Testimony of

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify today about the inspection conducted by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) into the release of possibly live *Bacillus anthracis* (anthrax) at the Centers for Disease Control and Prevention's (CDC) Roybal campus. APHIS conducted a full and thorough investigation of the incident to learn how it happened and determine appropriate remedial measures. We will continue to monitor the CDC's response to ensure all necessary corrective action is taken and that when work resumes at the laboratories, it will be done in full compliance with select agent and toxin regulations and with the health and safety of employees and the public at the forefront.

APHIS' Agriculture Select Agent Services (AgSAS) and CDC's Division of Select Agents and Toxins (DSAT) jointly operate the Federal Select Agent Program, which oversees the possession, use and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. While CDC authority over select agents dates back to the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), USDA's Agriculture Select Agent Services was created under authorities granted by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188).

USDA was designated by Congress as a partner with CDC in the oversight of select agents because of our expertise and experience effectively and safely working with select agents through our domestic pest and disease programs as well as our efforts to prevent dangerous disease agents from impacting U.S. agriculture and the environment—including zoonotic diseases that impact human as well as animal health. These programs and efforts have been in place for over 100 years; in this time, we have had success in completely eliminating high consequence diseases from the United States such as foot and mouth disease and contagious bovine pleuropneumonia. APHIS has also safely operated high containment laboratories for decades, including the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, and the United States' animal health reference laboratory, the National Veterinary Services Laboratories, in Ames, Iowa, that handle select agents, including those of concern for human health. Our personnel are leading diagnosticians and experts in the effective working of high-containment laboratories.

Under Public Law 107-188, entities such as private, State, and Federal research laboratories; universities; and vaccine companies that possess, use, or transfer select agents must register these agents with the appropriate federal agency. In the case of select agents that are deemed a threat to animal or plant health, the appropriate agency would be APHIS; select agents deemed a threat to public health fall under CDC-DSAT. Some agents such as anthrax may pose a severe threat to both animal and public health and safety, and are considered overlap select agents that fall under both APHIS and CDC jurisdiction.

In addition to registering with APHIS or CDC, a facility working with select agents or toxins must also meet biosafety requirements that are commensurate with the risk posed by the agents or toxins. Facilities must also establish security measures that provide protection based on the threat of the particular agents or toxins within their possession. Additionally, the U.S. Department of Justice, through the Federal Bureau of Investigation, completes a security risk assessment of the facility owners, the designated responsible official, and all individuals possessing, using, or transferring the agents or toxins. Specially trained APHIS-AgSAS and CDC-DSAT officials also conduct an inspection of the facility prior to granting registration and additional unannounced inspections are conducted to ensure compliance with select agent regulations and policies. Additionally, our agencies review, modify, and republish the list of select agents and toxins on a biennial basis.

To ensure objectivity, APHIS and CDC-DSAT put in place a memorandum of understanding (MOU) in October 2012 which makes APHIS the lead inspection agency for entities that are owned and operated by CDC. This includes the conduct of both select agent registration renewal inspections as well as compliance inspections. Since the MOU was finalized, APHIS has carried out 11 inspections of CDC laboratories.

APHIS Inspection of the CDC Anthrax Incident

APHIS takes any potential release of a select agent or toxin very seriously, with a goal of quickly ensuring that any release is contained and determining what led to the release to ensure no future incidents. On June 13, 2014, CDC officials discovered the potential release of anthrax at CDC's Roybal Campus in Atlanta, Georgia, and CDC voluntarily closed the impacted labs on June 16. CDC notified APHIS-AgSAS on June 19 of the incident.

APHIS made this inspection a priority and quickly began its work to ensure that all select agents were secured and that there were no other breaches in biosafety and security which could impact public safety. The APHIS inspection team was comprised of a team leader and 4 veterinary medical officers. From June 23 through July 3, 2014, the inspection team conducted a facility review of the laboratories involved in the incident followed by interviews with CDC personnel. The AgSAS inspection team provided an exit briefing to CDC officials on July 2, outlining the deficiencies found during the inspection so that CDC laboratories could immediately begin taking corrective actions.

Through our inspection and interviews, we identified lapses in procedures which led to the accidental release and made a number of key findings that we have provided to CDC. Between June 6 and June 13, 2014, a CDC researcher improperly inactivated cultures of *B. anthracis* in a

select agent registered laboratory and moved the cultures to several laboratories on the Roybal Campus that are not approved to work with the live agent. Laboratory workers may have been exposed to live anthrax spores and vegetative cells through incidental contact or movement through seven laboratories in three separate buildings on the CDC Roybal campus. The APHIS inspection team verified that no livestock were exposed.

Our inspection confirmed that this was an unintentional release of anthrax. However, our inspection also found a number of deficiencies in the biosafety, security, incident response, occupational health, and management controls of the incident, which will require corrective actions in order to prevent such incidents from reoccurring in the future.

First, the laboratory that inadvertently transferred the possibly live anthrax did not use an adequate inactivation protocol and did not ensure that the protocol was validated. The initial response to this incident by the impacted CDC laboratories was inadequate, both in fully securing as well as disinfecting exposed laboratory areas and equipment. Individuals without approval to handle select agents were able to access space containing or potentially contaminated with anthrax at least through June 17, or 4 days after the incident was discovered. Additionally, a number of the disinfectants used in the response were expired and impacted laboratories used inconsistent methods of disinfection. We found that employees did not have appropriate training in the application of the inactivation protocol, appropriate disinfection of exposed laboratory areas or actions to take in the event of exposure.

At the management level, we found no clear management oversight of the incident within the various laboratories that were impacted. There also was no clear, single manager overseeing the overall CDC incident response, which resulted in employee confusion about how to manage the response to the incident. In addition, CDC's Occupational Health Clinic was inadequately prepared to respond to the potential exposure of a large number of workers, resulting in some staff not knowing if they were at risk and at least one person who was in contact with contaminated material without proper personal protective equipment not being examined for 5 days.

APHIS currently has in place a cease and desist order for all work with select agents and toxins at the two impacted Roybal campus select agent labs, due to the deficiencies in biosafety and containment procedures we found during our inspection. We have provided a report of the full inspection findings to CDC and will require that a number of corrective actions be taken to ensure the integrity of its select agent research programs. We have directed CDC to provide APHIS with its plan for coming into compliance no later than July 25, 2014. Prior to allowing CDC to resume select agent work in the laboratories, APHIS will conduct a reinspection to ensure that all corrective actions have been taken.

APHIS Inspection of the CDC Avian Influenza Incident

APHIS learned on July 9, 2014, of an incident in which CDC sent a low pathogenic H9N2 avian influenza virus sample contaminated with high pathogenic H5N1 avian influenza virus to the USDA, Agricultural Research Service, Southeast Poultry Research Laboratory in Athens, Georgia. APHIS quickly dispatched a team of inspectors during the week of July 14, 2014, to

lead the compliance inspections at both the CDC and USDA-ARS laboratories and determine any needed corrective actions.

Mr. Chairman, this concludes my testimony. I would be happy to answer any questions that you or the members of this Subcommittee may have.