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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Electronic Filing of Certain Import Data into the Document Image System through the Automated Commercial Environment

AGENCY: Centers for Disease Control and Prevention,
Department of Health and Human Services

ACTION: Notice

SUMMARY: Through publication of this notice, the Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces a new policy and guidance for the electronic submission of data related to the importation of CDC-regulated items in the International Trade Data System (ITDS). Certain data, forms, and documents required to be submitted to HHS/CDC will be submitted through the U.S. Customs and Border Protection (CBP)'s Automated Commercial Environment (ACE) system, using the Document Image System (DIS). This electronic process will replace certain paper-based processes in keeping with Federal policy and improve operations to further assist HHS/CDC's mission to protect public health.

DATES: This action is effective December 30, 2016.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice: Ashley A. Marrone, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., MS-E03, Atlanta, GA 30329. For information regarding CDC operations related to this Notice: Kendra Stauffer, D.V.M., Division of Global Migration and Quarantine, Quarantine and Border Health Services Branch, Importations and Animal Contact Team, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., MS-E28, Atlanta, GA 30345. Either may also be reached by telephone 404-498-1600 or email CDCAntimalImports@cdc.gov.

SUPPLEMENTARY INFORMATION

I. Background

On February 19, 2014, the President signed Executive Order 13659, Streamlining the Export/Import Process for America's Businesses (79 FR 10655), that requires the completion and government-wide utilization by December 31, 2016 of the International Trade Data System (ITDS) and

establishes a two-tiered governance process to oversee its implementation. Once fully implemented, ITDS, through the Automated Commercial Environment (ACE), will allow importers to submit the data required by U.S. Customs and Border Protection and its Partner Government Agencies (PGAs) relating to the import or export of cargo through a "single window" concept. CBP has developed ACE as the single window for the trade community to transmit electronically all required cargo-related information.

This notice announces HHS/CDC's updated policy concerning the electronic transmission of HHS/CDC permits, forms, and documents using CBP's Document Image System (DIS). This DIS capability will satisfy the HHS/CDC data and electronic document requirements for any entry filed electronically in ACE and enable the trade community to have a CBP-managed single window for the electronic submission of data and documents required by HHS/CDC during the cargo importation and review process. The list of PGA forms and documents, including documents required by HHS/CDC, which may be transmitted using DIS may be found at <http://www.cbp.gov/trade/ace/features> under the DIS tab by clicking on the "ACE PGA Forms List" hyperlink in the "References" column. The HHS/CDC permits, forms, and

documents listed in the ACE PGA Forms List are those eligible to be transmitted using DIS.

II. Current HHS/CDC Paper-based Procedures

Under current applicable HHS/CDC policy and operations, the importation of HHS/CDC-regulated commodities into the customs territory of the United States typically requires the submission of one or more of the following documents:

- (1) Animal and Plant Health Inspection Service (APHIS)/CDC Form 2 - Request to Transfer Select Agents and Toxins (42 CFR 73);
- (2) CDC Form 0.0728 - Permit to Import or Transfer Etiologic Agents or Vectors of Human Disease (42 CFR 71.54);
- (3) Rabies Vaccination Certificate (42 CFR 71.51);
- (4) CDC Approval of Confinement Agreement Issuance Letter (42 CFR 71.51);
- (5) CDC Permission Letter - Permit to Import African Rodents, Civets, or Turtles (42 CFR 71.56, 42 CFR 71.32(b), 42 CFR 71.52);
- (6) CDC Nonhuman Primate Notification Message - Confirmation from CDC to the importer that CDC has given

permission to import the nonhuman primate shipment (42 CFR 71.53); and

(7) Certification statement of a material that is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious (42 CFR 71.54).

Under the new policy, for those HHS/CDC items filed within ACE, individuals will continue to use the designated HHS/CDC application and filing processes; however, the processes will be electronic rather than paper-based.

III. Implementation of EO 13659

Under this new Federal policy, which HHS/CDC has adopted, importers and brokers who file electronic entries for HHS/CDC-regulated items are now required to:

- Obtain the copy of the permit/permission letter, form, or document for submission to DIS:

- (1) The APHIS/CDC Form 2, Request to Transfer Select Agents and Toxins, is used by entities to request prior authorization of a transfer including importation into the United States of select agent(s) or toxin(s) from the Federal Select Agent Program as required by regulations (7 CFR 331, 9 CFR

121, and 42 CFR 73). The form is available at:
<http://www.selectagents.gov/form2.html>.

- (2) CDC Form 0.0728 - Permit to Import or Transfer Etiologic Agents or Vectors of Human Disease:
<http://www.cdc.gov/od/eaipp/index.htm> h

For infectious biological agents, infectious substances, and vectors of human disease, importers must have a permit from HHS/CDC's Import Permit Program.

- (3) A rabies vaccination certificate for a dog must be issued by a licensed veterinarian.

- (4) and (5) For certain animals and animal products capable of causing human disease, you must have a permit or letter of permission. See <https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/index.html>. Email inquiries about these importations to CDCAAnimalImports@cdc.gov. Note that CDC is transitioning to the CDC Import Permit for a Dog not immunized against Rabies during the first quarter of 2017. Permits will be issued using an online application process.

- (6) Only registered importers may bring nonhuman primates into the United States. HHS/CDC emails this

approval to the broker after receiving notification of an incoming shipment by a registered importer. For information on how to become a registered importer, see <http://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/monkeys.html>. The HHS/CDC Nonhuman Primate Notification Message is automatically generated when a registered importer notifies HHS/CDC of an incoming shipment.

- (7) For material that is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious, importers must provide an importer certification statement with the imported material. The certification statement must include a detailed description of the material and a statement on official letterhead signed by the sender or recipient clearly stating that 1) the material is not known or suspected to contain an infectious biological agent and 2) how the person making the certification knows that the specimen does not contain an infectious biological agent; or why that person believes there is no reason to suspect that the specimen contains an infectious biological agent; or a detailed

description of how the material was rendered noninfectious. For more information, see the Import Regulations for Infectious Biological Agents, Infectious Substances and Vectors at <http://www.cdc.gov/phpr/ipp/regulations.htm>.

- Follow all applicable rules for obtaining and certifying DIS software as set forth by CBP. For more information, see <https://www.cbp.gov/trade/automated/systems>.
- Transmit import filings to CBP via ACE.
- Transmit only information to CBP that has been requested by CBP or CDC.
- Check CDC's Importation Website <http://www.cdc.gov/importation/index.html> regularly for updated guidance for electronic filing.

The following processes will remain as paper-based submissions:

- A. Human remains for interment or cremation after entering the United States will not have an electronic entry within ACE. The required paper-based documents must continue to accompany the human remains, including those required by 42 CFR 71.55. For more information, see <http://www.cdc.gov/quarantine/human-remains.html>.

B. Form 75.37 - "Notice to Owners and Importers of Dogs (Requirement for Dog Confinement)" Dogs imported into the United States are expected to be healthy and vaccinated against rabies. There is no requirement to have this information electronically available within ACE. CBP issues a notice to owners and importers post-arrival only when dogs arrive in the U.S. port of entry without the required vaccination, meet certain criteria, and have been preapproved by HHS/CDC. For more information, visit the CDC web page for how to bring an animal into the United States at <http://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/dogs.html>.

For more information on this policy and updates or changes to the forms eligible for electronic submission, please see <http://www.cdc.gov/importation/index.html>.

IV. Paperwork Reduction Act

This change does not institute a new collection of information. The collection of information, including the use of the DIS, has been previously approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C.3507)

and assigned the following OMB control numbers: (1) Foreign Quarantine: OMB Control No. 0920-0134, expiration date 5/31/2019; (2) Import Permit Applications: OMB Control No. 0920-0199, expiration date 1/31/2017 ; (3) Requirements for the Importation of Nonhuman Primates into the United States: OMB Control No. 0920-0263, expiration date 9/30/2017; and (4) Possession, Use, and Transfer of Select Agents and Toxins: OMB Control No. 0920-0576, expiration date 12/31/18.

Dated: December 27, 2016

Lauren Hoffmann

Acting Executive Secretary

Centers for Disease Control and Prevention

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