cases. These examples demonstrate the reach and speed of these zoonotic diseases.<sup>11</sup>

Changing climate patterns cause changing disease patterns for humans, plants, and animals. One example of a changing disease pattern is the Zika virus, a zoonotic disease spread by mosquitoes that has the potential to cause birth defects and long-term neurological effects in affected populations. The *Aedes aegypti* and *Aedes albopictus* mosquitoes, which are the known vectors of the disease, are now endemic to almost half of the continental United States—implying negative prospects for preventing endemic Zika.<sup>12</sup> While there is no evidence of Zika being passed directly from livestock to humans, we do know that livestock can become infected by the Zika virus through mosquito bites. Additional research is necessary to understand the effects of the Zika virus in animals, including livestock.<sup>13</sup>

Equally concerning is the potential for the deliberate introduction of these diseases or bioterrorism. Such an event would have serious national security and economic effects.

## A National Security and Economic Security Issue

The Amerithrax attacks in 2001 caused a serious reevaluation of the potential for deliberate use of a biological pathogen to inflict harm, kill people, and even destroy economies. The

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<sup>9</sup> World Organization for Animal Health, “Foot and Mouth Disease: What is Foot and Mouth Disease,” undated.

<sup>10</sup> Joel L. Greene, “Update on the Highly-Pathogenic Avian Influenza Outbreak of 2014–2015,” *Congressional Research Service*, July 20, 2015.

<sup>11</sup> CDC, “Ebola (Ebola Virus Disease): 2014–2016 Ebola Outbreak in West Africa,” last updated June 22, 2016.

<sup>12</sup> CDC, “Zika Virus: Potential Range in US,” last updated September 20, 2017.

<sup>13</sup> Daniel M. Gerstein, “Cuts to US Bioterror Funds Risk Peril in Event of Attack,” *The Hill*, June 6, 2017.

mailing of five anthrax-laden letters through the U.S. postal system resulted in the infection of 22 people, five of whom died; the treatment of some 30,000 people with high-strength antibiotics; and the decontamination of several buildings.<sup>14</sup> The total cost of the decontamination was estimated to be over \$320 million.<sup>15</sup> Another important outcome was the dramatic increase in funding for U.S. government civilian biodefense spending, from \$685.1 million in 2001 to over \$8 billion in 2009.<sup>16</sup>

In considering the potential for an agricultural bioterror attack, one must remember that opportunity and malicious actors coexist in what could be a dangerous combination should such actors decide to attack agricultural targets. One analysis assessed that FMD-endemic countries collectively contain three-quarters of the world's population.<sup>17</sup> Furthermore, the nature of many zoonotic diseases is such that little planning or weaponization would be required to perpetrate such an attack. In the case of FMD or ASF, only an exchange of fluids containing the virus would be necessary to cause such an outbreak. Finally, as much of the focus has been on human bioterrorism, this leaves agro-bioterrorism as a perceived soft target.

Recognition of the biological attack threat became so pervasive that in the 2005 Homeland Security Planning Scenarios, four of the 15 scenarios were directly related to a bioterror attack (a fifth was a natural outbreak of pandemic influenza). Particularly noteworthy, two of the scenarios involved attacks on the agriculture and food system (terrorists infecting livestock at specific locations and terrorists contaminating food with anthrax in processing facilities).<sup>18</sup>

The economic impact of an agricultural biological incident would include direct loss of crops, livestock, and assets; secondary losses in upstream and downstream markets; lost export markets; significant price effects; and an overall reduction in economic growth. It would also require the unplanned expenditure of resources for response and recovery. Secondary and tertiary effects include long-term environmental problems (the need to bury/lime the killed animals) and social and political impacts, such as reduced confidence in government, reduced confidence in food safety, and social disruption resulting from fear.

In the United Kingdom, a 2001 FMD outbreak resulted in dire consequences, with 57 farms affected, 2,026 cases confirmed, six million animals destroyed, and economic losses of estimated

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<sup>14</sup> Department of Justice, *Amerithrax Investigative Summary*, Washington, D.C., February 19, 2010.

<sup>15</sup> Ketra Schmitt and Nicholas A. Zacchia, "Total Decontamination Cost of the Anthrax Letter Attacks," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 10, No. 1, 2012.

<sup>16</sup> Crystal Franco, "Billions for Biodefense: Federal Agency Biodefense Funding, FY2008–FY2009," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 6, No. 2, 2008.

<sup>17</sup> T. J. D. Knight-Jones and J. Rushton, "The Economic Impacts of Foot and Mouth Disease—What Are They, How Big Are They and Where Do They Occur?" *Preventative Veterinary Medicine*, Vol. 112, No. 3–4, November 1, 2013, pp. 161–173.

<sup>18</sup> Brookings Institute, "Homeland Security Planning Scenarios and Summary Descriptions," undated.

losses from FMD of U.S. \$10.7 to \$11.7 billion.<sup>19</sup> Additionally, 60 farmers' suicides were attributed to loss of livelihood from the FMD incidents.<sup>20</sup>

More recently, a Kansas State University study on the potential effects of an FMD outbreak found “estimated losses to producers and consumers at approximately \$188 billion and additional government losses at \$11 billion, assuming no emergency vaccination was implemented.”<sup>21</sup> Even with an emergency vaccination program, the losses were estimated to be \$56 billion for producers and consumers and \$1.1 billion in governmental costs.<sup>22</sup>

The HPAI outbreak was costly for the poultry industry, with turkey and laying hen losses estimated at nearly \$1.6 billion and economy-wide losses are estimated at \$3.3 billion. Eighteen U.S. trading partners imposed bans on U.S. poultry and products, and 38 others imposed partial or regional bans on shipments from states or parts of states with HPAI cases. Three of the top 10 destinations for U.S. poultry meat in 2014—China, Russia, and South Korea—have banned all imports of U.S. poultry.<sup>23</sup>

Both experience and estimates indicate the potential for adverse national and economic security outcomes from a biological incident, either naturally occurring or deliberate. Entire industries could be devastated, and recovery from such an event could take years even in the best of cases.

## U.S. Laws, Policies, and Regulations as Part of a Larger International System

International public health and security institutions provide the basis for U.S. agricultural biodefense efforts. The World Health Organization, Food and Agriculture Organization of the United Nations, and World Organization for Animal Health combine to provide technical information on diseases, strategies for preventing outbreaks of infectious diseases and monitoring for human and animal health issues.

The global “One Health” concept recognizes that human health, animal health, and the environment are inextricably related.<sup>24</sup> These linkages allow for better understanding of the complex relationships between humans, animals, and the environment, in many cases allowing earlier disease identification in one sector by observing the spread of disease in another sector. For example, understanding which strains are circulating in the flyways of the avian populations

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<sup>19</sup> Dustin L. Pendell, John Leatherman, Ted C. Schroeder, and Gregory S. Alward, “The Economic Impact of a Foot-and-Mouth Disease Outbreak: A Regional Analysis,” paper prepared for presentation at the Western Agricultural Economics Association Annual Meeting, Portland, Ore., July 29–August 1, 2007.

<sup>20</sup> Oklahoma Agriculture Food and Forestry, “At What Cost? 2001 and 2007 Foot and Mouth Disease Outbreak United Kingdom,” undated.

<sup>21</sup> Kansas State University, “New Research Shows the Simulated Economic Impact of a Foot-And-Mouth Disease Outbreak,” *ScienceDaily*, October 27, 2015.

<sup>22</sup> Kansas State University, 2015.

<sup>23</sup> Greene, 2015.

<sup>24</sup> CDC, “One Health,” last updated August 1, 2017.

can assist in predicting which strains of seasonal influenza are likely to be most prevalent in humans.<sup>25</sup>

The Biological and Toxin Weapons Convention prohibits the “development, production, acquisition, transfer, retention, stockpiling and use of biological and toxin weapons.”<sup>26</sup> It entered into force in 1975 and has served as the unequivocal norm against the use of biological weapons. This international convention pertains to the use of biological pathogens or toxins for use against humans, animals or plants.

United Nations Security Council Resolution 1540, established in 2004, mandates “all states shall refrain from providing any form of support to non-state actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes.”<sup>27</sup>

U.S. law concerning biological weapons is contained in law regarding weapons of mass destruction in 18 U.S.C. Sec. 2332a. The law was originally established in 1996 (and has been updated several times). It prohibits use of “any weapon involving a biological agent, toxin, or vector.”<sup>28</sup> Other legal mechanisms codified in international and national export control laws serve to limit the proliferation of potentially dangerous dual-use material, equipment and knowledge.

The security of our agriculture and food production systems is critical to our economic, social, political well-being, and security. Given this broad array of interests, a wide range of stakeholders have direct and indirect interests in agricultural biodefense.

The public health and security institutions collectively have served as foundations for numerous U.S. presidential policies, directives, and executive orders for biodefense including in the agricultural sector.

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<sup>25</sup> Mathieu Fourment, Aaron E. Darling, and Edward C. Holmes, “The Impact of Migratory Flyways on the Spread of Avian Influenza Virus, *BMC Evolutionary Biology*, Vol. 17, No. 1, May 25, 2017.

<sup>26</sup> United Nations Office for Disarmament Affairs (UNODA), “The Biological Weapons Convention,” undated.

<sup>27</sup> UNODA, “UN Security Council Resolution 1540 (2004),” undated.

<sup>28</sup> United States Code, Title 18, Section 2332a, Use of Weapons of Mass Destruction, 1996.

**Table 1. Presidential Directives and Legislation Related to Agricultural Biodefense**

Presidential Directives and Legislation Related to Agricultural Biodefense	Description
Homeland Security Act of 2002	PIADC transferred to DHS; DHS provides for USDA/APHIS/ARS activities on site
Animal Health Protection Act (7 U.S. Code § 8306—Seizure, Quarantine, and Disposal) (2002)	Authorized the Secretary of Agriculture to declare an extraordinary emergency due to “the presence in the United States of a pest or disease of livestock and that the presence of the pest or disease threatens the livestock of the U.S.” The Secretary is granted authority to take action within states if state-directed control/eradication measures are found to be inadequate
Emergency Support Function (ESF) 11—Agriculture and Natural Resources	Activation of a coordinated federal incident response (as part of the <i>National Response Framework</i> ) in the event of a threat to U.S. agriculture or food security. Integrates the federal, state, tribal, and local response to an outbreak of a contagious and/or economically significant pest or disease
HSPD-9—Defense of United States Agriculture and Food (January 30, 2004)	DHS and USDA are to “develop 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-10—Biodefense for the 21st Century (April 28, 2004)	Assigns roles and responsibilities for preventing, protecting against, and mitigating biological events. Describes the four key areas—or pillars—of national biodefense (including agriculture).
HSPD-18—Medical Countermeasures against Weapons of Mass Destruction (January 31, 2007)	Establishes policy to address the challenges presented by chemical, biological, radiological, and nuclear weapons of mass destruction and the need for medical countermeasures.
HSPD-21—Public Health and Medical Preparedness (October 18, 2007)	Applies and expands the four pillars of biodefense from HSPD-10 to public health preparation.
Food, Conservation, and Energy Act of 2008 (Farm Bill 2008) (June 18, 2008)	Authorizes Secretary of Agriculture to issue FMD permit to successor facility to Plum Island (removes statue to require FMD on PIADC)
A National Blueprint for Biodefense (Bipartisan Report of the Blue Ribbon Study Panel on Biodefense) (October 2015)	Panel on Biodefense to assess how much has been done to address the biological threat and what remains undone. Despite significant progress on several fronts, the Nation is dangerously vulnerable to a biological event. The root cause of this continuing vulnerability is the lack of strong centralized leadership at the highest level of government.

NOTE: APHIS = Animal and Plant Health Inspection Service; ARS = Agricultural Research Service; HSPD = Homeland Security Presidential Directive.

## Research and Development is an Essential Component of Maintaining a Healthy and Vibrant Agricultural Sector

Multiple government and nongovernmental organizations have responsibilities and authorities in agricultural biodefense. The types of R&D each organization performs relate directly to the missions implied and specified by the responsibilities and authorities of each. Furthermore, since the agricultural sector is almost exclusively owned and operated by the private sector, close collaboration between the government and industry is imperative.

For example, USDA is the lead for food, agriculture, natural resources, rural development, and nutrition. Therefore, R&D directly related to these activities would be conducted by the USDA. Embedded in these responsibilities is the requirement for preparedness and response for

any FAD incident affecting domestic livestock or poultry.<sup>29</sup> This requirement is shared by USDA and DHS. Specifically, if requested by the Secretary of Agriculture, directed by the President, or if more than one federal agency becomes “substantially” involved in the incident, DHS may assume the lead for coordination of the response to a FAD incident.<sup>30</sup>

Therefore, in the case of preventing, protecting, mitigating, responding and recovering from an agriculture biodefense event (either naturally occurring or deliberate), USDA and DHS exercise a shared role, which requires “development of a coordinated strategy to adequately protect the Nation against biological threats to animal agriculture.”<sup>31</sup> DHS, through the S&T Directorate, largely focuses on supporting the nation’s response to a large-scale FAD incident and the bioterror threat.

The Homeland Security Act of 2002 made DHS the lead for bio and agro-defense research and development at PIADC. HSPD 9 in 2004 tasked the Secretaries of Agriculture and Homeland Security to develop a joint agro-defense strategy and criteria for the NBAF facility location. Specifically, it required the departments to “develop 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.”

Since this legislation was enacted, DHS has managed the PIADC with elements from the USDA—APHIS and ARS—working on agro-biodefense issues. While the type of work has varied over time, a majority of the recent R&D at PIADC has focused on FMD, ASF and Classic Swine Fever (CSF). This relatively narrow R&D focus is based on several factors, including capacity limitations at PIADC, workforce expertise, and program cost.

To offset these factors, several strategies have been pursued for gaining access to necessary R&D. Commensurate with their responsibilities and authorities, other departments and agencies within the U.S. government conduct and/or fund R&D to support preparedness and response activities. For example,

- The Department of Health and Human Services develops policy on pandemic preparedness. It also provides guidance on using antiviral or antibiotic prophylaxis and personal protective equipment, and it supports U.S. border surveillance efforts.
- The Department of the Interior monitors and investigates wildlife disease, manages and protects public health on federal lands, and supports response to zoonotic outbreaks.
- The Environmental Protection Agency (EPA) provides technical assistance, expertise, and support for decontamination and disposal issues; supports investigations and provides intelligence support; and provides assistance and information on public health/medical aspects of hazardous materials.
- The Department of Justice coordinates the investigation of criminal activities if bioterrorism or agroterrorism are suspected.

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<sup>29</sup> USDA, “About the U.S. Department of Agriculture,” undated.

<sup>30</sup> USDA, *APHIS Foreign Animal Disease Framework Roles and Coordination: FAD PReP, Foreign Animal Disease Preparedness and Response Plan*, Washington, D.C., September 2016.

<sup>31</sup> DHS, *National Bio and Agro Defense Facility (NBAF): Site Cost Analysis*, July 25, 2008.

- The Department of Defense supports USDA for animal disease preparedness, response, and recovery efforts.<sup>32</sup>

Additionally, in areas where departments and agencies overlap responsibilities and authorities, cross-government coordination of R&D efforts normally occurs. For example, on the management of the depopulation of infected livestock from a potential FMD outbreak, DHS, USDA, and EPA have important roles and dialogue and coordination has occurred on the issue.

Within DHS S&T, a variety of R&D programs were underway in key FAD areas. Tools to support planning and response drive requirements for countermeasures development and inform post-outbreak response activities by creating scalable (local to national) simulation and modeling tools to analyze potential responses and control options to minimize FAD spread were being developed. Diagnostic tests, agricultural screening tools, biosurveillance capabilities and data integration procedures to identify infected animals more rapidly were also being considered. Vaccines to prevent disease in healthy animals, limit disease spread among a herd, and maintain business continuity were being developed. Depopulation activities including disposal and decontamination were also being examined.

One of the major accomplishments from this R&D was the development of an FMD vaccine. Research from academia supported early efforts, PIADC scientists conducted R&D—including herd studies—and a vaccine developer from industry licensed and manufactured the vaccine. It is now available for use in the event of an FMD outbreak.

NBAF, the replacement for the PIADC, will provide new and important capabilities in agricultural biodefense. It will provide modern Biosafety Level (BSL)-2, BSL-3Ag, and BSL-4 laboratory space to conduct research and provide enhanced diagnostic capabilities on high-consequence foreign animal and zoonotic diseases in livestock. It will also provide increased capacity for herd studies and trials, which should decrease the time required to gain USDA approval for agricultural countermeasures and vaccines.<sup>33</sup> Increased capacity could also allow the study of zoonotic diseases other than FMD, CSF, and ASF. These diseases include Rift Valley Fever, Newcastle Disease Virus, Ebola, Venezuelan Equine Encephalitis, HPAI, and perhaps even a new zoonotic EID that would require study in a BSL-4 containment facility.

One cautionary note is in order regarding NBAF. Operating and maintaining high-containment biological laboratories is costly and requires consistent funding. The recent proposal by DHS to close the National Biodefense Analysis and Countermeasures Center (NBACC), a specially designed facility for conducting bioterror threat assessments and bioforensics, was based on fiscal pressures.<sup>34</sup> While the final disposition of NBACC has yet to be determined, NBAF could experience the same tensions if it is not properly utilized and funded.

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<sup>32</sup> These examples come from a USDA briefing (USDA, “Roles and Coordination, APHIS Foreign Animal Disease Framework” September 2016.)

<sup>33</sup> The Center for Veterinary Biologics, a unit in Veterinary Services under APHIS in the USDA, under the jurisdiction of the Virus-Serum-Toxin Act, regulates veterinary biologics products in the United States.

<sup>34</sup> Daniel M. Gerstein, “A Countering Bioterrorism Facility Worth a Second Look,” *RAND Corporation*, June 2, 2017.

Another strategy has been collaboration with international partners on FAD issues. Australia maintains an agricultural high containment laboratory that is investigating the Nipah and Hendra viruses, two relatively recently discovered zoonotic diseases that are of concern. By collaborating closely with Australia on researching these viruses, the U.S. benefits without having to directly conduct the R&D. Collaboration with Sweden on *Francisella tularensis* (the causative agent for tularemia)—a potential bioterror weapon—has expanded our knowledge of this pathogen. Likewise, collaboration with the United Kingdom, following their two FMD outbreaks in 2001 and 2006, filled in important knowledge gaps for development of preparedness and response capabilities.

The National Animal Health Laboratory Network (NAHLN) has its roots in the Homeland Security Act of 2002 and the HSPD-9. The network represents a shared enterprise bringing together Federal, State, and university-associated animal health laboratories to support “early detection, rapid response, and appropriate recovery from high-consequence animal diseases.”<sup>35</sup> The network contains two reference laboratories in Ames, Iowa, and Plum Island, New York, operated by the federal government and includes over 60 state and university-associated laboratories. State support for the NAHLN has totaled almost \$100 million annually.<sup>36</sup>

State and local authorities—in particular, those with large agricultural industries—have developed plans for preparing for and responding to an agricultural biodefense incident. While these entities are not involved in R&D, they must coordinate with the federal and industry planning efforts and would benefit by awareness of R&D that is ongoing.

The private sector and academia have made and must continue to make essential contributions to agro-biodefense R&D. Industry's central role is obvious given the that ownership and operation of the enterprise is almost exclusively within the private sector. As such, industry is involved in all aspects of ensuring the continuing vitality of and innovation in the agricultural sector, including in biodefense. Any disruption to normal functioning of the agricultural system could result in loss of access to U.S. and foreign markets and large financial losses. Programs such as tracking of livestock, control at border locations, pen-side diagnostics, tracking of agricultural by-products from farm to table, and rapid response and recovery to outbreaks are essential functions that involve and are supported by the agricultural industry.

Academia provides R&D as well as innovation that are imperative for continued improvements in agro-biodefense. Early research on specific diseases improves understanding of the mechanisms of action of specific diseases and can help develop diagnostics, countermeasures, and vaccines. The DHS S&T Directorate recently funded two Centers of Excellence co-led by three universities doing agro-biodefense: the Food Protection and Defense Institute, led by the University of Minnesota, and the Zoonotic and Animal Disease Defense, co-led by Texas A&M University and Kansas State University.<sup>37</sup>

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<sup>35</sup> USDA, “About NAHLN,” last updated November 2, 2016.

<sup>36</sup> APHIS, “National Animal Health Laboratory Strategic Plan,” September 2014.

<sup>37</sup> DHS, “Science and Technology: Welcome to the Centers of Excellence,” undated.

## Looking to the Future

Several areas of emphasis should be considered for future agricultural biodefense R&D.

- R&D solutions must be systems-oriented. The full range of threats—from naturally occurring dangers to deliberate use of biological pathogens—should be examined. Analysis should also include the full range of activities, from international spread of disease to the U.S. supply chain, which begins with transborder crossing of livestock to the farm-to-table activities that underpin the agricultural sector. Improvements in processes and technologies can improve outcomes and protect these critical sectors.
- Good disease monitoring will be important to continuity of business. It enables early detection, rapid response and recovery, and accurate communications across all interested governmental and nongovernmental entities. Delays in any of these critical components will cause greater economic losses and delay recovery.
- Cross-sector collaboration, including end-user participation, is vital for preparedness and response capabilities. The livestock industry and producers, government officials (including state animal health officials), the biopharmaceutical industry and veterinarians, first responders and diagnostic laboratories will need to collaborate in real-time to solve problems and break any logjams that occur. This must also include developing trust between government and industry to accelerate capability development. R&D collaboration can be important to ensuring that the full range of needs are being met.
- Opportunities to field test technologies worldwide should be identified. Countries with endemic zoonotic diseases of interest to the U.S. government and agricultural sector should be identified and approached to ascertain their willingness to work as partners for countermeasure and vaccine trials.
- Next-generation zoonotic disease professional training should continue to be developed. Education programs that target gaps in agriculture defense workforce (to include in R&D) would be useful. Standardized training programs for first responders and the agriculture sector could assist in preparedness and response for an agricultural biodefense incident.
- Consistent funding for agricultural biodefense efforts is essential. Achieving the level of protection for this area will require investments in R&D, including in facilities such as PIADC and NBAF. States and local communities also must have the funding to operate and maintain the labs that are part of the NAHLN. Underfunding endangers a \$1 trillion portion of the U.S. economy.

## Conclusions

Agricultural biodefense is a crowded space with responsibilities shared across federal, state and local government officials to private industry that largely owns and operates the sector.

Since the establishment of DHS in 2003, USDA and DHS have had a shared role in agricultural biodefense, particularly in the area of R&D.

While much progress has been made in developing systems to oversee, track, and monitor FAD internationally and in the United States, the threats continue to grow because of socio-economic, environmental and ecological factors. With more global travel and trade and

encroachment into formerly uninhabited areas, the opportunities for the spread of disease continues to increase as does the potential for a FAD to penetrate the United States.

I appreciate the opportunity to discuss Federal Research and Development for Agricultural Biodefense and look forward to your questions.