

Importation Regulations (42 CFR 71 Subpart F)

(OMB Control No. 0920-1383)

Supporting Statement A

Request for a Revision of an Existing Information Collection

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Contact:

Rudith Vice

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: nhr9@cdc.gov

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Importation Regulations (42 CFR 71 Subpart F)

Statement in Support of Importation Regulations (42 CFR Part 71 Subpart F)

(OMB Control No. 0920-1383)

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 (CFR). 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 Subpart F, 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 to revise an existing information collection (OMB Co. No 0920-1383) related to the importation of animals, animal products, and human remains. This revised

information collection includes both new forms and updates to existing forms. CDC is requesting three-year approval for this revision.

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) (Attachment 1) 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 CDC port health protection 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 CDC port health protection officers and other CDC staff when indicated. These practices and procedures ensure protection against the introduction and spread of communicable diseases into and within the United States.

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, 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 do not spread disease into the United States.

2. Purpose and Use of Information Collection

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

In July 2021, CDC issued a temporary suspension of dogs entering the United States from countries at high-risk for DMRVV (DMRVV high-risk countries). The suspension was modified in June 2022 and was extended on July 10, 2023 through July 31, 2024 due to the continued risk of the reintroduction of rabies into the United States by dogs from DMRVV high-risk countries that are unvaccinated or inadequately vaccinated for rabies (Attachment 25). During the temporary suspension, CDC continues to require that importers of dogs from DMRVV high-risk countries must have either a valid *CDC Rabies Vaccination and Microchip Record* form (Attachment 7) and continues to issue *CDC Dog Import Permits* for importers with foreign-vaccinated dogs. To receive a permit, importers must complete the *Application for Special Exemption for a Permitted Dog Import* (Attachment 5).

Using lessons learned from the temporary suspension, CDC published a Notice of Proposed Rulemaking (Attachment 24) on July 10, 2023 with proposals to update the requirements for dog and cat importation (42 CFR 71.50 and 71.51). On May 13, 2024, CDC published a Final Rule (Attachment 2) updating the requirements for dogs and cats importation under 42 CFR 71.50 and 71.51.

Through the Final Rule, HHS/CDC seeks to prevent the reintroduction and spread of DMRVV in the United States. The requirements in the Final Rule will prevent and deter the importation of dogs with falsified or fraudulent rabies vaccine documentation. In 2020, CDC observed a 52 percent increase in the number of dogs that were ineligible for admission due to falsified or fraudulent documentation, as compared to 2018 and 2019 (450 dogs compared to the previous baseline of 300 dogs per year). This troubling trend continued in 2021, with an additional 24 percent increase of dogs ineligible for admission in just the first half of the year, compared to the full 2020 calendar year (January-December) (approximately 560 dogs with falsified or fraudulent documentation).

In this Final Rule, HHS/CDC requires that forms be endorsed by exporting government officials, making it harder for importers to falsify records. The Final Rule also aligns U.S. import requirements for dogs with the importation requirements of other DMRVV-free countries by requiring proof of rabies vaccination for all dogs from DMRVV high-risk countries and adequate serologic test results from a CDC-approved laboratory for foreign-vaccinated dogs from DMRVV high-risk countries. The Final Rule requires that all dogs have a microchip and be at least six months of age, and it requires that all importers submit a *CDC Dog Import Form* (Attachment 6). Additionally, the Final Rules includes requirements for airlines to confirm documentation, provide safe housing for animals, and assist public health officials in determining the cause illness or death for animals that arrive ill or dead. The revision to this information collection includes forms and collections necessary for the implementation of this updated regulation.

In this revision, CDC is also making minor updates to forms related to the importation of nonhuman primates (NHP). NHPs may carry infectious diseases that are dangerous and sometimes fatal to humans. These infections include those caused by *Shigella*, *Salmonella*, Ebola virus, herpes B virus, *Mycobacterium tuberculosis* complex (bacteria that cause tuberculosis, or TB), yellow fever virus, and many others. Due to the risk NHP importation poses to public health, CDC has requirements found in 42 CFR 71.53 for the importation of NHP. This regulation includes requirements that necessitate the collection of information from NHP importers to ensure the protection of the public's health.

3. Use of Improved Information Technology and Burden Reduction

CDC will be using a free, online form for the *CDC Dog Import Form* (Attachment 6). Upon successfully completing the form, importers will automatically receive a receipt that they must present to their airline prior to boarding and to government officials upon arrival in the United States. They may either present the receipt as a hard copy or digital copy from a phone or other electronic device. Utilizing this system will make for a fast and easy process for importers to submit their information, while allowing CDC to collect vital information about dog importations that is not currently being tracked by any federal

agency.

CDC is also utilizing the U.S. Department of Agriculture's (USDA) Veterinary Export Health Certification System (VEHCS) for importers of U.S.-vaccinated dogs. U.S. veterinarians will use this system to complete the *Certification of U.S.-Issued Rabies Vaccination* form (Attachment 10). By employing this system for the completion of the form, CDC is reducing costs by not creating a duplicate system. This approach also streamlines the process since U.S. veterinarians are already familiar with VEHCS, making this approach the easiest method for both veterinarians and for the endorsement of the form by USDA.

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 USDA, 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 its 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 information collection request was published in the Federal Register on July 10, 2023 (Vol. 88, No. 130, PP 43978-44029). CDC received 2,106 comments with one comment that included 118,312 signatures. CDC has responded to the comments in Attachment 2.

B. CDC notified public health and animal health partners as well as dog rescue organizations of the publication of the NPRM and 60-day Federal Register Notice to allow them to comment.

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.

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 3). There are no changes to the privacy aspects of this package.

Personal identifiers (name, address, telephone number, cell number, etc.) will be collected and maintained under the SORN listed above from importers who are attempting to import regulated animals into the United States and from operators and staff of ACF.

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.

There is no guarantee of confidentiality provided to respondents. 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.

Data will be kept private to the extent allowed by law.

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 4).

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. Since no federal agencies collect information on all dog importations, the figures below are estimates based on U.S. Customs and Border Protection (CBP) data for dogs that were imported as cargo. CBP tracks those importations through the air waybills that are created when dogs are imported as cargo; however, CBP does not track dogs that arrive as hand-carried or checked-baggage. CDC also considered the number of *CDC Dog Import Permits* that have been issued during the temporary suspension to calculate these estimates, though, those estimates only capture imports of foreign-vaccinated dogs from DMRVV high-risk countries whose importers have rabies serologic titer results. Therefore, there is considerable uncertainty in these estimates, which 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
Importers of Foreign-Vaccinated Dogs from DMRVV high-risk countries	Application for Special Exemption for a Permitted Dog Import (Attachment 5)	15,000	1	60/60	15,000
Veterinarians of Foreign-Vaccinated Dogs from DMRVV high-risk countries	CDC Rabies Vaccination and Microchip Record (Attachment 7)	15,000	1	15/60	3,750
Veterinarians of U.S. Vaccinated Dogs from DMRVV high-risk countries	U.S. rabies vaccination certificate (no form)	3,000	1	15/60	750
All Dog Importers	CDC Dog Import Form (Attachment 6)	750,000	1	7/60	87,500
Veterinarians of Dogs from DMRVV-free and low-risk countries and Official Government Veterinarians in Exporting Country of Dogs from DMRVV-free or low-risk countries	Certification of Dog Arriving from DMRVV-free or Low-risk Country (Attachment 8)	1,382,000	1	15/60	345,500
Veterinarians of Foreign-Vaccinated	Certification of Foreign Rabies Vaccination and	52,000	1	15/60	13,000

Dogs and Government Veterinarians in Exporting Country of Foreign-Vaccinated Dogs	Microchip (Attachment 9)				
USDA-accredited veterinarians	Certification of U.S.-Issued Rabies Vaccination (Attachment 10)	33,000	1	30/60	16,500
Importers of foreign-vaccinated dogs from high-risk countries	Titer results from CDC-approved laboratory (no form)	25,000	1	60/60	25,000
Air Carriers Transporting Dogs into the U.S.	CDC Airline Job Aid for Dogs Imported as Cargo (Attachment 15)	223	224	5/60	4,163
Air Carriers Transporting Dogs into the U.S.	CDC Airline Job Aid for Dogs Imported as Hand-Carried or Checked Baggage (Attachment 16)	223	1,121	5/60	20,832
Air Carriers	Technical Instructions for Air Carriers that are Unable to Create Air Waybills (Attachment 17)	10	1	120/60	20
Animal Care Facility Applicant	Application to Operate as a CDC-registered Animal Care Facility (Attachment 11)	10	1	120/60	20
Animal Care Facility Applicant	Rules of Behavior Agreement for	10	1	5/60	1

	Access to the Centers for Disease Control and Prevention Division of Global Migration and Quarantine System for Animal Care Facility Electronic Tracking of Quarantine (SAFE TRaQ) (Attachment 12)				
Animal Care Facility Applicant	Standard Operating Procedures for SAFE TRaQ use by CDC-Registered Animal Care Facilities Participating in Public Health Evaluations of Imported Animals (Attachment 13)	10	1	10/60	2
Animal Care Facility Applicant	Technical Instructions for CDC-registered Animal Care Facilities (ACF) (Attachment 14)	10	1	10/60	2
NHP Importer Applicant	Application for Registration as an Importer of Nonhuman Primates (Attachment 18)	5	1	30/60	3
NHP Importer	CDC Notification of Proposed Nonhuman Primate (NHP) Importation to the United States	25	6	15/60	38

	(Attachment 19)				
NHP Importer Applicant	Registration Form for NHP Importation Part 2 - Full Quarantine Standard Operating Procedures (Attachment 20)	25	1	120/60	50
NHP Importer Applicant	Registration Form for NHP Importation Part 2 – Lab-to-Lab Standard Operating Procedures (Attachment 21)	5	1	120/60	10
NHP Importer Applicant	Registration Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures (Attachment 22)	10	1	120/60	20
Importers of Turtles, Civets, African Rodents, and Bats	Request to Import CDC-Regulated Animals (Attachment 23)	15	1	15/60	4
Dog and Cat Importers	Record of sickness or death (no form)	50	1	30/60	25
Human Remains Importers	Provide death certificate (no form)	50	1	15/60	13
Importer of Animal Products	Statement or documentation of non-infectiousness (no form)	5,000	1	15/60	1,250

				Total	533,453
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Estimates of Annualized Cost

Respondents for this information collection include dog owners, dog sellers, dog rescue organizations, veterinarians, air carrier employees, and importers of NHPs, other animals, and human remains. There is no Bureau of Labor Statistics category for dog owners, dog sellers, dog rescue organizations, or importers of other animals or human remains.

Therefore, we are using the general occupational category for these importers, which is a mean hourly wage of \$29.76 (00-0000 All Occupations:

http://www.bls.gov/oes/current/oes_nat.htm#00-0000) with the exception for the form that is specifically used by zoos (*Registration Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures*). For this form, we are using \$34.91 for the mean hourly wage for Zoologists and Wildlife Biologists (www.bls.gov/oes/current/oes191023.htm).

For veterinarians, we are used the general occupational category for veterinarians (<https://www.bls.gov/oes/current/oes291131.htm>), which has a mean hourly wage of \$62.07.

For animal care facility workers, we are using the general occupational category for animal caretakers (<https://www.bls.gov/oes/current/oes392021.htm>), which has a mean hourly wage of \$15.46.

For airline, we use are using the general occupational category for aircraft cargo handling supervisors (<http://www.bls.gov/oes/current/oes531041.htm>), which has a mean hourly wage of \$29.40.

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Importers of Foreign-Vaccinated Dogs from DMRVV high-risk countries	Application for Special Exemption for a Permitted Dog Import (Attachment 5)	15,000	\$29.76	\$446,400
Veterinarians of Foreign-Vaccinated Dogs from DMRVV high-risk countries	CDC Rabies Vaccination and Microchip Record (Attachment 7)	3,750	\$62.07	\$232,763
Veterinarians of U.S.	U.S. rabies vaccination	750	\$62.07	\$46,553

Vaccinated Dogs from DMRVV high-risk countries	certificate (no form)			
All Dog Importers	CDC Dog Import Form (Attachment 6)	87,500	\$29.76	\$2,604,000
Veterinarians of Dogs from DMRVV-free and low-risk countries and Official Government Veterinarians in Exporting Country of Dogs from DMRVV-free or low-risk countries	Certification of Dog Arriving from DMRVV-free or Low-risk Country (Attachment 8)	345,500	\$62.07	\$21,445,185
Veterinarians of Foreign-Vaccinated Dogs and Official Government Veterinarians in Exporting Country of Foreign-Vaccinated Dogs	Certification of Foreign Rabies Vaccination and Microchip (Attachment 9)	13,000	\$62.07	\$806,910
USDA-accredited veterinarians	Certification of U.S.-Issued Rabies Vaccination (Attachment 10)	16,500	\$62.07	\$1,024,155
Importers of foreign-vaccinated dogs from high-risk countries	Titer results from CDC-approved laboratory (no form)	25,000	\$29.76	\$744,000

Air Carriers Transporting Dogs into the U.S.	CDC Airline Job Aid for Dogs Imported as Cargo (Attachment 15)	4,163	\$29.40	\$122,392
Air Carriers Transporting Dogs into the U.S.	CDC Airline Job Aid for Dogs Imported as Hand-Carried or Checked Baggage (Attachment 16)	20,382	\$29.40	\$599,231
Air Carriers	Technical Instructions for Air Carriers that are Unable to Create Air Waybills (Attachment 17)	20	\$29.40	\$588
Animal Care Facility Applicant	Application to Operate as a CDC-registered Animal Care Facility (Attachment 11)	20	\$15.46	\$309
Animal Care Facility Applicant	Rules of Behavior Agreement for Access to the Centers for Disease Control and Prevention Division of Global Migration Health System for Animal Care Facility Electronic Tracking of Quarantine (SAFE TRaQ) (Attachment 12)	1	\$15.46	\$15
Animal Care Facility Applicant	Standard Operating Procedures for SAFE TRaQ use by CDC-	2	\$15.46	\$31

	Registered Animal Care Facilities Participating in Public Health Evaluations of Imported Animals (Attachment 13)			
Animal Care Facility Applicant	Technical Instructions for CDC-registered Animal Care Facilities (ACF) (Attachment 14)	2	\$15.46	\$31
NHP Importer Applicant	Application for Registration as an Importer of Nonhuman Primates (Attachment 18)	3	\$29.76	\$89
NHP Importer	CDC Notification of Proposed Nonhuman Primate (NHP) Importation to the United States (Attachment 19)	38	\$29.76	\$1,131
NHP Importer Applicant	Registration Form for NHP Importation Part 2 - Full Quarantine Standard Operating Procedures (Attachment 20)	50	\$29.76	\$1,488
NHP Importer Applicant	Registration Form for NHP Importation Part 2 – Lab-to-Lab Standard Operating Procedures (Attachment 21)	10	\$29.76	\$298
NHP Importer	Registration	20	\$34.91	\$698

Applicant	Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures (Attachment 22)			
Importers of Turtles, Civets, African Rodents, and Bats	Request to Import CDC-Regulated Animals (Attachment 23)	4	\$29.76	\$119
Dog and Cat Importers	Record of sickness or death (no form)	25	\$29.76	\$744
Human Remains Importers	Provide death certificate (no form)	13	\$29.76	\$387
Importer of Animal Products	Statement or documentation of non-infectiousness (no form)	1,250	\$29.76	\$37,200
Total				\$28,114,717

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

The table below first calculates the cost to CDC to review permits through the end of the temporary suspension on July 31, 2024 as well as the time required to review other dog importation forms and documents, CDC-regulated animals, animal products, or human remains covered by 42 CFR part 71 (Subpart F). This work is being conducted by CDC veterinary medical officers and quarantine staff at the GS-13 level. While some of this work will be done by staff at different locations (i.e., different ports of entry), we have used Atlanta Metropolitan Area locality pay since that is the locality for the majority of staff doing this work.

For the *Certification of U.S.-Issued Rabies Vaccination* form, those will be reviewed and endorsed by USDA official veterinarians. They are at the GS-13 level and are located throughout the United States; therefore, we used the general pay base to calculate that cost.

Form name/information collection	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
Application for Special Exemption for a Permitted Dog Import (Attachment 5)	15,000 x 0.25 hours (15 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$196,350
Certification of U.S.-Issued Rabies Vaccination (Attachment 10)	33,000 x 0.5 hours (30 minutes)	\$42.41 (GS13 general pay base)	\$699,765
Technical Instructions for Air Carriers that are Unable to Create Air Waybills (Attachment 14)	10 x 1 hour (60 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$524
Application to Operate as a CDC-registered Animal Care Facility (Attachment 11)	10 x 1 hour (60 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$524
Rules of Behavior Agreement for Access to the Centers for Disease Control and Prevention Division of Global Migration Health System for Animal Care Facility Electronic Tracking of Quarantine (SAFE TRaQ)	10 x 0.08 hours (5 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$44

(Attachment 12)			
Standard Operating Procedures for SAFE TRaQ use by CDC-Registered Animal Care Facilities Participating in Public Health Evaluations of Imported Animals (Attachment 13)	10 x 0.08 hours (5 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$44
Technical Instructions for CDC-registered Animal Care Facilities (ACF) (15)	10 x 0.08 hours (5 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$44
Application for Registration as an Importer of Nonhuman Primates (Attachment 18)	5 x 1 hour (60 min)	\$52.36 (GS13 Atlanta locality adjustment)	\$262
CDC Notification of Proposed Nonhuman Primate (NHP) Importation to the United States (Attachment 19)	150 x 0.25 hours (15 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$1964
Registration Form for NHP Importation Part 2 - Full Quarantine Standard Operating Procedures (Attachment 20)	25 x 1 hour (60 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$1,309
Registration Form for NHP Importation Part 2 – Lab-to-Lab Standard Operating Procedures	5 x 1 hour (60 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$262

(Attachment 21)			
Registration Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures (Attachment 22)	10 x 1 hour (60 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$524
Request to Import CDC-Regulated Animals (Attachment 23)	15 x 0.15 hours (15 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$196
Record of sickness or death (no form)	50 x 0.5 hours (30 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$1,309
Provide death certificate (no form)	50 x 0.25 hours (15 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$655
Statement or documentation of non-infectiousness (no form)	5,000 x 0.25 hours (15 minutes)	\$52.36 (GS13 Atlanta locality adjustment)	\$65,450
		Total	\$1,463,776

There are also two CDC systems used for this information collection – SAFE TRaQ and the Port Health Activity Reporting System (PHARS). Annual costs for routine maintenance and development of PHARS are approximately \$200,000. Initial costs for the development of SAFE TRaQ are approximately \$1,000,000 with less costs to maintain the system in the future. These costs include the IT staffing costs and associated SME staffing costs. The PHARS related costs dedicated only to animal importations cannot be separated from the total PHARS system costs; therefore, the total PHARS costs are presented here. These costs are as follows:

SAFE TRaQ	\$1,000,000
PHARS System Costs	\$200,000
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	\$139,424
Total	\$1,339,424

The total estimated cost to the government for this ICR is approximately \$2,803,200.

15. Explanation for Program Changes or Adjustments

This is a revision of an existing information collection (OMB Co. No. 0920-1383).

In July 2021, CDC issued a temporary suspension of dogs entering the United States from countries at high-risk for DMRVV (DMRVV high-risk countries). The suspension was modified in June 2022 and has been extended through July 31, 2024. Importers of dogs from DMRVV high-risk countries must have either a valid *CDC Rabies Vaccination and Microchip Record* form (Attachment 7) or a valid, U.S.-issued rabies vaccination certificate. The *CDC Rabies Vaccination and Microchip Record* form may be used by importers of U.S. dogs as their valid U.S.-issued rabies vaccination certificate if it is completed by their U.S. veterinarian. If they do not use that form, they must provide the following information: owner name and address; dog's microchip number, breed, sex, date of birth (approximate age if date of birth unknown), color, and markings; vaccine product name, manufacturer, lot number, and product expiration date; date of rabies vaccination; date the vaccination expires; name, license number or official seal, address, telephone or email address, date, and signature of veterinarian who administered the vaccine. CDC is not amending the previously approved *CDC Rabies Vaccination and Microchip Record* form at this time nor the information required for a U.S.-issued rabies vaccine certificate; however, CDC will only use and require the *CDC Rabies Vaccination and Microchip Record* form and will only require a U.S. rabies vaccination certificate through July 31, 2024.

During the temporary suspension, CDC is issuing *CDC Dog Import Permits* for importers with dogs who have been in a high-risk country within the last six months and do not have a current, valid U.S.-issued rabies vaccination certificate. To receive a permit, importers must complete the *Application for Special Exemption for a Permitted Dog Import* (Attachment 5). CDC will continue to use this form to issue *CDC Dog Import Permits* through the end of the temporary suspension on July 31, 2024. Following the temporary suspension, CDC will only use this form for importers who would like to request a permit to import a dog from a DMRVV-restricted country. DMRVV-restricted countries are countries that have repeatedly exported rabid dogs to any country or that lack adequate controls to monitor and prevent the export of dogs to the United States with falsified or fraudulent rabies vaccine credentials, invalid rabies vaccination forms, or other fraudulent, inaccurate, or invalid exportation/importation documents. CDC will maintain a list of DMRVV-restricted countries on its website. It is not including any countries on the DMRVV-restricted list at the time of this publication. Therefore, CDC does not anticipate using this form in 2024 after July 31, 2024, but CDC may do so in the future if countries are added to the DMRVV-restricted list.

Using lessons learned from the temporary suspension, CDC published a Notice of Proposed Rulemaking (Attachment 24) in July 2023 with proposals to update the requirements for dog and cat importation. On May 13, 2024, CDC published a Final Rule (Attachment 2) updating importation requirements for dogs and cats found under 42 CFR 71.50 and 71.51.

CDC amended the requirements for dog importation in the Final Rule to require that all dogs be at least six months old and microchipped. CDC continues to require that dogs be healthy upon arrival to be cleared for entry. All importers must now complete a new form titled *CDC Dog Import Form* (Attachment 6). Additional requirements are dependent on

whether the dog has been in a DMRVV high-risk country within six months of arrival in the United States.

Importers of dogs from DMRVV high-risk countries must have either a valid *Certification of U.S.-Issued Rabies Vaccination* form (Attachment 10) or a valid *Certification of Foreign Rabies Vaccination and Microchip* form (Attachment 9). Those with a *Certification of Foreign Rabies Vaccination and Microchip* form must have it completed and signed by their veterinarian and endorsed by an official veterinarian of the exporting country. They must also have a reservation with an ACF for their dog to be examined and revaccinated for rabies upon arrival. These importers must provide rabies serologic titer results from a CDC-approved laboratory, or their dog is required to quarantine for 28 days.

For importers of U.S.-vaccinated dogs from DMRVV high-risk countries, they must have a valid *Certification of U.S.-Issued Rabies Vaccination* form that is completed by their USDA-accredited veterinarian and endorsed by then endorsed by a USDA official veterinarian. If they do not, they must meet the requirements for foreign-vaccinated dogs.

For importers of dogs from DMRVV-free or low-risk countries, they may provide any of the following forms for their dog to be admissible for entry into the United States:

- A valid *Certification of Foreign Rabies Vaccination and Microchip* form completed in a DMRVV rabies-free or DMRVV low-risk country.
- A valid *Certification of U.S.-Issued Rabies Vaccination* form.
- A valid USDA export certificate.
 - The export certificate must be for the country where the dog's return itinerary originated.
- A foreign export certificate from a DMRVV rabies-free or DMRVV low-risk country stating the dog is six months old and listing the microchip number.
 - The export certificate must be certified by an official veterinarian in the exporting country.
 - Foreign veterinary records (such as the EU pet passport) or proof of veterinary payment for services completed in a DMRVV rabies-free or DMRVV low-risk country at least six months prior to traveling to the United States must accompany the export certificate.
 - All documents must be for the country where the dog's return itinerary originated.
- A *Certification of dog arriving from DMRVV-free or DMRVV low-risk country into the United States* form (Attachment 8).
 - Accompanying foreign veterinary records or proof of veterinary payment for services completed in a DMRVV rabies-free or DMRVV low-risk country at least six months prior to traveling to the United States.
 - All documents must be from the same country where the dog's itinerary originated.

Importers of foreign-vaccinated dogs from DMRVV high-risk countries must have their dog examined and revaccinated upon arrival at an ACF in order for their dog to be cleared for entry. ACF are privately run businesses that register with CDC. To register as an ACF, a business must complete the following forms:

- *Application to Operate as a CDC registered Animal Care Facility (Attachment 11)*
- *Rules of Behavior Agreement for Access to CDC DGMH SAFE TRaQ (Attachment 12)*
- *Standard Operating Procedures for SAFE TraQ data use by CDC Registered Animal Care Facilities (Attachment 13)*
- *Technical Instructions for CDC registered Animal Care Facilities (ACF) (Attachment 14)*

Requiring facilities to complete these forms helps ensure that they understand the role of ACFs and the requirements that they must adhere to in order to maintain their registration with CDC.

This revised information collection request also includes three collections of information from air carriers. The first two are forms titled *CDC Airline Job Aid for Dogs Imported as Cargo* (Attachment 15) and the *CDC Airline Job Aid for Dogs Imported as Hand-Carried or Checked Baggage* (Attachment 16). These forms are not required in the Final Rule but are forms that CDC recommends air carriers use at specific ports of entry. Both forms will aid air carriers in the clearance of dogs that arrive into the United States on their airline because they provide a quick snapshot of the requirements dogs must meet to be admitted into the United States. The third collection of information is for air carriers that are unable to create air waybills for dogs transported on their flights to the United States. The Final Rule requires that an air waybill be created for each dog arriving into the United States. This collection of information allows air carriers who cannot create air waybills to apply for a waiver from CDC by submitting specific information (e.g., how an air carrier will handle a dog that is ill, injured, abandoned, or placed on-hold pending an admissibility determination) to CDC. The information that air carriers must submit to CDC to receive a waiver is outlined in the *Technical Instruction for Air Carriers that are Unable to Create Air Waybills* (Attachment 17).

Other animals 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. CDC is making minor, non-substantive changes to five, previously approved forms associated with NHP importation:

- *Application for Registration as an Importer of Nonhuman Primates (Attachment 18)*
- *CDC Notification of Proposed Nonhuman Primate (NHP) Importation to the United States (Attachment 19)*

- *Registration Form for NHP Importation Part 2 – Full Quarantine Standard Operating Procedures (Attachment 20)*
- *Registration Form for NHP Importation Part 2 – Lab-to-Lab Standard Operating Procedures (Attachment 21)*
- *Registration Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures (Attachment 22)*

16. Plans for Tabulation and Publication and Project Time Schedule

CDC's Final Rule updating the dog and cat regulation (42 CFR 71.51) goes into effect on August 1, 2024; however, all forms included in this package will be implemented upon approval of this information collection. CDC is making forms that will not be required until August 1, 2024 available to the public upon publication of this package because CDC understands importers need to prepare for the new requirements. Making the forms available in advance of when they will be required gives importers time to obtain the signatures and endorsements required for entry on August 1, 2024. 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 on all but one form/collection of information in this revision. The *Certification of U.S.-issued Rabies Vaccination* (Attachment 10) is an online form contained within USDA's VEHCS system. USDA uses VEHCS for the importation of multiple animals. The system lists multiple OMB control numbers for the multiple information collections that use VEHCS. It includes the OMB control number for this information collection (0920-1383); however, it does not list the expiration dates for each collection.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment 1 – Section 361 Public Health Service Act (42 USC 264)

Attachment 2 – Final Rule

Attachment 3 - Privacy Impact Assessment

Attachment 4 – IRB Determination

Attachment 5 – Application for Special Exemption for a Permitted Dog Import

Attachment 6 - CDC Dog Import Form

Attachment 7 - CDC Rabies Vaccination and Microchip Record

Attachment 8 - Certification of Dog Arriving from DMRVV-free or Low-risk Country

Attachment 9 - Certification of Foreign Rabies Vaccination and Microchip

Attachment 10 - Certification of U.S.-issued Rabies Vaccination

Attachment 11 - Application to Operate as a CDC registered Animal Care Facility

Attachment 12 - Rules of Behavior Agreement for Access to CDC DGMH SAFE TRaQ

Attachment 13 - Standard Operating Procedures for SAFE TraQ data use by CDC
Registered Animal Care Facilities

Attachment 14 - Technical Instructions for CDC registered Animal Care Facilities (ACF)

Attachment 15 - CDC Airline Job Aid for Dogs Imported as Cargo

Attachment 16 - CDC Airline Job Aid for Dogs Imported as Hand-Carried or Checked
Baggage

Attachment 17 - Technical Instructions for Air Carriers that are Unable to Create Air
Waybills

Attachment 18 - Application for Registration as an Importer of Nonhuman Primates

Attachment 19 - CDC Notification of Proposed Nonhuman Primate (NHP) Importation to
the United States

Attachment 20 - Registration Form for NHP Importation Part 2 – Full Quarantine
Standard Operating Procedures

Attachment 21 - Registration Form for NHP Importation Part 2 – Lab-to-Lab Standard
Operating Procedures

Attachment 22 - Registration Form for NHP Importation Part 2 – Zoo-to-Zoo Standard Operating Procedures

Attachment 23 - Request to Import CDC-Regulated Animals

Attachment 24 – Control of Communicable Diseases; Foreign Quarantine: Importation of Dogs and Cats

Attachment 25 - Extension of Temporary Suspension of Dogs Entering the United States From Countries With a High Risk of Rabies