Supporting Statement A

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

(OMB Control No. 0920-0576) Expiration 10-31-2014

Revision

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

Lazenia D. Harris, MPH

(404) 718-2002

(404) 718-2097 FAX

cwx3@cdc.gov

July 30, 2012

Table of Contents

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, Expiration October 30, 2014. 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 C.F.R. Part 73 (**Attachment 1**). The original forms were approved in February, 2005. However, this request reflects revisions to the forms approved in October, 2011. The current versions of the standard forms have been revised to: 1) reflect changes to the select agent regulations, 2) improve surveillance, 3) improve the registration/certification process, 4) enhance methods for monitoring the reports of select agents and toxins identified by registered entities, and 5) improve process flow. The newly proposed rule requires revisions to the following forms: 1) Application for Registration, 2) Identification of a Select Agent or Toxin, and 3) Request for Exemption which may be found in (**Attachments 16, 17, 18**). A summary of all revisions made to the forms are found in (**Attachment 15**). The Centers for Disease Control and Prevention and the United States Department of Agriculture are requesting a 3-year approval for this data collection.

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 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. The purpose of collecting this information is to assist with meeting the goals of the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and to ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety. The forms are used for information collection and have been revised due to association with the proposed rule Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73); Rule Identification Number RIN 0920–AA34; Docket No. CDC-2011-0012. The collection of select agents and toxins data has produced positive outcomes and useful outcomes such as 1) maintaining a national registration database containing information on all entities possessing select agents, 2) developing a system for reporting theft, loss and release, 3) establishing safety and security requirements for all entities working with select agents and toxins and 4) providing guidance to the regulated community by way of workshops and seminars.

2.1 Privacy Impact Assessment

The Responsible Official, Alternate Responsible Official and personnel who wish to use, transfer or possess select agents and toxins are required to provide the following data: name, date of birth, department of justice identification number and job title. The data is needed to obtain a certificate of registration. 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

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 CDC/DSAT. The entity can retain an electronic copy of their submission which will make it easier for the entity to amend any future submissions.

CDC/DSAT and USDA/APHIS 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/DSAT and USDA/APHIS 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; requests for approvals for transfers, exemptions, or exclusions; and reports of identification and theft, loss, or release of a select agent or toxin.

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. 8A. The 60 day Federal Register Notice was published on Friday, December 16, 2011 Vol.76, No. 242, page 78215-78215. There were 112 public comments. (**Attachment 3**)

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

Robert Rice
Program Security Specialist
Animal Plant Health and Inspection Service
U.S. Department of Agriculture
4700 River Road, Unit 40
Riverdale, MD 20737-1231
Phone: (301) 734-5557
Robert.L.Rice@aphis.usda.gov

Celeste Sickles
Animal Plant Health and Inspection Service
U.S. Department of Agriculture
4700 River Road, Unit 40
Riverdale, MD 20737-1231
Phone: (301) 734-7477
Celeste.l.sickles@aphis.usda.gov

Lidia M. Carrera, Ph.D.
Compliance Manager
United States Department of Agriculture
APHIS, PPQ, PHP, RIPPS
Agriculture Select Agent Program
4700 River Road, Unit 2
Riverdale, MD 20737
Lidia.Carrera@aphis.usda.gov

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).** The information provided by the responsible official will be secured in NSARS.

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

Estimated Annualized Burden Hours

Annualized burden hours and cost 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 2011 Possession, Use, and Transfer of Select Agents and Toxins submission was 8,878 hours. The 2012 estimated annualized burden hours are 8,921 hours. The increase in burden hours is directly related to the revision of the application for registration. To determine the annual burden hours regarding the revisions made to the application for registration, CDC/DSAT sent the draft form to the following entities:

1. MRI Global (Kansas City, MO)
2. Tennessee Department of Health (Nashville, TN)
3. University of Texas Medical Branch (Galveston, TX)
4. University of Wisconsin-Madison (Madison, WI)

The revised forms 1) Application for Registration is associated with the proposed rule Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73); Rule Identification Number RIN 0920–AA34; Docket No. CDC-2011-0012. The revised application for registration (Form 1) will continue to be used by entities to register with the 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 to 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/DSAT. Unlike the previous application for registration, the revised version of the form requires the entity to only complete the sections that are applicable to the individual facility. There is not an electronic skip pattern in place, however; the form has been formatted in a manner which allows the entity to select the appropriate attachment which describes the type of work taking place and biosafety

level of the laboratory. Therefore, the entity is no longer required to read and provide a response of “N/A” to a series of questions that are not applicable to the facility.

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	13.5	68
73.(h)(1)	Amendment to Registration Application	320	8	1	2560
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					8,923

Estimated Annualized Burden Costs

CFR	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
73.3(d)	Application for Registration	68	$31.40	$2,135.00
73.7(h)(1)	Amendment to Registration	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				$280,179.60

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 2012 is $16,315,108 and includes FTE's and contracts.

Compensation summary	$5,532,576
Personnel benefits	$1,689,059
Travel & transportation: Inspectors	$861,806
Transportation: Shipping	$31,819
Rent, telecommunication, other comm & utilities	$106,648
Printing & reproduction	$2,000
Consulting and other services	$7,908,741
Supplies & materials	$58,867
Equipment	$123,591
Grand Total:	$16,315,108

15. Explanation for Program Changes or Adjustments

The revised Application for Registration (Form 1) is associated with the proposed rule Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73); Rule Identification Number RIN 0920–AA34; Docket No. CDC-2011-0012. Revisions to the data collection instruments have been structured to reflect changes to the select agent regulations, improve surveillance and monitoring, improve the registration/certification process, enhance methods for monitoring the reports of select agents and toxins identified by registered entities, and improve process flow.

This information collection request is associated with a proposed rule/final rule. The proposed rule serves as the 60 day Federal Register Notice, it was published on Friday, December 16, 2011 Vol.76, No. 242, page 78215-78215. The final rule will satisfy the 30-day notice requirement.

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	Federal Register Notice 60 Day
Attachment 3	Executive Summary: Public Comments and Response to Public Comments
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	Form 5 Request for Exemption of Select Agents and Toxins
Attachment 11	Request for Exclusions/Restrictions
Attachment 12	Request for Expedited Review
Attachment 13	Administrative Review
Attachment 14	Inspections
Attachment 15	Summary of Changes
Attachment 16	Revised Form 1 Applications for Registration
Attachment 17	Revised Form 4 Reports of Identification of Select Agents and Toxins
Attachment 18	Revised Form 5 Requests for Exemption of Select Agents and Toxins
Attachment 19	OMB Burden Statement Email