



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

December 30, 2015

David Schmitt, President  
United States Animal Health Association  
4221 Mitchell Avenue  
Saint Joseph, MO 64507

Dear Dr. Schmitt:

As the Director of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response, I want to thank you for your letter informing us of the United States Animal Health Association Resolution 16 concerning "Select Agent Inspections." In that resolution, you specifically requested CDC and the Animal and Plant Health Inspection Service (APHIS) accept each other's inspection results rather than conducting independent inspections. Further, you urged that "where select agent registrants are already regulated and inspected by APHIS that the lead agency be APHIS."

The Federal Select Agent Program (FSAP) represents the collaborative efforts of the CDC, Division of Select Agents and Toxins (DSAT) and APHIS, Agriculture Select Agent Services (AgSAS). Since 2012, DSAT and AgSAS have participated in a Memorandum of Understanding which 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. We believe this coordination has led to a significant reduction in the number of separate inspections conducted by both FSAP agencies. In addition, the FSAP has coordinated lead agency overlap inspections with inspections of USDA-only or HHS-only agents to occur at the same time to, again, reduce the number of inspections an entity undergoes from either agency that is charged with the regulation of select agents and toxins.

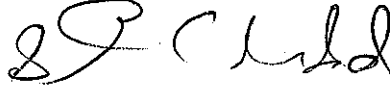
Regarding your request that "where select agent registrants are already regulated and inspected by APHIS that the lead agency be APHIS." Please note that according to section 8411 of title 7, United States Code, an entity is allowed to choose its lead agency unless the entity's registration includes either "USDA-only" or "HHS-only" select agents or toxins. DSAT must conduct inspections for HHS-only agents and AgSAS must conduct inspections for USDA-only agents. We wish to convey to you that to the extent that the law and our authorities allow, we have been coordinating inspections and accepting the inspection result of the other agency. In addition, we are actively working on improving the timeliness of our inspection reports and are in the process of making other improvements in our programs to provide more efficient service to the regulated community.

Please know that we value your comments and suggestions. In our efforts to be more transparent regarding our improvements to the program, we will be posting the results on our website

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([www.selectagent.gov](http://www.selectagent.gov)). Thank you again for sharing your concerns. If you have any further questions or concerns, please feel free to contact Dr. Dan Sosin, Acting Director of CDC's Division of Select Agents and Toxins, at (404) 718-2000.

Sincerely,

A handwritten signature in black ink, appearing to read "S. C. Redd". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Stephen C. Redd, M.D.  
RADM, USPHS  
Director, Office of Public Health Preparedness  
and Response