Supporting Statement A

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

(OMB Control No. 0920-0576) Expiration 12-31-2011

Revision

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

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Supporting Statement A

A. Justification

This is a request for revisions to OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins. The Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) will use the revised forms for data collection. The reporting and data collection requirements are provided in 42 CFR Part 73 (**Attachment 1**). The original forms were approved in February, 2005. However, this request reflects revisions to the forms approved in February, 2008. The current versions of the standard forms have been revised to: 1) reduce the burden expended by the regulated entities and CDC by removing similar questions, 2) enhance clarification of the transfer process, 3) determine the level of potential exposure, 4) improve surveillance methods for monitoring the reports of select agents and toxins identified by registered entities, and 5) improve process flow. The revised forms are found in (**Attachments 7, 8, 9**) and a summary of all revisions made to the forms are found in (**Attachment 16**). We are requesting a 3-year approval for this data collection.
The key factors in reducing burden in this submission are removing similar questions and placing the forms in a pdf-fillable format for electronic submission. The removal of similar questions from the revised forms has reduced the burden by 778.5 hours. The use of a pdf-fillable format allows respondents to save the document to their local drive, complete the form, and upload the form to CDC.

1. Circumstances Making the Collection of Information Necessary

On June 12, 2002, the President signed the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), which specifies the Secretary of Health and Human Services (HHS) shall provide for the establishment of standards and procedures governing the possession, use, and transfer of select biological agents and toxins. In addition, entities that possess, use, and transfer these agents and toxins must register with the Federal Select Agent Program. The HHS Secretary has designated CDC as the agency within HHS responsible for collecting this information. Equally, the USDA Secretary must establish

standards and procedures for governing the possession, use, and transfer of select agents that could pose a severe threat to animal or plant health, or animal or plant products.
Entities that possess, use, and transfer these pathogens and toxins must register with the Federal Select Agent Program. The USDA Secretary has designated APHIS as the agency within USDA responsible for collecting this information.

The Application for Registration (42 CFR, 73.7(d)) (**Attachment 5**) is used by entities to register with Federal Select Agent Program. 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 CDC. The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) (**Attachment 7**) is used by entities requesting pre-authorization from CDC to receive or send a select agent or toxin.
The Report of Theft, Loss, or Release of Select Agent or Toxin form (42 CFR 73.19(a) (b)) (**Attachment 8**) is completed by entities whenever there is theft, loss, or release of a select agent or toxin.
The Report of Identification of Select Agent or Toxin form (42 CFR 73.5(a) (b) and 73.6(a) (b)) (**Attachment 9**) is used by clinical or diagnostic laboratories and other entities to notify CDC that a select agent or toxin identified as the result of diagnosis, verification, or proficiency testing have been disposed of in a proper manner.

1.1 Privacy Impact Assessment

The Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) will use the revised forms for data collection. The data collection system consists of five forms: 1) Application for Registration, 2) Request to Transfer Select Agent or Toxin, 3) Report of Theft, Loss, or Release of Select Agent and Toxin, 4) Report of Identification of Select Agent or Toxin, and 5) Request for Exemption. The Application for Registration (42 CFR, 73.7(d)) is used by each entity to register with CDC. It requires 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. The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) **(Attachment 7)** is used by entities for pre-authorization from CDC to receive or send a select agent or toxin. The Notification of Theft, Loss, or Release of Select Agent or Toxin form (42 CFR 73.19(a) (b)) **(Attachment 8)** is completed by entities when there is theft, loss, or release of a select agent or toxin. The Report of Identification of Select Agent or Toxin form (42 CFR 73.5(a) (b) and 73.6(a) (b)) **(Attachment 9)** is used by clinical or diagnostic laboratories and other entities to notify CDC that a select agent or toxin identified as a result of diagnosis, verification, proficiency testing and proper disposition. The Request for Exemption form (Attachment 10) (42 CFR 73.5(d) (e) and 73.6(d) (e)) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins or in cases of public health emergency. In addition to the standardized forms listed above, requests for expedited reviews, administrative reviews and inspections are also submitted to CDC. There is not a standardized form for the request for expedited review, administrative review and inspections. Therefore, an entity must submit a written request to the Secretary of Health and Human Services, through the United States Attorney General for expedited reviews (42 CFR 73.10(e)) and exclusions of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e) (1) and 73.4(e) (1)). Inspections take place prior to issuance of a certificate of registration to ensure compliance with regulation 42 CFR 73.18. Following the inspection an entity may be asked to respond to written requests and submits the documentation to CDC. Entities may also amend their registration by using the Application for Registration (UDSA/CDC Form 1) (42 CFR, 73.7(h) (1)) if any changes occur to the information previously submitted. When applying for an amendment to a certificate of registration, an entity must obtain and complete the relevant portion of the application package.

All documents are scanned and maintained in the National Select Agent Registry (NSAR). Paper documents are collected and stored for two years at CDC/DSAT, following the two year period; documents are moved to an off-site secured Facility Records Center (FRC) for an additional two years. Finally the documents are stored at the National Archive of Records (NAR) and destroyed after ten years.

All forms are available electronically on the Federal Select Agent website at http://www.selectagents.gov/Forms.html in a pdf-fillable format for electronic submission. Users can access the website as needed. The website does not contain any information that is directed to children.

The Application for Registration (USDA/CDC Form 1) requires the Responsible Official or Alternate Responsible Official provide the name, date of birth, department of justice identification number and job title of each individual that has access to select agents and toxins. CDC/DSAT only collects the minimum amount of personal data necessary, which is needed to limit access to the select agents listed in 42 C.F.R. Part 73, 9 C.F.R. Part 121, and 7 C.F.R. Part 331. The system does not host a website.

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.

2.1 Privacy Impact Assessment

The Responsible Official or Alternate Responsible Official provides the name, date of birth, department of justice identification number and job title. The information will be shared with the HHS Secretary, the United States Attorney General and the Federal Bureau of Investigation (FBI)/ Criminal Justice Information Service (CJIS). The HHS Secretary approves the individual or entity to posses, use and transfer select agents and toxins. The United States Attorney General and the Federal Bureau of Investigation / Criminal Justice Information Service performs a security risk assessment which certifies the individual or entity has meet the requirements to posses, use and transfer select agents and toxins. The proposed collection of the required

information will be processed by government agencies with the ability to secure information in identifiable form.

3. Use of Improved Technology and Burden Reduction

DSAT has implemented an electronic data collection system that uses electronic forms which are available on the Federal Select Agent 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 CDC. This approach supports data entry security; eliminating the possibility of another entity overwriting the submission. The entity can retain an electronic copy of their submission which will make it easier for the entity to amend any future submissions.

CDC and USDA are 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, CDC and USDA 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 creating, amending, and submitting registration applications and requests for approvals for transfers, exemptions, or exclusions.

4. Efforts to Identify Duplication and Use of Similar Information

DSAT and APHIS continue 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 and 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 not 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

Consequences of collecting the information less frequently would result in a direct infringement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 which requires entities to register with HHS or USDA if they possess, use, or transfer select agents or toxins that could pose a severe threat to public health and safety, to animal or plant health, or animal or plant products. The Act also requires HHS and USDA to maintain a national database of entities that are registered for possession of select agents and toxins, which is carried out by CDC/DSAT and APHIS. The Application for Registration form is required for the initial registration to posses, use or transfer select agents and toxins. All other forms used in this data collection will be used as needed.

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

8A. The 60 day Federal Register Notice was published on Monday, May 23, 2011 Vol.76, No. 99, page 29754-29755. There was one public comment. (**Attachment 3**)

8B. APHIS and DSAT began revising the proposed data collection instruments in fall 2010. The following representatives from APHIS assisted with the development of the data collection instruments:

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9. Explanation of Any Payment or Gift to Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the Information Collection Request Office (ICRO) who determined that the Privacy Act does apply. The following information in identifiable form (IIF) will be collected: name, date of birth, department of justice identification number and job title. 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 4**), National Select Agent Registry (NSAR)/Select Agent Transfer and Entity Registration Information System (SATERIS), HHS/CDC/COTPER. 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.

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 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.

Privacy Impact Assessment Information

The responsible official is informed that providing the name, date of birth, department of justice identification number and job title of each individual is mandatory to process the APHIS/CDC Form 1. All documents are maintained and secured in the National Select Agent Registry

(NSAR). Physical and procedural safeguards have been implemented. A modified SORN was published on January 25, 2011 to alter the System of Records, 09-20-0170, National Select Agent Registry (NSAR)/Select Agent Transfer and Entity Registration Information System (SATERIS), HHS/CDC/COTPER. **(Attachment 4)**

11. Justification of Sensitive Questions

There are questions in the data collection instruments that are directly related to criminal behavior which is considered sensitive information. 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. Therefore, questions in reference criminal behavior are necessary to obtain information regarding possible criminal activity.

12. Estimates of Annualized Burden Hours and Costs

Annualized burden hours were calculated by multiplying the average number of hours used to complete the: 1) Application for Registration; 2) Request to Transfer Select Agent or Toxin; 3) Report of Theft, Loss, or Release of Select Agent or Toxin; 4) Report of Identification of Select Agent or Toxin; and 5) Request for Exemption. The estimated annualized burden for the 2008 Possession, Use, and Transfer of Select Agents and Toxins submission was 9,656.5 hours. The 2011 estimated annualized burden hours are 8,878. Burden has been reduced by 778.5 hours due to the removal of similar questions on the Request to Transfer Select Agent or Toxin (Form 2), Report of Theft, Loss, or Release of Select Agent or Toxin (Form 3) and the Report of Identification of Select Agent or Toxin (Form 4). Therefore respondents are not required to answer as many questions as requested in the previous data collection tool.
The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility. CDC in conjunction with APHIS has revised the Request to Transfer Select Agent or Toxin form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur. Estimated average time to complete this form is 1 hour, 30 minutes. Based on data regarding the transfer requests received since the last submission, CDC estimates

1 transfer requests submitted per registered entity on an annual basis.

The Notification of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 1 report per respondent will be received on an annual basis.

The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b)) will be used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form will be used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. CDC in conjunction with APHIS has revised the Report of Identification of Select Agent or Toxin form to ensure duplicate reports are not submitted by requesting the entity that makes the final identification report the select agents or toxins identified as the result of diagnostic or verification testing. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 9 reports per respondent will be received on an annual basis.

Estimated Annualized Burden Hours

CFR	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response	Total Burden Hours
73.3(d)	Application for Registration	5	1	4.5	23
73.7(h)(1)	Amendment to Registration Application	320	8	1	2,560
73.16	Request to Transfer Select Agents or Toxins	320	1	1.5	480
73.19(a)(b)	Notification of Theft, Loss or Release	180	1	1	180

73.5 & 73.6 (a) (b)	Report of Identification of Select Agent	320	9	1	2,880
73.5 & 73.6 (d-e)	Request of Exemption	3	1	1	3
73.3 & 73.4 (e) (1)	Request for Exclusions/Restricted	71	1	1	71
73.10(e)	Request for Expedited Review	1	1	1	1
73.20	Administrative Review	30	1	4	120
73.18	Inspections	320	1	8	2,560
Total Hours					8,878

Estimated Annualized Burden Costs

CFR	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
73.3(d)	Application for Registration	23	$31.40	$722.00
73.7(h)(1)	Amendment to Registration Application	2,560	$31.40	$80,384.00
73.16	Request to Transfer Select Agents or Toxins	480	$31.40	$15,072.00
73.19(a)(b)	Notification of Theft, Loss or Release	180	$31.40	$5,652.00
73.5 & 73.6 (a) (b)	Report of Identification of Select Agent	2,880	$31.40	$90,430.00
73.5 & 73.6 (d-e)	Request of Exemption	3	$31.40	$94.20
73.3 & 73.4 (e) (1)	Request for Exclusions/Restrictions	71	$31.40	$2,229.00
73.10(e)	Request for Expedited Review	1	$31.40	$31.40

73.20	Administrative Review	120	$31.40	$3,768.00
73.18	Inspections	2,560	$31.40	$80,384.00
Total Cost				$278,816.60

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 $49.47 for managerial staff and $13.32 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $31.40. These rates were obtained from the Bureau of Labor Statistics, from the 2009 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 2011 is $15,573,024 and includes FTE's and contracts.

Compensation summary	$5,405,016
Personnel benefits	$1,764,008
Travel & transportation: Inspectors	$1,008,268
Transportation: Shipping	$21,819
Rent, telecommunication, other comm & utilities	$106,648
Printing & reproduction	$2,000

Consulting and other services	$7,063,858
Supplies & materials	$54,800
Equipment	$146,608
Grand Total:	$15,573,024

15. Explanation for Program Changes or Adjustments

Revisions to the data collection instruments have been structured to reduce the previous annualized burden hours of 9,656.5 hours to 8,878 hours. Removing similar questions, enhanced clarification of the transfer process, improving surveillance methods for monitoring the reports of select agents and toxins identified by registered entities and improving process flow will result in a decrease of 778.5 hours burden hours upon the regulated community.

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 not inappropriate.

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 (42CFR Part 73) – Final Rule
Attachment 2	Federal Register Notice 60 Day
Attachment 3	Public Comment and Response to Public Comment
Attachment 4	System of Record Notice: 01/25/2011
Attachment 5	-Form 1 Application for Registration
Attachment 6	-Form 1 Amendment to Registration (Sections 4 and 6)
Attachment 7	- Form 2 Request to Transfer Select Agents and Toxins
Attachment 8	- Form 3 Notification of Theft, Loss, or Release of Select Agents and Toxins
Attachment 9	- Form 4 Report of Identification of Select Agents and Toxins
Attachment 10	-Request for Exemption
Attachment 11	-Request for Exclusions/Restrictions
Attachment 12	-Request for Expedited Review
Attachment 13	-Administrative Review
Attachment 14	-Inspections
Attachment 15	Summary of Changes