Testimony of

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify today about the role of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) in the operation of the Federal Select Agent Program (FSAP). APHIS, through its Agriculture Select Agent Services (AgSAS), and the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins jointly oversee the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products. I assure you that we recognize the gravity of incidents involving the inappropriate release of regulated select agents and have been taking actions to strengthen the select agent program.

USDA has a long history of 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. For decades, APHIS has safely operated high containment laboratories that handle select agents. This includes the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, which is operated in conjunction with the Department of Homeland Security, and the United States' animal health reference laboratory, the National Veterinary Services Laboratories, in Ames, Iowa. Our personnel are leading diagnosticians and experts in the effective operation of high-containment laboratories.

We take the safety and security of select agents and toxins with the level of seriousness they deserve given their potentially devastating impacts to plant, animal, and human health. Accordingly, through our oversight role, we are regularly and proactively evaluating and assessing the select agent program and taking steps to ensure that these agents and toxins are handled and transferred securely.

The most prominent of these efforts is the Federal Experts Security Advisory Panel (FESAP). President Obama created FESAP in July 2010 to examine and provide recommendations to the Secretaries of Agriculture, Health and Human Services (HHS) and the Attorney General regarding the security of biological select agents and toxins[1]. The group was re-chartered in July 2014 to further evaluate approaches to enhance biosafety and security[2]. The panel is chaired by USDA and HHS and includes members from numerous agencies throughout the government. Overall the panel concluded that the U.S. government has developed a robust set of rules, regulations and practices to inform safe, secure and responsible work and research with infectious agents and toxins. However, it also identified several improvements that would further mitigate the risks of working with these agents and toxins.

[1] http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf
[2] http://www.phe.gov/s3/Documents/fesap.pdf

Additionally in August 2014, the White House Office of Science and Technology Policy created the Fast Track Action Committee on the Select Agent Regulations (FTAC-SAR)[3] to examine – with input from the research community, interested stakeholders, and the public – the select agent regulations in order to identify challenges and make recommendations to improve and strengthen the regulations. FTAC-SAR recommendations included increased transparency of research and laboratory-related incidents; standardization of the inspection process; categorization of inspection findings so as to distinguish between administrative and direct safety findings; and timeliness and better communication surrounding inspection reports.

Broadly, these two panels and their recommendations address the need for a culture of responsibility; oversight, outreach and education; applied biosafety research; incident reporting; materials accountability; inspection process improvements; and regulatory changes and guidance documents to improve biosecurity and safety. Together, the FESAP and FTAC-SAR recommendations were included in an October 2015 implementation plan. [4] USDA and our partners have made significant progress in accomplishing and implementing many of these recommendations.

Chief among these is the development of a rule to strengthen and improve the select agent regulations. The proposed rule, which USDA published in January 2016, would amend the select agent regulations to add provisions to address the inactivation of select agents, biocontainment and biosafety, and would clarify regulatory language concerning security, training, incident response, and records. These changes would help regulated entities better understand their responsibilities under the select agent regulations as well as provide for enhanced program oversight. USDA is finalizing the rule as quickly as possible, and we are coordinating with HHS to ensure that the rule is in line with CDC regulations.

USDA and HHS have also committed to increasing transparency and the public's understanding of the FSAP. In June, we published the first annual report of aggregate program data[5]. These data provide insight into work conducted with biological select agents and toxins at laboratories across the nation, as well as the regulatory functions of the FSAP. The report summarizes program data in areas such as:

- Numbers and types of registered entities
- Security risk assessments performed
- Number of inspections conducted
- Top select agents or toxins registered by entities
- Key observations related to inspection findings and compliance with the select agent regulations
- Identifications and transfers of select agents or toxins
- Thefts, losses, and releases of select agents or toxins

Beyond providing a snapshot of the program, the data, through the collection process, ensures a level of accountability, and can help USDA and HHS identify trends and other areas of concern on which we can take action.

APHIS has also taken actions to strengthen the performance and build the capabilities of its select agent program. The President's fiscal year 2017 budget includes a $4.71 million increase, for a total of about $9.6 million. The proposed increase will enhance our select agent program and allow us to hire additional personnel with strong scientific, security and policy backgrounds. It is critical that we have personnel

[3] http://www.phe.gov/s3/Documents/ftac-sar.pdf
[4] http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf
[5] http://www.selectagents.gov/resources/FSAP_Annual_Report_2015.pdf

with the expertise to address the increasing scientific complexity of the regulatory issues related to research with select agents and toxins. The additional personnel funded by this request would allow APHIS to strengthen the inspection program – addressing critical incidents while also carrying out the daily responsibilities associated with overseeing these agents.

Another effort to strengthen the program was APHIS' own internal audit. The agency's auditors reviewed AgSAS in December 2015 in an effort to improve program efficacy and efficiency. Overall, the audit found that AgSAS has designed its program to effectively carry out its program objectives and mandates. However, the review made several recommendations, which included suggestions to improve program documentation and to strengthen policies related to incident reporting and permitting. APHIS has begun implementing those recommendations.

Beyond these internal USDA and Executive Branch reviews, we appreciate the recommendations of the Government Accountability Office (GAO). GAO has provided regular reviews and recommendations to strengthen the select agent program, and we value their independent perspective.

The report GAO is releasing today, "High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk" includes five recommendations for USDA. As our response to the audit indicates, we are already taking significant actions to address all of the recommendations. In particular, under FSAP, USDA is working to finalize a rule to strengthen the select agent regulations, which will include additional clarification around the inactivation of select agents. Specifically, the rule will provide regulatory definitions of inactivation and viability testing. We feel that the rule, along with guidance documents on inactivation and viability testing, will help regulated entities understand what they need to do to ensure that the materials they are working with are handled in accordance with the regulations, protecting human, animal and plant health.

The report also highlights the gaps in the science of inactivation and viability testing. APHIS and CDC, as part of the FESAP interagency working group,examined current gaps in scientific knowledge and agreed with the importance of a robust federally-supported program of biosafety research. The working group has been working with researchers and laboratories, per FESAP recommendation 1.3, to try to ensure that a qualified review entity validates local policies and protocols regarding the inactivation, sterilization or decontamination of biohazardous materials at research institutions. The group continues to make progress in this area, and when combined with the pending regulatory changes and guidance documents, the government and regulated entities will have more consistent understanding of the processes for inactivation and sterilization of select agents and other biohazards.

We are taking other steps in accordance with the recommendations of this report and other reviews. We are committed to updating APHIS/CDC Form 3 to better identify incidents involving incomplete inactivation. The increased information we collect on this form will allow FSAP to analyze trends to reduce the risk of future incidents. We have also developed a three-tier risk scoring system to ensure consistency in enforcement actions, particularly for those involving incomplete inactivation. We have shared this proposed system with the regulated community to gather feedback and to indicate the seriousness with which we take incidents involving incomplete inactivation. Our intent is to finalize the system and to use it as a tool within the FSAP.

APHIS takes any potential release of a select agent or toxin very seriously. While we cannot completely eliminate all risk of a potential release, we can develop overlapping safeguards and processes to reduce the risk to as low as possible. By working closely with our Federal partners and the regulated community, we can develop strong cultures of safety and responsibility and policies and procedures that are science-based and, to the maximum extent possible, ensure the safety and security of these potentially dangerous agents.

This concludes my testimony. I would be happy to answer any questions you or the members of the subcommittee may have.