

## Federal Select Agent Program

### SA-Grams

**Date of issuance:** 3/31/16

**Title:** Inspection Observation Dispute Process

**Text:** On February 8, 2016, the Federal Select Agent Program (FSAP) offered the ability for the regulated community to submit written comments on a process for a registered entity to dispute FSAP inspection report findings. FSAP would like to thank those that provided feedback. Based on the comments received, FSAP is announcing a process for a Responsible Official (RO) at a registered entity to dispute an inspection report observation requiring the registered entity to take a corrective action.

Within fourteen (14) calendar days from receipt of the inspection report, an RO may provide written notification to the Agriculture Select Agent Services (AgSAS) Unit Director or the Division of Select Agents and Toxins (DSAT) Operations Branch Chief of the registered entity's intention to dispute a specific inspection report observation requiring the registered entity to take a corrective action. Information on how to submit the written notification will be available on the inspection reports sent to the RO.

Within thirty (30) calendar days of the receipt of the inspection report, the RO will be expected to provide written evidence that clearly states the reason(s) why the registered entity believes an inspection report observation requiring corrective action is in error. The RO will be expected to include any supporting documentation.

The goal of the FSAP will be for the AgSAS Unit Director or the DSAT Operations Branch Chief to resolve the dispute with the RO within thirty (30) calendar days of the receipt of the RO's written evidence that clearly states the reason(s) why the registered entity believes an inspection report observation requiring corrective action is in error. The attempt for resolution of a dispute may include discussions with the entity or site visits.

If resolution of a dispute is not reached to the satisfaction of the RO, the RO may submit a request for reconsideration to the AgSAS Director or DSAT Director, as appropriate.

If the resolution of a dispute results in a change to an observation of an inspection report or to the required corrective action, the agency issuing the inspection report will issue an addendum to the inspection report.

Based on seriousness and need for immediate action, the FSAP may notify a registered entity that a corrective action specified in an inspection report will be required to proceed notwithstanding the dispute of an inspection report observation.

If you have any questions regarding this email, please contact your File Manager with the Federal Select Agent Program for APHIS/AgSAS entities, 301-851-3300 option 3 (voice only) and for CDC/DSAT entities, 404-718-2000.