



RESOLUTION NUMBER: 16 **APPROVED AS AMENDED**

SOURCE: **COMMITTEE ON Biologics and Biotechnology**

SUBJECT MATTER: **Select Agent Inspections**

BACKGROUND INFORMATION:

The Federal Select Agent Program is overseen by the Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). This overlapping jurisdiction has led to duplicative inspections and sometimes conflicting findings. The Government Accountability Office (GAO) issued a report in 2013 that found, "There is no apparent value added when specific inspection activities are duplicative and occur, in some cases, before entities have had time to respond to findings from a previous inspection." Among its recommendations for Executive action, the GAO recommended that where possible CDC and USDA-APHIS accept each other's inspection results rather than conducting independent inspections.

For the veterinary biologics industry and others currently regulated and inspected by USDA-APHIS, the lead agency for these inspections should be USDA-APHIS.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) and the Centers for Disease Control and Prevention (CDC) to implement the findings of the Government Accountability Office report of 2013 titled, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program" with specific focus on the recommendation that USDA-APHIS and CDC accept each other's inspection results rather than conducting independent inspections. Further, USAHA urges that where Select Agent Registrants are already regulated and inspected by USDA-APHIS that the lead agency be USDA-APHIS.

INTERIM RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services shares the concerns of the U.S. Animal Health Association (USAHA) and appreciates the opportunity to respond. The Federal Select Agent Program (FSAP) represents the collaborative, regulatory efforts of APHIS' Agriculture Select Agent Services (AgSAS) and the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT). Since 2012, AgSAS and DSAT have participated in a Memorandum of Understanding that states that the non-lead agency in the FSAP will accept the inspection findings of the lead agency with respect to overlap-select agents and toxins.

For those entities which possess HHS-only and USDA-only agents, FSAP has implemented a policy for joint FSAP, thus eliminating the need to conduct separate inspections for agency-only agents. In response to Executive Order 13546—Optimizing the Security of Biological Select Agents and Toxins in the United States (July 8, 2010), FSAP implemented a policy to allow inspectors from Federal partners (such as the Department of Homeland Security, Department of Defense, or the Environmental Protection Agency) to accompany FSAP inspectors during, and conduct inspections simultaneous to, a select agent

inspection. Following the joint inspection, all participating agencies share their respective reports. The FSAP also provides training for both DSAT and AgSAS inspectors to improve consistency in inspection processes and regulatory interpretation.

For APHIS movement permits (animal and plant pathogens), AgSAS has implemented a policy to reduce duplicative inspections. Upon receipt of a permit application requiring inspection, the VS or Plant Protection and Quarantine permit unit coordinates with AgSAS to determine whether a select agent inspection has been conducted recently and if it would satisfy the permit requirements. If so, no additional inspection is required to issue the movement permit. APHIS believes these coordination and policy changes have led to a significant reduction in the number of separate inspections necessary at regulated entities.

In response to the USAHA recommendation that APHIS become the lead agency for Select Agent Registrants already regulated and inspected by APHIS, APHIS stresses that the lead-agency concept is purely for administrative purposes within FSAP. A registered entity may choose the agency with which they want to register, provided at least one of their select agents fall under the selected agency's regulatory authority. For example, an entity that possesses a USDA-only agent and an overlap select agent may choose to register with either the CDC or APHIS; an entity possessing only USDA-only agents must register with APHIS.

APHIS appreciates USAHA's comments and recommendations. The FSAP strives to become more efficient and transparent in its regulatory duties and, as such, provides information, holds annual webinars, and posts program results on the FSAP website (www.selectagents.gov).