

eFSAP Information System (eFSAP)

May 2024 Updates



eFSAP May 2024 Updates - Overview

- Simple Registration Withdrawal
- Automated co-Principal Investigator (PI) removal

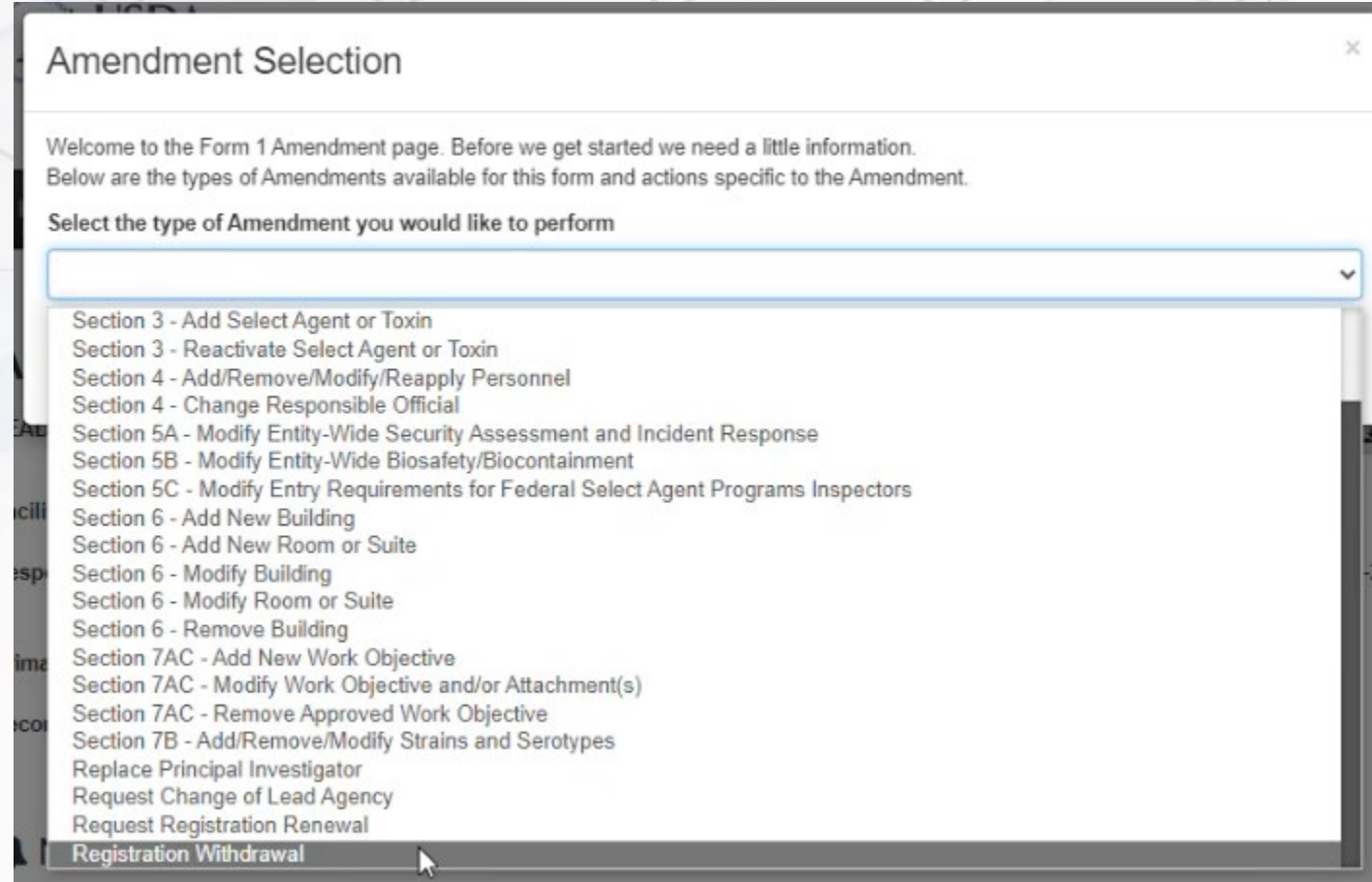


Simple Registration Withdrawal



Simple Registration Withdrawal

- eFSAP has an additional amendment type:
“Request Registration Withdrawal”



Amendment Selection

Welcome to the Form 1 Amendment page. Before we get started we need a little information. Below are the types of Amendments available for this form and actions specific to the Amendment.

Select the type of Amendment you would like to perform

Section 3 - Add Select Agent or Toxin
Section 3 - Reactivate Select Agent or Toxin
Section 4 - Add/Remove/Modify/Reapply Personnel
Section 4 - Change Responsible Official
Section 5A - Modify Entity-Wide Security Assessment and Incident Response
Section 5B - Modify Entity-Wide Biosafety/Biocontainment
Section 5C - Modify Entry Requirements for Federal Select Agent Programs Inspectors
Section 6 - Add New Building
Section 6 - Add New Room or Suite
Section 6 - Modify Building
Section 6 - Modify Room or Suite
Section 6 - Remove Building
Section 7AC - Add New Work Objective
Section 7AC - Modify Work Objective and/or Attachment(s)
Section 7AC - Remove Approved Work Objective
Section 7B - Add/Remove/Modify Strains and Serotypes
Replace Principal Investigator
Request Change of Lead Agency
Request Registration Renewal
Registration Withdrawal



Simple Registration Withdrawal (slide 2)

- Users select a reason for withdrawal from the dropdown list

Amendment Selection

Welcome to the Form 1 Amendment page. Before we get started we need a little information. Below are the types of Amendments available for this form and actions specific to the Amendment.

Select the type of Amendment you would like to perform

Registration Withdrawal

Reason for Registration Withdrawal

Entity no longer possesses any select agents or toxins [Section 7(k)]
Entity no longer uses any select agents or toxins [Section 7(k)]
Entity only possess excluded strain(s)
Entity possess strain(s) recently excluded
Agent(s) in possession no longer included in the select agents and toxins list
Lack of funding to conduct select agents and toxins work
Entity never possessed select agents and toxins
Regulation changes
Ability to use registered space more freely for non-select work
Low number of select agents and toxins received for confirmation in the past 5 years
No plans to conduct any research related to select agents and toxins in the foreseeable future
Lack of institutional support
Cost of maintaining BSL-3/ABSL-3 facilities
Entity unable to meet Tier 1 requirements
Entity no longer wishes to meet Tier 1 requirements



Simple Registration Withdrawal (slide 3)

- Users select a reason for withdrawal from the dropdown list
- Users complete a cover letter section to include any additional information pertinent to the request

Amendment Selection

Welcome to the Form 1 Amendment page. Before we get started we need a little information. Below are the types of Amendments available for this form and actions specific to the Amendment.

Select the type of Amendment you would like to perform

Registration Withdrawal

Reason for Registration Withdrawal

No plans to conduct any research related to select agents and toxins in the foreseeable future

Complete your cover letter for this amendment:

The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed. |

OK



Simple Registration Withdrawal (slide 4)

- Before the registration can be withdrawn, the user signs and attests that:
 - All select agents and toxins have been destroyed/inactivated/rendered non-functional and/or transferred
 - Registered locations where select agent and toxin work was performed are decontaminated
 - The entity is no longer in possession of regulated materials
- User uploads files in support of the attestation

Certification of Registration Withdrawal Page
Responsible Official Certification of Registration Withdraw

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7CFR 331, 9CFR 121, and 42 CFR 73]:

	Check when completed
<ul style="list-style-type: none">• I certify that all select agents and toxins that were in our possession have been destroyed/inactivated/rendered non-functional and/or transferred. Supporting documentation of final disposition has been provided. If applicable, I certify any select toxins in possession are under the regulated amount.	<input type="checkbox"/>
<ul style="list-style-type: none">• I certify that registered locations where select agent and toxin work was performed are decontaminated and documentation has been provided. If applicable, I certify a risk assessment was conducted for rooms where final decontamination was deemed unnecessary.	<input type="checkbox"/>
<ul style="list-style-type: none">• I certify that the entity is no longer in possession of regulated materials.	<input type="checkbox"/>

Responsible Official Name
Owen Gonzalez

Date
10/26/2023

Please type name as above

▲ Incomplete checklist.
▲ Missing signature.

[Navigate to Amendment](#) [Save as Draft and Continue](#) [Save as Draft and Exit](#)

⊕ Upload a file
[Upload](#)



Simple Registration Withdrawal (slide 5)

- At the amendment review and discussion page, eFSAP indicates if there are still strains/serotypes listed on Form 1 Section 7b
 - All strains/serotypes must be removed from Section 7b before the amendment can be submitted

Amendment Cover Letter

The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed.

19848 of 20000 characters left

RO Checklist not completed
RO Signature not completed
There are still strains/serotype in possession in 7B

Form(s) open for this registration

- Form 2 - T-F2-010505
- Form 3 - TLR-F3-000242
- Form 4B - CID-F4-010473
- Form 4A - Section AB - CID-F4-010468
- Form 4A - Section CD - CID-F4-010448

Inspection(s) open for this registration

- 7963

General Discussion FTE Discussion

Conversation Mode Search FTE Discussions

Type your message here...

Previous 1 Next Send

Withdraw Amendment Review or Make Changes Save Draft ~~Submit~~



Simple Registration Withdrawal (slide 6)

- At the amendment review and discussion page, eFSAP indicates if there are still strains/serotypes listed on Form 1 Section 7b
 - Once all strains/serotypes are removed from Section 7b, the amendment can be submitted

Amendment Cover Letter

The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed.

19848 of 20000 characters left

RO Checklist not completed
RO Signature not completed

Form(s) open for this registration

Form 2 - T-F2-010505
Form 3 - TLR-F3-000242
Form 4B - CID-F4-010473
Form 4A - Section AB - CID-F4-010468
Form 4A - Section CD - CID-F4-010448

Inspection(s) open for this registration

7963

General Discussion **FTE Discussion**

Conversation Mode Search FTE Discussions

Type your message here...

Previous 1 Next Send

Submit



Simple Registration Withdrawal (slide 7)

- The amendment review and discussion page will also indicate if the entity has not completed and signed the attestation, and if there are any “open” Form 2s, Form 3s, Form 4s, and inspections
 - The amendment can be submitted with these open items

Amendment Cover Letter

The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed.

19848 of 20000 characters left

RO Checklist not completed
RO Signature not completed

Form(s) open for this registration

- Form 2 - T-F2-010505
- Form 3 - TLR-F3-000242
- Form 4B - CID-F4-010473
- Form 4A - Section AB - CID-F4-010468
- Form 4A - Section CD - CID-F4-010448

Inspection(s) open for this registration

- 7963

General Discussion | **FTE Discussion**

Conversation Mode | Search FTE Discussions

Type your message here...

Previous | 1 | Next | **Send**

Withdraw Amendment | Review or Make Changes | Save Draft | **Submit**



Simple Registration Withdrawal (slide 8)

- The amendment review and discussion page will also indicate if the entity has not completed and signed the attestation, and if there are any “open” Form 2s, Form 3s, Form 4s, and inspections
 - The amendment can be submitted with these open items
 - However, all Form 2s, Form 3s, Form 4s, and inspections must be “closed,” and the attestation signed, before FSAP can approve the registration withdrawal

The screenshot displays the FSAP registration withdrawal interface. At the top, there are tabs for "Amendment Cover Letter", "General Discussion", and "FTE Discussion". The "Amendment Cover Letter" tab is active, showing a text area with the following content: "The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed." Below the text area, it indicates "19848 of 20000 characters left".

Below the text area, there are two yellow warning boxes:

- RO Checklist not completed**
RO Signature not completed
- Form(s) open for this registration**
 - Form 2 - T-F2-010505
 - Form 3 - TLR-F3-000242
 - Form 4B - CID-F4-010473
 - Form 4A - Section AB - CID-F4-010468
 - Form 4A - Section CD - CID-F4-010448
- Inspection(s) open for this registration**
 - 7963

At the bottom of the interface, there are several buttons: "Request More Information", "Approve" (highlighted with a red box and a checkmark), "Reject", "Withdraw Amendment", "Route", and "Review or Make Changes".

On the right side, there is a "Conversation Mode" section with a "Search FTE Discussions" input field. Below this is a text area for "Type your message here..." and a "Send" button. At the bottom of the message area, there are "Previous", "1", and "Next" buttons.



Simple Registration Withdrawal (slide 10)

- Once the attestation has been completed and signed, and all Form 2s, Form 3s, Form 4s, and inspections are be “closed,” FSAP can approve the registration withdrawal

The screenshot displays a web interface for managing a registration withdrawal. The main content area is titled "Amendment Cover Letter" and contains a text box with the following text: "The PI working with the select agent has retired and there are no plans to continue their research. All strains are currently scheduled to be destroyed." Below the text box, it indicates "19848 of 20000 characters left".

Below the text box, there are two yellow boxes indicating the status of forms and inspections:

- Form(s) open for this registration
- Inspection(s) open for this registration

At the bottom of the main content area, there are several action buttons: "Request More Information", "Approve" (highlighted with a red box), "Reject", "Withdraw Amendment", "Route", and "Review or Make Changes".

On the right side of the interface, there is a "Conversation Mode" section with a search bar for "Search FTE Discussions". Below this is a text input field labeled "Type your message here..." and a "Send" button. Navigation buttons for "Previous", "1", and "Next" are also visible.



Simple Registration Withdrawal (slide 11)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



Before

Amendment Type	Number	Date Approv.∞	Status
Section 7AC - Add Ne...	00333968	10/18/2023	Approved
Section 7AC - Add Ne...	00333883		Pending
Section 7AC - Modify ...	00333877		Pending
Section 7AC - Add Ne...	00333876	08/14/2023	Approved
Section 7AC - Add Ne...	00333872	08/14/2023	Approved



Simple Registration Withdrawal (slide 12)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection




After

Amendment Type	Number	Date Approv.∞	Status
Section 7AC - Add Ne...	00333968	10/18/2023	Approved
Section 7AC - Add Ne...	00333883		Deactivated
Section 7AC - Modify ...	00333877		Deactivated
Section 7AC - Add Ne...	00333876	08/14/2023	Approved
Section 7AC - Add Ne...	00333872	08/14/2023	Approved



Simple Registration Withdrawal (slide 13)

- Upon approval of the amendment, eFSAP will automatically:

- Withdraw all open technical amendments
- “Terminate” all individuals from Form 1 Section 4 
- Update the status of all current work objectives to “removed”
- Change the entity’s status to “withdrawn”
- Deposit an official registration withdrawal certification letter into the entity’s document collection


Before

Last Name	First Name	DOJ#	Approval Sta.	Roles
Bierre	Anastasia	AB070962	Approved	Laboratorian, Principal Inv...
Gorilla	Carey	CG070991	Approved	Animal Care Staff
IT	Click	CI070997	Approved	IT
Simmons	Gabriel	GS070959	Approved	Owner/Controller
Canales	Justino	JC071190	Approved	Principal Investigator



Simple Registration Withdrawal (slide 14)

- Upon approval of the amendment, eFSAP will automatically:

- Withdraw all open technical amendments
- “Terminate” all individuals from Form 1 Section 4 
- Update the status of all current work objectives to “removed”
- Change the entity’s status to “withdrawn”
- Deposit an official registration withdrawal certification letter into the entity’s document collection

After

Last Name	First Name	DOJ#	Approval Sta.	Roles
Bierre	Anastasia	AB070962	Terminated	Laboratorian, Principal Inv...
Gorilla	Carey	CG070991	Terminated	Animal Care Staff
IT	Click	CI070997	Terminated	IT
Simmons	Gabriel	GS070959	Terminated	Owner/Controller
Canales	Justino	JC071190	Terminated	Principal Investigator



Simple Registration Withdrawal (slide 15)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



Before

Work Objective: WO002333.001	Status: Approved	Date Approved: 08/02/2023	Active Work <input checked="" type="checkbox"/>
None	Verified: branch chief 8/2/2023	Verify	
Principal Investigators: Michael Cornwall	Work and Storage Michael Cornwall works with B. cereus biovar anthracis	View Modify	
Agents/Toxins: Bacillus cereus Biovar anthracis	Required Attachments: Buildings/Rooms: HG Building - 12345 \ 5	A B C D E F G	Biosafety Levels: BSL3

Work Objective: WO002331.001	Status: Approved	Date Approved: 08/02/2023	Active Work <input checked="" type="checkbox"/>
x Inactivation	Verified: branch chief 8/2/2023	Verify	
Principal Investigators: Anastasia Bierre	Work and Storage Work with botulinum neurotoxins and C. botulinum.	View Modify	
Agents/Toxins: Botulinum neurotoxin producing species of Clostridium Botulinum neurotoxins	Required Attachments: Buildings/Rooms: HG Building - 12345 \ 2 - 12345 \ 5	A B C D E F G	Biosafety Levels: BSL3



Simple Registration Withdrawal (slide 16)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



After

Work Objective: WO002333.001	Status: Removed	Date Approved: 08/02/2023	Date Removed: 10/27/2023	Active Work <input checked="" type="checkbox"/>
None	Verified: branch chief 8/2/2023		Verify	
Principal Investigator: Michael Cornwall	Work and Storage Michael Cornwall works with B. cereus biovar anthracis			View Modify
Agents/Toxins: Bacillus cereus Biovar anthracis	Required Attachments: A B C D E F G		Buildings/Rooms: HG Building - 12345 \ 5	Biosafety Levels: BSL3

Work Objective: WO002331.001	Status: Removed	Date Approved: 08/02/2023	Date Removed: 10/27/2023	Active Work <input checked="" type="checkbox"/>
x Inactivation	Verified: branch chief 8/2/2023		Verify	
Principal Investigator: Anastasia Bierre	Work and Storage Work with botulinum neurotoxins and C. botulinum.			View Modify
Agents/Toxins: Botulinum neurotoxin producing species of Clostridium Botulinum neurotoxins	Required Attachments: A B C D E F G		Buildings/Rooms: HG Building - 12345 \ 2 - 12345 \ 5	Biosafety Levels: BSL3



Simple Registration Withdrawal (slide 17)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



Before

The screenshot shows the USDA Federal Select Agent Program Information System interface. At the top left is the USDA logo. The title is "Federal Select Agent Program Information System". On the top right, it shows the user "responsible.official@dev.cdcpas.cor (responsible official)" with a "Sign Out" link. A navigation bar contains "Home", "Form 1", "Form 2", "Form 3", "Form 4", "Inspections", and "Admin Center". The main content area displays "ATL Laboratory" with "LEAD AGENCY: CDC". A red box highlights "REGISTRATION STATUS: Approved". To the right, it says "REGISTRATION EXPIRES: 07/31/2033" with a download icon.



Simple Registration Withdrawal (slide 18)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



After

The screenshot displays the USDA Federal Select Agent Program Information System interface. At the top left is the USDA logo. The page title is "Federal Select Agent Program Information System". On the top right, the user is identified as "responsible.official@dev.cdcpisas.com (responsible official)" with a "Sign Out" link. A navigation bar contains links for "Home", "Form 1", "Form 2", "Form 3", "Form 4", "Inspections", and "Admin Center". The main content area shows the entity "ATL Laboratory" with "LEAD AGENCY: CDC". A red-bordered box highlights the "REGISTRATION STATUS: Withdrawn". To the right, it shows "REGISTRATION EXPIRES: 07/31/2033" with a download icon.



Simple Registration Withdrawal (slide 19)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



Upload a file

Upload

Current Files Archived Files

Send to Archive

Select All	Unique File Identifier	Uploaded Date
<input type="checkbox"/>		Start Date End Date
<input type="checkbox"/>	F1-Entity Withdrawal Documentation-10/27/2023 11:20:37 AM-2023-Reg ...	10/27/2023 11:20 AM
<input type="checkbox"/>	F4-010471-9/19/2023 4:23:18 PM-Form 4 Compliance Letter-test-TEST do...	9/19/2023 4:23 PM
<input type="checkbox"/>	I-7947-42-15-00100-9/15/2023 12:47:18 PM-post-Response to Dispute of I...	9/15/2023 12:47 PM



Simple Registration Withdrawal (slide 20)

- Upon approval of the amendment, eFSAP will automatically:
 - Withdraw all open technical amendments
 - “Terminate” all individuals from Form 1 Section 4
 - Update the status of all current work objectives to “removed”
 - Change the entity’s status to “withdrawn”
 - Deposit an official registration withdrawal certification letter into the entity’s document collection



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 Agents and Toxins
Riverdale, MD



October 27, 2023

RE: Federal Select Agent Program Registration: ATL Laboratory Registration Number: 20230802-153611

ATL Laboratory request to withdraw its registration with the Federal Select Agent Program (FSAP) for the approved possession, use, and transfer of select agents and toxins became effective on October 27, 2023

Be advised that all records created under the select agent regulations, 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73, must be maintained for 3 years from the date of their creation.

If you have questions, contact CDC at 404-718-2000 or lrnat@cdc.gov/AgSAS at 301-851-3300, option 3 or agsas@usda.gov.

Samuel S. 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
Division of Agricultural Select Agents and Toxins
Animal and Plant Health Inspection Service
United States Department of Agriculture



Automatic Co-Principal Investigator (PI) Removal



Automatic Co-Principal Investigator (PI) Removal

- Automatic co-Principal Investigator (PI) removal
 - Upon removal of a PI from Form 1 Section 4, eFSAP will automatically remove that PI from any work objective on which that PI is listed in conjunction with other PIs
 - This prevents entity users from having to submit multiple technical “Modify Approved Work Objective” amendments to remove a co-PI



www.selectagents.gov

CDC Contact Information
Division of Regulatory Science
and Compliance
LRSAT@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Animal and Plant Health Inspection Service.

