

July 23, 2020

то:	(b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
CC:	(b)(3):42 U.S.C. § 262a(h)(1)(E)
FROM:	Federal Select Agent Program (FSAP)
RE:	Opportunity to show cause why the select agent and toxin registration of National Animal Disease Center (Registration # (b)(3):42 U.S.C. § should not be suspended or revoked.
Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)
VS)], an e	on 8 of the select agents and toxins regulations [42 CFR Part 73 (HHS), 9 CFR Part 121 (USDA-entity's registration may be suspended or revoked for failure to meet the requirements of the
	ent regulations. /h\/3\·4211 S.C. 8.262a/h\/1\/F\
	S.C. §), is being provided the opportunity to show cause why its registration for the possession, ansfer of select agents should not be suspended or revoked for failure to meet the requirements
	ect agents regulations.
	on is based on failures ofo meet the requirements of the select agents and toxins
	ns. Specifically exhibited non-compliance with Section 12 (Biosafety), demonstrated by
	failures of and releases from (b)(3):42 U.S.C. § 262a(h)(1)(E) These failures and are outlined below (UIDs refer to specific observations in the eFSAP Inspection Module and
	umbers refer to APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and
Toxins).	
42 CFR §	73.12(b): Biosafety UID: 42-12-38300
On June !	The state of the s
for monito (b)(3):42	pring points located in (b)(3):42 U.S.C. § 262a(h)(1)(E)
	These alarms monitor the (b)(3):42 U.S.C. § 262a(h)(1)(C) nat feed into the tment plant - Building (b)(3) (b)(3):42 U.S.C. § 262a(h)(1)(E)
(b)	(b)(3):42 U.S.C. § 262a(h)(1)(C) These (v)(3):4 poperational design failures were subsequently
	by FSAP during the June 2019 verification inspection (b)(3):42 and cited in the
associate	d inspection report.
double-wa	conses to this UID did not adequately address FSAP's request of a timeline and schedule for alled drain line integrity testing, evaluation, and planned repairs. The (b)(3):42 initial s to this UID, as well as additional information provided in May 2020, indicated that:

A contract was awarded in Fall 2019 to repair and replace existing double-walled drain lines and install redundant drain lines in all sections where the double-walled drain line design failed.
 However, these efforts did not begin until April 2020 and only focused on double-walled drain lines betweer
 (b)(3):42 U.S.C. §

Page 2

- (b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(7)(C) were investigating methods to seal the ensure integrity. However, these efforts have not been further addressed and no results have been provided to FSAP.
- Evaluation of the root cause(s) for the failures of double-walled drain line integrity would be conducted at the time of repairs. However, repair efforts did not begin until April 2020 and no further updates have been provided to FSAP regarding the cause for failures in operational design.

9 CFR § 121.12(b): Biosafety

UID: 9-12-32300

(b)(3):42 U.S.C.

(b)(3):42 U.S.C. § 262a(h)(1)(C)

(b)(3):42 U.S.C. § 262a(h)(1)(C)

These sensors were calibrated in 2009 upon commissioning of the system but have not been calibrated in an ongoing basis or annually. The NCAH/NADC response indicated that these operational design components would not be calibrated on an annual basis. Refer to the November 20, 2014 FSAP Policy Statement, BSL-3/ABSL-3 Verification for more information.

APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins:

TLR-F3-000683 and TLR-F3-000690

4/16/2020 and 5/3/2020

(b)(3):42 U.S.C. § 262a(h)(1)(D); (b)(3):42 U.S.C. § 262a(h)(1)(C)

TLR-F3-000421

6/5/2019

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Collectively, the deficiencies identified in repeated Form 3 reports and observed during the June 2019 (b)(3):42 verification inspection represent a failure of (b)(3):42 U.S.C. § 262a(h)(1)(E) originally designed to maintain containment of select agent effluent waste materials. The continued, compounding failures within the (b)(3): represent risk to the safety of agriculture and public health.

U.S.C

(b)(3):42 U.S.C. § 262a(h)(1)(E)

In lieu of taking steps to immediately suspend or revoke the possession, use, or transfer of select agents, FSAP will allow the entity to participate in a Corrective Action Plan (CAP) program under the conditions listed below.

- 1. Within 10 business days of the date of this letter (July 23, 2020), which intention to participate in the CAP program and its agreement to meet the terms specified in subparagraph (2) below.
- 2. (b)(3):42 must notify FSAP immediately of any situation that impacts U.S.C. § ability to adhere to the above CAP or otherwise comply with the select agent regulations.

Should (b)(3):4 decline to participate in the CAP program, all departures noted for Inspection § 262a(h)(1)(E) must be resolved, and documentation of the resolution submitted, by August 06, 2020, stipulated in the eFSAP Inspection Module.

FSAP retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agent regulations (See Section 18). Resolution of all departures from the select agent regulations will be confirmed by onsite verification inspections by FSAP.

Contact	(b)(6)	with questions regarding this
correspondence.		

Sincerely,

Samuel Edwin, PhD

Director

Division of Select Agents and Toxins

Centers for Disease Control and Prevention

Department of Health and Human Services

Jacek Taniewski, DVM

Director

Agriculture Select Agent Services

United States Department of Agriculture

Animal and Plant Health Inspection Service



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



United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Agricultural Select Agent Program (AgSAS) Riverdale, Maryland

July 18, 2019

(h	1/3	1.421	ISC	§ 262a(h)/1)/	(E)
(10	110	1.72	,	3 20201	11/1/1/	

(Responsible Official)

U.S. Army Medical Research Institute of Infectious Disease (Registration 1425 Porter Street

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Fort Detrick, MD 21702

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject:

Suspension of Registration, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Dear (b)(3):42 U.S.C. §

In accordance with Section 8 of the Select Agent Regulations, this letter serves as formal notice that he Federal Select Agent Program (FSAP) is suspending the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) certificate of registration (Registration (b)(3):42 U.S.C. for the possession, use and transfer select agents and toxins. FSAP implemented this suspension because USAMRIID does not currently meet the requirements of 42 CFR part 73, 9 CFR part 121, and 7 CFR 331. The suspension is effective July 12, 2019.

All activities with select agents and toxins must cease immediately at USAMRIID. All select agents and toxins in USAMRIID's possession must be securely stored to prevent theft, loss, or release. FSAP will consider granting specific limited exclusions from the suspension action for ongoing studies that prevent the immediate stoppage of select agent and toxin work. To be considered, USAMRIID must provide a list of ongoing studies, the expected duration of these studies, number of staff involved, and a summary of the means to ensure adequate internal oversight through the conclusion of these studies.

This suspension of registration is based on the continued failure of USAMRIID to meet the requirements of Section 12 (Biosafety) in that USAMRIID is not implementing the USAMRIID biosafety plan in a manner that safeguards select agents against release. This failure to implement biosafety practices resulted in an increased risk of exposure to USAMRIID personnel and the preventable releases of select agents and toxins from primary containment. Specifically:

Section 12 (Biosafety)

Recent FSAP inspections of USAMRIID in March 2019 and June 2019 revealed:

(b)(3):42 U.S.C. § 262a(h)(1)(D)

FSAP also noted significant departures from the regulatory requirements in the areas of training, security, and Responsible Official oversight. Specifically:

Section 15: Training

(b)(3):42 U.S.C. § 262a(h)(1)(C)

Section 11: Security

(b)(3):42 U.S.C. § 262a(h)(1)(C)

An entity may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal. Submit the appeal to the Federal Select Agent Program within 30 calendar days of receipt of this letter (Section 20). During the appeal, USAMRIID must halt all activities with select agents and toxins, and securely store all select agents and toxins in its possession to prevent theft, loss, or release.

FSAP will provide a detailed inspection report by July 23, 2019. The report will include the corrective actions that USAMRIID must implement for FSAP to consider restoration of the entity's registration. Additionally, USAMRIID must:

- 1. Adequately addresses all departures from the March 2019 inspection.
- 2. Provide the measures implemented to ensure the biosafety practices are sufficient to contain select agents and toxins given the work described on USAMRIID's APHIS/CDC Form 1.
- 3. Provide the measures implemented by the Responsible Official to ensure compliance with the requirements of the select agent and toxin regulations.
- 4. Demonstrate staff have been trained on the USAMRIID biosafety plan, and provide the means used to ensure staff understand the training.

Contact		(b)(6)	CDC Division of Select Agents and Toxins, at	(b)(6)
(b)(6)	with any questions req	garding this correspondence.	

Sincerely,

Samuel Edwin, Ph.D.

Director,

Division of Select Agents & Toxins

Samuel S. Edwin

Centers for Disease Control and Prevention

Department of Health and Human Services

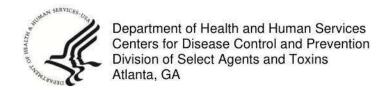
Jacek (Jack) Taniewski, DVM

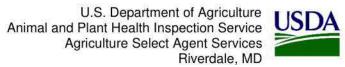
National Director,

Agriculture Select Agent Services

Animal and Plant Health Inspection Service

United States Department of Agriculture





March 27, 2020

(b)(3):42 U.S.C. §
PhD, RBP (Responsible Official)
U.S. Army Medical Research Institute of Infectious Disease (Registration # (b)(3):42 U.S.C. §)
1425 Porter Street
Fort Detrick, MD 21702
(b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: Pegueet to Pegin third Cohort

Subject: Request to Begin third Cohort of Studies, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Dear (b)(3):42 U.S.C.

The Federal Select Agent Program (FSAP) has reviewed the March 9, 2020 request to resume all work associated with storing biological select agents and toxins (BSAT), (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

After reviewing information pertaining to your request and conducting on-site inspections at USAMRIID, FSAP conditionally approves your request to resume full activities under your registration.

Prior to resuming full activities and every two weeks following, USAMRIID must provide FSAP with written documentation to confirm:

- Each approved individual has completed the revised training curriculum relevant to their work duties prior to accessing BSAT.
- All training records are maintained as required under Section 15.
- All records required to be maintained under Section 17(a)(6) are complete.
- The HVAC system associated with each registered laboratory has been verified and documented to be operating as designed prior to resuming work with BSAT. For more guidance, see the FSAP Policy Statement, BSL-3/ABSL-3 HVAC Verification: https://www.selectagents.gov/regBSL3ABSL3policy.html.
- The effluent decontamination system is operating as designed.
- No mechanical failures in the registered space.

FSAP reserves the right to revoke this conditional approval, or suspend any activities with BSAT at USAMRIID, if actions at your entity are deemed insufficient to ensure the safe containment and security of the select agents in your possession. FSAP will continue to monitor USAMRIID's compliance with the federal select agent regulations in the future via remote and on-site inspections.

Contact	(b)(6)	CDC Division of Select Agents and Toxins, at
	(b)(6)	with any questions regarding this correspondence.

Sincerely,

Samuel Edwin, PhD

Director

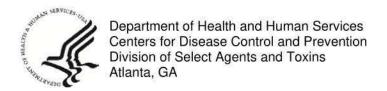
Division of Select Agents and Toxins Centers for Disease Control and Prevention Department of Health and Human Services

Samuel S. Edwin

Agriculture Select Agent Services
United States Department of Agriculture
Animal and Plant Health Inspection Service

Jacek Taniewski, DVM

Director



(b)(3):42 U.S.C. §

(b)(3):42

July 10, 2019

	TO:	(b)(3):42 U.:		e Official				
				0. § 262a(h)(1)(E)	¥-			
	cc:	d))(3):42 U.S.C. § 262	²a(h)(1)(E)				
	FROM:	Centers f (DSAT)	or Disease Contro	ol and Prevention	(CDC), D	ivision of Se	lect Agents and	Toxins
	Re:		(b)(3):42 U.S.C. §	262a(h)(1)(E)			(b)(3):42 U.S.C. §	(b)(3):42 Should
	Dear (b)	(3):42 U.S.C. §						
	may be s regulatio opportun toxins sh	suspended or ns. nity to show c	elect agents and revoked for failur (b)(3):42 ause why its regis suspended or revo	e to meet the rec U.S.C. § 262a(h)(1 stration for the po	quirements ()(E) ssession,	of the selectuse, or trans	t agents and too s being providuster of select age	kins ed the ents and
	Program	(FSAP) iden	May 21-23, 2019, tified the following or to the specific of	serious departu	res from th	ne select age	ents and toxins r	
				bool valion in the	EL SAL II	ispection ivid	dule).	
(3):42	42 CFR	§ 73 <u>.9(a)(</u> 4):	Responsible Off		er SAF II	ispection inc	UID: 42-09-0	00400
(3):42 S.C. §		The Re		icial failed to ensure o	compliance		UID: 42-09-0	
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(b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. §	J.S.C. § (1)(E)	The Reregulations as 1 biosa 3. inspe	Responsible Official sevidenced by the failed to implement failed to provide fety plan and the failed to correct of the f	failed to ensure of the following observant the (b)(3): securate training (b)(3): security plane (b)(3): security	compliance vations: urity plan (s g to FSAP an (see Ull ified during er 1 select	e with the se see UID 42-1 access-appr D 42-15-004 g the 2017 ar	UID: 42-09-0 lect agents and 11-00100). loved staff on the 00). nd 2018 RO and	toxins (b)(3): 42 U.S.C.
(b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. §	J.S.C. § (1)(E)	The Reregulations as 1 biosa 3. inspe	Responsible Official sevidenced by the failed to impleme failed to provide fety plan and the failed to correct of ctions (see UID 4 failed to report the	failed to ensure of the following observant the (b)(3): security played security played (b)(3): securi	compliance vations: urity plan (s g to FSAP an (see Ull ified during er 1 select	e with the se see UID 42-1 access-appr D 42-15-004 g the 2017 at agent outsic	UID: 42-09-0 lect agents and 11-00100). roved staff on the 00). and 2018 RO and de of the primary	toxins (b)(3): 42 U.S.C. hual barriers of
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(b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. §	J.S.C. § (1)(E) 2 U.S.C. § (h)(1)(E)	The Reregulations as 1 biosa 3. inspe 4. the bi	Responsible Official sponsible Official sponsible Official sponsible of the failed to implement failed to provide fety plan and the failed to correct octions (see UID 4 failed to report the ocontainment are	failed to ensure of the following observed following observed for the following observed following observed following in the following in the following foll	compliance vations: urity plan (s to FSAP an (see Ull ified during er 1 select 9-00400).	e with the se see UID 42-1 access-appr D 42-15-004 g the 2017 at agent outsic	UID: 42-09-0 lect agents and 11-00100). roved staff on the 00). and 2018 RO and de of the primary	toxins (b)(3): 42 U.S.C. hual barriers of
(b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (c)(3):42 U.S.C. §	J.S.C. § (1)(E) 2 U.S.C. § h)(1)(E)	he Reregulations as 1 biosa 3. inspe 4. the bi 5. State of the state of the Responsions are sto	Responsible Official sevidenced by the failed to impleme failed to provide fety plan and the ailed to correct of the failed to report t	failed to ensure of a following observent the (b)(3): security plane (b)(3): 42 U.S.C. § 262a(h)(d) (b)(d): 42 U.S.C. § 262a(h)(d) (d) (d) (d) (d) (d) (d) (d) (d) (d)	compliance vations: urity plan (so FSAP an (see Ull ified during 9-00400). S.C. § 262a (1)(D)	e with the se see UID 42-1 access-appr D 42-15-004 g the 2017 and agent outsic a(h)(1)(D)	UID: 42-09-0 lect agents and 11-00100). roved staff on the 00). and 2018 RO and de of the primary (see UID 42-17) UID: 42-09-0 e where select a	toxins (b)(3): 42 U.S.C. hual barriers of 7-00200) 00600 gents or
(b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (c)(3):42 U.S.C. §	J.S.C. § (1)(E) 2 U.S.C. § h)(1)(E)	biosa 3. inspe 4. the bi 5. State of the Response toxins are sto deficient:	Responsible Official sevidenced by the failed to impleme failed to provide fety plan and the ailed to correct octions (see UID 4 failed to report the occurrence occu	failed to ensure of a following observent the (b)(3): security played security played for the following observent the (b)(3): security played for the following security played	compliance vations: urity plan (so FSAP an (see Ull ified during 9-00400). S.C. § 262a (1)(D) f each regine ecember 2	e with the se see UID 42-1 access-appr D 42-15-004 g the 2017 and agent outsic a(h)(1)(D)	UID: 42-09-0 lect agents and 11-00100). roved staff on the 00). and 2018 RO and de of the primary UID: 42-09-0 e where select a the following item also noted in the	(b)(3): 42 U.S.C. hual barriers of 7-00200) 00600 gents or ns as

Show Cause:	(b)(3):42 U.S.C. § 262a(h)(1)(E)	Page 2
2. 3. 4.	Disinfectant was expired or missing (also noted in the 2017 Finspection). Short-term inventory records were not updated as required by Bags of waste were full and not autoclaved and/or not double	$\frac{(b)(3):4}{2}$ security plan.
5.	(b)(3):42 U.S.C. § 262a(h)(1)(C)	tod that a disposition board (b)(3):42
(b)(3):42 U.S.C. § 262a(h)(1)(E)	The 2017 RO internal inspection of registered room used with select agent infected animals was stored in a draw. There was no documented corrective action implemented for needle stick/potential exposure hazard.	ver with needles held in it. U.S.C. §
U.S.C. § correct May 20	vup by the RO in February 2019 noted that several of these it ed. Additionally, four months later FSAP inspectors noted these 19 inspection of the egistered laboratories. vely, these observations represent a failure of to correct	se deficiencies during the (b)(3):42 U.S.C.
identifie		t deliciencies, some § 262a(h)(1)(E)
262a/h)(1)	Attachment 3.000 K1, section 6.9.3 describes the record kee Principle Investigator (PI) must follow when working with mat "checked out" from long-term storage. However, a review of for PI (b)(3):42 showed that record keeping requirements desplan were not followed (b)(3): security plan procedures that we documenting of the unique identifier of the material that corresponds, date materials were created, and date materials were transferred. Section 10.5 described the ability to administratively revoke as	eping procedures that each terials that have been the short-term inventory logs cribed in the (b)(3): security were not followed include esponds with the research used, disposed, or
3,	(b)(3):42 U.S.C. § 262a(h)(1)(C); (b)(7)(C) Attachment 3.000 E1, section 6.9 states that all visitors are in containment suite access card and are required to complete 2017 and 2018 there were 216 instances of FSAP access-approximately not possess a containment suite access card entering register without any evidence of visitor training.	ndividuals without a visitor training. However, in oproved individuals who did
42 CFR § 73.11	(c)(7): Security	UID: 42-11-01000
comply the pro keeping	19 of the security plan requires all individuals with access ap with the security procedures, but this provision is insufficient. cedures and provisions in the security plan that describe short requirements (b)(3):42 U.S.C. § 262a(h)(1)(D) ments, administrative revocation of access, and ongoing suital	Entity staff failed to follow t term inventory record visitor training
42 CFR § 73.15	5(c): Training	UID: 42-15-00400

instructs FSAP access approved personnel to review plans and take a quiz for refresher training. This training is ineffective as evidenced by: (b)(3):42 U.S.C. 8 personnel to follow the procedures and provisions described in the Failure of biosafety plan (see UIDs 42-11-00100, 42-11-00200, and 42-12-

security plan and 38200). (b)(3):42 (b)(3):42 U.S.C. § U.S.C. §

UID: 42-12-44800

(b)(3):42 U.S.C. § 262a(h)(1)(E)

2. Interviews with FSAP access approved personnel revealed that some had no knowledge of the (b)(3): suitability program and did not perform suitability assessments as required by the security plan. One staff member stated that it was not the individual's responsibility to know the federal regulations, only perform the work.

42 CFR § 73.12(b): Biosafety

Multiple laboratory groups at (b)(3): infect animals with select agents using an aerosol exposure system that is contained in a Class III biosafety cabinet (BSC). After the exposure procedures are completed, the interior of the Class III BSC is decontaminated using vaporized hydrogen peroxide, and the aerosol system tubing is flushed with water. These methods would not adequately decontaminate the tubing and internal parts of the aerosol generating equipment.

Since 2016, (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E)

Failure to decontaminate this equipment adequately between agents increases the risk of cross-contamination, potentially exposing animals to unintended select agents. Animals unknowingly infected with multiple select agents may present additional safety concerns for entity staff. Additionally, failure to decontaminate the aerosol equipment adequately presents a risk of exposure for persons performing maintenance tasks. [BMBL: (BSL-3) B7]

42 CFR § 73.19(a): Notification of Theft, Loss, or Release UID: 42-19-00200 (b)(3):42 U.S.C. § 262a(h)(1)(D)

42 CFR § 73.19(b): Notification of Theft, Loss, or Release UID: 42-19-00400

(b)(3):42 U.S.C. § 262a(h)(1)(D)

In lieu of taking steps to immediately suspend or revoke the (b)(3):4 retificate of registration for the possession, use, or transfer of select agents and toxins, FSAP will allow Corrective Action Plan (CAP) program under the conditions listed below.

- 1. Within 14 business days of the date of this letter, July 30, 2019, must notify FSAP of its intention to participate in the CAP program and its agreement to meet the terms specified in subparagraphs (2) and (3) below.
- 2. (b)(3): must submit responses to all inspection observations and provide routine updates, as necessary, through the eFSAP Inspection Module. All departures must be resolved according to the due date listed in the eFSAP Inspection Module.
- 3. (b)(3):4 must notify FSAP immediately of any situation that impacts of 42 u.s.c. ability to adhere to the

01	^	
Show	1,011	00

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Page 4

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Should decline to participate in the CAP program, all departures noted for Inspection 7113 must be resolved, and documentation of the resolution submitted, by the due date, August 21, 2019, stipulated in the eFSAP Inspection Module.

We note that the FSAP retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agents and toxins regulations (See Section 18). Resolution of all departures from the select agents and toxins regulations will be verified by onsite inspections by FSAP.

Contact (b)(6) with questions regarding this correspondence.

Sincerely,

Samuel 5 - Edwin Samuel Edwin, Ph.D.

Director,

Division of Select Agents & Toxins

Centers for Disease Control and Prevention

Department of Health and Human Services

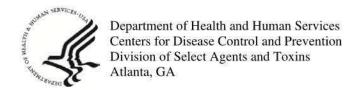
Jack Taniewski, DVM

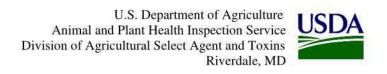
Director

Agriculture Select Agent Services

Animal and Plant Health Inspection Service

Department of Agriculture





February 19, 2021

reoruary 19, 2021
(b)(3):42 U.S.C. § Responsible Official (b)(3):42 U.S.C. § 262a(h)(1)(E) Registration # (b)(3):42 U.S.C. §
(b)(3):42 U.S.C. § 262a(h)(1)(E) Registration # (b)(3):42 U.S.C. § (b)(4)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E)
Subject: Suspension of Registration, (b)(3):42 U.S.C. § 262a(h)(1)(E)
Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)
This letter serves as formal notice that the certificate of registration (Registration (b)(3):42 U.S.C. § for the (b)(3):42 U.S.C. § 262a(h)(1)(E) to possess, use and transfer select agents and toxins is suspended , effective February 19, 2021 .
This suspension of registration is based on the failure to comply with the regulatory requirements specified in sections 7 (Registration and Restricted Experiments), 9 (Responsible Official and Theft, Loss or Release), 11 (Security), 12 (Biosafety-General), 14 (Incident Response), 15 (Training), and 17 (Records) of the select agent regulations (9 CFR Part 121 and 42 CFR Part 73) observed during the January 19 – 22, 2021 inspection.
The Federal Select Agent Program (FSAP) provided the inspection report to (b)(3):42 U.S.C. § on February 1, 2021. The report includes the corrective actions that (b)(3):42 U.S.C. § (b)(3):42 U.S.C. § nust implement for FSAP to consider restoration of the entity's registration.
A suspension of registration would not impact the diagnostic work performed by (b)(3):42 U.S.C. § s long as the entity meets all the provisions outlined under Sections 5 and 6 of the select agent regulations (9 CFR 121 and 42 CFR 73).
An entity may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal. Submit the appeal to the Secretary of the U.S. Department of Agriculture through the Division of Agricultural Select Agent and Toxins within 30 calendar days of receipt of this letter (9 CFR 121.20). During the appeal, all activities with select agents and toxins must be halted, and all select agents in possession must be securely stored to prevent theft, loss, or release.
Contact (b)(6) or <u>DASAT@usda.gov</u> with any questions regarding this correspondence.
Sincerely,
Samuel S- Edwin

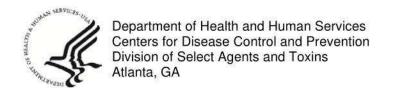
Samuel S. Edwin, Ph.D

Director

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

Director

Division of Agricultural Select Agent and Toxins Animal and Plant Health Inspection Service United States Department of Agriculture



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(b)(3):42 U.S.C. §

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

USDA

July 23, 2020

(b)(3):42 U.S.C. § TO: Responsible Official 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) CC: (b)(3):42 U.S.C. § 262a(h)(1)(E) FROM: Federal Select Agent Program (FSAP) (b)(3):42RE: Opportunity to show cause why the select agent and toxin registration of (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 | should not be suspended or revoked. (b)(3):42 U.S.C. § Dear Per section 8 of the select agents and toxins regulations [42 CFR Part 73 (HHS), 9 CFR Part 121 (USDA-VS)], an entity's registration may be suspended or revoked for failure to meet the requirements of the select agents regulations (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C., within the (b)(3):42 U.S.C. § 262a(h)(1)(E) , is being provided the opportunity to show cause why its registration for the possession, use, or transfer of select agents and toxins should not be suspended or revoked for failure to meet the requirements of the select agents regulations. This action is based on failures of (b)(3):42 to meet the requirements of the select agents and toxins regulations. Specifically (b)(3):42 exhibited non-compliance with Section 12 (Biosafety), demonstrated by repetitive failures of and releases from the effluent decontamination system (EDS). These failures and releases are outlined below (UIDs refer to specific observations in the eFSAP Inspection Module and TLR-F3 numbers refer to APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins). (b)(3):42 U.S.C. § 262a(h)(1)(E) 42 CFR § 73.12(b): Biosafety UID: 42-12-38300 On June 5, 2019. Facilities and Engineering employees responded to three leak detection alarms (b)(3):42for monitoring points located in (b)(3):42 U.S.C. § 262a(h)(1)(E) U.S.C. § (b)(3):42 These alarms monitor the (b)(3):42 U.S.C. § 262a(h)(1)(E) that feed into the 262a(h)(1)((b)(3):42 U.S.C. § 262a(h)(1)(E) These compromises in pperational design were reported to the (b)(3):42L E) operational design failures were subsequently FSAP as release events These U.S.C. § evaluated by FSAP during the June 2019 renewal inspection 262a(h)(1)(and cited in the E) associated inspection report. (b)(3):42 U.S.C. § (b)(3):42 U.S.C. § (b)(3):42 U.S.C. § 262a(h)(1)(E) 262a(h)(1)(E) Initial responses to this UID did not adequately address FSAP's request of a timeline and schedule for double-walled drain line integrity testing, evaluation, and planned repairs. The (b)(3):42 U.S.C. § initial responses to this UID, as well as additional information provided in May 2020, indicated that:

A contract was awarded in Fall 2019 to repair and replace existing double-walled drain lines and install redundant drain lines in all sections where the double-walled drain line design failed. However, these efforts did not begin until April 2020 and only focused on double-walled drain

Show Cause:	(b)(3):42 U.S.C. § 262a(h)	(1)(E)	Page 2
 ensure integrity been provided Evaluation of the conducted at the	es and Engineering staff were investig y. However, these efforts have not be to FSAP. The root cause(s) for the failures of dou he time of repairs. However, repair eff is have been provided to FSAP regard	en further addressed and no uble-walled drain line integrity orts did not begin until April 2	/ would be 2020 and no
9 CFR § 121.12(b): Bid	osafety		UID: 9-12-32300
	(b)(3):42 U.S.C. § 262a(n)(1)(C)	
APHIS/CDC Form 3 F	Concret of Theft I age or Poleges of	79287 (1911 19 1977 75T) 19 (1920) 4200	
TLR-F3-000684 and T	LR-F3-000691		20 and 5/3/2020
TLR-F3-000684 and T		4/16/20	20 and 5/3/2020
	LR-F3-000691 (b)(3):42 U.S.C. § 262a(h)(1)(D); (b)(3)	4/16/20 42 U.S.C. § 262a(h)(1)(C)	
TLR-F3-000684 and T	LR-F3-000691	4/16/20 42 U.S.C. § 262a(h)(1)(C)	20 and 5/3/2020

C.	how Cause: (b)(3):42 U.S.C. § 262a((h)(1)(E) Page 3
301	(b)(0).42 0.0.0. § 202a(
for	I lieu of taking steps to immediately suspend or revolution the possession, use, or transfer of select agents, FSAF orrective Action Plan (CAP) program under the condition	will allow the entity to participate in a
(b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42	sub-paragraph (2) below.	its agreement to meet the terms specified in (b)(3):42 U.S § 262a(h)(1)(
U.S.C. § 262a(h)(1)(E)	adhere to the above CAP or otherwise comply with	
	adhere to the above only of otherwise comply with	The select agent regulations.
70	decline to participate in the CAP property must be resolved, and documentation of the resolution of the resolution of the resolution of the resolution module.	rogram, all departures noted for Inspection tion submitted, by August 06, 2020, stipulated
co	SAP retains the authority to conduct announced or unang ompliance with the select agent regulations (See Section elect agent regulations will be confirmed by onsite verifica	18). Resolution of all departures from the
Co	ontact (b)(6)	vith questions regarding this
co	prrespondence.	
	Samuel 5 - Edwin	Mah
	amuel Edwin, PhD	Jacek Taniewski, DVM
1,550	irector ivision of Select Agents and Toxins	Director Agriculture Select Agent Services
Ce	enters for Disease Control and Prevention	United States Department of Agriculture
De	epartment of Health and Human Services	Animal and Plant Health Inspection Service



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

U.S. Department of Agriculture Animal and Plant Health Inspection Service Division of Agricultural Select Agent and Toxins Riverdale, MD



1	July 23, 2021
(b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official	
(b)(3):42 U.S.C. § 262a(h)(1)(E) (Registration	(b)(3):42 U.S.C. § 262a(h)(1)(E)
Subject: Status of Registration (b)(3):42 U.S.C. § Dear 262a(h)(1)(E)	3):42 U.S.C. § 262a(h)(1)(E)
Thank you for your responses on April 7 registration (Registration (b)(3):42	23, May 28, and July 9, 2021 to the suspension of U.S.C. § 262a(h)(1)(E)
the observations of noncompliance and suspension letter. As a result, the FSAP	A Select Agent Program (FSAP) agrees that (b)(3): has addressed compliance concerns initially noted in the March 11, 2021 (b)(3):42 is permitted and toxins in accordance with the entity's approved FSAP
	with 9 CFR 121.18, 42 CFR. 73.18, and 7 CFR. 331.18, the FSAP o ensure compliance with the select agent and toxin regulations.
locations described in your application,	select agents and toxins listed, the specified activities at the and for the conditions that were approved under 9 CFR. Part 121, to possess, use, or transfer select agents or toxins.
Contact (b)(
questions regarding this correspondence	
Sincerely,	
IN no	Samuel 5 - Edwin
Jacek Taniewski, DVM	Samuel S. Edwin, Ph.D

Director

Division of Agricultural Select Agent and Toxins Animal and Plant Health Inspection Service United States Department of Agriculture

Director

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



Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins U.S. Department of Agriculture Animal and Plant Health Inspection Service Division of Agricultural Select Agent and Toxins Riverdale, MD



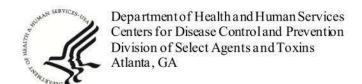
	March 11, 2021	
	262a(h)(1)(E) Responsible Official (b)(3):42 U.S.C. § 262a(h)(1)(E) (Registration # (b)(3):42 U.S.C. § 262a(h)(1)(E)	
	FROM: Federal Select Agent Program (FSAP)	
	Re: Suspension of Registration, (b)(3):42 U.S.C. § 262a(h)(1)(E)	
	Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)	
2 § 1)(This letter serves as formal notice that the certificate of registration (Registration # (b)(3):42 U.S.C. § for (b)(3):42 U.S.C. § to possess, use, and transfer select agents and toxins is suspended, effective March 11, 2021.	
	All activities with select agents and toxins must cease immediately at (b)(3):42 U.S.C. § 262a(h)(1)(E) All select agents and toxins in possession must be securely stored to prevent theft, loss, or release.	(b)(3):42
	Pursuant to section 8 of the select agent and toxin regulations, FSAP may suspend an entity's certificate of registration if the entity does not meet the requirements of the select agent and toxins regulations. 9 CFR 121.8(a)(3); 42 CFR Part 73.8(a)(3). This suspension of	
	activities covered under this part. Such records must include an accurate, current inventory for each select agent held in long-term storage." Inventory records held by were not accurate to the final disposition of vials, nor the quantity of vials stored and/or transferred between inventories.	
	As described in more detail below, the (b)(3):42 U.S.C. § reports and notification of inventory discrepancies made in January 2019, October - November 2020, and most recently in January 2021.	

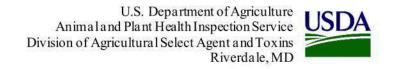
indicate systemic noncompliance with inventory record keeping and effective training requirements that would prevent these repeated occurrences. Despite written assurances by the Responsible Official (RO) after each aforementioned incident that staff had been retrained on inventory practices and reminded of

(b)(3):42 U.S.C. § 262a(h)(1)(E) the importance of proper communication, continued to report inventory discrepancies. Specifically systemic noncompliance with the requirements of the select agent and toxin regulations are evidenced by the following:					
'•	• TLR-F3-000312 - (b)(3):42 U.S.C. § 262a(h)(1)(D)				
	(b)(3):42 U.S.C. § 262a(h)(1)(D)				
	TLR-F3-000806 -	(b)(3):42 U.S.C. § 262a(h)(1)(D)			
	(b)(3):42 U.S.C. § 262a(h)(1)(D)				
•	• Inventory discrepancy report – On November 12, 2020, (b)(3): reported to the DASAT Point of Contact and Compliance Officer via email of the discovery of inaccuracies in the documentation of the March 2020 transfer of (b)(3):42 between registered laboratories. The transfer involved 24 vials from two different stocks. At the time of the transfer, (b)(3) believed 16 vials were of one stock and 8 vials were of another stock. Howeve (b)(3):4 discovered that the correct number of vials transferred was 17 vials of one stock and 7 vials of the other stock. Because all vials were accounted for and no vials were missing or stolen, no APHIS/CDC Form 3 was submitted.				
	TLR-F3-000853 -	(b)(3):42 U.S.C. § 262a(h)(1)(D)			
(b)(3):42 U.S.C. § 262a(h)(1)(E)	(b)(3):42 U.S.C. § 262a(h)(1)(D)				
imple suspe Upon	nsion appeal, immeding receipt of this letter	registration. Regardless of any (b)(3):42 U.S.C. § (b)(1)(E) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c			

(b)(3):42
U.S.C. §

)(3):42 .S.C. §		system confirming that all work with select agents and the select agents and toxins possessed by (b)(3):42 U	(b)(3):42 U.S.C. §				
	are securely stored by March 18, 2021.	8-262a(h)	2.00				
FSAP follow showin	te of registration when has taken the documentation in eFSAP information system	(b)(3):42 U.S.C. §					
1.	1. 100% vial-by-vial inventory has been completed for all select agents at Section 11(e)(3)).						
2.	 Updated inventory procedures in compliance with section 17(a)(1) of the select agent and toxin regulations. 						
3.	 Updated and improved quarterly inventory procedures to ensure that vials in storage match the quantity and description assigned to each storage container; (Sections 11 (e)(3) and 17 (a)(1)). 						
4.	4. All FSAP approved staff members with access to select agents and toxins have been trained on the updated inventory procedures; and (Section 15)						
5.	 Greater oversight and involvement by Responsible Official in inventory verification. (Section 9 (a)). 						
	FSAP may perform an onsite verification of the above corrective actions prior to restoration of (b)(3):42 certificate of registration.						
appeal basis f	Pursuant to section 20 of the select agent and toxin regulations (9 CFR 121.20; 42 CFR 73.20), (b)(3): may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal. (b)(3) must submit the appeal to the Secretary of the U.S. Department of Health and Human Services, through the DSAT Director, or the Administrator of the Animal and Plant Health						
Inspec During	Inspection Services, through the DASAT Director, of the Administrator of						
(b)(3):42 U.S.C. § 262a(h)(1)(E)	nust complete the above listed corrective ac	tions by August 11, 2021. Failure to complete the					
certific		certificate of registration. If $(b)(3):42 \cup S.C.$ nts and toxins at $(b)(3):$ will need to be transferred to					
Contac	(b)(6)	or DASAT@usda.gov with any					
questio	questions regarding this correspondence.						
Sincer	ely,						
U	I n In	Samuel S. Edwin					
Jacek	Taniewski, DVM	Samuel S. Edwin, Ph.D					
Direc		Director					
	ion of Agricultural Select Agent and Toxins	Division of Select Agents and Toxins					
	al and Plant Health Inspection Service and States Department of Agriculture	Centers for Disease Control and Prevention Department of Health and Human Services					





August 27, 2021

(b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official	
(b)(3):42 U.S.C. § 262a(h)(1)(E)	
RE: Federal Select Agent Program Registration:	(b)(3):42 U.S.C. § 262a(h)(1)(E)
(Entity Registration Number: (b)(3):42 U.S.C. § 262a(h)(1))(E)
(b)(3):42 U.S.C. § 262a(h)(1)(E) request to withdraw its registra program (FSAF) for the approved possession, use, and trans became effective on August 27, 2021.	ation with the Federal Select Agent efer of select agents and toxins
Be advised that all records created under the select agent reg Part 121, and 42 CFR Part 73, must be maintained for 3 year	그리고 하는 사람들이 가는 사람들이 되었다. 그 사람들이 살아 있는 것이 없는 것이 없는 것이 없는 것이 없는 것이 없다면 없다.
If you have questions, contact APHIS at 301-851-2070 or das	at@usda.gov.
Sincerely,	

Technical Unit Director
Division of Agricultural Select Agents and Toxins
Emergency and Regulatory Compliance Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

(b)(6)