

Title: Characterization of regulatory departures identified during inspections conducted by the United States Federal Select Agent Program, 2014–2015

Subject of Planned Report: A report of regulatory departures identified on U.S. Federal Select Agent Program (FSAP) inspections to improve transparency regarding biosafety and security risk at FSAP-regulated entities and identify areas for programmatic improvement.

Purpose of Planned Report: Disseminate information on select agent departures and corrective actions as part of the Federal Select Agent Program.

Type of Dissemination: ISI Publication intended in a peer-reviewed journal

Timing of Review (including deferrals): 2.5 months (3/17/2017 to 5/31/2017)

Type of Review (panel, individual or alternative procedure): This report was reviewed by subject matter experts including the Office of the Associate Director for Laboratory Safety and Science (OADLSS), the chain of command including the Director of the Office of Public Health Preparedness and Response (OPHPR) and the CDC Office of the Associate Director for Science (OADS), and an external reviewer at the United States Department of Agriculture (USDA).

Opportunities for the Public to Comment (how and when): Not until journal embargo is lifted

Peer Reviewers Provided with Public Comments before the Review: Journal reviewers and USDA reviewer (outside of HHS)

Anticipated Number of Reviewers: Journal reviewers (2), Clearance reviewers (10), USDA (1)

Primary Disciplines or Expertise: Public Health Practice, Preparedness and Response, Microbiology, Regulatory Practice, Policy

Reviewers Selected by (agency or designated outside organization): Both

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: Scientific accuracy and integrity

Additional elements to be added to the public posting as they become available

For each Peer Reviewer Selected: *Only listing the external reviewer at USDA*

Last Name, First Name, Middle Initial: Isaac, Freeda E.

Academic and Professional Credentials: Doctor

Current Position Title: USDA/APHIS Director

Organizational Affiliation(s): U.S. Department of Agriculture (USDA)

Areas of Expertise, Discipline, Relevant Experiences: AgSAS partner for animal and plant health components of the Federal Select Agent Program at USDA

Recommended by Scientific/Professional Society or General Public: Subject matter expert's recommendation

Charge to Peer Reviewers: Scientific accuracy and integrity

Peer Reviewers' Comments: Sent to authors for inclusion in final version of manuscript

CDC/ATSDR's Response to Reviewers' Comments: Addressed in current version – available after journal embargo

The ISI/HISA Dissemination Itself: NA