

Foreign Quarantine Regulations (42 CFR 71)
(OMB Control No. 0920-0134)
Supporting Statement A
Request for Revision of Currently Approved Data Collection
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Foreign Quarantine Regulations (42 CFR 71)
Statement in Support of Foreign Quarantine Regulations (42 CFR Part 71)
(OMB Control No. 0920-0134)

This is a request for a revision of a currently approved information collection request that expires July 31, 2015. The Centers for Disease Control and Prevention Division of Global Migration and Quarantine (DGMQ) is requesting approval for a set of adjustments and program changes to the previously approved burden total for this information collection. These requested adjustments and program changes are the result of the upcoming implementation of the International Trade Data System (ITDS) and the associated Automated Commercial Environment (ACE) software, as well as revised estimates and improvements in program administration. The changes in law and program estimates have resulted in CDC requesting a net increase in the estimated number of burden hours in the amount of 8,313. The adjustments and program changes are as follows:

Adjustments

CDC is providing an updated estimate of the number of respondents for the CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement.

- As described in section A 12 below, the revised estimate is for 2,800 respondents per year, which results in an additional 133 burden hours per year.

CDC is also providing wholly revised instructions for the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form and Maritime Conveyance Illness or Death Investigations form. No additional burden is requested for this change, because no increase in complexity of instructions or reporting information is requested. For both forms, the wholly revised instructions:

- Are more comprehensive in explaining the situations which trigger the use of the forms and which sections should be filled out in sequence,
- include red markings and asterisks to show which fields are required,
- include more specific instructions concerning where to send the report and how to communicate with CDC about the case or cases of illness

For the Maritime Conveyance Illness or Death Investigations form, there are clearer instructions concerning the use of PII, as well as instructions on how to clear reporting options that have been incorrectly chosen.

For the Cumulative ILI form there are instructions both for when the Maritime Conveyance Illness or Death Investigations form should be used and when gastro-intestinal issues should be reported to the Vessel Sanitation Program.

Program Changes due to Statutory Requirements

CDC is requesting the following changes based on the upcoming implementation of ITDS and ACE, which allows importers/filers to voluntarily submit certain information concerning CDC-regulated imports electronically using CDC Partner Government

Agency (PGA) Message Sets. These estimates of additional burden are based on operational observation by Quarantine Staff at US ports of entry as well as data included in the Quarantine Activity Reporting System (QARS). These hours are in addition to the currently approved respondent burden.

- 30,000 responses using CDC PGA Message Set data for dogs and cats, resulting in 7,500 additional requested burden hours.
- 60 responses using CDC PGA Message Set data for importations of African Rodents, resulting in an additional 15 requested burden hours.
- 2,000 responses using CDC PGA Message Set data for importations of African Rodent and All Family Viverridae products. This results in an additional 500 hours of requested burden.

The following change is a correction to clarify the public burden associated with providing the required statements and documentation that an animal product has been rendered non-infectious.

- 2,000 responses using CDC PGA Message Set data for statements/documentation of non-infectiousness for imported animal products (currently African Rodent and All Family Viverridae products), resulting in an additional 167 burden hours. These responses can be accomplished via the Document Imaging System (described below). CDC retains the right to collect these in hard copy.

There have been no changes in the estimates for requested burden under:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35 (977 hours of burden),
- Medical record keeping requirements under 42 CFR 71.21 (850 hours of burden),
- Report by persons in isolation or surveillance 42 CFR 71.33 (1 hour of burden),
- Passenger Locator Form (225,000 or 67 hours of burden depending on scenario; large outbreak of public health significance or limited use).
- The number of burden hours requested for 42 CFR 71.52(d) Turtle Importation Permits (3 burden hours)
- The text or format of CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement.
- The number of burden hours requested for 42 CFR 71.55 Dead Bodies (5 burden hours)
- The number of burden hours requested for 42 CFR 71.56(a)(iii) and (c) Appeal (2 burden hours)

The estimates provided in this information collection request assume that every commercial import covered by CDC’s regulations will file a data entry using ITDS and ACE. However, CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget (OMB), because the use of ITDS/ACE and CDC PGA Message Sets will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of import-related documentation until the use of ITDS/ACE is required for cargo entering the United States.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The purpose of this ICR is to request a revision of a currently approved data collection “Foreign Quarantine Regulations” which is due to expire on July 31, 2015. This revision focuses on requesting authorization to collect information associated with imports and cargo that is submitted via the “single window” provided by ITDS and the ACE software. This information will be requested by CDC in an electronic format that is not currently approved under this ICR.

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment A1) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Legislation and the existing regulations governing quarantine activities (42 CFR 71) (Attachment A2) authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals and etiologic agents in order to protect the public’s health. Other inspection agencies, such as Customs and Border Protection (CBP), assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to quarantine station staff when indicated. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting procedures, as well as a minimum of interference with trade and travel.

The Security and Accountability For Every Port Act (SAFE Port) of 2006 (Attachment A3) requires that all agencies that require documentation for clearing or licensing the importation and exportation of cargo participate in ITDS. ACE is the software portal for ITDS and will ultimately become the single window through which the international trade community will electronically provide all information needed by federal agencies for the import and export of cargo.

As part of this legal authority, CDC is authorized to access and use entry, entry summary and manifest data to further its public health mission. CDC is also permitted access to the Automated Commercial Environment (ACE) data pursuant to 6 CFR § 29.8(b) (Attachment A4) and 49 CFR §1520.11(b) (Attachment A5), which permit federal employees with a need to know to have access to this data. As a government agency that requires documentation from an importer/filer in order for CBP to process and clear an import into the United States, CDC is submitting this revision to obtain authority to request certain electronic information from importers/filers on specific types of animals and cargo over which CDC has authority, specifically those found in 42 CFR Part 71.

The regulations found at 42 CFR 71 that are pertinent to this revision include the following general authorities, reporting, and recordkeeping procedures pertaining to the importation of animals, cargo or other items:

- 42 CFR 71.32 Persons, carriers, and things (This includes the authority to regulate the importation of all family Viverridae and certain animal products. In this revision these animal products are generally African rodent and viverridae products, but may include others if thought to present a risk to public health)¹
- 42 CFR 71.51 (b)(3) and (d) Reporting – requirement to admit dogs and cats
- 42 CFR 71.56 (a)(2) Record keeping - Request for exemption: African rodents

No changes to the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35,
- Medical record keeping requirements under 42 CFR 71.21,
- Report by persons in isolation or surveillance 42 CFR 71.33,
- Passenger Locator Form,
- The text or format of CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement (Attachment C).

1.1 Privacy Impact Assessment

Overview of the Data Collection System

The data collection systems for this information collection request consists of electronic data transfers, web-based reporting portals, personal interviews, and radio/phone, and hard copy document submission to CDC quarantine stations.

Concerning this revision, ITDS is intended to provide an electronic “single-window” for reporting imports and exports to the government. Currently, traders must make redundant reports to multiple agencies (often on paper). When completed, ITDS will allow importers/filers to make a single electronic report, and the relevant data will be distributed to the appropriate agencies. Costs will be reduced for business and government. Agencies will obtain data more quickly through electronic filings, and with automated processing, be able to process cargo more expeditiously, and be better able to identify unsafe, dangerous, or prohibited shipments. The associated ACE Secure Data Portal software offers approved CDC staff near real-time review of Customs and Border Protection entry, entry summary and manifest data accessible via the Reports tab, as well as other information to which the user may be granted access, as appropriate.

¹ Pursuant to 42 CFR 71.32(b), no person may import or attempt to import any civets (Family: Viverridae), whether dead or alive, or any products derived from civets. This prohibition does not apply to any person who imports or attempts to import products derived from civets if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the SARS virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies. This prohibition also does not apply to any person who receives permission from the CDC to import civets or unprocessed products from civets for educational, exhibition, or scientific purposes as those terms are defined in 42 CFR 71.1.

CDC will request that specifically constructed CDC PGA Message Sets be submitted by importers/filers to CBP and the ITDS/ACE system depending on the import CDC regulates. All import specific data will be submitted into CBP's ITDS/ACE system by the importer/filer. This information includes documentation or forms submitted in the Document Imaging System (DIS), a system that is available to store and transmit scanned images of relevant documents. It is CDC's intent to allow the CDC form 75.37, "Notice of Importers of Dogs" and the Statement of Non-infectiousness to be submitted via the DIS. As part of this ICR, the following CDC PGA Message Sets will be available to importers/filers to submit when importing a CDC-regulated import:

- CDC Requested Data on Regulated Imports: Domestic Dogs (Attachment D)
- CDC Requested Data on Regulated Imports: Domestic Cats (Attachment E)
- CDC Requested Data on Regulated Imports: African Rodents (Attachment F)
- CDC Requested Data on Regulated Imports: Products of African Rodent and All Family Viverridae (Attachment G)

No changes to the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35
- Medical record keeping requirements under 42 CFR 71.21
- Report by persons in isolation or surveillance 71.33
- Passenger Locator Form,
- The text or format of CDC form 75.37 "NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement are requested.

Items of Information to be Collected

This ICR involves information collected from importers/filers seeking to import certain animals and cargo into the United States. Import related information may include individually identifying information such as address, passport number, driver's license, and phone number.

The requested revision to this information collection involves the addition of electronic information related to the regulated animals and animal products included in 42 CFR part 71 via CDC PGA Message Sets. The information requested of the importers/filers in the CDC PGA Message Sets is voluntary and includes the number, description, intended use, identification of holding facilities, and measures taken to reduce the risk of zoonotic transmission of disease. This information is limited to that sufficient to identify the type of import, e.g. dog, cat, African rodent, and to determine if all requirements for entry have been met, i.e. permit or statement of non-infectiousness. A portion of this information collected is composed of Intended Use Codes, such as For Exhibition or For Research. CDC including the PGA Message Sets for review because there is no set form or format for the electronic submission of import related data to CBP and CDC.

Use of ITDS/ACE and relevant descriptive data will enable CBP, with CDC consultation, to clear or release an import much faster than with previous paper-based submissions.

No changes to the Items of Information to be Collected for the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35
- Medical record keeping requirements under 42 CFR 71.21
- Report by persons in isolation or surveillance 71.33
- Passenger Locator Form,
- The CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement.

2. Purpose and Use of Information Collection

The reporting, documentation and recordkeeping requirements contained in 42 CFR 71 regulations are used by CDC to carry out quarantine responsibilities as required by law. This data collection is critical to CDC in fulfilling regulatory requirements that aim to reduce the risk that an infectious disease is imported into the United States via contaminated or infected animals or other cargo, and for illness reporting on air and maritime conveyances under 42 CFR Part 71.

The burdens imposed have been reduced to the minimum considered necessary to permit CDC to carry out the purpose of the regulation, i.e., to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Including the use of import data submitted electronically via ITDS and ACE is warranted because CDC is required to participate in the ITDS/ACE implementation process, and there are public health benefits associated with preventing the introduction, transmission or spread of communicable diseases from foreign countries into the United States.

2.1 Privacy Impact Assessment

1. In the event that an import requires enhanced evaluation for public health reasons, some data may be extracted from CDC PGA Message Sets within ITDS/ACE and included in reports in the Quarantine Activity Reporting System (QARS). Only data extracted from CDC PGA Message Sets will be entered into QARS. Additionally, as approved by OMB, data collected from individuals, air conveyance commanders, and maritime conveyance operators who are reporting illnesses or death during travel is recorded in QARS.

On December 13, 2007, CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under 42 CFR 71 (72 FR 70867). The data will become part of CDC Privacy Act System of Records 09-20-0171, “Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71.” CDC is currently in the process of updating this SORN to include importers. The updated SORN for QARS will be applicable to importers and any other information pertinent to clearing cargo not included in ACE.

Information may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

2. Highly sensitive information is being collected and would affect a respondent's privacy if there were a breach of confidentiality. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records include 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 back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical records containing Privacy Act information. Finally, CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures 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. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversees compliance with these requirements.

3. Use of Improved Information Technology and Burden Reduction

With respect to this revision, importers/filers of CDC-regulated items may voluntarily be using the ITDS/ACE single window to submit data to Customs and Border Protection and CDC. This electronic data system is intended to make importation quicker and more efficient. Use of the information technologies made available by ITDS/ACE will enable CBP, with consultation from CDC, to reduce the amount of time it takes to review import information and release imports. Also, because importers/filers have the option to interface with ITDS/ACE using customizable, proprietary software, their ability to enter data quickly into ITDS/ACE will speed the process of data submission for CBP and CDC to review. This has the potential to reduce burden on the importers/filers when ITDS/ACE are fully implemented.

While the DIS will be available to importers/filers to scan paper documents into ITDS/ACE, CDC will retain the right to ask for the hard copies in the event that they are needed to evaluate an import. These hard copies include the CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement, and the statements or documentation of non-infectiousness.

No changes to illness reporting or recordkeeping procedures are requested as part of this revision. Current reporting and recordkeeping requirements imposed by the 42 CFR 71 (with regard to inspection and surveillance procedures at ports of entry) have been facilitated by the use of radio, email, or telephone notification of illness reports.

Reporting of death or illness onboard aircrafts can be reported via Air Traffic Control, who will notify CDC’s Emergency Operations Center (EOC) through the Domestic Events Network; the EOC will notify the appropriate CDC Quarantine Station and the local health department of jurisdiction. Quarantine staff will communicate with the airline’s designated point of contact to obtain necessary information about the death or ill traveler. Alternatively, the aircraft operator may communicate with the airline’s land-based point of contact (e.g., Operations Center, Flight Control, airline station manager). The airline’s point of contact will notify CDC by contacting the Quarantine Station with jurisdiction for the arrival airport or CDC Emergency Operations Center, who will notify the appropriate Quarantine Station.

Reporting of illness or death aboard maritime conveyances is accomplished by the use of sections 1-3 of the Maritime Conveyance Illness or Death Investigation Form (Attachment H) and the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (Attachment I). These forms are then emailed to CDC containing information sufficient to determine if further public health actions is needed.

Reporting of gastrointestinal illnesses are reported to CDC’s Vessel Sanitation Program is reported via a Web-based application; Maritime Illness and Death Reporting System (MIDRS), <https://wwwn.cdc.gov/midrs/GILogin.aspx> (Attachment J).

4. Efforts to Identify Duplication and Use of Similar Information

Regarding the current hard copy collection of information on the animal and animal products listed in Part 71, CDC has regulatory authority to collect this data and must have this information to perform its public health responsibilities. Concerning the voluntary electronic collection of information via ITDS/ACE, CDC will rely on CBP to administer the collection of information pertaining to imports. While CDC may request information in common with other agencies, the importer/filer only fills out a data field once, which may then be made available via memorandums of understanding or other data sharing agreements among multiple agencies, if needed. Importer/filer software may also pre-populate data fields for other agencies' Message Sets, so repeat entry may not be necessary. CBP is the sole authority to which import information must be submitted via ITDS/ACE, so it is very unlikely that any duplication will occur.

Concerning illness reporting, the existing regulations were widely reviewed by other federal inspection agencies, the World Health Organization (WHO), and the United States Army, Air Force, Navy, and Coast Guard. There is no duplication of data. The PLF is universally accepted as a result of collaborations between CDC/DGMQ, WHO and the International Civil Aviation Organization (ICAO).

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed CDC's PGA Message Sets and illness reporting procedures have been reduced to the minimum necessary for CDC to meet its regulatory responsibilities.

6. Consequences of Collecting the Information Less Frequently

Further reduction of required and requested recordkeeping or reporting would prevent CDC from meeting its legislative mandate and could therefore endanger the public's health. There are no legal obstacles to reduce the burden.

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

Information regarding the potential presence of disease or the arrival of a potential vector of disease via animals or cargo must be reported on a real-time basis if it is to be used to prevent the importation and spread of disease into the United States

Information regarding the incidence of disease or death aboard maritime or air conveyances must also be reported on a real-time basis if it is to be used to prevent the importation and spread of disease into the United States. Depending on the situation, reporting may be verbal, written with no specific form specified, or written on the provided illness and death investigation and PLF forms with no extra copies required.

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

A. A notice to the public concerning CDC's use of the ITDS/ACE to collect import related information was published in the Federal Register Wednesday, March 19, 2014, VOL 79, 15345 - 15347). (Attachment B).

B. Concerning this revision, CDC has collaborated with CBP on the development of the data sharing and collection process used to develop the PGA message sets for each import regulated by CDC. Since the passing of the SAFE Port Act, CDC has been actively involved with the development of the ACE software. CDC has worked directly with CBP as well as with other federal agencies, through workgroups, to account for foreseeable regulated importation and the data necessary to make a release decision. In order to reduce costs and to streamline the data input that will be necessary, CDC will leverage the PGA Message Set instead of developing its own electronic system.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the Information Collection Review Office, and it has been determined that the Privacy Act does apply to some aspects of this information collection request. The applicable System of Records Notice is 09-20-0171.

Personal identifiers (name, address, telephone number, cell number, etc.) will be collected and maintained under the Privacy Act system of records listed above. This information will be collected on importers/filers who are attempting to import certain animals and cargo into the United States and for individuals for whom an illness report is required according to 42 CFR 71.

Import related information collected from ITDS/ACE in the form of CDC PGA Message Sets, and illness and death reports from maritime and air conveyances, may be entered into a computer system, QARS, for analysis and later retrieved, if necessary. Data containing personal identifiers and source documents, e.g. Notice to Importers of Dogs, will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule. Data not containing personal identifiers will be retained indefinitely for statistical and historical documentation purposes. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

The Privacy Act is not applicable to the information being collected for CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement. While full names and some limited information of those completing the information collection request documents are requested, the primary method of retrieval would not be performed by searching for address or passport number, and individuals would be providing data primarily relating to their roles as an importer of dogs. Importers/filers will not be providing personal information on themselves, but providing information on the measures taken to prevent exposure of persons and animals during the importation and the use of adequate disease control practices. Therefore, this form does not meet the definition of a Privacy Act system of records.

10.1 Privacy Impact Assessment Information

Privacy Impact Assessment Information

1. Respondents to this data collection will be informed whether or not providing the information described in this supporting statement is mandatory or voluntary. Concerning this revision, CDC is not requiring that importers/filers use ITDS/ACE when submitting import information to CBP and CDC. CDC is providing the option to use ITDS/ACE to importers/filers who wish to use ITDS/ACE and the CDC PGA Message Sets. Use of the ITDS/ACE system is voluntary until a later date. CDC retains the authority to collect hard copies of the documentation currently required by regulation and currently approved under 0920-0134 Foreign Quarantine Regulations.

The response to the information collection is mandatory for illness reporting on air and maritime conveyances.

2. Import related data from CDC PGA Message Sets is reviewed and collected from ITDS/ACE and entered into QARS will be used to ensure that CDC regulated items are reviewed for their risk to public health prior to release. The illness reporting data is reviewed and entered into QARS to ensure records are kept with regard to the public health activities taken to mitigate the risk of infectious disease entering the United States via international travelers. Data from some imports and illness reports will become part of CDC Privacy Act System 09-20-0171, "Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71", and may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

3. Electronic media entered into QARS will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide “need to know” in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special “certified” process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

4. Parts of this data collection are subject to the Privacy Act. The existing applicable Systems of Records Notice for this revision is 09-20-0171.

11. Justification for Sensitive Questions

This information collection requests certain personally identifying information of both imports and travelers. Some personally identifying information is required in illness reports in order to identify ill travelers. This information is necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

Some questions relating to a travelers illness may be considered sensitive; however, no changes to the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35
- Medical record keeping requirements under 42 CFR 71.21
- Report by persons in isolation or surveillance 71.33
- Passenger Locator Form,
- The text or format of CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement are requested.

12. Estimates of Annualized Burden Hours and Costs

The burden imposed by this revision is based upon the estimated amount of time needed to perform each particular information submission multiplied by the number of responses to CDC. Figures are based on estimates from Quarantine Staff activity at ports of entry. The requested burden includes those information requirements currently outlined in regulation and approved by OMB, as well as the voluntary submission of electronic information via ITDS/ACE using the CDC PGA Message Sets. The total number of additional hours requested in the revision is 8313.

CDC estimates the following burden for these imports:

- CDC estimates that there will be 2,800 responses to 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37). This increased estimate is based data collected from the CDC Quarantine Station concerning the

number of confinement letter issued over the last year. Each response will take approximately 10 minutes, for a total of 467 respondent hours.

- CDC estimates that there will be 20 responses to 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review). Each response will take approximately 15 minutes each, for a total of 5 hours of respondent burden.
- CDC estimates that there will be 30,000 submissions of CDC PGA Message Set for Importing Cats and Dogs. Each submission will take approximately 15 minutes, for a total of 7,500 hours of respondent burden.
- CDC estimates that there will be 20 responses to 71.56 (a)(2) African Rodents - Request for exemption (no form, written request only). These responses will take approximately 1 hour each for a total of 20 hours of respondent burden.
- CDC estimates that there will be 60 submissions of CDC PGA Message Set for Importing African Rodents. These responses will take approximately 15 minutes per response, for a total of 15 respondent hours.
- CDC estimates that there will be 2,000 responses to the requirement for a statement of non-infectiousness. CDC estimates that each response will require approximately 5 minutes, for a total of 167 hours. This estimate includes both hard copy and electronic submission via the DIS.
- CDC estimates that there will be 2,000 submissions of CDC PGA Message Set for Importing African Rodent and All Family Viverridae Products. CDC estimates that each response will require approximately 15 minutes, for a total of 500 respondent burden hours.

There have been no changes in the estimates for requested burden under:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35 (977 hours of burden),
- Medical record keeping requirements under 42 CFR 71.21 (850 hours of burden),
- Report by persons in isolation or surveillance 71.33 (1 hour of burden),
- Passenger Locator Form (225,000 or 67 hours of burden depending on scenario; large outbreak of public health significance or limited use).

CDC is providing two estimates of the total annualized burden of this information collection request, because CDC needs the flexibility to use the PLF in a widespread manner during an outbreak of public health significance. The first total, 235,579 burden hours, is the total estimated burden to respondents per year with the use of the Passenger Locator Form used in an outbreak of public health significance. The second total, 10,579 burden hours, includes the limited use of the PLF. It is more likely that the average annual burden for reporting and recordkeeping will be the second total.

12 A. Estimates of Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	# of Respondents	# of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Maritime conveyance	71.21(a) Radio Report of death/illness -	2,000	1	2/60	67

operators	illness reports from ships (fillable PDF (individual case and cumulative report), phone, transcribed email)				
Aircraft commander or operators	71.21 (b) Death/Illness reports from aircrafts (verbal, no form)	1,700	1	2/60	57
Maritime conveyance operators	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS)	17,000	1	3/60	850
Maritime conveyance operators	71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)	17,000	1	3/60	850
Isolated or Quarantined individuals	71.33(c) Report by persons in isolation or surveillance (verbal, no form)	11	1	3/60	1
Maritime conveyance operators	71.35 Report of death/illness during stay in port (verbal, no form)	5	1	30/60	3
Aircraft commander or operators	Locator Form used in an outbreak of public health significance	2,700,000	1	5/60	225,000
Aircraft commander or operators	Locator Form used for reporting of an ill passenger(s)	800	1	5/60	67
Importer	71.51(b)(2)	2,800	1	10/60	467

	Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)				
Importer	71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)	20	1	15/60	5
Importer	71.52(d) Turtle Importation Permits (no form, just written request)	5	1	30/60	3
Importer/ Filer	CDC PGA Message Set for Importing Cats and Dogs	30,000	1	15/60	7500
Importers	71.55 Dead bodies (death certificates submitted)	5	1	1	5
Importer	71.56 (a)(2) African Rodents - Request for exemption (no form, written request only)	20	1	1	20
Importer	71.56(a)(iii) Appeal (no form, written request only)	2	1	1	2
Importer/ Filer	CDC PGA Message Set for Importing African Rodents	60	1	15/60	15
Importer	Statement or documentation of Non- infectiousness (Documented, no form; authority under 71.32(b))	2,000	1	5/60	167
Importer/ Filer	CDC PGA Message Set for	2,000	1	15/60	500

	Importing African Rodent and All Family Viverridae Products				
Total 1: PLF used in an outbreak of public health significance		2,775,428			235579
Total 2: PLF used for reporting of an ill passenger(s)		75,428			10,579

12 B. Estimates of Annualized Cost

Respondents for this information collection include airline maritime conveyance operators, importers/filers, and the general public. Average wages for each category of respondent were calculated using occupation and wage statistics from the Bureau of Labor Statistics.

- For conveyance operators (air and maritime), an average of 53-2011 Airline Pilots, Copilots, and Flight Engineers and 53-5021 Captains, Mates, and Pilots of Water Vessels is used. This yields an average of \$48.68 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: <http://www.bls.gov/oes/current/oes535021.htm>. 53-2011 Airline Pilots, Copilots, and Flight Engineers: <http://www.bls.gov/oes/current/oes532011.htm>)
- For the isolated or quarantined individuals, the general public occupational category is used. The hourly wage for this occupational category is \$22.01. (00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)
- For importers and importers/filers, the general public occupational category is used as no BLS category was available for importers/filers or a similar occupation. The average wage is \$22.01 (00-0000 All Occupations. 00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)

CDC is providing two estimates of the annualized cost of this information collection request. The first total cost, \$11,236,358, is the total estimated cost to respondents per year with the use of the Passenger Locator Form used in an outbreak of public health significance. The second total cost, \$283,358, includes the limited use of the Passenger Locator Form. It is more likely that the average annual cost for reporting and recordkeeping will be the second figure.

Types of Respondents	Form Name/CFR reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Maritime conveyance operators	71.21(a) Radio Report of death/illness - illness reports from ships (fillable PDF (individual case and cumulative report), phone, transcribed email)	67	\$48.68	\$3,262
Aircraft commander or operators	71.21 (b) Death/Illness reports from aircrafts	57	\$48.68	\$2,775
Maritime conveyance operators	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (VSP)	850	\$48.68	\$41,378
Maritime conveyance operators	71.21 (c) Recordkeeping - Medical logs	850	\$48.68	\$41,378
Isolated or Quarantined individuals	71.33(c) Report by persons in isolation or surveillance	1	\$22.01	\$22
Maritime conveyance operators	71.35 Report of death/illness during stay in port	3	\$48.68	\$146
Aircraft commander or operators	Locator Form used in an outbreak of public health significance	225,000	\$48.68	\$10,953,000
Aircraft commander or operators	Locator Form used for reporting of an ill passenger(s)	67	\$48.68	\$3,262
Importer	71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)	467	\$22.01	\$10,279
Importer	71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)	5	\$22.01	\$110
Importer/ Filer	CDC PGA Message Set for Importing Cats and Dogs	7,500	\$22.01	\$165,075
Importer	71.52(d) Turtle	3	\$22.01	\$66.03

Types of Respondents	Form Name/CFR reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	Importation Permits (no form, just written request)			
Importers	71.55 Dead bodies (death certificates submitted)	5	\$22.01	\$110.05
Importer	71.56 (a)(2) African Rodents -Request for exemption (no form, written request only)	20	\$22.01	\$440
Importer	71.56(a)(iii) Appeal (no form, written request only)	2	\$22.01	\$44.02
Importer/ Filer	CDC PGA Message Set for Importing African Rodents	15	\$22.01	\$330
Importer/ Filer	Statement of Non-infectiousness (Documented, no form; authority under 71.32(b))	167	\$22.01	\$3,676
Importer/ Filer	CDC PGA Message Set for Importing African Rodent and All Family Viverridae Products	500	\$22.01	\$11,005
	Total 1: with a disease outbreak, extensive use of PLF	235579		\$11,236,358
	Total 2: without a disease outbreak, limited use of PLF	10,579		\$283,358

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

CDC estimates the cost of reviewing hard copy information and PGA message sets on imports as a portion of annual time spent at work by individuals who specialize in CDC regulated imports. CDC uses this estimation method as not every import will come to the attention of CDC, only those which require review to determine if a public health risk exists. The personnel costs are as follows:

Staff GS Level	Average annual salary of staff	Percent of time spent on reviewing	Total Cost

	reviewing data	CDC PGA Message Set Data	
GS-13	\$71,674	100%	\$71,674
GS-9	\$41,563	50%	\$20,782
Total			\$92,456

Finally, there are system and personnel costs associated with the use and maintenance of QARS. These costs include the IT costs and associated staffing costs. These costs are as follows:

QARS System Costs	\$218,172
Staff Costs: 1xGS-12(50% base) 1xGS-9(75% base)	\$50,919
Total	\$269,091

For each report of illness in travelers covered by 42 CFR part 71, Quarantine staff collect and review the information to determine whether a public health response is necessary. Their actions are determined by the statutory and regulatory requirements for each report, and the time required to appropriately respond varies. The amount of time to respond depends on the specifics of the report, requiring action such as filing and/or data entry to conducting an investigation involving multiple staff.

CDC estimates the yearly cost for this information collection request as a function of the staff time required to provide only the initial collection and review of the information provided by the respondents, the pay level of the average CDC staff member reviewing the data, as well as the IT costs associated with the QARS system.

The total staff hours used for this estimation correlate to the total hours requested from the public to respond to the data, plus an additional 50% to account for variation in the amount of time it takes CDC to collect and review the initial information in complicated cases. This cost accounting is for routine annual activities and does not take into account the widespread use of the PLF in a public health emergency, which would increase costs beyond this estimate.

	Time in hours required to review and collect initial incoming data	Average hourly wage of staff reviewing data (GS12 base)	Total Estimated Yearly Cost
Radio, hard copy, verbal reports	$2263 + (.5 \times 2263) = 3395$	\$28.88	\$98,048

The total estimated cost to the government for this ICR is \$459,595 per year.

15. Explanation for Program Changes or Adjustments

These requested revisions are the result of the upcoming implementation of ITDS and the associated ACE software, as well as revised estimates and improvements in program administration. The changes in law and program estimates have resulted in a net increase

in the estimated number of burden hours (see Section 12 A) requested in this information collection. The total number of additional hours requested for this information collection total 8313 hours. The adjustments and program changes are as follows:

Adjustments

CDC is providing an updated estimate of the number of respondents for the CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement.

- As described in section A 12 above, the revised estimate is for 2,800 respondents per year, which results in an additional 133 burden hours per year.

CDC is also providing wholly revised instructions for the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form and Maritime Conveyance Illness or Death Investigations form. No additional burden is requested for this change, because no increase in complexity of instructions or reporting information is requested.

For both forms, the wholly revised instructions:

- Are more comprehensive in explaining the situations which trigger the use of the forms and which sections should be filled out in sequence,
- include red markings and asterisks to show which fields are required,
- include more specific instructions concerning where to send the report and how to communicate with CDC about the case or cases of illness

For the Maritime Conveyance Illness or Death Investigations form, there are clearer instructions concerning the use of PII, as well as instructions on how to clear reporting options that have been incorrectly chosen.

For the Cumulative ILI form there are instructions both for when the Maritime Conveyance Illness or Death Investigations form should be used and when gastrointestinal issues should be reported to the Vessel Sanitation Program.

Program Changes due to Statutory Requirements

CDC is requesting the following changes based on the upcoming implementation of ITDS and ACE, which allows importers/filers to voluntarily submit certain information concerning CDC-regulated imports electronically using CDC Partner Government Agency (PGA) Message Sets. These estimates of additional burden are based on operational observation by Quarantine Staff at US ports of entry as well as data included in the Quarantine Activity Reporting System (QARS). These hours are in addition to the currently approved respondent burden.

- 30,000 responses using CDC PGA Message Set data for dogs and cats, resulting in 7,500 additional requested burden hours.
- 60 responses using of CDC PGA Message Set data for importations of African Rodents, resulting in an additional 15 requested burden hours.
- 2,000 responses using of CDC PGA Message Set data for importations of African Rodent and All Family Viverridae products. This results in an additional 500 hours of requested burden.

The following change is a correction to clarify the public burden associated with providing the required statements and documentation that an animal product has been rendered non-infectious.

- 2,000 responses using of CDC PGA Message Set data for statements/documentation of non-infectiousness for imported animal products (currently African Rodent and All Family Viverridae products), resulting in an additional 167 burden hours. These responses can be accomplished via the Document Imaging System (described below). CDC retains the right to collect these in hard copy.

There have been no changes in the estimates for requested burden under:

- Air and maritime illness reporting under 42 CFR 71.21 and 71.35 (977 hours of burden),
- Medical record keeping requirements under 42 CFR 71.21 (850 hours of burden),
- Report by persons in isolation or surveillance 42 CFR 71.33 (1 hour of burden),
- Passenger Locator Form (225,000 or 67 hours of burden depending on scenario; large outbreak of public health significance or limited use).
- The number of burden hours requested for 42 CFR 71.52(d) Turtle Importation Permits (3 burden hours)
- The text or format of CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement.
- The number of burden hours requested for 42 CFR 71.55 Dead Bodies (5 burden hours)
- The number of burden hours requested for 42 CFR 71.56(a)(iii) and (c) Appeal (2 burden hours)

The estimates provided in this information collection request assume that every commercial import covered by CDC’s regulations will file a data entry using ITDS and ACE. However, CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget (OMB), because the use of ITDS/ACE and CDC PGA Message Sets will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of import-related documentation until the use of ITDS/ACE is required for cargo entering the United States.

16. Plans for Tabulation and Publication and Project Time Schedule

Data are not collected for statistical purposes, but only to meet the regulatory mandate as implemented in the foreign quarantine regulations found at 42 CFR 71.

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

Display of the expiration date is appropriate. No exemption is requested.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A1 - Section 361 Public Health Service Act (42 USC 264)

Attachment A2 - 42 Code of Federal Regulations part 71

Attachment A3 - SAFE Port Act of 2006

Attachment A4 - 6 Code of Federal Regulations part 29.8(b)

Attachment A5 - 49 Code of Federal Regulations part 1520.11(b)

Attachment B - 60 Day Federal Register Notice

Attachment C - CDC form 75.37 "NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement

Attachment D - CDC Requested Data on Regulated Imports: Domestic Dogs

Attachment E - CDC Requested Data on Regulated Imports: Domestic Cats

Attachment F - CDC Requested Data on Regulated Imports: African Rodents

Attachment G - CDC Requested Data on Regulated Imports: Products of African Rodent and All Family Viverridae

Attachment H - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form

Attachment I - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form

Attachment J - Maritime Illness and Death Reporting System