Supporting Statement A

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576)

Expiration 12/31/2018

Revision

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

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- The goal of the study is to support the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety.
- The intended use of the study is to fulfill the requirements promulgated by Health and Human Services under this part and also subject to corresponding regulations promulgated by the United States Department of Agriculture at 9 CFR Part 121 and 7 CFR Part 331.
- The method used to collect data/information is an electronic data collection system that uses electronic forms, which are available on the Federal Select Agent Program website at http://www.selectagents.gov/forms.html in a pdf-fillable format for electronic submission.
- The subpopulation to be studied are those individuals or entities reporting the theft, loss or release of a select agent or toxin.
- This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 73.

A. Justification

This request reflects revisions only to the Report of Theft, Loss, or Release of Select Agent or Toxin (United States Department of Agriculture (USDA) – Animal and Plant Health Inspection Service (APHIS)/Centers for Disease Control and Prevention (CDC) Form 3) (42 CFR 73.19(a)(b)) that the Office of Management and Budget (OMB)'s approved until December 31, 2018 (OMB Control No. 0920-0576). The reporting requirements for Form 3 are required under 42 CFR Part 73 (**Attachment 1**). In summer 2015, the CDC Director, Dr. Tom Frieden, ordered an internal 90-day review of CDC's select agent and toxin regulatory program overseen by DSAT. A CDC Internal Review Workgroup was established to examine the Federal Select Agent Program and make recommendations to improve CDC's responsibilities within FSAP. Based on this review, the Workgroup made a recommendation regarding the Form 3 to make the "reporting more informative about the actual and potential risk of reported incidents. DSAT, with AgSAS, shall complete a review to update the APHIS/CDC Form 3, to include subcategories of "release" and "loss" and additional fields to more consistently categorize an incident with regard to such matters as the type of release (e.g., potential release, spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure (e.g., none, intact personal protective equipment (PPE), skin, mucosal, waste water, etc.), and the understanding of safety and security risk levels relative to human illness. Input shall be solicited from the regulated community and interested stakeholders before the new form is put into practice." Therefore, the revisions to the APHIS/CDC Form 3 are made in response the recommendation by CDC Workgroup and to are to further clarify what needs to be reported as a "release" and "loss" and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness and to include a guidance document to assist respondents with completing APHIS/CDC Form 3. The CDC is requesting to revise the currently approved

APHIS/CDC Form 3 that expires on December 31, 2018. No other changes are being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). Guidance Documents and Templates have been added to assist with the completion of select forms described below.

1. Circumstances Making the Collection of Information Necessary

Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the USDA to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, the Department of Health and Human Services (HHS) and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or APHIS. See 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

2. Purpose and Use of Information Collection

The agents and toxins subject to the HHS data collection are those that pose a serious threat to public health and safety. These agents and toxins are further identified as non-overlap or overlap agents or toxins. These agents and toxins are subject to requirements promulgated by HHS under this part and also subject to corresponding regulations promulgated by USDA at 9 CFR Part 121 and 7 CFR Part 331. This information will assist with meeting the goals of the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety. Since the previous revision request in 2015, the CDC Director, Dr. Tom Frieden ordered an internal 90-day review of CDC's select agent and toxin regulatory program overseen by DSAT in the summer of 2015. A CDC Internal Review Workgroup was established to examine the Federal Select Agent Program and make recommendations to improve CDC's responsibilities within FSAP. Based on this review, the Workgroup made a recommendation regarding the Form 3 to make the "reporting more informative about the actual and potential risk of reported incidents. DSAT, with AgSAS, shall complete a review to update the APHIS/CDC Form 3, to include

subcategories of “release” and “loss” and additional fields to more consistently categorize an incident with regard to such matters as the type of release (e.g., potential release, spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure (e.g., none, intact personal protective equipment (PPE), skin, mucosal, waste water, etc.), and the understanding of safety and security risk levels relative to human illness. Input shall be solicited from the regulated community and interested stakeholders before the new form is put into practice.” Therefore, the revisions to the APHIS/CDC Form 3 are made in response the recommendation by CDC Workgroup and to are to further clarify what needs to be reported as a “release” and “loss” and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness and to include a guidance document to assist respondents with completing APHIS/CDC Form 3. There were no other recommendations or other changes being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). Therefore, there are no changes being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). The below outlines how the information is being used:

The Application for Registration (APHIS/CDC Form 1) (42 CFR, 73.7(d)) (**Attachment 5**) is used by entities to register with FSAP. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. This form is also used by the entity to amend their registration (42 CFR, 73.7(h) (1)) if any changes occur in the information submitted. When applying for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to FSAP (**Attachment 5)**. The Application for Registration (APHIS/CDC Form 1) Guidance Document (**Attachment 5a**) has been added to assist respondents with completion of this form.

The Request to Transfer Select Agent or Toxin (APHIS/CDC Form 2) (42 CFR 73.16) (**Attachment 6**) is used by entities requesting pre-authorization from FSAP to receive or send a select agent or toxin. The Transfer (APHIS/CDC Form 2) Guidance Document (**Attachment 6a**) has been added to assist respondents with completion of this form.

The Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) (42 CFR 73.19(a) (b)) (**Attachment 4**) is completed by entities whenever there is theft, loss, or release of a select agent or toxin. The entity is required to provide immediate notification and then required to submit the APHIS/CDC Form 3 within 7 days of incident.

CDC proposes the following changes to clarify the intent and meaning of the following questions on APHIS/CDC Form 3:

Form	Current Item	Requested Change	Justification
APHIS/CDC Form 3, Sections 1 and 2	"SECTION 1 – TO BE COMPLETED BY ALL ENTITIES & SECTION 2 – TO BE COMPLETED BY ALL ENTITIES"	Split "SECTION 1 – TO BE COMPLETED BY ALL ENTITIES" into 2 sections and title "SECTION A – ENTITY INFORMATION" and "SECTION B – INCIDENT INFORMATION." For section A, include blocks 4-13 and 21. For section B, blocks 1-3, 14, 17, 19, and 22-24.	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, blocks 1 and 16	"1. Date of Incident:" & "16. Time incident occurred:"	Combined blocks and put under Section B, block 1 "1. Date and Time of Incident:"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 10	"10. Responsible Official (registered) or Name of Laboratory Supervisor (non-registered):"	"7. Name of Responsible Official or Laboratory Supervisor:"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 11	"11. Telephone #:"	"9. Telephone Number:"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 12	"12. Fax #:"	"10. Fax Number:"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, blocks 14a and 25	For blocks 14a "Theft" and information requested for block 25 regarding theft, created different section and block.	Block "8. Type of Incident: 0 Theft (After completing Section B. Go to Section C)´ 0 Loss (After completing Section B. Go to Section D) ´ 0 Release/ Potential Exposure (After completing Section B. Go to Section E) ´ Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident." and "SECTION C – REPORT OF THEFT 1. Type of Theft: 0 Forced Entry 0 Insider/Insider-assisted access 0 Unauthorized access 2. Has Local Law Enforcement been Notified: (If yes, complete sections C3-C5) 0 Yes 0 No 3. Local Law Enforcement Agency: 4. Local Law Enforcement Agent Name: First: MI: Last: 5. Local Law Enforcement Contact Information: 6. Has the FBI been Notified: (If yes, fill out #s C7-8): 0 Yes 0 No 7. FBI Agent Name: (First M. Last) 8. FBI Agent Contact Information:	This change clarifies the meaning/intent of the question.

Form	Current Item	Requested Change	Justification
		9. Was the stolen BSAT material recovered: 0 Yes 0 No 10. Was there a potential exposure: (If yes, go to section E- Q: 5-11) 0 Yes 0 No 0 Unsure”	
APHIS/CDC Form 3, blocks 14a and 25	For blocks 14a “Loss” and information requested for block 25 regarding loss, created different section and block.	Block “8. Type of Incident: 0 Theft (After completing Section B. Go to Section C)´ 0 Loss (After completing Section B. Go to Section D) ´ 0 Release/ Potential Exposure (After completing Section B. Go to Section E) ´ Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.” and “SECTION D- REPORT OF LOSS” 1. Type of Loss: 0 Inventory/Recordkeeping error 0 Sample lost/discarded at entity 0 Sample lost in transit (Go to Appendix B to enter add’l info) 0 Other:_____ 2. Has Local Law Enforcement been Notified: (If yes, fill out #s D3-D5) 0 Yes 0 No 3. Local Law Enforcement Agency: 4. Local Law Enforcement Agent Name: First: M: Last: 5. Local Law Enforcement Contact Information: (phone/email) 6. Was the FBI Notified: (If yes, fill out #s D7-D8) 0 Yes 0 No 7. FBI Agent Name: First: M: Last: 8. FBI Agent Contact Information: 9. Was the lost BSAT material found? 0 Yes 0 No 10. How long was the BSAT material missing? Date recovered: Duration of loss (hrs/days): 11. Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement:	This change clarifies the meaning/intent of the question.

Form	Current Item	Requested Change	Justification
		12. Was there a potential exposure: (If yes, complete Section E- Q: 5-11) 0 Yes 0 No	
APHIS/CDC Form 3, blocks 14a and 25	For blocks 14a "Release" "Unintended Animal Infection, Unintended Plant agent Release Other" and information requested for block 25 regarding release, created different section and block.	Block "8. Type of Incident: 0 Theft (After completing Section B. Go to Section C)´ 0 Loss (After completing Section B. Go to Section D) ´ 0 Release/ Potential Exposure (After completing Section B. Go to Section E) ´ Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident." and "SECTION E- REPORT OF RELEASE" Block "1. Type of Potential Exposure/Release: 0 Animal bite/scratch 0 Equipment/mechanical failure 0 PPE failure 0 Package damaged in transit (fill out Appendix B) 0 Spill 0 Unintended Animal Infection 0 Needle stick/Sharps 0 Unintended Plant Pathogen Release 0 Decontamination failure 0 Work performed on an open bench 0 Inactivation failure 0 Other_____ _____"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 15	15. Did the release result in a potential exposure? Yes No N/A (If Yes, explain in Blocks 28 or 30)	"SECTION E- REPORT OF RELEASE" Block "4. Did the release result in potential exposure(s)? 0 Yes If yes, how many individuals/animals/plants were exposed? _____ 0 No	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 15	15. Did the release result in a laboratory-acquired infection? Yes No N/A (If Yes, explain in Blocks 28 or 30)	"SECTION E- REPORT OF RELEASE" Block "5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment? 0 Yes 0 No 0 Not currently known"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 15	15. If yes, has medical surveillance been initiated? Yes No N/A (If	"SECTION E- REPORT OF RELEASE" Block "6. Has medical surveillance been initiated? 0 Yes	This change clarifies the meaning/intent

Form	Current Item	Requested Change	Justification
	Yes, explain in Blocks 28 or 30)	0 No”	of the question.
APHIS/CDC Form 3, block 14b	14b, Transfer: 0 Transfer incident (complete Sections 1 and 2 and Appendix B	2 blocks created in “SECTION B – INCIDENT INFORMATION 11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): 0 Yes (Fill out Appendix B, if incident occurred during transfer.) 0 No APHIS/CDC Form 2 transfer #: _____ 12. Is this incident associated with an APHIS/CDC Form 4 (Identification): 0 Yes 0 No APHIS/CDC Form 4 clinical ID#: _____”	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, blocks 17 & 18	17. Location of incident (building and room#) 18. Location of incident within room (e.g., freezer, incubator, centrifuge:	Merge into one block in “SECTION B – INCIDENT INFORMATION “4. Location of Incident (bldg., room, equipment, etc.):	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 19	Biosafety Level:	Move to “SECTION B – INCIDENT INFORMATION” to block 10 and question revised to “What Biosafety Level did the incident occur?”	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 20	20. Date of last inventory (for reporting loss only:)	Move to SECTION D- REPORT OF LOSS to block 11 and question revised to “Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement:”	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 23	Characterization of Agent (e.g., strain, ATCC#)	Move to “SECTION B – INCIDENT INFORMATION” to block 6 and revised to “Strain designation of Select Agent or Toxin:”	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 24	Quantity/Amount	Move to “SECTION B – INCIDENT INFORMATION” to block 7 and revised to “Quantity (Unit (vial, plates, etc.))”	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 25	25. Provide a detailed summary of events including a timeline of what occurred. Whenever possible, conduct a risk assessment of the event and determine if the root cause can be identified. State specifically what personal protective equipment was worn and what, if any, medical	Move to Appendix A and revised to “Provide a detailed summary of events including a timeline of what occurred.”	This change clarifies the meaning/intent of the question.

Form	Current Item	Requested Change	Justification
	surveillance was provided or planned. If incident involves a non-human primate, please state species. For discovery of select agents and toxins in unregistered locations, include your entity's plan of action to assure no future discoveries, how discovered agents were found and disposition of the discovered agents, inventory reconciliation and assurance that the discovered material was safeguarded against unauthorized access, theft, loss, or release.		
APHIS/CDC Form 3, block 26	26. An internal review of laboratory procedures and policies has been initiated to lessen the likelihood of recurrences of theft, loss or release of select agents and toxins at this entity. No Yes If yes, please provide additional details.	Move to SECTION E- REPORT OF RELEASE to "8. Has an internal review of laboratory procedures and policies been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity? 0 Yes (If yes, please provide additional details.) 0 No	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 27	27. What were the hazards posed to humans by the extent of the release or occupational exposure?	Move to SECTION E- REPORT OF RELEASE to "2. Was there a release outside containment barriers? (choose all that apply) 0 Release outside primary containment (e.g. biosafety cabinet, storage vial within storage unit, etc…) 0 Release beyond secondary containment (e.g. PPE, laboratory) 0 Release outside all containment barriers of the facility (e.g. resulting in possible agricultural/environmental/public health threat)"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 28	28. What is the estimated extent of the release or exposure in relation to the proximity of susceptible humans, animals, and plants?	Move to SECTION E- REPORT OF RELEASE to "3. What PPE was worn at the time of the incident? 0 Hand Protection (gloves) 0 Foot Protection (booties, shoe covers, etc...) 0 Head Protectors/Covers 0 Eye/Face Protection (googles, face shield, etc.) 0 Body Protection 0 Respiratory Protection: Type_____	This change clarifies the meaning/intent of the question.

Form	Current Item	Requested Change	Justification
		0 Other:¬¬¬- _____" _____"	
APHIS/CDC Form 3, block 29	29. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the release.	Move to SECTION E- REPORT OF RELEASE to "10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident."	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, block 30	30. In select agents and toxins posing a risk to humans, please state how many laboratorians were potentially exposed and provide a brief summary of the medical surveillance provided (do not provide names or confidential information).	Move to SECTION E- REPORT OF RELEASE to "7. Has prophylaxis or treatment been provided? 0 Yes 0 No 9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident? 11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 3, Appendix B	APPENDIX B IF THE INCIDENT OCCURRED DURING TRANSFER, COMPLETE SECTIONS 1 AND 2 OF FORM 3 AND PROVIDE THE FOLLOWING INFORMATION (INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2)	APPENDIX B IF THE INCIDENT OCCURRED DURING TRANSFER, COMPLETE SECTIONS A AND B OF FORM 3 AND PROVIDE THE FOLLOWING INFORMATION (INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2)	This change clarifies the meaning/intent of the question.

In addition, CDC has developed a guidance document for entities to use to assist with completing the APHIS/CDC Form 3 - APHIS/CDC Guidance Document for Reporting Potential Theft, Loss, Release, or Occupational Exposure (**Attachment 4a**).

The Report of Identification of Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A) (42 CFR 73.5(a) and 73.6(a)) (**Attachment 7A**) is used by clinical or diagnostic laboratories and other entities to notify FSAP that a select agent or toxin identified as the result of diagnosis or proficiency testing have been disposed of in a proper manner.

The Report of Identification of Select Agent or Toxin from a proficiency testing (APHIS/CDC Form 4B) (42 CFR 73.5(b) and 73.6(b)) (**Attachment 7B**) is used by clinical or diagnostic laboratories and other entities to notify FSAP that a select agent or toxin identified as the result of proficiency testing have been disposed of in a proper manner.

The Report of Identification of Select Agent or Toxin from a Federal law enforcement agency that seizes a select agent or toxin (APHIS/CDC Form 4c) (42 CFR 73.3(f) and 73.4(f))

(**Attachment 7C**) is used a Federal law enforcement agency used to report the seizure of a select agent or toxin.

The Report of Identification of Select Agents and Toxins (APHIS/CDC Form 4) Guidance (Attachment 7i) has been added to assist respondents with Forms 4A, 4B, and 4C (**Attachments -7A, B, C**).

The Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) (42 CFR 73.5(d)(e) and 73.6(d)(e)) (**Attachment 8**) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins. The Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance (**Attachment 8a**) has been added to assist respondents with this form.

In addition to the standardized forms listed above, CDC has not developed standardized forms to use in the below situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Request for Exclusion (**Attachment 9**): An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety (42 CFR 73.3 and 4 (e)). The Request for Exclusion Guidance (**Attachment 9a**) has been added to assist respondents with this form.

Documentation of Self-Inspection (**Attachment 10**): Prior to issuance of a certificate of registration, CDC inspects entities to ensure compliance with this regulation (42 CFR 73.18). As part of the inspection process, the entity may need to respond to written requests from CDC. CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Request for Expedited Review (**Attachment 11**): An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Security Plan (**Attachment 12**): An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release (42 CFR 73.11(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Security Plan Guidance (**Attachment 12a**) has been added to assist respondents with this information collection.

Biosafety Plan (Attachment 13): An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select

agent or toxin, given its intended use. 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 (42 CFR 73.12(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. CDC has added a guidance document, Biosafety Plan Guidance (**Attachment 13a**) to provide information to the registered entities on how to develop a biosafety plan and template (**Attachment 13b**) to use as outline for the entities to develop a biosafety plan.

Request Regarding a Restricted Experiment (**Attachment 14**): An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:
(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.
(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight (42 CFR 73.13 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Request Regarding a Restricted Experiment Guidance (**Attachment 14a**) has been added to assist respondents with this form.

Incident Response Plan (**Attachment 15**): An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site-specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review (42 CFR 73.14 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Incident Response Plan Guidance and Template (**Attachment 15a**) have been added to assist respondents with this information collection.

Training (**Attachment 16**): The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training (42 CFR 73.16(d)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Training Guidance (**Attachment 16a**) has been added to assist respondents with this information collection.

Records (**Attachment 17**): An individual or entity required to register under this part must maintain complete records relating to the activities covered by the select agent regulations (42 CFR 73.17 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Guidance on the Inventory of Select Agents (**Attachment 17a**) has been added

to assist respondents with this information collection.

Administrative Review (**Attachment 19**): An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision. (42 CFR 73.20 (a) and (b)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

3. Use of Improved Technology and Burden Reduction

CDC/DSAT has implemented an electronic data collection system that uses electronic forms, which are available on the Federal Select Agent Program website at http://www.selectagents.gov/forms.html in a pdf-fillable format for electronic submission. The use of a pdf-fillable format, allows respondents to save the document to their local drive, complete the form, and then upload the form to FSAP. The entity can retain an electronic copy of their submission, which will make it easier for the entity to amend any future submissions.

The FSAP is also committed and pursuing to a single shared web-based system that will allow the regulated community to conduct transactions electronically with either agency. By providing the regulated community a single web portal, FSAP will be able to interact efficiently, effectively, while reducing the burden on the public. This environment will provide for the electronic exchange of information for reports of theft, loss, or release of a select agent or toxin.

4. Efforts to Identify Duplication and Use of Similar Information

The FSAP continues to working closely to identify duplication of the proposed data collection. DSAT has established relationships with the following federal agencies: Department of Homeland Security (DHS), the Department of Defense; Department of Army Inspector General (DoD, DAIG) and the Department Veterans Affairs. Each of these agencies shares a similar interest in the possession, use, transfers of select agents and toxins, and has participated in joint inspections.

The Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107) required the development of a common registration system for the purpose of verifying the credentials, licenses, accreditations, and hospital privileges of such professionals during public health emergencies. There is no similar database available to identify individuals or entities registered to possess, use and transfer select agents and toxins.

5. Impact on Small Businesses or Other Small Entities

CDC recognizes that a small number of entities affected by the data collection requirements of this regulation may be small businesses. For this reason, the information needed in the data collection has been kept to a minimum.

6. Consequences of Collecting the Information Less Frequently

There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for DSAT to carry out its commitments to protect the public health as mandated by these regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8A. A **"60 Day Federal Register Notice"** was published in the Federal Register on Friday, December 30, 2016, Vol. 81, No. 251, Pages 96456-96457. CDC received one comment that the term "laboratory supervisor" should be removed, all communication should be through the Responsible Official (RO) and not a laboratory manager. The commenter stated that this would ensure that the RO is apprised of all situations in the laboratory as they are occurring. CDC made no changes based on this comment as the term "laboratory supervisor" is used for entities not registered with FSAP. The same commenter recommended revising the block that list the type of personal protective equipment (PPE) worn during the incident because the commenter stated the examples were very generic. CDC made no changes based on this comment because CDC only wants to confirm that PPE was used during the incident. The same commenter recommended to modify the question to ask if an internal incident investigation has been initiated to identify the root cause versus only a review of procedures and policies. CDC agreed with the commenter and revised the form and guidance document accordingly.

A8B. Consultation Outside the Agency

FSAP began revising the proposed data collection instruments in the fall of 2015. The following representatives from AgSAS assisted with the development of the data collection instruments:

Cassie Armiger
Animal Plant Health and Inspection Service
U.S. Department of Agriculture
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9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act applies to this information collection request.

To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, a Federal Register notice Vol. 76, No. 16, Tuesday, January 25, 2011 was published to alter the System of Records, 09-20-0170 (**Attachment 2**), National Select Agent Registry (NSAR)/Select Agent Transfer and Entity Registration Information System (SATERIS), HHS/CDC/COTPER. The System of Records is currently being revised because the information system is being modified from "NSAR" to "Electronic Federal Select Agent Program portal (eFSAP portal)/Electronic Import Permit Program portal (eIPP portal) (**Attachment 2**)."

The following special safeguards are provided to protect the records from inadvertent disclosure:

Authorized Users: A database security package is implemented on CDC computers to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have routine access to these records are limited to Select Agent Program staff (DSAT Full Time Employees) and contractors) who have responsibility for conducting regulatory oversight of individuals and entities that possess, use, or transfer select agents and toxins.

Physical Safeguards: Paper records are maintained in locked cabinets in locked rooms in a restricted access location that is controlled by a cardkey system, and security guard service provides personnel screening of visitors. Electronic data files are password protected and stored in a restricted access location. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure location. Computer workstations, lockable personal computers, and automated records are located in secured areas.

Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system; mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure off-site storage is available for backup files.

Knowledge of individual tape passwords is required to access tapes, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer tapes and/or other magnetic media. When possible, a backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.

CDC/DSAT and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Appropriate Privacy Act provisions are included in contracts and the CDC/DSAT Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC/DSAT or destroyed, as specified by the contract.

The USDA/APHIS/AgSAS maintains similarly stringent safeguards that are discussed within that agency's Select Agent system of records notice.

Implementation Guidelines: The safeguards outlined above are in accordance with the HHS Information Security Program Policy and FIPS Pub 200, "Minimum Security Requirements for Federal Information and Information Systems." Data maintained on CDC's Mainframe and the OPHPR Local Area Network is in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications.

Because of the national security sensitivity of the information in this database, CDC has determined that making this information available through a public database would compromise one of the primary purposes of the legislation. Therefore, CDC will not create a publicly available database of information. Disclosure of any registration or transfer documentation by the federal government is prohibited by P.L. 107-188.

Institutional Review Board

Institutional Review Board approval is not required. (**Attachment 21**)

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board
Institutional Review Board approval is not required. (Attachment 21)

Justification for Sensitive Questions
There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

Annualized burden hours and cost were calculated based on data obtained from 2016 Annual Report of the Federal Select Agent Program for submissions to FSAP for 2016. The estimated annualized burden for the 2015 submission was 8,527 hours. Burden has been reduced to 8,408 hours due to the decrease in the number of Respondents.

For the changes reflected for the APHIS/CDC Form 3, the estimated annualized burden is 307.5 and is a reduction of 122.5 from the 2015 submission, which was 430. The burden includes the addition of the questions noted above and the revised guidance document that accounts for addition of 30 minutes to complete the form.

Estimated Annualized Burden Hours

Attachment	Section	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
5	73.7	Application for Registration (APHIS/CDC Form 1)	1	1	4	4
5	73.7	Amendment to a Certificate of Registration	238	7	1	1,666
5a	73.7	Application for Registration (APHIS/CDC Form 1) Guidance	1	1	1	1
6	73.16	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)	188	1	1	188
6a	73.16	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance	188	1	30/60	94
4	73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)	205	1	1.5	308
4a	73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance	205	1	30/60	103
7A	73.5 & 6	Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A)	1030	1	30/60	515
7B	73.5 & 6	Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)	10	1	30/60	5
7C	73.5 & 6	Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)	1	1	30/60	1
7i	73.5 & 6	Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance	1030	1	30/60	515

8	73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)	1	1	30/60	1
8a	73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance	1	1	30/60	1
9	73.3 & 73.4	Request for Exclusions	3	1	30/60	2
9a	73.3 & 73.4	Request for Exclusions Guidance	3	1	30/60	2
10	73.9	Documentation of Self-inspection	238	1	1	238
11	73.1	Request for Expedited Review	1	1	15/60	1
12	73.11	Security Plan	238	1	5	1,190
12a	73.11	Security Plan Guidance	238	1	30/60	119
12b	73.11	Security Plan Template	238	1	30/60	119
13	73.12	Biosafety Plan	238	1	5	1,190
13a	73.12	Biosafety Plan Guidance	238	1	30/60	119
13b	73.12	Biosafety Plan Template	238	1	30/60	119
14	73.13	Request Regarding a Restricted Experiment	1	1	30/60	1
14a	73.13	Request Regarding a Restricted Experiment Guidance	1	1	30/60	1
15	73.14	Incident Response Plan	238	1	5	1,190
15a	73.14	Incident Response Plan Guidance	238	1	30/60	119
15b	73.14	Incident Response Plan Template	238	1	30/60	119
16	73.15	Training	238	1	30/60	119
16a	73.15	Training Guidance	238	1	30/60	119
17	73.17	Records	238	1	30/60	119
17a	73.17	Guidance on the Inventory of Select Agents	238	1	30/60	119
19	73.20	Administrative Review	1	1	1	1
	Total					8,407

Estimated Annualized Burden Costs

Section	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
73.7	Application for Registration (APHIS/CDC Form 1)	1	1	4	4	$35.12	$140.48
73.7	Amendment to a Certificate of Registration	238	7	1	1,666	$35.12	$58,509.92
73.7	Application for Registration (APHIS/CDC Form 1) Guidance	1	1	1	1	$35.12	$35.12
73.16	Request to Transfer Select	188	1	1	94	$35.12	$6,602.56

	Agents and Toxins (APHIS/CDC Form 2)						
73.16	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance	188	1	30/60	94	$35.12	$3,301.28
73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)	205	1	1.5	205	$35.12	$10,816.96
73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance	205	1	30/60	103	$35.12	$3,617.36
73.5 & 6	Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A)	1030	1	30/60	515	$35.12	$18,086.80
73.5 & 6	Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)	10	1	30/60	5	$35.12	$175.60
73.5 & 6	Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)	1	1	30/60	1	$35.12	$35.12
73.5 & 6	Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance	1030	1	30/60	515	$35.12	$18,086.80
73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)	1	1	30/60	1	$35.12	$35.12
73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product	1	1	30/60	1	$35.12	$35.12

	(APHIS/CDC Form 5) Guidance						
73.3 & 73.4	Request for Exclusions	3	1	30/60	2	$35.12	$70.24
73.3 & 73.4	Request for Exclusions Guidance	3	1	30/60	2	$35.12	$70.24
73.9	Documentation of Self-inspection	238	1	1	238	$35.12	$8,358.56
73.1	Request for Expedited Review	1	1	15/60	1	$35.12	$35.12
73.11	Security Plan	238	1	5	1190	$35.12	$41,192.80
73.11	Security Plan Guidance	238	1	30/60	119	$35.12	$4,179.28
73.11	Security Plan Template	238	1	30/60	119	$35.12	$4,179.28
73.12	Biosafety Plan	238	1	5	1190	$35.12	$41,792.80
73.12	Biosafety Plan Guidance	238	1	30/60	119	$35.12	$4,179.28
73.12	Biosafety Plan Template	238	1	30/60	119	$35.12	$4,179.28
73.13	Request Regarding a Restricted Experiment	1	1	30/60	1	$35.12	$35.12
73.13	Request Regarding a Restricted Experiment Guidance	1	1	30/60	1	$35.12	$35.12
73.14	Incident Response Plan	238	1	5	1190	$35.12	$41,792.80
73.14	Incident Response Plan Guidance	238	1	30/60	119	$35.12	$4,179.28
73.14	Incident Response Plan Template	238	1	30/60	119	$35.12	$4,179.28
73.15	Training	238	1	30/60	119	$35.12	$4,179.28
73.15	Training Guidance	238	1	30/60	119	$35.12	$4,179.28
73.17	Records	238	1	30/60	119	$35.12	$4,179.28
73.17	Guidance on the Inventory of Select Agents	238	1	30/60	119	$35.12	$4,179.28
73.2	Administrative Review	1	1	1	1	$35.12	$35.12
							$295,359.20

When estimating the annualized burden costs, CDC assumes that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an average hourly respondent labor rate of $55.81 for managerial staff and $ 14.42 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $35.12. These rates were obtained from the Bureau of Labor Statistics, from the 2013 Occupational Employment Statistics Survey by Occupation (http://www.bls.gov/oes/).

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

14. Annualized Cost to the Government

The total cost for implementing these regulatory activities budgeted for Fiscal Year 2016 is $20,210,121 and includes FTE's and contracts.

Compensation summary	$6,571,707
Personnel benefits	2,372,450
Travel & transportation: Inspectors	840,771
Transportation: Shipping	9,000
Rent, telecommunication, other communication & utilities	92,000
Printing & reproduction	8,000
Consulting and other services	10,165,257
Supplies & materials	50,000
Equipment	31,984
Grand Total:	$20,210,121

15. Explanation for Program Changes or Adjustments

There was no change in program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of these data.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

List of Attachments:

Attachment 1	Possession, Use and Transfer of Select Agents and Toxins (42 CFR Part 73) – Final Rule
Attachment 2	60-Day Federal Register Notice
Attachment 2a	60-Day Federal Register Notice Comments
Attachment 3	System of Record Notice
Attachment 4	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)
Attachment 4a	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance
Attachment 5a	Application for Registration (APHIS/CDC Form 1)
Attachment 5b	Application for Registration (APHIS/CDC Form 1) Guidance
Attachment 6	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)
Attachment 6a	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance
Attachment 7A	Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A)
Attachment 7B	Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)
Attachment 7C	Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)
Attachment 7i	Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance
Attachment 8	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)
Attachment 8a	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance
Attachment 9	Request for Exclusions

Attachment 9a	Request for Exclusions Guidance
Attachment 10	Documentation of Self-inspection
Attachment 11	Request for Expedited Review
Attachment 12	Security Plan
Attachment 12	Security Plan Guidance
Attachment 12	Security Plan Guidance and Template
Attachment 13	Biosafety Plan
Attachment 13a	Biosafety Plan Guidance and Template
Attachment 13b	Biosafety Plan Template
Attachment 14	Request Regarding a Restricted Experiment
Attachment 14a	Request Regarding a Restricted Experiment Guidance
Attachment 15	Incident Response Plan
Attachment 15a	Incident Response Plan Guidance and Template
Attachment 16	Training
Attachment 16a	Training Guidance
Attachment 17	Records
Attachment 17a	Guidance on the Inventory of Select Agents
Attachment 18	Administrative Review
Attachment 19	Amendment to Certificate of Registration
Attachment 20	Determination of Applicability of Human Subjects Regulations