Federal Select Agent Program (FSAP) Severity Spectrum of Regulatory Departures

General Considerations:

Severity Spectrum: Departures from the select agent and toxin regulations are communicated through an inspection report. Departures may include findings of low risk as well as findings that may lead to an immediate stoppage of some or all activities. **The intention of this document is to provide awareness of how FSAP considers severity of inspection findings and provide visibility to the application of enforcement options to these findings.**

Serious: Departures that are an immediate threat to human, plant, or animal health, animal or plant products, and/or security of biological select agents and toxins (BSAT) and those that indicate a need for systemic improvements. In selected cases, an Immediate Action Report will be submitted within 10 days from the Monday following the last day of the inspection. Required corrective action may include ceasing work or addressing departures within a shortened period of time. Other departures will be reported in the routine inspection report submitted within 30 days from the Monday following the last day of the inspection.

Moderate: Departures that have the potential to be a threat to human, plant, or animal health, animal or plant products, and/or security of BSAT. If not corrected, such departures will likely impact the safety of humans, animals, and/or plants, animal or plant products, and/or security of BSAT and increase the risk of more serious departures. A routine inspection report will be submitted within 30 days from the Monday following the last day of the inspection.

Low: Departures that are unlikely to pose an immediate threat to human, plant, or animal health, animal or plant products, and/or security of BSAT but are not consistent with safe and secure standards of practice. If not corrected, such departures degrade the culture of safety and security. Repetition of departures may be considered more serious and lead to enforcement actions. A routine inspection report will be submitted within 30 days from the Monday following the last day of the inspection.

Federal Select Agent Program (FSAP) Enforcement Options

Revocation: An entity's registration will be revoked if the FSAP determines that an entity is unwilling or unable to meet the requirements of the select agent and toxin regulations such that the entity presents a threat to the safety of humans, animals, plants, animal products or plant products; and/or the security of BSAT cannot be maintained even in a storage only capacity. Refer to

Section 8 of the select agent and toxin regulations.

Suspension: An entity may be suspended if any regulatory departure presents an imminent danger to the safety of humans, animals, and/or plants, animal or plant products, and/or the security of BSAT. Suspension for such regulatory departures is applied entity-wide, is communicated through a "cease and desist letter," and is not voluntary. Suspended entities must not conduct activities with select agents and toxins, but will be allowed to securely store to prevent theft, loss, or release of the select agents and toxins in their possession. All suspensions are referred to external agencies for further investigation (see below for more details). Refer to Section 8 of the select agent and toxin regulations.

Immediate action: A limited suspension action for a serious regulatory departure that presents a danger to the safety of humans, animals, and/or plants, animal or plant products, and/or the security of BSAT that can be mitigated with an immediate stoppage of the activity or an immediate change in entity work and/or security practices. This order is communicated through an "immediate action letter" that specifies conditions that must be met within a defined period of time. An immediate action order may include a **partial suspension** of an entity to possess, use, or transfer BSAT specific to certain agents/toxins, of the activities of a principal investigator, and/or the use of a registered area.

Corrective Action Plan (CAP): Multiple serious, moderate, and/or repeated regulatory departures indicate a systemic failure to comply with the requirements of the select agent and toxin regulations. An entity must fully resolve the departures within 30 days from receipt of the inspection report; or the entity may develop and implement a CAP to resolve the regulatory departures according to a timeline specified by the FSAP. As a part of the CAP program, an entity must submit progress reports in accordance with the timeline documenting actions it has taken to correct regulatory departures. The availability to participate in the CAP program is communicated through an "opportunity to show cause" letter and is voluntary.

Increased Monitoring: Some specific regulatory departures or a history of repeated regulatory departures may indicate an entity is having difficulty complying with the requirements of the select agent and toxin regulations. The FSAP closely monitors implementation of corrective actions and may conduct additional onsite inspections.

Referrals: There are two types of referrals for civil penalties: (1) DRSC may make a referral to the HHS OIG with a recommendation that the HHS OIG seek civil penalties; and (2) DASAT may make a referral to the APHIS IES with a recommendation that APHIS seek civil penalties. Either DRSC or DASAT may make a referral to the FBI when DRSC or DASAT has reason to believe that there has been a violation of Federal criminal law. FSAP may make a referral to another Federal Department or Agency when the FSAP has reason to believe that a regulation under the jurisdiction of that Department or Agency has been violated.

Note: the following examples are not a complete list of departures in these categories. Some of the examples describe multiple regulatory departures that individually may represent the level severity or trigger the enforcement action.

Severity	Regulation	Examples of Departures
Serious Departure	Registration, Section 7	Discovery of BSAT in unregistered space and/or possession of BSAT without approval. The entity conducts work with BSAT that is not described on APHIS/CDC Form 1. Possession of Tier 1 BSAT at non-Tier 1 entity and requirements of section 11(f) are not in place.
Serious Departure	Responsible Official, Section 9	Failure of entity and RO to ensure compliance with the select agent and toxin regulations, resulting in widespread departures. Failure of entity to provide adequate authority to an RO to act on behalf of the entity. Failure to report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.
Serious Departure	Security, Section 11	Evidence that an entity allowed a non-SRA approved person access to BSAT. Security breach that has the potential to result in theft or loss of BSAT. Failure to implement Tier 1 requirements, such as a suitability program for personnel with access to Tier 1 BSAT, three physical security barriers to Tier 1 BSAT, and/or functional Intrusion Detection System (IDS).
Serious Departure	Biosafety, Section 12	Release that has the potential to result in a laboratory-acquired infection in humans without identification of root cause and/or releases or repeated incidents to which the entity has failed to take adequate corrective action(s) to prevent further containment breaches. Failure to adhere to validated inactivation method. Systemic failure to implement the Occupational Health Plan for Tier 1 BSAT, SARS-CoV, or Reconstructed 1918 influenza virus. The facility is inadequate for BSAT work conducted (refer to specific examples in immediate action category)

Severity	Regulation	Examples of Departures
Serious Departure	Restricted Experiments, Section 13	Conducting a restricted experiment, or possession of a product of a restricted experiment, without prior approval
Serious Departure	Training, Section 15	Systemic failure to provide refresher training to SRA-approved individuals or training to visitors on a consistent basis
Serious Departure	Transfers, Section 16	Transfer of a select agent or regulated quantities of select toxin to another entity without APHIS/CDC Form 2 authorization
Serious Departure	Records, Section 17	BSAT inventory is inaccurate to a degree that material accountability is not possible. Entity does not have a system to ensure that records and databases are accurate and their authenticity can be verified, to the extent that it cannot be determined if there has been a theft or loss of BSAT. Systemic failure to provide records required by section 17 upon request.
Serious Departure	Inspections, Section 18	Entity does not allow FSAP inspectors access to any site at which select agent and toxins activities are conducted. Entity does not allow FSAP inspectors access to and copying of entity select agent and toxin records.
Moderate Departure	Registration, Section 7	Principal investigator designated on the APHIS/CDC Form 1 does not provide scientific/technical oversight of BSAT activities. Entity does not report accurate and/or current information for BSAT strains/serotypes on APHIS/CDC Form 1.
Moderate Departure	Responsible Official, Section 9	Annual inspections by the registered entity are not conducted.
Moderate Departure	Security, Section 11	Entity fails to provide graded protection to BSAT (*e.g.*, laboratory has false ceiling that can be overcome without the use of special tools). A complete inventory audit of BSAT is not conducted upon departure of a principal investigator.

Severity	Regulation	Examples of Departures
Moderate Departure	Biosafety, Section 12	PPE donning/doffing procedures are not followed. The biosafety plan lacks provisions for intentionally or accidentally infected animals/arthropods/plants. The entity works with avian influenza virus but has not developed a written personnel quarantine policy. Centrifuges do not have adequate safety cups or sealed rotors for BSAT work.
Moderate Departure	Incident Response, Section 14	The incident response plan lacks provisions for intentionally or accidentally infected animals/arthropods/plants. The plan has not been coordinated with local responders. The plan does not contain evacuation procedures.
Moderate Departure	Training, Section 15	Annual insider threat awareness training is not provided by an entity with Tier 1 BSAT. Refresher training was not provided after the entity significantly amended its plans
Moderate Departure	Transfers, Section 16	Due diligence is not conducted prior to transfers of excluded amounts of select toxin
Moderate Departure	Records, Section 17	Visitor entry records do not document name of the escort. BSAT inventory record is missing multiple requirements (*i.e.,* lacks source, strain, date of acquisition). Animal/plant/arthropod accounting is incomplete (*i.e.,* lacks number, species, location, or final disposition).
Low Departure	Registration, Section 7	Information is not described accurately on the APHIS/CDC Form 1 (i.e. inaccurate administrative information, security or laboratory features, *etc.*).
Low Departure	Responsible Official, Section 9	Annual inspections conducted by the registered entity were incomplete, such as the entity conducted a biosafety inspection but did not assess other requirements of the Select Agent and Toxin Regulations.
Low Departure	Security, Section 11	Shipping and receiving procedures are not described in plan. Plan does not contain sufficient information on physical security, inventory control or information security systems. A BSAT intra-entity transfer protocol is not developed. Annual review of plan is not performed. Annual drills or exercises are not conducted.
Low Departure	Biosafety, Section 12	Signage posted for registered areas containing BSAT is inadequate. Durable leak proof containers are not used for transport of BSAT waste. Annual review of plan not performed. Annual drills or exercises not conducted.

Severity	Regulation	Examples of Departures
Low Departure	Incident Response, Section 14	Plan does not contain name(s) of personnel as required by section 14(d). The plan does not fully describe incident response procedure(s). Annual review of plan is not performed. Annual drills or exercises are not conducted.
Low Departure	Training, Section 15	Training for visitors does not include all select agent and toxin regulatory requirements, such as security, biosafety, and/or incident response training.
Low Departure	Records, Section 17	The entity's list of Security Risk Assessment (SRA)-approved personnel is not current or accurate. The BSAT inventory record contains transcriptional errors.

Enforcement Action	Regulation	Examples of Departures
None	Select Agents and Toxins Regulations	Inspection report with no departures cited - no further action required by entity
Action Required	Select Agents and Toxins Regulations	Inspection report with departures cited - corrective action required by entity
Increased Monitoring	Select Agents and Toxins Regulations	Refer to FSAP increased monitoring definition
Corrective Action Plan	Select Agents and Toxins Regulations	Refer to FSAP Corrective Action Plan (CAP) definition

Enforcement Action	Regulation	Examples of Departures
Immediate Action	Registration, Section 7	Manipulating BSAT in unregistered areas by a single registered principal investigator
Immediate Action	Registration, Section 7	Use of select toxin under the control of registered principal investigator in unregistered areas and/or by personnel without FSAP approval
Immediate Action	Security, Section 11	Non SRA-approved personnel control access to registered areas and have access to BSAT
Immediate Action	Security, Section 11	Three physical security barriers are not in place to safeguard Tier 1 BSAT
Immediate Action	Biosafety, Section 12	A room/suite is not adequate for the work being conducted and an alternate registered laboratory is not available
Immediate Action	Biosafety, Section 12	Laboratory does not meet the facility criteria for the designated biosafety level, such as inward airflow for BSL-3
Immediate Action	Biosafety, Section 12	BSC certification record, or cabinet airflow observations, do not confirm that the cabinet maintains primary containment
Immediate Action	Biosafety, Section 12	Decontamination systems such as autoclave or effluent decontamination system (EDS) are currently inoperable
Immediate Action	Biosafety, Section 12	Laboratory exhaust HEPA filters failed certification and room exhaust HEPA filtration is required for the agent in use
Immediate Action	Biosafety, Section 12	Use of aerosol generating equipment outside of primary containment
Immediate Action	Restricted Experiments, Section 13	Conducting a denied restricted experiment or possession of a product of a denied restricted experiment
Immediate Action	Records, Section 17	BSAT inventory records are inaccurate to a degree that material accountability is not possible

Enforcement Action	Regulation	Examples of Departures
Suspension	Registration, Section 7	Working with BSAT in unregistered space by more than one registered principal investigator and/or unregistered individuals
Suspension	Suspension, Section 8	Any departure from the select agent regulations that is considered a present danger to human, plant, or animal health, animal or plant products and/or security of BSAT. Refer to Section 8 of the Select Agent and Toxin Regulations.
Suspension	Responsible Official, Section 9	Entity does not have an RO. The suspension is in effect until such time that a new RO is approved
Suspension	Security, Section 11	Evidence that entity allowed a restricted person access and use of BSAT
Suspension	Security, Section 11	Security breach is of such high risk that theft or loss is imminent - continuation of work puts BSAT in jeopardy
Suspension	Biosafety, Section 12	Release that results in laboratory-acquired infection of humans or accidental infection of animals/plants
Suspension	Biosafety, Section 12	Release that leaves secondary containment and jeopardizes public health, animals or plants, and/or animal or plant products
Suspension	Biosafety, Section 12	Systemic failure to implement biosafety and containment procedures commensurate with the risk of BSAT such that continued failure jeopardizes the safety of humans/animals/plants inside and outside of the laboratory
Suspension	Biosafety, Section 12	Failure to adhere to validated inactivation method and product(s) transferred outside of entity, with potential exposures to humans/animals/plants

Enforcement Action	Regulation	Examples of Departures
Suspension	Transfers, Section 16	Transfer of select agent or regulated quantities of select toxin without APHIS/CDC Form 2 authorization in multiple cases
Suspension	Records, Section 17	Systemic failure to create, maintain, and produce BSAT records required by the select agent and toxin regulations
Suspension	Inspections, Section 18	Failure to allow inspection in the absence of a reasonable justification
Suspension	Select Agents and Toxins Regulations	Failure to adhere to a CAP agreement may result in suspension until such time that all departures are resolved
Revocation	Registration, Section 7	False registration (*e.g.*, entity is not located at address provided on APHIS/CDC Form 1)
Revocation	Revocation, Section 8	Any departure from the select agent regulations that is considered a present danger to human, plant, or animal health, animal or plant products and/or security of BSAT and which the entity is unwilling or unable to resolve. Refer to Section 8 of the Select Agent and Toxin Regulations.
Revocation	Security, Section 11	Security breach is of such high risk that theft or loss is imminent- continuation of storage of BSAT is in jeopardy.
Revocation	Transfers, Section 16	Recurrent shipping of BSAT without APHIS/CDC Form 2 to unregistered entity

Referral	Statute	Examples
FBI	18 USC 175b(c)	The knowing possession of a select agent or toxin by a unregistered individual or entity
FBI	18 USC 175b(b)	The knowing transfer of a select agent or toxin to an unregistered individual or entity
FBI	18 USC 175b(a)	The knowing possession of a select agent or toxin by a “restricted person.”
FBI	18 USC 175b(a)	The knowing transport of a select agent or toxin by a “restricted person.”
FBI	18 USC 1001	Knowing submitting a false or fraudulent document to the FSAP.
FBI	Title 18	Evidence of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins

Referral	Regulation	Examples of Departures
HHS OIG and/or APHIS IES	Select Agents and Toxins Regulations	Registered individual or entity issued a suspension. FSAP will refer regulatory departures resulting in a "cease and desist" letter that present an imminent danger to the safety of humans, animals, and/or plants, animal or plant products, and/or the security of BSAT. FSAP may refer regulatory departures that result from an immediate action letter and a partial suspension of BSAT activities.
HHS OIG and/or APHIS IES	Select Agents and Toxins Regulations	Failure to address regulatory departures cited in a "show cause" letter that resulted in a CAP agreement may result in referral.
HHS OIG and/or APHIS IES	Select Agents and Toxins Regulations	Any departure from the select agent and toxin regulations or the submission of documentation of a corrective action that is associated with the entity's knowing submission of false information to FSAP. (Note: The knowing submission of a false or fraudulent document to the FSAP may also result in a referral to the FBI).
HHS OIG and/or APHIS IES	Select Agents and Toxins Regulations	Continued failure to adequately resolve repeated inspection departures (i.e., specific observations noted repeatedly on follow-up inspections) that demonstrate a registered entity's failure to maintain institutional integrity.
HHS OIG and/or APHIS IES	Select Agents and Toxins Regulations	Any departure from the select agent regulations that is considered a present danger to human, plant, or animal health, animal or plant products and/or security of BSAT.