



Doc. 10

United States
Department of
Agriculture

June 20, 2013

Animal and Plant
Health Inspection
Service

[Redacted]
Responsible Official
Centers for Disease Control and Prevention
Select Agent Compliance, Roybal Campus
1600 Clifton Road NE, Mail Stop A-22
Atlanta, Georgia 30333

Veterinary Services

National Center for
Import and Export

4700 River Road,
Unit 2, Mailstop 22,
Cub. 1A07
Riverdale, MD 20737

Dear [Redacted]

(301) 851-3300, 1
FAX (301) 734-3652

The Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Program (ASAP) and the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) conducted an APHIS-Led CDC joint inspection January 14, 2013 to January 17, 2013, at the Centers for Disease Control and Prevention. ASAP and DSAT have completed the review of the Viral Special Pathogens Branch (VSPB) facility inspection. ASAP does not have any questions at this time but DSAT requires additional information from you. Please provide this information to DSAT's office no later than 14 calendar days from receipt of this letter. Please see the CDC attached letter dated June 14, 2013. We will provide the Pox Branch facility inspection report to you at a later date.

If there are any questions or concerns in reference to this correspondence the DSAT letter states to contact [Redacted]. Instead of [Redacted], please contact [Redacted] at [Redacted] with the Centers for Disease Control and Prevention, Division of Select Agents and Toxins for any questions. Thank you

Sincerely,

[Redacted Signature]

Staff Veterinary Medical Officer
Agricultural Select Agent Program



Safeguarding American Agriculture

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1-800-877-8339



Department of Health and Human Services
Centers for Disease Control and
Prevention
Division of Select Agents and Toxins
Atlanta, Georgia

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Select Agent Program
Riverdale, Maryland



June 14, 2013

[REDACTED] Responsible Official)
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop A-22
Atlanta, GA 30333
FAX: (404) 639-0437

RE: Entity Inspection Report: Centers for Disease Control and Prevention

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS). The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73, and the Animal and Plant Health Inspection Service (APHIS) Select Agent Program (ASAP) inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at <http://www.selectagents.gov/>.

DSAT inspectors visited your facility located at 1600 Clifton Road, NE, Mailstop A-22 Atlanta, GA 30333 from January 14, 2013 to January 17, 2013. A list of laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from the CDC and APHIS Select Agent Programs inspected the facility:

[REDACTED] Lead Inspector
[REDACTED] Inspector
[REDACTED] Inspector
[REDACTED] Inspector
[REDACTED] Inspector
[REDACTED] Inspector

Individuals from Centers for Disease Control and Prevention present during the inspection included:

[REDACTED] Research Microbiologist
[REDACTED] Support: Animal Care
[REDACTED] Laboratorian
[REDACTED] Microbiologist
[REDACTED] Laboratorian/PI
[REDACTED] Support Staff: Animal Care
[REDACTED] PI
[REDACTED] Guest Researcher
[REDACTED] Quality Assurance Associate
[REDACTED] Support Staff: Animal
[REDACTED] RO, Safety and Occupational Health Manager

[REDACTED] CCID Safety Manager
[REDACTED] SRP, Alternate Attending Veterinarian
[REDACTED] Support Staff: Animal Care
[REDACTED] Support: Admin
[REDACTED] Laboratorian
[REDACTED] Informatic Specialist
[REDACTED] Section Chief Molecular
[REDACTED] PI
[REDACTED] Veterinary Medical Officer
[REDACTED] Team Leader, SPB
[REDACTED] HCL Manager/Microbiologist
[REDACTED] Laboratorian
[REDACTED] Clinical Veterinarian
[REDACTED] Support: Animal Care
[REDACTED] Laboratorian
[REDACTED] Microbiologist
[REDACTED] ARO, Safety and Occupational Health Manager

During the inspection, departures from regulatory requirements cited above were noted. Please address each of the items described in Attachment 1 (List of Entity Departures) and include in your response the specific actions or changes to be adopted to correct these departures. A detailed response should be received by this office not later than 14 calendar days from receipt of this letter. An electronic copy of your response should be sent to the lead inspector. Failure to fully respond may result in the initiation of proceedings for the withdrawal of your facility registration to possess, use, or transfer select agents and toxins.

If you have any questions concerning this correspondence please contact [REDACTED] at [REDACTED].

Sincerely,

[REDACTED]
[REDACTED]

Director, Division of Select
Agents and Toxins
Department of Health and Human
Services
Centers for Disease Control and
Prevention

[REDACTED]
[REDACTED]

Director, Agriculture Select Agent
Program
United States Department of
Agriculture
Animal and Plant Health
Inspection Service

Attachment: 1:
List of Entity Departures

Attachment 1: Entity Departures

Departures noted from January 14, 2013 to January 17, 2013 at Centers for Disease Control and Prevention (citations from 42 CFR Part 73 specifying each requirement are given in brackets).

- 1 **Requirement:** The security plan must contain provisions for the control of access to select agents and toxins including the safeguarding of animals, including arthropods, or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release. [Section 11(c)(2)]

Observation: At the time of inspection, a laboratorian was observed sending select agents through the decontamination tank for removal from the laboratory. However, at the time there was no SRA approved individual present to receive the samples. The CDC [REDACTED] High Containment BSL3 / BSL4 Safety and Operations Manual (Appendix 11) states that select agents should only be removed from the laboratory in this manner if a select agent approved user is on the other side to receive the sample(s). Please provide DSAT with clarification on how this procedure will be enforced.

- 2 **Requirement:** The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. [Section 12(a)]

Observation: At the time of inspection, biohazard waste containers were observed that contained recapped needles. Since the CDC [REDACTED] High Containment BSL3 / BSL4 Operations and Safety Manual (Section 5.5) states that needles should never be recapped, please provide DSAT with clarification on how these procedures described in your biosafety plan will be implemented.

- 3 **Requirement:** Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS. [Section 19(b)]

Observation: Please provide a Form 3 for the incident logged on December 5, 2012. Please note that any incident that results in the activation of a post exposure medical surveillance/prophylaxis protocol should be reported as a release.

- 4 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. Decontaminate all wastes (including animal tissues, carcasses, and contaminated bedding) and other materials before removal from the ABSL-4 laboratory by an effective and validated method. [BMBL: (ABSL-4) A8]

Observation: The High Containment BSL3/BSL4 Safety and Operations Manual (section 5.5.3.f) describes the decontamination of animal carcasses at 250F for 65 minutes prior to removal from the laboratory. These conditions are apparently used for frozen and refrigerated carcasses as well as those that are decontaminated immediately after necropsy. Please provide validation data to demonstrate that frozen animal carcasses are effectively decontaminated at these conditions.

Attachment 1: Entity Departures

- 5 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. Removal of biological materials that are to remain in a viable or intact state from the ABSL-4 laboratory must be transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. These materials must be transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, packaged viable material must not be opened outside BSL-4 containment unless inactivated by a validated method. [BMBL: (ABSL-4) B5]

Observation: RNA or DNA samples extracted from RG4 virus stocks and tissues collected from infected animals in studies conducted by SPB are transferred to lower biocontainment level laboratories after removal from the BSL4 laboratory. Please provide validation data, specific to procedures currently used by SPB, for non-viability of RNA or DNA extracted from RG4 virus stocks and tissues.

- 6 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. All incidents must be reported to the laboratory supervisor, institutional management and appropriate laboratory personnel as defined in the laboratory biosafety manual. [BMBL: (BSL-4) B8]

Observation: During a review of incident records, there were several instances noted where procedures for evaluation of potential occupational exposures to RG4 agents did not appear to be consistent with the High Containment BSL3/BSL4 Safety and Operations Manual specified reporting chain. This Safety and Operations Manual (section 6.2.6.1) states that events that may result in exposure to BSL4 agents should be reported to the Chief or to the SPB-HCL Supervisor, the Safety Manager, the Select Agent RO, and the HCL Manager as soon as possible. If a significant risk is judged to have occurred, the Occupational Health Clinic physician will be involved in decisions of management. Initiation of Occupational Health Clinic involvement in decisions for exposure management was not always consistent with these written biosafety plans. For instance, one incident that occurred on December 5, 2012 took 3 days until the Occupational Health Clinic was involved in a risk management assessment. It also appears that some inconsistencies with the biosafety plan procedures for incident evaluation may have occurred after an event recorded in the incident log book on December 16, 2012. Please provide DSAT with clarification on how these procedures will be enforced.

In addition, please provide an updated protocol for medical evaluation of incidents involving Tier 1 BSAT. (See 42 CFR 73.12.d: The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. In addition, please see BMBL, p117: All occupational injuries, including exposures to human pathogens, should be reported to the medical support services provider.)

- 7 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. Equipment that may produce aerosols must be contained in devices that exhaust air through HEPA filtration before being discharged into the laboratory. [BMBL: (BSL-4) C(B)1]

Observation: At the time of the inspection it was not clear that that all aerosol-producing equipment was properly protected. Please verify that all instruments and equipment that may produce infectious aerosol in laboratory spaces are equipped with HEPA filters. Please verify that all table top centrifuges have primary containment rotors or are placed in BSCs when used.

- 8 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. These HEPA filters should be tested annually and replaced as needed. [BMBL: (BSL-4) C(B)1]

Attachment 1: Entity Departures

Observation: Please verify that all HEPA filters in aerosol producing equipment are tested or replaced annually.

- 9 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. The HEPA filter housings should be designed to allow for in situ decontamination and validation of the filter prior to removal. [BMBL: (BSL-4) D(B)9]

Observation: At the time of inspection, it was not clear how in situ decontamination of some HEPA filters, e.g., vent filters, was validated. Please provide a description of the validation method as well as representative copies of validation test results.