I. Background and Authority

Rabies, one of the deadliest zoonotic diseases, accounts for an estimated 59,000 human deaths globally each year—equates to one human death every 9 minutes. Canine rabies virus variant (CRVV) is responsible for 98% of these deaths. The rabies virus can infect any mammal, and once clinical signs appear, the disease is almost always fatal. In September 2007, at the Inaugural World Rabies Day Symposium, HHS/CDC declared the United States to be free of CRVV. However, this rabies virus variant is still a serious public health threat in the more than 120 countries where CRVV remains enzootic. Preventing the entry of animals infected with CRVV into the United States is a public health priority. Under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), the Secretary of Health and Human Services may make and enforce such regulations as in the Secretary’s judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one State or possession into any other State or possession. Since at least 1956, Federal quarantine regulations (currently found at 42 CFR 71.51) have controlled the entry of dogs into the United States. See 21 FR 9870, Dec. 12, 1956. One of the principal goals of these regulations is to prevent the reintroduction and spread of CRVV into the United States. While the United States continues to battle rabies lyssavirus (rabies viruses that are enzootic to bat populations) and multiple terrestrial variants of rabies circulating in wildlife species (e.g., fox, raccoon, skunk), it has been free of CRVV since 2007 and now focuses its regulatory efforts on preventing the reintroduction of this rabies variant. Under 42 CFR 71.51, all dogs admitted into the United States must be accompanied by a valid rabies vaccination certificate.

II. SUPPLEMENTARY INFORMATION:

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces a temporary suspension in the importation of dogs from high-risk rabies-enzootic countries (hereinafter referred to as high-risk country or countries) into the United States. Due to the unprecedented global response to the Coronavirus Disease 2019 (COVID–19) pandemic and limited availability of public health resources at the Federal, state, and local level, this action is necessary to protect the public health against the reintroduction of canine rabies virus variant (CRVV) into the United States and to ensure the welfare of dogs being imported into the U.S. This suspension, with limited exceptions, includes dogs imported from low-risk or CRVV-free countries if the dogs have been in any high-risk countries during the previous six months.

DATES: This notice is effective July 14, 2021.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice contact: Ashley C. Altenburger, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H16–4, Atlanta, GA 30329 or 404–498–1600. For information regarding HHS/CDC regulations for the importation of dogs, please contact: Dr. Emily Pieracci, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–V–18–2, Atlanta, GA 30329 or 404–498–1600. Either Mrs. Altenburger or Dr. Pieracci may also be reached by email at CDCAnimalImports@cdc.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Temporary Suspension of Dogs Entering the United States From High-Risk Rabies Countries

Supplementary Information:

By direction of the Commission.

Joel Christie,
Acting Secretary.

[FR Doc. 2021–12701 Filed 6–15–21; 8:45 am]

BILLING CODE 6750–01–P
requirement applies unless the dog’s owner or importer submits satisfactory evidence that the dog is less than 6 months old and has only been in a CRVV-free or low-risk country, or has only been in a CRVV-free or low-risk country for the 6 months before arrival if it is older than 6 months. CDC maintains a current, publicly available list of countries with high risk of CRVV and provides guidance for dog entry requirements based on the dog’s country of import.

Additionally, under 42 CFR 71.51(e), CDC may temporarily suspend the entry of animals, articles, or things from designated foreign countries and places into the United States when it determines there exists in a foreign country a communicable disease that threatens the public health of the United States and the entry of imports from that country increases the risk that the communicable disease may be introduced. When such a suspension is issued, CDC designates the period of time or conditions under which imports into the United States may be suspended. CDC bases this temporary suspension on these legal authorities.

II. Public Health Rationale

The United States was declared CRVV-free in 2007. Importing dogs from high-risk CRVV countries involves a significant public health risk. CDC requires strict compliance with all its public health entry requirements. Although the U.S. Government does not track the total number of dogs imported into the United States from areas determined to have high rates of rabies, Under 42 CFR 71.63, CDC may temporarily suspend the entry of animals, articles, or things from designated foreign countries and places into the United States when it determines there exists in a foreign country a communicable disease that threatens the public health of the United States and the entry of imports from that country increases the risk that the communicable disease may be introduced. When such a suspension is issued, CDC designates the period of time or conditions under which imports into the United States may be suspended. CDC bases this temporary suspension on these legal authorities.

CBP does record, by country, the number of dogs imported with formal entry under Harmonized Tariff Schedule (HTS) code 0106199112 and HTS Description: Other live animals, other, dogs. The total number of dogs imported into the United States from all countries under this HTS category varied from 25,232 in 2018 to 58,540 in 2020. The number of dogs from high-risk countries under this HTS category averaged 16,390 and varied from 9,966 to 24,031 over this 3-year period. The number of dogs reported under this HTS category does not include dogs imported as checked baggage, hand-carried in airplane cabins, or crossing at land borders without formal entry. Thus, the number underestimates the true number of dogs imported into the United States.

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. CRVV has been highly successful at adapting to new host species, particularly wildlife. One CRVV-infected dog could result in transmission to humans, domestic pets or wildlife. The importation in 2019 of a single dog with rabies cost more than $400,000 USD for the public health investigations and rabies port-exposure prophylaxis (PEP) of exposed persons.

Since 2015 there have been three known rabid dogs imported into the United States. All three were rescue dogs imported by different rescue organizations for the purposes of adoption. These three cases, discussed below, highlight the immense public health resources required to investigate, respond to, and mitigate the public health threat posed by the importation. In 2015, a rabid dog was part of a group of eight dogs and 27 cats imported from Egypt by a rescue group. The dog had an unhealed leg fracture and began showing signs of rabies four days after arrival. Following the rabies diagnosis, the rescue workers in Egypt admitted that the dog’s rabies vaccination certificate had been intentionally falsified to evade CDC entry requirements. Eighteen persons were recommended to receive rabies PEP, seven dogs underwent a six-month quarantine, and eight additional dogs housed in the same home as the rabid dog had to receive rabies booster vaccinations and undergo a 45-day monitoring period.

In 2017, a “flight parent” (a person solicited through social media, often not affiliated with the rescue organization, and usually compensated with an airline ticket) imported four dogs on behalf of a rescue organization. One of the dogs appeared agitated at the airport and bit the flight parent prior to the flight. The dog also had tooth fractures from reportedly having been hit by a car. A U.S. veterinarian examined the dog one day after its arrival and then euthanized and tested the dog for rabies. A post-mortem rabies test showed that the dog was positive for the virus.

Public health officials recommended that at least four people receive rabies PEP, and the remaining three dogs underwent quarantine periods ranging from 30 days to 4 months. An investigation revealed the possibility of falsified rabies vaccination documentation presented on entry to the United States. In 2019, twenty-six dogs were imported into the United States by a rescue organization. All dogs had rabies vaccination certificates and serologic documentation, indicating the development of rabies antibodies (in response to immunization), based on results from an Egyptian government-affiliated rabies laboratory. However, one dog developed signs of rabies three weeks after arrival and had to be euthanized. The dog tested positive for rabies. Forty-four persons received PEP, and the 25 dogs imported on the same flight underwent re-vaccination and quarantines of 4–6 months. An additional 12 dogs had contact with the rabid dog and had to be re-vaccinated and undergo quarantine periods ranging


from 45 days to 6 months based on their previous vaccination status.\textsuperscript{17} HHS/CDC estimates a range of costs for public health investigations and subsequent cost of care for people exposed to rabid dogs to cost between $215,386 and $508,879 per importation event as summarized in Section IV.\textsuperscript{18,19} This cost estimate does not account for the worst-case outcomes, which include (1) transmission of rabies to a person who dies from the disease or (2) ongoing transmission to other domestic and wildlife species in the United States. Re-establishment of CRVV into the United States, while unlikely, could result in costly efforts over several years to again eliminate the virus.

A previous campaign to eliminate domestic dog-coyote rabies virus variant jointly with gray fox (Texas fox) rabies virus variant in Texas over the period from 1995 through 2003 cost $34 million\textsuperscript{20,21}, or $52 million in 2019 U.S. dollars. Since January 2020, public health resources globally have been diverted to COVID–19 response activities which may have caused a lapse in canine rabies vaccination efforts in high-risk countries. The increased number of dogs with inadequate or falsified rabies vaccination certificates arriving in the United States\textsuperscript{22} may increase the likelihood of a CRVV-importation event. An importation of a dog with CRVV would divert U.S. public health resources away from ongoing and time sensitive COVID–19 response activities.

On January 21, 2020, CDC launched an agency-wide response to the COVID–19 pandemic, dedicating over 7,200 of the approximately 10,000 CDC personnel to support the outbreak response. CDC’s focus from the beginning has been to assist health departments, frontline healthcare workers, businesses, communities, and the public to protect themselves and save lives. As of March 15, 2021, over one thousand CDC personnel have conducted 3,150 deployments to 265 cities across the United States and abroad, and over three thousand documents have been developed providing information and guidance for government agencies, business and the public.\textsuperscript{23} The unprecedented nature of this public health response has naturally drawn federal, state, and local public health resources away from other important public health efforts, including preventing the reimportation of CRVV into the United States.

Historically, approximately 60–70% of CDC’s dog entry denials (or about 200 cases annually) have been due to fraudulent paperwork.\textsuperscript{24} This number is less than 1 percent of dog importations. Between January and December 2020, (during the COVID–19 pandemic), CDC documented more than 450 instances of incomplete, inadequate, or fraudulent rabies vaccination certificates for dogs arriving from high-risk countries. These cases resulted in the dogs being denied entry into the United States and returned to their countries of origin. The increase in the number of dogs inadequately vaccinated against rabies that importers are attempting to import into the United States has created a public health risk of importing CRVV into the U.S. and public health management of these dogs is unsustainable during the current COVID–19 pandemic.

To be considered complete and adequate, rabies vaccination certificates currently must include all the following information:

- Name and address of owner
- Breed, sex, date of birth (approximate age if date of birth unknown), color, markings, and other identifying information of the dog
- Date of rabies vaccination and vaccine product information
- Date the vaccination expires
- Name, license number, address, and signature of veterinarian who administered the vaccination

Upon the dog’s arrival, federal officials examine the rabies vaccination certificates and ensure the description of the dog listed on the paperwork matches the dog presented. For a rabies vaccine to be effective, the dog must be at least 12 weeks (84 days) of age at the time of administration. A dog’s initial vaccine must also be administered at least 4 weeks (28 days) before arrival in the United States.

CDC has documented instances of fraudulent paperwork for dogs based on various factors. These include: Dogs that were younger than the age indicated on their rabies vaccination paperwork—based on dental examination by U.S. veterinarians; differences between the breed, sex, color, or microchip number listed on the rabies vaccine certificate and the dog presented for entry; suspicious veterinary stamps and inconsistent signatures between different veterinary paperwork; inconsistent dates of rabies vaccination between different veterinary documents; and vaccines administered after expiration date of the vaccine lot.

Under CDC’s regulatory authority, dogs arriving from high-risk countries without appropriate rabies vaccination certificates are denied entry and returned to the country of origin on the next available flight.\textsuperscript{25} Airlines are required to house dogs awaiting return to their country of origin at a facility, preferably a live animal care facility, that has an active custodial bond and a Facilities Information and Resource Management System (FIRMS) code issued by U.S. Customs and Border Protection (CBP), which indicates the facility can provide accommodation that meets the US Department of Agriculture’s Animal Welfare Act standards. However, there are insufficient live animal care facilities with a CBP-issued FIRMS code available to house dogs that are denied entry. Currently only one facility exists nationwide (www.arkjk.com).

If a live animal facility with a CBP-issued FIRMS code is not available, the airline must, at a minimum, provide accommodation that meets the U.S. Department of Agriculture’s Animal Welfare Act standards.\textsuperscript{26} Many airlines choose to leave dogs in cargo warehouses, which can create an unsafe environment for the dogs due to the prolonged periods of time between flights, inadequate cooling and heating, unacceptable cleaning and sanitization of crates, and inability to physically

separate the animals from areas of the warehouse where other equipment, machinery, and goods are used and stored.

During 2020, due to the COVID–19 pandemic, there were fewer international flights worldwide, resulting in delayed returns for dogs denied entry. In August 2020, while in the custody of an airline, a dog died at Chicago O’Hare International Airport after CDC denied entry based on falsified rabies vaccination certificates. Despite CDC’s request to find appropriate housing at a local kennel or veterinary clinic, the airline left the dog, along with 17 other dogs, in a cargo warehouse without food and water for more than 48 hours.29

While airlines are ultimately responsible for finding appropriate housing for dogs denied entry, the decreased number of flights combined with inadequate numbers of live animal care facilities with a CBP-issued FIRMS code for holding animals creates significant administrative and financial burden for federal, state, and local governments. The government may be required to find individualized solutions to ensure appropriate accommodations for prolonged periods of time for these animals.

While costs associated with housing, caring for dogs, and returning dogs are the responsibility of the importer (or airline if the importer abandons the dog), some importers and airlines are reluctant to pay these costs, requiring the Federal government to find appropriate interim housing facilities and veterinary care. The cost for housing, care, and returning improperly vaccinated dogs ranges between $1,000–$4,000 per dog depending on the location and time required until the next available return flight. The Federal government bears these costs when airlines and importers do not.

During 2020, CDC observed a 52% increase in dogs that were ineligible for entry compared to 2018 and 2019.30 The increasing demand to vaccinate and quarantine dogs that have been denied entry presents an increased burden to federal, state and local public health agencies already responding to the COVID pandemic. The increased inspections, medical care, and appropriate quarantine of dogs inadequately vaccinated against rabies has financially burdened federal and state public health agencies.

Between May through December 2020, CDC spent more than 3,000 personnel-hours at an estimated cost of $270,000 to respond to the attempted importation of unvaccinated or inadequately vaccinated dogs from high-risk rabies countries during these eight months. The time spent represented a substantial increase from previous years because of (1) the 52% increase in dogs with inadequate documentation; and (2) the additional time spent identifying interim accommodations for the dogs because of the reduced outbound international flight schedules due to the pandemic. These are resources and personnel-hours diverted from CDC’s current paramount objective in mitigating the COVID–19 pandemic and do not include time from other Federal, state, and local public health partners.

Pursuant to the terms of this notice, HHS/CDC is temporarily suspending the importation of dogs from high-risk countries. This suspension includes dogs originating in low-risk or CRVV-free countries that have been in a high-risk country in the previous six months (not including animals transiting through high-risk countries). The suspension will reduce the risk of importation of CRVV and preserve public health resources needed for the COVID–19 response. The suspension will also allow CDC to work with Federal and state partners, airlines, and other stakeholders to consider options for a more streamlined and efficient dog importation process that will be safer for pets. Most importantly, it will ensure that U.S. public health remains protected.

This notice creates a narrow set of exceptions for certain categories of dogs imported into the United States with advance written approval from CDC. The requirement for advanced written approval will help ensure that the limited number of dogs imported into the United State from high-risk countries have valid documentation of rabies vaccination upon entry. CDC will also mitigate the costs placed upon the U.S. government, airlines, and importers associated with reexporting dogs that do not meet CDC entry requirements.

III. Advance Written Approval

The suspension provisions of this notice do not apply if advance written approval from CDC has been obtained to import a dog from a high-risk country that has been fully immunized against rabies. This includes a dog that has been in a high-risk country in the previous 6 months and is being imported from a low-risk or CRVV-free country. Such approvals will be granted on a limited and case-by-case basis and at CDC’s discretion. CDC’s decision will be considered final.

The following categories of importers are eligible to request advance written approval to import a dog into the United States:

• U.S. government personnel who are relocating back to the United States with Permanent Change of Station (PCS) orders or Temporary Duty (TDY) orders.
  • U.S. citizens and lawful residents relocating to the United States. The application should include written documentation from an employer or other official source stating the reason for the relocation, such as a letter by an employer or university stating that the U.S. citizen or lawful resident is relocating for reasons of employment or education.
  • Importers who wish to import dogs for purposes related to science, education, or exhibition, as these terms are defined in 42 CFR 71.50, or for a bona fide law enforcement purpose.
  • Owners of service animals, if the dog is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. In accordance with U.S. Department of Transportation regulations at 14 CFR part 382, emotional support animals, comfort animals, companionship animals, and service animals in training are not considered service animals for the purposes of this Notice.

During this temporary suspension, importers who meet the eligibility criteria listed above may make a one-time request to import up to three dogs as part of a single importation. All dogs must be six months of age or older at the time of entry and, as further explained in this notice, must enter the United States on a port of entry with a live animal care facility with a CBP-issued FIRMS code. Importers of dogs for science, education, or exhibition, as these terms are defined in 42 CFR 71.50, or bona fide law-enforcement purposes may import more than three dogs.

To request the advance written approval of the CDC, importers who

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29 Dog Dies At O’Hare Airport Warehouse, 17 Others Saved After Being Left Without Food Or Water For 3 Days—CBS Chicago (chicentral.com).
meet the eligibility criteria listed above must submit the Application for a Permit to Import a Dog Inadequately Immunized Against Rabies, (approved under OMB Control Number 0920–0134 Foreign Quarantine Regulations [exp. 03/31/2022], or as revised). To request an application for the permit, an importer must send an email to the Director, Division of Global Migration and Quarantine, at cdcanimalimports@cdc.gov.

Once an importer receives instructions and the permit application, the importer’s request with all supporting documentation must be submitted at least 30 business days before the date on which the dog will enter the United States. A request cannot be made at the port of entry upon the dog’s arrival into the United States: dogs that arrive without advance written approval from the CDC will be returned to their country of origin on the next available flight. As required by the permit application, a request must present sufficient and reliable evidence conclusively demonstrating that the dog to be imported has been fully immunized against rabies. Such evidence includes:

1. A valid rabies vaccination certificate that was issued in the United States by a U.S.-licensed veterinarian. The certificate must state that the vaccine was administered on or after the dog was 12 weeks (84 days) of age and at least 28 days prior to entry, if it was the dog’s initial vaccine. OR

2. A valid rabies vaccination certificate from a non-U.S.-licensed veterinarian AND serological evidence of rabies vaccination from an approved rabies serology laboratory. The certificate must state that the vaccine was administered on or after the dog was 12 weeks (84 days) of age and at least 28 days prior to entry, if it was the dog’s initial vaccine. OR

- Permanent Change of Station (PCS) orders, or Temporary Duty Orders (TDY) (U.S. Government personnel);
- Documentation or evidence that the dog to be imported is a service dog (as defined in this Notice);
- Employment letter or other evidence of relocating to the United States after living abroad; or
- Other justification that meets the above-listed eligibility criteria along with supporting documentation.

Dogs arriving from a high-risk country with a CDC permit must enter the United States at a port of entry with a live animal care facility with a CBP-issued FIRMS code that can provide accommodation that meets the U.S. Department of Agriculture’s Animal Welfare Act standards. Currently, John F. Kennedy International Airport in New York City is the only U.S. port of entry with a live animal care facility that meets these standards. However, if any additional ports of entry become capable of meeting these standards, CDC will publish the list of ports of entry in the Federal Register and on the CDC animal importation website. Animals imported for bona fide law-enforcement purposes are not required to enter the United States at a port of entry with a live animal care facility with a CBP-issued FIRMS code.

CDC additionally requires dogs arriving from a high-risk country with a CDC permit be microchipped on or before the date that they receive their rabies vaccination. The microchip number must be listed on the rabies vaccination certificate. Photographs of the dog’s teeth are required for age verification. CDC will respond to an importer’s request in writing and may impose additional conditions in granting the approval. An importer must present CDC’s written response and approval upon entry into the United States. If a request for advance approval is denied, CDC’s written denial will constitute final agency action.

Any dog from a high-risk country will be excluded from entering the United States and returned to its country of origin on the next available flight, regardless of carrier or route, if it arrives without advance written approval from the CDC, arrives at a port of entry without a live animal care facility with a CBP-issued FIRMS code, or if the animal presented does not match the description of the animal listed on the permit. The importer (or airline carrier if the importer abandons the animal) will be financially responsible for all housing, care, and return costs. In keeping with current practice, importers should continue to check with Federal, state, and local government officials regarding additional requirements of the final destination prior to entry or re-entry into the United States.

IV. Economic Impact of This Temporary Suspension

Executive Orders 12866: “Regulatory Planning and Review” and 13563: “Improving Regulation and Regulatory Review” direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Although the temporary suspension of dogs from countries at high-risk for CRVV is expected to reduce the number of dogs imported into the United States, importers of dogs from high-risk countries will be able to submit a request for advanced written permission at least 30 days prior to planned importation in the United States. Thus, some importers will be able to import up to three dogs from high-risk countries with CDC-issued permits.

CDC has previously estimated that between 87,000 and 116,000 dogs are imported from high-risk countries each year. This estimate is significantly greater than the numbers recorded by CBP for formal entry under HTS code 0106199120 and HTS Description: Other live animals, other, dogs, which averaged 16,390 and varied from 9,966 to 24,031 over the 3-year period from 2016 through 2020.

The number of dogs reported under this HTS category do not include hand-carried dogs traveling in airplane cabins or crossing at land borders without formal entry and, thus, are not inclusive of all dog imports. To account for the uncertainty in the number of dogs imported to the United States from high-risk countries without formal entry, CDC used the following assumptions in the analysis of this action: (1) Most likely estimate: 3 times the average number of dogs with formal entry from 2018–2020 = 60,696 dogs per year, (2) Lower bound: 2 times the average number of dogs with formal entry from 2018–2020 = 32,274, and (3) Upper bound: 5 times the number of dogs arriving in the highest year (2019) =

32 The permit is currently under revision (Permit to Import a Dog Inadequately Immunized Against Rabies, (OMB Control Number 0920–0134 Foreign Quarantine Regulations [exp. 03/31/2022]). Despite the permit application’s current title, inadequately immunized dogs do not qualify for the exception.

33 Will provide link to CDC website with list of approved laboratories.

120,155. These baseline estimates are used throughout the analysis (Table 1). CDC assumed that the temporary suspension would reduce the number of dogs imported from high-risk countries by 75% and considered a range of 50%–90% to calculate lower and upper bound estimates. This would result in estimates of 15,124 (range: 3,203–60,040 dogs) dogs imported with CDC-issued permits per year with the suspension in place. The temporary suspension would reduce the estimated numbers of dogs imported per year by 45,572 (range: 29,758–60,115). CDC also estimated the numbers of dogs denied entry under the baseline and with the temporary suspension in effect. An estimated 500 (range: 300–750) dogs would be denied entry under the baseline based on data from 2020 and previous years. The temporary suspension and CDC permit process are expected to reduce the number of dogs denied entry by 90% (range: 75%–95%) such that only 50 (range: 15–188) dogs would be denied entry with the temporary suspension.

**Table 1—Estimated Numbers of Dogs from High-Risk Countries Imported or Denied Entry Under the Baseline and With the Temporary Suspension**

<table>
<thead>
<tr>
<th>Category</th>
<th>Most likely estimate</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated number of dogs imported from high-risk countries at baseline</td>
<td>60,696</td>
<td>32,781</td>
<td>120,155</td>
</tr>
<tr>
<td>Estimated % reduction in number of dogs imported from high-risk countries with temporary suspension</td>
<td>75%</td>
<td>90%</td>
<td>50%</td>
</tr>
<tr>
<td>Estimated number of dogs imported from high-risk countries with temporary suspension</td>
<td>15,174</td>
<td>3,278</td>
<td>60,078</td>
</tr>
<tr>
<td>Change in number of dogs imported from high-risk countries</td>
<td>45,522</td>
<td>29,503</td>
<td>60,078</td>
</tr>
<tr>
<td>Estimated number of dogs denied entry from high risk countries at baseline</td>
<td>500</td>
<td>300</td>
<td>750</td>
</tr>
<tr>
<td>Estimated % reduction in dogs denied entry with temporary suspension</td>
<td>90%</td>
<td>95%</td>
<td>75%</td>
</tr>
<tr>
<td>Estimated number of dogs denied entry with temporary suspension</td>
<td>50</td>
<td>15</td>
<td>188</td>
</tr>
<tr>
<td>Change in numbers of dogs denied entry with temporary suspension</td>
<td>450</td>
<td>285</td>
<td>563</td>
</tr>
</tbody>
</table>

The estimated costs and benefits (in 2019 U.S. dollars) associated with the temporary suspension of dogs from countries at high-risk for CRVV are summarized in Table 2. CDC estimates that importers, CDC, and DHS/CBP will incur about $11.8 million in costs (range: $2.2–$57.6 million) over the one-year period anticipated for the suspension. The large difference between the lower and upper bound is due to both uncertainty in the number of dogs imported from high-risk countries under the baseline as well as uncertainty in many of the costs associated with the suspension. Most of the costs will be incurred by importers (most likely estimate of $10.8 million, 91% of the total), who will have to (1) spend time requesting advance written permission, (2) pay for serologic testing unless the imported dog already has a valid U.S. rabies vaccination certificate issued by a U.S.-licensed veterinarian, (3) re-route travel to a port of entry with a live animal care facility with a CBP-issued FIRMS code, and (4) the potential economic costs of being unable to import a dog from a high-risk country (either the inability to travel with a pet from a high-risk country or the need to substitute the importation of a dog from CRVV-free or low-risk country instead of a dog from a high-risk country).

The one-year benefits (averaged costs) from the temporary suspension are estimated to be $2.3 million, range: $1.0–$5.1 million). Most of the benefits (most likely estimate of $1.5 million, 64% of total) of the temporary suspension accrue to CBP due to the reduction in the number of dogs imported from high-risk countries (which require screening), the number of dogs denied entry, and an estimated decrease in the amount of time to review a CDC permit vs. the time required to review documentation under the baseline. Importers, CDC, and airlines also benefit from the averted costs associated with the reduction in the number of dogs denied entry with the suspension relative to baseline. The net cost of the temporary suspension is calculated from the annual costs – annual benefits resulting in an estimate of $9.5 million (range: $1.2–$52.5 million).

**Table 2—Summary Table of Costs and Benefits in 2019 Dollars, Over a 1-Year Time Horizon**

<table>
<thead>
<tr>
<th>Category</th>
<th>Most likely estimate</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual monetized benefits to importers/owners of dogs from high risk countries</td>
<td>$579,260</td>
<td>$215,765</td>
<td>$1,508,443</td>
</tr>
<tr>
<td>Annual monetized benefits to airlines</td>
<td>54,000</td>
<td>11,400</td>
<td>168,750</td>
</tr>
<tr>
<td>Annual monetized benefits to DHS/CBP</td>
<td>1,491,418</td>
<td>678,417</td>
<td>3,055,534</td>
</tr>
<tr>
<td>Annual monetized benefits to HHS/CDC</td>
<td>198,369</td>
<td>92,153</td>
<td>398,948</td>
</tr>
<tr>
<td>Total annual monetized benefits</td>
<td>2,175,209</td>
<td>920,521</td>
<td>4,836,488</td>
</tr>
<tr>
<td>Quantified, but unmonetized, benefits</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The estimated response costs associated with a dog imported while infected with canine rabies virus variant (CRVV) are $315,682, range: $215,386 to $508,879. The permit requirement for high risk countries should reduce the risk of importation of dogs infected with CRVV.
The primary public health benefit of the temporary suspension is the reduced risk that a dog with CRVV will be imported from a high-risk country. Based on experience with previous importations, CDC estimated the cost per imported dog with CRVV to be $315,682, range $215,386 to $508,879. This cost estimate includes health department staff time for the public health response, payments for post-exposure prophylaxis for exposed persons, and the costs associated with quarantining or euthanizing exposed animals. Any importation of a dog with CRVV would also likely divert public health resources away from COVID–19 response activities.

Using the most likely estimates of the net cost ($9.5 million) and the most likely estimate of the potential benefits of averting the importation of a dog with CRVV from a high-risk country ($316,000), it is possible to calculate how many dogs with CRVV would need to be imported under the baseline for the benefits to equal costs. The net costs ($9.5 million) divided by the cost per importation ($316,000) suggests that at least 30 dogs with CRVV would need to be imported under the baseline for benefits to exceed costs. This would require a huge increase in the number of dogs imported into the United States while infected with CRVV, which could only occur as a result of widespread failures of rabies control programs in multiple high-risk countries.

The above estimate of the cost of an importation of a dog with CRVV does not account for the worst-case outcomes, which include (1) transmission of rabies to a person who dies from the disease or (2) ongoing transmission to other domestic and wildlife species in the United States. Re-establishment of CRVV into the United States, while unlikely, could result in costly efforts over several years to again eliminate the virus.

The cost of re-introduction could be especially high if CRVV spreads to other species of U.S. wildlife. Both of these worst-case outcomes may be more likely to occur during the COVID–19 pandemic because public health resources have been diverted to COVID–19 response activities and vaccination programs.

Human deaths from rabies continue to occur in the United States after exposures to wild animals. However, no U.S. resident has died after exposure to an imported dog with CRVV in at least 20 years. CDC uses the value of statistical life (VSL) to assign a value to interventions that can result in mortality risk reductions. For 2019, the estimated VSL is $10.6 million with a range of $5.0 to $16.2 million. However, CDC is unable to estimate the potential magnitude of the mortality risk reduction associated with the temporary suspension.

Re-establishment of CRVV into the United States, while unlikely, would also result in costly efforts over a number of years to eliminate the virus. A previous campaign to eliminate domestic dog-coyote rabies virus variant jointly with gray fox (Texas fox) rabies virus variant in Texas over the period from 1993 through 2003 cost $34 million, or $52 million in 2019 U.S. dollars. The costs to contain any reintroduction would depend on the time period before the reintroduction was realized, the wildlife species in which CRVV was transmitted, and the geographic area over which reintroduction occurs. The above estimate is limited to the cost of rabies vaccination programs for targeted wildlife and does not include the costs to administer post-exposure prophylaxis to any persons exposed after the reintroduction has been identified.

Assumptions Used To Estimate Costs and Benefits

CDC estimated costs and benefits to importers, CDC, CBP, and airlines under the baseline and with the temporary

suspension in place. All cost estimates were converted to 2019 U.S. dollars. The costs to importers with the temporary suspension were calculated using the following assumptions:

- The opportunity costs for importer time were estimated at $36.41 (range: $25.72–$47.10) per hour based on the average U.S. wage rate and a Department of Transportation estimate specific to international travelers.41 42
- Importers seeking advance written permission for 15,124 (range: 3,263–59,890) dogs.
- An assumption of 1 hour (range: 0.5–2 hours) to submit advance written approval and fulfill the informational and testing requirements for a permit.
- Estimated costs of $50 (range: $20–$65) for a rabies titer test at an approved rabies serology laboratory.
- Assumed cost of $100 (range: $80–$120) for a veterinarian to draw blood and ship it to an approved rabies serology laboratory.
- Estimated cost of $40 (range: $25–$50) to microchip a dog.
- An assumption that 40% of importers will already have a valid rabies vaccination certificate issued by a U.S.-licensed veterinarian and will not need testing from an approved rabies serology laboratory or microchip.

An assumption that 75% of importers from high-risk countries would need to re-route travel to a port of entry with a live animal care facility with a CBP-issued FIRMS code, which would incur an increased ticket cost of $200 and 4 additional hours of travel time.

- Importers who are unable to import a dog from a high-risk country because of the temporary suspension (45,572, range: 29,518–60,265 dogs) would incur an assumed cost of $100 (range: $50–$400) per dog because of time spent away from their places of business or increased costs of substitution to import a dog from a CRVV-free or low-risk country.

The costs for CDC were estimated based on:

- An assumed staff time cost of 20 minutes (range: 15–30 minutes) per permit issued by a GS–12, step 5 reviewer.
- Oversight of the permit process by two GS–13, step 5 veterinarians.
- 30 minutes of staff time to revise training materials for CBP staff.
- CDC staffing costs are estimated using the GS pay scale for the Atlanta area and multiplying by 2 to account for non-wage benefits and overhead.

The costs for CBP included 5 minutes (range: 0–10 minutes) for 25,052 (range: 20,402–30,602) CBP officers (average level GS–12, step 5) to receive training on the temporary suspension. CBP staffing costs are estimated using the GS pay scale for the Washington, DC area and multiplying by 2 to account for non-wage benefits and overhead.

CDC assumed that airlines would not incur new costs for this temporary suspension because the time required to review CDC-issued permits prior to boarding dogs from high-risk countries should be similar to the amount of time required to review vaccination certificates under the current baseline. There may be some reduction in cargo fees revenue associated with the reduction in dogs imported from countries at high risk for CRVV (range: 29,518–60,265 dogs), but this lost revenue may be offset by revenues received to import dogs from CRVV-free or low-risk countries or revenue received for cargo other than dogs. CDC lacks sufficient data to estimate such costs but expects the net cost to airlines to be limited.

The expected annual benefits (averted costs) were estimated for importers, CDC, CBP, and airlines based on the reduced numbers of dogs delayed entry and the reduced time spent by CBP officers to screen dogs from high-risk countries.

The estimated benefits (averted costs) for importers were estimated based on:

- An estimated reduction in time spent by CBP to review documentation for dogs from high-risk countries assuming an estimate of 17 minutes (range: 13.6–20.4 minutes) per dog to review documentation under the baseline43 to 5 minutes (range: 3–8 minutes) per dog to review permits during the suspension.
- An estimated 2 hours per dog denied entry (estimated at 450 fewer dogs denied entry, range: 285–563) with the suspension relative to baseline.

The estimated benefits (averted costs) to CDC were estimated based on:

- An estimated 4 hours of CDC staff time per dog denied entry at an average GS-level 13, step 5 at CDC Headquarters and an average of 30 minutes of CDC quarantine station staff time per dog denied entry at an average GS-level 11, step 5. The actual mix of staff at CDC Headquarters who need to support denials of entry would vary from GS–11 through Senior Executive Staff and varies depending on time spent on appeals and finding shelter for abandoned dogs.

The estimated benefits (averted costs) to CBP were estimated based on:

- An estimated reduction in the number of dogs imported from high-risk countries due to the temporary suspension: 45,572 (range: 29,758–60,115) relative to baseline.

- Under the baseline, CDC estimated that each dog imported from a high-risk country requires 17 minutes (range: 13.6–20.4 minutes) of CBP officer time to review documents (GS–12, step 5).47

- With the temporary suspension in place, CDC estimates that the time required to review CDC-issued permits would decrease from the above to 5 (range: 3–8) minutes per dog for the estimated 15,124 (range: 3,263–59,890) dogs arriving with permits.

- An estimated reduction in the number of dogs denied entry because of the temporary suspension: (estimated at 450 fewer dogs denied entry, range: 265–563).

- An estimate of 71 (range: 47–95) minutes of CBP staff time required per dog denied entry (GS–12, step 5).48

The estimated benefits (averted costs) for airlines were estimated based on:

- The reduction in the estimated numbers of dogs denied entry and abandoned by importers (100 under the baseline vs. 10 with the suspension of entry).

- CDC assumed that 80% of dogs denied entry would be re-imported to the United States at a round-trip cost of $1,200 per dog to the importer.46

- CDC assumed that 20% of dogs denied entry would be abandoned by importers at a cost of $100 per dog to the importer.

The estimated benefits (averted costs) to CDC were estimated based on:

- An estimated 4 hours of CDC staff time per dog denied entry at an average GS-level 13, step 5 at CDC Headquarters and an average of 30 minutes of CDC quarantine station staff time per dog denied entry at an average GS-level 11, step 5. The actual mix of staff at CDC Headquarters who need to support denials of entry would vary from GS–11 through Senior Executive Staff and varies depending on time spent on appeals and finding shelter for abandoned dogs.

The estimated benefits (averted costs) to CBP were estimated based on:

- An estimated reduction in the number of dogs imported from high-risk countries due to the temporary suspension: 45,572 (range: 29,758–60,115) relative to baseline.

- Under the baseline, CDC estimated that each dog imported from a high-risk country requires 17 minutes (range: 13.6–20.4 minutes) of CBP officer time to review documents (GS–12, step 5).47

- With the temporary suspension in place, CDC estimates that the time required to review CDC-issued permits would decrease from the above to 5 (range: 3–8) minutes per dog for the estimated 15,124 (range: 3,263–59,890) dogs arriving with permits.

- An estimated reduction in the number of dogs denied entry because of the temporary suspension: (estimated at 450 fewer dogs denied entry, range: 265–563).

- An estimate of 71 (range: 47–95) minutes of CBP staff time required per dog denied entry (GS–12, step 5).48

The estimated benefits (averted costs) for airlines were estimated based on:

- The reduction in the estimated numbers of dogs denied entry and abandoned by importers (100 under the baseline vs. 10 with the suspension of entry).

- CDC assumed that 80% of dogs denied entry would be re-imported to the United States at a round-trip cost of $1,200 per dog to the importer.46

- CDC assumed that 20% of dogs denied entry would be abandoned by importers at a cost of $100 per dog to the importer.

The estimated benefits (averted costs) to CDC were estimated based on:

- An estimated 4 hours of CDC staff time per dog denied entry at an average GS-level 13, step 5 at CDC Headquarters and an average of 30 minutes of CDC quarantine station staff time per dog denied entry at an average GS-level 11, step 5. The actual mix of staff at CDC Headquarters who need to support denials of entry would vary from GS–11 through Senior Executive Staff and varies depending on time spent on appeals and finding shelter for abandoned dogs.

The estimated benefits (averted costs) to CBP were estimated based on:

- An estimated reduction in the number of dogs imported from high-risk countries due to the temporary suspension: 45,572 (range: 29,758–60,115) relative to baseline.

- Under the baseline, CDC estimated that each dog imported from a high-risk country requires 17 minutes (range: 13.6–20.4 minutes) of CBP officer time to review documents (GS–12, step 5).47

- With the temporary suspension in place, CDC estimates that the time required to review CDC-issued permits would decrease from the above to 5 (range: 3–8) minutes per dog for the estimated 15,124 (range: 3,263–59,890) dogs arriving with permits.

- An estimated reduction in the number of dogs denied entry because of the temporary suspension: (estimated at 450 fewer dogs denied entry, range: 265–563).

- An estimate of 71 (range: 47–95) minutes of CBP staff time required per dog denied entry (GS–12, step 5).48

The estimated benefits (averted costs) for airlines were estimated based on:

- The reduction in the estimated numbers of dogs denied entry and abandoned by importers (100 under the baseline vs. 10 with the suspension of entry).
An assumed cost of $600 per dog for airlines to fly abandoned dogs back to their countries of origin.49

The costs associated with an importation of a dog with CRVV includes health department staff time for the public health response, payments for post-exposure prophylaxis treatment for exposed persons, and the costs associated with quarantining or euthanizing exposed animals. CDC estimated the response cost per imported dog with CRVV to be $315,682, range $215,386 to $508,879 based on the following assumptions:

• An estimate of 800 hours of health department staff time per importation,50

• The public health response time is split evenly among veterinarians (code 29–1131, $50.39 per hour), epidemiologists (19–1041, $37.64 per hour), registered nurses (29–1141, $37.24 per hour), licensed practical nurses (29–2061, $23.32 per hour), and office and administrative assistants (43–0000, $19.73 per hour).51 52 These wage estimates are multiplied by 2 to account for non-wage benefits and overhead.

• An average of 25 (range: 16–44) individuals will require post-exposure prophylaxis because of exposure to the dog with CRVV.53 54

• The average cost of post-exposure prophylaxis was estimated to be $9,290.55

• An estimated 29.6 animals would need to be quarantined or euthanized due to exposure to the dog with CRVV.

• Each exposed animal would incur economic costs of $1,000 for quarantine or euthanasia.56

V. Terms of This Notice

Therefore, pursuant to 42 CFR 71.51(e) and 42 CFR 71.63, and subject to the terms of this notice, CDC hereby excludes the entry and suspends the importation of dogs from high-risk countries, including dogs from low-risk and CRVV-free countries if the dogs have been present in a high-risk country in the previous six months.

Additionally, under 42 CFR 71.63, CDC finds that CRVV exists in countries designated as high-risk countries and that, if reintroduced into the United States, CRVV would threaten the public health of the United States. The continued entry of dogs from high-risk countries in the context of the current limited CDC resources and personnel diverted to respond to COVID–19 further increases the risk that CRVV may be reintroduced, transmitted, or spread into the United States. CDC has coordinated in advance with other federal agencies as necessary to implement and enforce this notice.

This notice is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather notice of an emergency action taken under the existing authority of 42 CFR 71.51(e) and 42 CFR 71.63. In the event that this notice qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this notice. Considering the public health emergency caused by the virus associated with COVID–19, the ongoing diversion of public health resources and personnel to respond to the pandemic, and the risk of reintroduction of CRVV from dogs being imported from high-risk countries, it would be impractical and contrary to the public’s health, and by extension the public’s interest, to delay the issuance and effective date of this notice.

Effective July 14, 2021: Pursuant to the exception, dogs from high-risk countries must be 6 months of age to be imported and fully vaccinated against rabies, and eligible importers may only import up to 3 dogs upon receipt of advanced written approval from the CDC. Importers wishing to import dogs from high-risk countries should:

1. Submit a request for advanced written permission (i.e., Application for a Permit to Import a Dog Inadequately Immunized Against Rabies, approved under OMB Control Number 0920–0134 Foreign Quarantine Regulations (exp. 03/31/2022), or as revised)) at least 30 days prior to planned importation in the United States.

2. Submit all documentation listed above in Section III Advanced Written Approval.

The request for advance written permission must include proof of the dog’s identity including pictures of the dogs’ teeth, other descriptive details, proof of rabies vaccination, and microchip information. Dogs arriving from high-risk countries must enter the United States at a port of entry with a live animal care facility with a CBP-issued FIRM code that can provide accommodation that meets the U.S. Department of Agriculture’s Animal Welfare Act standards.

This temporary suspension will remain in place until the earliest of (1) the expiration of the Secretary of Health and Human Services’ declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies this suspension based on specific public health or other considerations; or (3) 360 days from publication in the Federal Register.

Dated: June 9, 2021.

Sandra Cashman,
Executive Secretary, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10494 and CMS–10773]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed...