

Supporting Statement  
Foreign Quarantine; Import Regulations for Infectious Biological Agents,  
Infectious Substances, and Vectors (42 CFR 71.54)  
(OMB Control No. 0920-0199)  
Extension

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

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Table of Content

A. Justification.....3

- 1. Circumstances Making the Collection of Information Necessary.....3
- 2. Purpose and Use of Information Collection.....4
- 3. Use of Improved Technology and Burden Reduction.....4
- 4. Efforts to Identify Duplication and Use of Similar Information.....4
- 5. Impact on Small Businesses or Other Small Entities.....5
- 6. Consequences of Collecting the Information Less Frequently.....5
- 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....5
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....5
- 9. Explanation of Any Payment or Gift to Respondents.....5
- 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....5
- 11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....7
- 12. Estimates of Annualized Burden Hours and Costs.....8
- 13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers.....9
- 14. Annualized Cost to the Government.....9
- 15. Explanation for Program Changes or Adjustments.....9
- 16. Plans for Tabulation and Publication and Project Time Schedule .....10
- 17. Reason(s) Display of OMB Expiration Date is Inappropriate.....10

List of Attachments:.....11

## Supporting Statement A

- The goal of the study is to support Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents 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.
- The intended use of the resulting data is to fulfill the requirements promulgated by Health and Human Services under 42 CFR 71.54.
- The methods used to collect data/information is an electronic data collection system that uses electronic forms, which are available on the Centers for Disease Control and Prevention's Import Permit website at <http://www.cdc.gov/od/eaipp/> in a pdf-fillable format for electronic submission.
- The subpopulation to be studied are those 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 collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54.

### ***A. Justification***

This is a request for extension to OMB Control No. 0920-0199: Foreign Quarantine; Import Regulations for Infectious Biological Agents. The data collection and reporting requirements are required under 42 CFR 71.54 (Attachment 1). The Centers for Disease Control and Prevention (CDC) is requesting a 3-year approval for this data collection.

#### **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. The Centers for Disease Control and Prevention's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with these imported materials.

## **2. Purpose and Use of Information Collection**

This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents 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.

The *Permit to Import Biological Agents and Vectors of Human Disease 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; personnel qualifications; 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.

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; and secondary contact information for the permittee to provide in case the permittee is unavailable.

## **3. Use of Improved 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 or 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**

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**

**A. A 60 Day Federal Register Notice** was published in the Federal Register on April 26, 2016, Vol. 81, No.80, Pages 24616-24618 (**Attachment 2**). There were no public comments.

### **B. 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

This submission has been reviewed by the Office of Public Health Preparedness and Response (OPHPR) Information Systems Security Officer who determined that the Privacy Act does apply. The information is being collected to receive a permit as required under 42 CFR 71.54, and 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.

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

Institutional Review Board approval is not required. These activities were determined to be public health non-research. (Attachment 6)

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 burden for the one-time 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 (in hours)	Total Burden 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 Permit to Import or Transport 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 2016 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 2016 Annualized Government Cost

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

**15. Explanation for Program Changes or Adjustments**

This is a Request for Extension of a currently approved collection. There has been no change in burden from the current inventory.

**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.

***List of Attachments:***

Attachment 1	Foreign Quarantine; Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors (42 CFR 71.54)
Attachment 2	60-Day Federal Register Notice
Attachment 3	Public Comments to 60-Day Federal Register Notice
Attachment 4	System of Record Notice
Attachment 5a	Application for Permit to Import Infectious Biological Agents (Infectious Substance and Vectors) of Human Disease into the United States
Attachment 5b	Application for Permit to Import or Transfer Live Bats
Attachment 6	Determination of Applicability for Human Subjects