



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-0199; Docket No. CDC-2024-0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Import Permit. The goal of the information collection is to support the Public Health Service (PHS) Act and prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2024-0008 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Import Permit Applications (42 CFR 71.54) (OMB Control No. 0920-0199, Exp. 8/31/2024) - Revision - Office of Readiness and Response (ORR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F—Importations—contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC. The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. Based on questions we have received from prior applicants, CDC is proposing to reduce open text

questions and replace them with more streamlined check boxes. The goal is that this will clarify what is being asked of applicants and will increase efficiency and speed of processing by reducing back and forth communication necessary to clarify to applicants.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC does not plan to revise this application.

The Application for Permit to Import Infectious Human Remains into the United States is used by facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. This form will request applicant and sender contact information; facility processing human remains; cause of death; biosafety and containment information; and final destination(s) of imported infectious human remains. CDC does not plan to revise this application.

The Importer Certification Statement is a new form and will be used as an attestation by an importer stating that they are importing only noninfectious biological agent(s) or biological substance(s). The noninfectious, imported agent or substance must be accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent or has been rendered noninfectious. This form requests a detailed description of the material, statements affirming that the material is not known or suspected to contain an infectious biological agent, and one of the following: 1) How the person knows that the material does not contain an infectious biological agent; 2) Why there is no reason to suspect that the material contains an infectious biological agent; or 3) A detailed description of how the material was rendered noninfectious.

Annualized burden hours were calculated based on data obtained from CDC import permit database on the number of permits issued on annual basis since 2015, which is 2,000 respondents. The total estimated burden for the data collection is 2,097. There is an increase in burden from 1,097 hours to 2,097 hours which reflects the new, proposed form (Importer Certification Statement), to this project.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors.	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States.	2,000	1	30/60	1000
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors.	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States Subsequent Transfer.	380	1	10/60	63
Applicants Requesting to Import Live Bats.	Application for a Permit to Import Live Bats.	3	1	20/60	1
Applicants Requesting to Import Infectious Human	Application for Permit to Import Infectious Human	100	1	20/60	33

Remains into the United States.	Remains into the United States.				
Importers of Non-infectious Materials to the United States	Importer Certification Statement	2000	1	30/60	1000
Total					2097

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Lead,

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