Importation Regulations (42 CFR 71 Subpart F)

(OMB Control No. 0920-XXXX)
Supporting Statement A
Request for a New Information Collection

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Contact:
Chip Daymude
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: 404.718.7103
Email: qkh7@cdc.gov

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Statement in Support of Importation Regulations (42 CFR Part 71 Subpart F)
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Goal of the project: The goal of this information collection is to facilitate a CDC public health mission as provided under the Public Health Service Act and Code of Federal Regulations. This information collection is for regulating importations of animals, human remains, and animal products.

Intended use of the resulting data: CDC uses this information to meet its statutory and regulatory responsibilities outlined in 42 CFR part 71, which are to prevent the introduction of communicable disease into the United States and its territories.

Methods to be used to collect: No statistical methods are used. The information collection is intended solely to comply with statutory and regulatory responsibilities.

The subpopulation to be studied: There are no sub-populations to be analyzed. The universe of respondents is all individuals who seek to bring animals, animal products, and human remains into the United States.

How the data will be analyzed: Data is analyzed to ensure compliance with CDC regulations and to determine if program enhancements or refocus is needed to meet the needs of public health in the United States.

This is a request for a new information collection to consolidate forms and information collections related to the importation of animals, animal products, and human remains into one information collection. This information collection was previously part of three

separate, approved information collections - 0920-1034 that expires March 31, 2022, 0920-0263 that expires September 30, 2023, and 0920-0199 that expires August 31, 2024. This information collection also includes new forms. CDC is requesting three-year approval for this new information collection.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background
Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) 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. Statute and the existing regulations governing foreign quarantine activities (42 CFR 71) 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 U.S. 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 and within the United States with a minimum of recordkeeping and reporting procedures, as well as a minimum of interference with trade and travel.

CDC regulations govern the importation of human remains as well as animals and animal products capable of causing human disease. Animals that are regulated by CDC are dogs, cats, turtles, snakes, lizards, non-human primates (NHPs), civets, African rodents, and bats. CDC controls the importation of these animals to ensure that these animals, or animal products, being imported into the United States meet CDC regulations. CDC does this through a permitting process for certain animals.

2. Purpose and Use of Information Collection

On June 16, 2021 CDC published a Federal Register Notice informing the public about a temporary suspension of dogs entering the United States from high-risk rabies countries.

The canine rabies virus variant (CRVV) was declared eliminated in the United States in 2007. The importation of just one dog infected with CRVV risks re-introduction of the virus into the United States resulting in a potential public health risk with consequent monetary cost and potential loss of human and animal life. Since 2015 there have been four known rabid dogs imported into the United States.

During the suspension period, CDC will issue permits for importers with dogs who have been in a high-risk CRVV country within the last six months and do not have a current, valid U.S.-issued rabies vaccination certificate. Only importers who are permanently relocating to the United States, are a US government employee traveling on official

orders, are an owner of a service dog that is trained to assist them with a disability, or are an individual importing dogs for science, education, exhibition, or law enforcement purposes, or people who traveled with their dog before July 31, 2021 are eligible to apply for a permit. Dogs from CRVV-free or low risk countries and dogs with valid U.S.-issued rabies vaccination certificates that are microchipped, healthy, and at least six months of age do not require a permit. The current permit application to import a dog (Attachment C) is under collection 0920-1034. If an applicant is approved, they receive a permit (Attachment L) to import their dog. When a dog or cat does arrive at an airport and is sick or dead, importers are required to notify CDC. There is no form for this collection of information.

Other animals that require a permit and are included in this information collection are NHPs, which can carry of number of diseases that can cause severe infections in people. NHPs may not be imported as pets and may only be imported for bona fide scientific, educational, or exhibition purposes, as defined in the regulations. Forms for the importation of NHP (Attachment D and Attachment E) are currently under information collection 0920-0263. We would like to move those forms into this new information collection to consolidate all forms related to the importation of animals or animal products into one collection. There is also a new form that will be required when an NHP is being transferred from one laboratory to another laboratory (Attachment G).

Another new form (Attachment F) is included in this application. This form is an application to request a permit to import a regulated animal that is neither a dog nor an NHP (e.g. turtles, African rodents, civets). It also incorporates the addition of bats, which is currently approved under OMB control number 0920-0199.

Regarding human remains, the Division of Global Migration and Quarantine works with the Division of Select Agents and Toxins (DSAT) on the importation for human remains. DGMQ requests death certificates (no form) from those wishing to import remains and then determines if the importer will need a permit, which is issued by DSAT and will remain in 0920-0199.

Lastly, people importing animal products must make a statement or provide documentation demonstrating that the animal product is not infectious (no form).

The purpose of collecting all information mentioned above is to 1) prevent the introduction and spread of infectious disease and 2) ensure that we are able to monitor, track, and stop outbreaks, should they occur, among these imported animals. This information may also be shared with state, local, and territorial public health departments for public health follow up.

3. Use of Improved Information Technology and Burden Reduction

For the importation of foreign-vaccinated dogs requiring a CDC Dog Import Permit, CDC uses an online application system. This system was implemented following the temporary suspension of the importation of dogs from high-risk rabies countries that went into effect in July 2021. Using this improved technology, greatly improved the

experience of applying and receiving a permit for dog importers. It is more streamlined than emailing the application and allows for the permit review team to review permits faster and more efficiently than when applications were emailed. CDC will continue to work on improvements to the dog permitting system to improve the experience for dog importers, which make up the vast majority of people importing animals into the United States.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is the only public health authority with regulatory responsibility specifically for the importation of animal, animal products, and human remains capable of causing human disease. CDC recognizes that other federal agency, such as the U.S. Department of Agriculture, regulate some of the same animals as CDC (e.g. dogs); however, other agencies requirements differ from CDC's requirements since CDC's requirements focus on protecting public health.

5. Impact on Small Businesses or Other Small Entities

The burdens imposed on small businesses and other entities by the information collection requirements are the minimum necessary for CDC to meet its regulatory and public health responsibilities.

6. Consequences of Collecting the Information Less Frequently

Further reduction of required and requested recordkeeping or reporting would prevent CDC from meeting it legislative mandate and regulatory responsibilities and could therefore endanger the public's health.

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

This request fully complies with the regulation 5 CFR 1320.5.

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 revision of this ICR was published in the Federal Register on January 24, 2022 (Vol. 87, No. 15, PP 3542-3544). CDC received one comment and has responded in Attachment K.

B. CDC notified registered importers of NHPs of the 60-day Federal Register Notice to allow them to comment on the proposed collection.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

There is no guarantee of confidentiality provided to respondents.

The applicable System of Records Notice (SORN) is 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71. CDC uses this notice for both people subject to the terms of the quarantine regulations. A Privacy Impact Assessment of this system is attached (Attachment I).

Personal identifiers (name, address, telephone number, cell number, etc.) will be collected and maintained under the Privacy Act system of records listed above from importers who are attempting to import regulated animals into the United States as required according to 42 CFR 71.

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. Source documents and printouts will be safeguarded by storing them in locked cabinets in locked offices when not in use or by using password protection for electronic files.

Information collected under this control number may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health concern; to law enforcement 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. 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.

Highly sensitive information is being collected and would affect the security of a respondent's personal identifying information if there were a breach of security. However, stringent safeguards are in place to ensure the security of a respondent's personal identifying information 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. Access is granted to only a limited number of CDC staff 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. 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. Finally, CDC employees who maintain records are instructed to check with the system manager prior to making disclosures of data.

Respondents to this data collection are generally aware that the information collected under this control number is required under regulation, and CDC publishes content on its website and in the Federal Register concerning these collections.

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

IRB Approval

NCEZID has reviewed the material for the Information Collection request and determined that it is Non-Research and IRB review is not required (Attachment J).

Sensitive Questions

This information collection requests certain personally identifying information of importers. As part of this information collection, CDC is not requiring or requesting the submission of any information related to criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

The burden imposed by this information collection is based upon the estimated amount of time needed to perform each information submission multiplied by the number of responses to CDC. Figures are based on estimates from activities in 2019-2021. The estimates for each information collection are as follows:

Estimated Annualized Burden (Hours)

Type of Respondents	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Dog Importers (42 CFR 71.51(c)(2),	Dog Permit Application Form (Attachment C)	60,000	1	60/60	60,000

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
(d))					
NHP Importers (42 CFR 71.53)	NHP Shipment Arrival Notification Form (Attachment D)	120	1	15/60	30
First Time NHP Importer (42 CFR 71.53)	NHP Importer Form (Attachment E)	15	1	120/60	30
Regulated Animal Importer (42 CFR 71)	Other animal import form (Attachment F)	2	1	30/60	1
Dog and Cat Importers (42 CFR 71.51(b)(3))	Record of sickness or death (no form)	43	1	60/60	43
Human Remains Importers (42 CFR 71.55, 42 CFR 71.32)	Provide death certificate (no form)	50	1	15/60	13
Importer of animal products (42 CFR 71.32)	Statement or documentation of non-infectiousness (no form)	391	1	15/60	98
NHP Importers (42 CFR 71.53)	Lab-to-Lab Form (Attachment G)	2	1	60/60	2
NHP Importers (42 CFR 71.53)	Zoo-to-Zoo Form (Attachment H)	2	1	60/60	2
Total					60,219

12 B. Estimates of Annualized Cost

Respondents for this information collection include dog owners and importers of NHPs, other animals, and human remains. There is no Bureau of Labor Statistics category for

importers/filers or a similar occupation for all but the Zoo-to-Zoo category. Therefore, we are using the general occupational category for all importers, which is a mean hourly wage of $27.07 (00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000). For the Zoo-to-Zoo form, we are using $33.80 for the mean hourly wage for Zoologists and Wildlife Biologists (www.bls.gov/oes/current/oes191023.htm).

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Dog Importers (42 CFR 71.51(c)(2), (d))	Dog Permit Application Form (Attachment C)	60,000	$27.07	$1,624,200
NHP Importers (42 CFR 71.53)	NHP Shipment Arrival Notification Form (Attachment D)	120	$27.07	$3,248
First Time NHP Importer (42 CFR 71.53)	NHP Importer Form (Attachment E)	15	$27.07	$406
Regulated Animal Importer (42 CFR 71)	Other animal import form (Attachment F)	2	$27.07	$54
Dog and Cat Importers (42 CFR 71.51(b)(3))	Record of sickness or death (no form)	43	$27.07	$1,164
Human Remains Importers (42 CFR 71.55, 42 CFR 71.32)	Provide death certificate (no form)	13	$27.07	$352
Importer of animal products (42 CFR 71.32)	Statement or documentation of non-infectiousness (no form)	98	$27.07	$2,653
NHP Importers (42 CFR 71.53)	Lab-to-Lab Form (Attachment G)	2	$27.07	$54
NHP Importers (42 CFR 71.53)	Zoo-to-Zoo Form (Attachment H)	2	$33.80	$68
Total				$1,632,199

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

For each application to import CDC-regulated animals, animal products, or human remains covered by 42 CFR part 71 (Subpart F) quarantine staff collect and review the information to determine regulatory compliance. The amount of time to review each application depends on the type of proposed importation and whether all required elements are submitted by the applicant.

The total staff time is estimated by totaling the number of applications received by CDC and multiplying it by the average time it takes to process the application. This is then multiplied by a GS13 level wage at the Atlanta locality.

	Time in hours required to review and collect initial incoming data	Average hourly wage of staff reviewing data (GS13 Atlanta locality adjustment)	Total Estimated Yearly Cost
Dog Permit Application Form (Attachment C)	60,000 reports x 0.25 hours (15 min)	$46.06	$690,900
NHP Shipment Arrival Notification Form (Attachment D)	120 x 0.2 hours (12 min)	$46.06	$1,105
NHP Importer Form (Attachment E)	15 x 2 hours (120 min)	$46.06	$1382
Other animal import form (Attachment F)	2 x 0.75 hours (45 min)	$46.06	$69
Dog/Cat Record of sickness or death (no form)	20 x 2 hours (120 min)	$46.06	$1842
Human remains death certificate (no form)	50 x 0.2 hours (12 min)	$46.06	$461
Animal Product Statement or documentation of non-infectiousness (no form)	391 x 0.2 hours (12 min)	$46.06	$3602

NHP Lab-to-Lab Form (Attachment G)	2 x 1 hour (60 min)	$46.06	$92
NHP Zoo-to-Zoo Form (Attachment H)	2 x 1 hour (60 min)	$46.06	$92
		Total	698,301

There are also CDC system and personnel costs associated with the use, development, and maintenance of QARS. These costs include the IT staffing costs and associated SME staffing costs. The QARS related costs dedicated only to animal importations cannot be separated from the total QARS system costs; therefore, the total QARS costs are presented here. These costs are as follows:

QARS System Costs	$190,000
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	$140,375
Total	$330,375

The total estimated cost to the government for this ICR is approximately $1,028,676 per year.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

All forms included in this package will be implemented upon approval of this information collection. This project has no end date, though forms may be changed in the future

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

The display of the expiration data is not inappropriate. CDC requests no exemption.

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 B - 30 Day Federal Register Notice

Attachment C –Dog Permit Form

Attachment D- NHP Shipment Arrival Notification Form

Attachment E – NHP Importer Form

Attachment F – Other Animal Import Form

Attachment G – Lab-to-Lab Form

Attachment H – Zoo-to-Zoo Form

Attachment I - Privacy Impact Assessment

Attachment J – IRB Determination

Attachment K – 60-day FRN Comment

Attachment L – Dog Import Permit