Supporting Statement

Import Permit Applications

(OMB Control No. 0920-0199) Expiration 01-31-2014

Revision

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

Lori Bane

(404) 718-2006

(404)718-2097 FAX

zoz1@cdc.gov

December 9, 2013

Table of Contents

List of Attachments

A. Justification

This is a request for revisions to Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920-0199, exp. 1/31/2014). We are also requesting a title change to read *Import Permit Applications.* The Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) is requesting a three year approval for this data collection. This request reflects revisions to the forms approved in January 2011 (Attachment 5) and (Attachment 6) as well as a reduction in the number of respondents to the Application for Permit to Import Infectious Biologic Agents based on past experience. We estimate a decrease in the number of respondents from 2,000 in 2011 to 1,625 due to recent trends and changes in the regulation. The daily operations has observed a decrease in the number of request for an import permit since 2011. In addition, the changes in 42 CFR 71.54, which became effective April 5, 2013, specify situations where an application for a permit is no longer required. For example, the importation of a select agent that is regulated under 42 CFR Part 73 no longer requires a permit be issued.

1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes that the Secretary of Health and Human Services (HHS) make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F – Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC (Attachment 1).

The *Application for Permit to Import Infectious Biological Agents into the United States* is used by laboratory facilities, such as those operated by academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information and personnel qualifications. DSAT plans to revise this application to request information on where the imported material will be stored at the recipient facility and who would be responsible for this location; verification that the permittee has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use; and a secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will reduce the burden hours. We estimate a decrease in the number of respondents from 2,000 in 2011 to 1,625 due to recent

trends and changes in the regulation. The daily operations has observed a decrease in the number of request for an import permit since 2011. In addition, the changes in 42 CFR 71.54 which became effective April 5, 2013 specify situations where an application for a permit is no longer required. For example, the importation of a select agent that is regulated under 42 CFR Part 73 no longer requires a permit be issued.

A summary of all revisions made to the form is found in (Attachment 7). The revised form for the *Application for Permit to Import Infectious Biological Agents into the United States* is found in (Attachment 8).

The *Application for Permit to Import or Transfer Live Bats* is used by laboratory facilities such as those operated by government agencies; universities; research institutions; and for educational, exhibition or scientific purposes to request a permit for the importation, and any subsequent distribution after importation of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported and facility isolation and containment information. DSAT plans to revise this application to request secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours. A summary of all revisions made to the form is found in (Attachment 7). The revised form for the *Application for Permit to Import or Transfer Live Bats* is found in (Attachment 9).

1.1 Privacy Impact Assessment

Information is submitted through the requested forms as required by the provisions of 42 CFR 71.54 for issuance of permits by CDC to importers or distributors after importation of infectious biological agents, infectious substances and vectors of human disease. The forms are available to applicants on CDC's Import Permit website (http://www.cdc.gov/od/eaipp/importApplication/).

The information is kept in a database which consists of permitted entities importing or subsequently transferring biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DSAT has access to the information, and disclosure of information is stringently limited. The information being collected to receive a permit as required by 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address.

The DSAT records and associated information are retained and dispositioned in accordance with DSAT records retention schedule, N1-442-06-1. The DSAT records will be retained for 10 years in compliance with the records retention schedule requirements or until such time as no longer

needed for litigation or other records purposes. Records will be transferred to a Federal Records Center for storage when no longer in active use. Final disposition of records stored offsite at the Federal Records Center will be accomplished by a controlled process requesting final disposition approval from the record owner prior to any destruction to ensure records are not needed for litigation or other records purposes. Hard copy records will be placed in a locked container or designated secure storage area while awaiting destruction. Data will be destroyed in a manner that precludes its reconstruction, such as shredding.

Electronic information will be deleted or overwritten using overwriting software that wipes the entire physical disk and not just the virtual disk. Overwriting is required for the destruction of all electronic Sensitive But Unclassified (SBU) information.

2. Purpose and Use of Information Collection

The purpose of this information is to protect the public's health by monitoring the importation of infectious biological agents, infectious substances and vectors of human disease. Any imported material coming within the provisions of 42 CFR 71.54 will not be released prior to receipt by the U.S. Customs and Border Protection of a permit issued by CDC. In addition, the provision sets minimum packaging and labeling requirements such as infectious materials imported into this country must be packaged to withstand breakage and leakage of contents, and labeled, as specified in the following federal regulations: DOT 49 CFR PART 173 - Transportation of Etiologic Agents. For international shipments, the International Air Transport Association Dangerous Goods Regulations should be consulted. Information is submitted through the requested forms as required by the provisions of 42 CFR 71.54 for issuance of permits by CDC to importers or distributors after importation of infectious biological agents, infectious substances and vectors of human disease. The forms are available to applicants on the CDC's Import Permit website (http://www.cdc.gov/od/eaipp/importApplication/). Any individual who submits an application to receive a permit to import infectious biological agents, infectious substances, and vectors of human disease under 42 CFR 71.54 would include individuals from academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities. A permit is valid only for the time period and conditions indicated on the issued permit.

2.1 Privacy Impact Assessment

Information is submitted through the requested forms as required by the provisions of 42 CFR 71.54 for issuance of permits by CDC to importers or distributors after importation of infectious biological agents, infectious substances and vectors of human disease. Any individual who submits an application to receive a permit to import infectious biological agents, infectious substances, and vectors of human disease under 42 CFR 71.54 would include individuals from academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities; and educational facilities. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's

name, mailing address, phone numbers, and email address.

The information is kept in a database which consists of permitted entities importing or receiving biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DSAT has access to the information, and disclosure of information is stringently limited.

The DSAT records and associated information are retained and dispositioned in accordance with DSAT records retention schedule, N1-442-06-1, pending approval by the National Archives and Records Administration. The DSAT records will be retained for 10 years in compliance with the records retention schedule requirements or until such time as no longer needed for litigation or other records purposes. Records will be transferred to a Federal Records Center for storage when no longer in active use. Final disposition of records stored offsite at the Federal Records Center will be accomplished by a controlled process requesting final disposition approval from the record owner prior to any destruction to ensure records are not needed for litigation or other records purposes. Hard copy records will be placed in a locked container or designated secure storage area while awaiting destruction. Data will be destroyed in a manner that precludes its reconstruction, such as shredding.

Electronic information will be deleted or overwritten using overwriting software that wipes the entire physical disk and not just the virtual disk. Overwriting is required for the destruction of all electronic SBU information.

3. Use of Improved Information Technology and Burden Reduction

The electronic forms are available at the CDC's Import Permit website (http://www.cdc.gov/od/eaipp/importApplication) in pdf and pdf-fillable formats. Applications may be emailed, mailed or sent by fax. Using the pdf-fillable form, the applicant has the ability to save the document to the applicant's local drive, complete the form, and then mail or fax the application to CDC. The use of electronic forms will facilitate a reduction in burden for those applicants submitting more than one form to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

42 CFR 71.54 specifies that the importation permit is granted by CDC. No other component of HHS is involved in these procedures. The only way to obtain the necessary information is from the applicant.

5. Impact on Small Businesses and Other Small Entities

Collection of information may involve some small businesses or other small entities, but the burden has been limited to providing minimal information on forms, verifying information by telephone, and mailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

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 CDC 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

There are no special circumstances relating to the guidelines of 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 September 10, 2013, Vol. 78, No. 175, Pages 55259-55260 (Attachment 2). There were public comments.

A8B. Consultation Outside the Agency

There has been no consultation outside the agency due to the delegation of responsibilities to the CDC as described herein.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

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 information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address. 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, the attached draft *Federal Register* notice is in the clearance process for the System of Record Notice entitled, *Etiological Agent Import Permit Program (EAIPP) 2.0*, *HHS/CDC/OPHPR* (Attachment 4).

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

Authorized Users: Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have daily access to these records are limited to DSAT staff who have responsibility for conducting regulatory oversight of the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States.

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 the appropriate portable fire extinguishers are located throughout the computer room. 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. 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.

The 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 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 or destroyed, as specified by the contract.

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 (LAN) are 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.

The CDC will follow its established policies and procedures in releasing and/or withholding trade secret and/or confidential or financial information, in accordance with the Freedom of Information Act.

Institutional Review Board

Institutional Review Board approval is not required. These activities were determined to be public health non-research.

Privacy Impact Assessment Information

The following information is collected from the applicant to receive an import permit as required under 42 CFR 71.54. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address.

The information is kept in a database which consists of permitted entities importing or subsequently transferring biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DSAT has access to the information, and disclosure of information is stringently limited.

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, the attached draft *Federal Register* notice is in the clearance process for the System of Record Notice entitled, *Etiological Agent Import Permit Program (EAIPP) 2.0, HHS/CDC/OPHPR* (Attachment 4).

11. Justification for Sensitive Questions

This data collection does not include personal questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

We estimate based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010 that there will be approximately 1,625 respondents for permit requests per year and that the average response time to complete this questionnaire is 20 minutes. The total estimated annualized burden for the data collection is 545 hours. There are no costs to respondents except their time.

Table A12A. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response	Total Burden Hours

				(in hours)	
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Infectious Biological Agents into the United States	1625	1	20/60	542
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	20/60	3
Total					545

Table A12B. Estimate of Annualized Cost to Respondent

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rates	Total Respondent Costs
Applicants	1625	1	20/60	542	28.87	$15,647.54
Applicants	10	1	20/60	3	28.87	$86.61
Total				545		$15,734.15

To estimate costs to respondents, CDC assumed that the hourly burden rate would be evenly split between managerial staff and clerical staff. CDC assumed an average hourly respondent labor rate (including fringe and overhead) of $41.86 for managerial staff (e.g., researchers) and $15.88 for clerical staff (e.g., graduate students/assistants). To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $28.87. These rates were obtained from the Bureau of Labor Statistics, from the *2012 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 estimated cost for implementing these regulatory activities for fiscal year 2013 is $1,335,495. This estimate includes 6 full-time Federal Employees (FTE) currently working in the import permit program. It also accounts for the program performing 23 inspections per year

with two inspectors at a cost of $2000 per inspection. Additional costs incurred by the program are costs as shown below.

FY 2013 Annualized Government Cost

Personnel:	6 FTEs	$ 504,607
Travel:		$ 92,000
Import Permit Database:		$ 697,840
Equipment, supplies and materials:		$ 37,063
Administrative Costs:		$ 3,985
Total:		$ 1,335,495

15. Explanation for Program Changes or Adjustments

There have been regulatory changes to the *Import Regulations for Infections Biological Agent, Infectious Substances, and Vectors (71.54)* that clarifies when a permit is not required (e.g., select agents listed in 42 CFR Part 73; diagnostics specimens not known or suspected by the importer of containing an infectious biological agent; consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent; and product that bears or contains a biological agent that is cleared, approved, licensed, or otherwise authorized certain Federal laws). The rule requires that the applicant have biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use. The rule also allows CDC to evaluate whether the applicant's biosafety measures are commensurate with the risk of the item to be imported, given its intended use. As a result, there will be an increase in cost to carry out the daily operations (i.e., inspections, additional employees, enhancement to the import permit database). We estimate a decrease in the number of respondents from 2,000 in 2011 to 1,625 due to recent trends and changes in the regulation. The daily operations has observed a decrease in the number of request for an import permit since 2011. In addition, the changes in 42 CFR 71.54, which became effective April 5, 2013, specify situations where an application for a permit is no longer required. For example, the importation of a select agent that is regulated under 42 CFR Part 73 no longer requires a permit be issued.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of this data. The data collection is used solely to carry out the provisions of the regulation.

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 Submissions

There are no exceptions to the certification.