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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Guidance Regarding Agency Interpretation of "Rabies-Free" as it Relates to the Importation of Dogs into the United States.

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

ACTION: Notice of agency guidance.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is publishing this guidance for dog owners and importers who seek to admit a dog without a valid rabies vaccination certificate into the United States. Under current regulations, all dogs admitted into the United States must be accompanied by a valid rabies vaccination certificate unless the dog's owner or importer submits satisfactory evidence that the dog has only been in a rabies-free country if it is less than 6 months old or has only been in a rabies-free country for the 6 months before arrival if it is older than 6 months. Through this guidance, CDC is clarifying that it interprets "rabies-free" for the purposes of dog importation to mean "canine rabies virus variant (CRVV)-free." For all other public health purposes, CDC will continue to apply the general definition of

"rabies free," which includes and reflects the rabies status of all terrestrial animals and not just dogs. This guidance further describes the considerations taken into account by experts in determining whether a country qualifies as CRV-free. This notice also informs dog owners and importers on where to locate up-to-date information on a country's CRV status to facilitate a dog's entry or re-entry into the United States.

DATES: This guidance will be implemented on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION

I. Background and Current Operations

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 his or her 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 1956, Federal quarantine regulations (currently found at 42 CFR 71.51) have controlled the entry of dogs into the United States (21 FR 9870). One of the principal goals of these regulations is to prevent the introduction and spread of rabies into the United States. While the United States continues to have bat 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 efforts on preventing the reintroduction of the CRVV rabies variant.

In accordance with 42 CFR 71.51(c)(1)(i), CDC maintains a current, publicly available list of rabies-free countries to assist dog owners and importers in understanding its dog importation requirements. Under this provision, CDC also has the authority to deny entry to an inadequately immunized dog from a country that is not listed as "rabies free" or if the

dog was not born in (or spent at least the last 6 months before arrival in) a country that is considered "rabies-free." Under such circumstances, the dog's owner or importer assumes the costs of returning the dog to its country of origin unless the owner or importer is eligible to receive a dog confinement agreement (79 FR 39403).

Prior to today's clarification, owners or importers of dogs from countries with a low (or zero) prevalence of CRVV but which report some incidences of terrestrial or other rabies virus variants were required to provide proof of rabies vaccination for entry into the United States because such countries were not considered "rabies-free." 42 CFR 71.51 defines "valid rabies vaccination certificate" for purposes of demonstrating when a dog is considered adequately immunized. Thus, as discussed in more detail in Section IV, dog owners and importers wishing to import dogs from CRVV-free or low-risk countries were potentially subject to relatively high costs and burdens related to presenting a valid rabies vaccination certificate at ports of entry compared to the extremely low risk of importing a dog with CRVV from these CRVV-free or low-risk countries. Furthermore, because having low or zero prevalence of CRVV was not sufficient for a country to be considered "rabies-free," rabies prevention efforts at U.S. borders were weakened as attention, in part,

was diverted away from dogs coming from countries that pose a more significant risk of re-introducing CRVV into the United States. These policies also created public confusion concerning when an unvaccinated dog could be legally imported into the United States, as reflected by the number of public inquiries and appeals from denials of permission to import a dog. Thus, CDC has reassessed and clarified its policy to better focus on the risk of importing CRVV into the United States. Today's clarification seeks to address these issues. We have worked closely with our partners at the federal, state, and local levels to secure support and ensure a seamless transition.

II. New CRVV Risk Categories

Upon the publication of this guidance, CDC will shift enforcement of its United States dog importation regulations from the risk of dogs importing rabies of any variant to the risk of dogs importing CRVV into the United States. This clarification allows federal authorities to better focus their resources on preventing the reintroduction of CRVV from countries that pose the greatest risk. Specifically, CDC now identifies countries as CRVV-free, CRVV low-risk, or CRVV high-risk. For purposes of dog importation, these terms are defined as follows:

- CRVV-free means that CDC has assessed the country as not having CRVV present, based on internationally accepted standards.

- Low-risk means the country is at low risk for CRVV transmission based on the following considerations: the virus is limited to a localized area, surveillance and dog vaccination programs are adequate, and the virus is in a controlled status with the country heading toward eventual CRVV-free status.

- High-risk means the country is at high risk for CRVV transmission as demonstrated by the presence and geographic distribution of the virus and by low quality of or low confidence in the country's surveillance systems and its dog vaccination programs.

Owners and importers importing a dog from CRVV-free or low-risk countries will not need a rabies vaccination certificate for the dog to be admitted into the United States, although they will still be subject to the requirements set forth in 42 CFR 71.51(c)(1). Owners and importers importing a dog from a high-risk country will be required to have a valid rabies vaccination certificate.

We note that today's guidance is limited to the definition of "rabies-free" as it relates to the importation of CRVV by dogs. This guidance does not nor will not affect

CDC's interpretation or application of the term "rabies free" for other public health purposes, which will continue to include and reflect the rabies status of all terrestrial animals and not just dogs.

III. Provisions of this Notice

Upon the publication of this guidance, under 42 CFR 71.51, CDC will add or remove countries from its list of rabies-free countries based on the country's risk of importing CRVV into the United States. CDC rabies subject matter experts have reviewed (and continue to review) publicly available country data to estimate the risk posed of reintroducing CRVV into the United States. Data considered in this decision include peer-reviewed publications, publicly available government reports, data and recommendations from international agencies such as the World Health Organization and the World Organization for Animal Health, as well as information provided from global rabies experts.¹ CDC subject matter experts also consider the quality of rabies surveillance systems in the country, the prevalence of reported cases of rabies in humans and animals, characterization of rabies virus genomes, and efforts towards

¹ World Organisation for Animal Health. Ch 1.4 Animal Health Surveillance. In: Terrestrial Animal Health Code 27th ed; 2018. Available from: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_surveillance_general.htm. Accessed August 31, 2018.

control of the disease in dogs (i.e., dog vaccination coverage, population management, and enforcement of legal codes to curb rabies transmission in dogs). CDC intends to review relevant data on a yearly basis, revise prior risk classifications when new information becomes available, and publish its list of country rabies classifications, including CRVV-free countries, on its website at <https://www.cdc.gov/rabies/resources/index.html>.

In keeping with current practice, if a dog that is not adequately immunized against rabies arrives at a U.S. port of entry from a country that CDC considers a high-risk for CRVV transmission (See <https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/rabies-vaccine.html>), the dog will be returned to its country of origin immediately under standard operating procedures at U.S. ports of entry. CDC also will not issue a dog confinement agreement under 42 CFR 71.51(c)(2) and 79 Fed. Reg. 39403 (July 10, 2014) for dogs imported from high-risk CRVV countries. Regardless of vaccination status or country from which imported, CDC may require confinement of dogs that do not appear to be healthy and allow the owner an opportunity to arrange for a public health assessment by a local veterinarian at the owner's expense (42 CFR 71.51(b)(1), (2)). If unhealthy dogs are not adequately immunized against rabies, the dogs will be: (a)

returned to their country of origin once healthy enough for travel, (b) euthanized and tested for rabies, or (c) admitted if there is not a public health threat and the dogs, upon entry, were adequately immunized against rabies. In keeping with current practice, importers should continue to check with state and local government officials regarding requirements of the final destination prior to entry or re-entry into the United States; this new federal policy is not intended to invalidate or supersede such requirements. The policy and program operations described above will be implemented on **[INSERT DATE OF PUBLICATION]**.

IV. Economic Impact of Policy Clarification

Executive Orders 12866 and 13563 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. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs.

The proposed clarification to HHS/CDC guidance described in the preamble is not a regulatory change, but is expected to affect costs for dog importers/owners, airlines, Department of Homeland Security/Customs and Border Protection (DHS/CBP), Department of Health and Human Services/ Centers for Disease Control and Prevention (HHS/CDC), and state and local public health departments (PHDs). As noted above, owners and importers importing a dog will still be subject to the requirements set forth in 42 CFR 71.51. However, owners and importers importing dogs from CRVV-free or low-risk countries will no longer need a valid rabies vaccination certificate for the dogs to be admitted into the United States because in this new guidance CDC is revising how it interprets rabies-free for purposes of applying 42 CFR 71.51(c)(1)(i). In the economic analysis, HHS/CDC compares the costs set forth in this notice ("new guidance") to the costs under the guidance in effect immediately before publication of this notice ("previous guidance"). Owners and importers importing dogs from high-risk countries will still be required to have a valid rabies vaccination certificate for the dogs to enter the United States. This clarification in guidance will reduce the burden to import dogs into the United States from CRVV-free and low-risk countries, and it is anticipated that the costs to import dogs and inspect dogs at ports of entry (POEs) will be

reduced. In addition, HHS/CDC expects that considerably fewer Permits to Import a Dog Inadequately Immunized against Rabies (OMB No. 0920-0134)² will be sought and issued and that the costs of confinement, as required by the permits, will be reduced. These benefits (reduced costs) are estimated relative to the baseline in which the HHS/CDC guidance is not clarified.

The new guidance may slightly increase the probability that a dog infected with CRVV would be imported into the United States from a CRVV-free or low-risk country and that an imported dog could expose U.S. persons or animals and trigger a public health response with associated costs. However, HHS/CDC believes that there is a very small risk of importation of a rabies-infected dog from a country that is either CRVV-free or classified as low-risk under the new guidance. CRVV-free countries do not have CRVV circulating by definition. Mexico is considered a low-risk country and has only reported 11 dogs with CRVV during 2015 and 2016, the two most recent years with available data. Only three dogs with CRVV were identified in Mexico in the most recent year, 2016.³

² <https://www.cdc.gov/importation/pdf/Unimmunized-Dog-Permit-Application.pdf>. Accessed August 31, 2018.

³ Ma, X., et al. (2018). "Rabies surveillance in the United States during 2016." JAVMA 252(8): 945-957.

In addition, HHS/CDC believes that the potentially increased risk of rabies importation from a CRVV-free or low-risk country may be offset by the ability of DHS/CBP officers and HHS/CDC staff to better focus efforts on reducing the risk of rabies-infected dogs being imported from CRVV high-risk countries. Among dogs from high-risk countries, the CRVV incidence rate may approach 2 dogs per 1,000 per year in countries with low rabies vaccination coverage.⁴ During the past 15 years, six CRVV-infected dogs were imported into the United States. All of these imports were from countries where CRVV, at the time, was widely circulating,^{5,6,7,8,9} which would be considered high-risk under this new guidance.

Baseline under the Previous Guidance

When dogs enter the United States from terrestrial rabies virus-free countries or with proof of immunization, such dogs are not routinely tracked in any data systems. With limited data available on dog importations, estimating both the

⁴ Hampson, K., et al. (2015). "Estimating the Global Burden of Endemic Canine Rabies." *PLoS Negl Trop Dis* **9**(4): e0003709.

⁵ Castrodale, L., et al. (2008). "Rabies in a Puppy Imported from India to the USA, March 2007." *Zoonoses Public Health* **55**: 427-430.

⁶ Mangieri, N., et al. (2008). "Rabies in a dog imported from Iraq – New Jersey, June 2008." *MMWR* **57**(39): 1076-1078.

⁷ Manning, S., et al. (2008). "Human Rabies Prevention—United States, 2008 Recommendations of the Advisory Committee on Immunization Practices." *MMWR* **57**(RR03): 1-26.

⁸ Sinclair, J. R., et al. (2014). "Dogs Entering the United States from Rabies-Endemic Countries, 2011-2012." *Zoonoses Public Health* **62**: 393-400.

⁹ Sinclair, J. R., et al. (2015). "Rabies in a Dog Imported from Egypt with a Falsified Rabies Vaccination Certificate – Virginia, 2015." *MMWR* **64**(49): 1359-1362.

baseline and the change relative to the baseline is difficult. HHS/CDC estimates that about 1.06 million dogs (Table 1) enter the United States each year including 700,000 arriving at airports and 360,000 arriving at land border POEs with Canada and Mexico. In total, 795,492 imported dogs (75% of all imported dogs) are estimated to arrive from CRRV-free or low-risk countries. The remaining 269,303 dogs are from high-risk countries (108,303) or from terrestrial rabies virus-free countries (161,000). Dogs from terrestrial rabies virus-free countries would not require valid rabies vaccination certificates under either the previous or new guidance. For additional details, refer to Section 2 of the supplemental appendix.

Under the previous guidance (baseline), each dog would be screened at U.S. ports of entry. DHS/CBP field officers at U.S. POEs would review rabies immunization documents, review permits for unimmunized dogs, issue dog confinement agreements for dogs allowed to enter the United States without documentation of vaccination or permits, and may deny entry for dogs from CRVV-free, low-risk or high-risk countries. Specifically, HHS/CDC estimated that, each year:

- 791,301 dogs (99.5% of the total from CRVV-free or low-risk countries) enter the United States with rabies immunization certificates.

- o For each dog, DHS/CBP field officers have reported that either 1 or 2 officers spend about 8 minutes to screen each dog of which 3-4 minutes per dog are spent reviewing the rabies immunization certificate and verifying documentation with other agency/official when needed. For more detail on the baseline cost calculations refer to Tables A7a-b, A8a-b, A13, and A14 of the supplemental appendix.
- 2,492 dogs enter the United States with HHS/CDC-issued permits for dogs from CRVV-free or low-risk countries.
 - o For each permit, importers were estimated to spend 15-60 minutes to apply and HHS/CDC staff to spend about an hour for review and follow up. 1-2 DHS/CBP officers were estimated to spend 11 minutes per dog of which about 6 minutes are spent to review each permit at POEs. For more detail on the baseline cost calculations refer to Appendix Tables A7a-b, A8a-b, A13, A14, A16 and A17 of the supplemental appendix.

- o After entering the United States, importers were also assumed to spend time confining dogs and state or local health departments were assumed to spend time to contact importers to monitor confinement requirements. For more detail on the baseline cost calculations refer to Tables A11 and A20 of the supplemental appendix.
- 1,378 dogs from CRVV-free and low-risk countries enter the U.S. with DHS/CBP-issued dog confinement agreements (DCAs).
 - o 1-2 DHS/CBP officers were estimated to spend 26 minutes per dog of which 20 minutes are spent to issue DCAs at POEs inclusive of time to call HHS/CDC officers for technical support. Importers would also spend time to confine dogs and state/local health departments would follow up and monitor. For more detail on the baseline cost calculations refer to Appendix Tables A7a-b, A8a-b, A13, and A14 of the supplemental appendix.
- 322 dogs from CRVV-free and low-risk countries were denied entry at POEs because of lack of rabies

immunization under the previous guidance. In addition to importers and DHS/CBP, the costs associated with denial of entry may also be incurred by airlines to transport dogs back to their country of origin. For more detail on the baseline cost calculations refer to Tables A9, A10, A13, and A14 of the supplemental appendix.

Table 1. Estimated average annual numbers of dog imports by country and by immunization status			
Baseline estimate of dog imports	Best estimate	Lower bound ^b	Upper bound ^c
Airports ^a	700,000	560,000	840,000
From rabies-free countries	161,000	128,800	193,200
From CRVV-free countries	235,900	188,720	283,080
Dogs with rabies vaccination certificates	234,750	187,800	281,700
Dogs with unimmunized dog permits	920	736	1,104
Dogs with DCAs	62	50	74
Dogs denied entry	168	134	202
From CRVV low-risk countries under new guidance	196,000	128,800	277,200
Dogs with rabies vaccination certificates	195,910	128,728	277,092

Dogs with DCAs	48	38	58
Dogs denied entry	42	34	50
From CRVV high-risk countries	107,100	113,680	86,520
Dogs with rabies vaccination certificates	106,634	113,307	85,961
Dogs with DCAs	12	10	14
Dogs denied entry	454	363	545
Land borders	364,796	324,036	405,555
Canada-US land borders	122,000	97,600	146,400
Dogs with rabies vaccination certificates	120,344	96,275	144,413
:Dogs from Canada, other CRVV-free or low-risk countries	119,141	94,350	143,691
:Dogs from high-risk countries	1,203	1,926	722
Dogs with unimmunized dog permits	1,572	1,258	1,886
Dogs with DCAs	84	67	101
Dogs denied entry	0	0	0
Mexico-US land borders	242,796	226,436	259,155
Dogs with rabies vaccination certificates	241,500	225,400	257,600
Dogs with DCAs	1,184	947	1,420
Dogs denied entry	112	90	134

Total	1,064,796	884,036	1,245,555
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^a DHS/CBP field staff provided estimates of the proportions of dogs from (1) rabies-free countries (23%) (2) CRVV-free countries (34%), (3) CRVV low-risk countries under the new guidance, including Mexico and Israel (28%), and (4) CRVV high-risk countries (15%, these countries are considered high-risk under both the previous and new guidance).

^b For the lower bound estimate, it was assumed that a larger proportion of dogs arrive from high-risk countries, which would result in less benefits (reduced costs) from the clarification in guidance. For the lower bound the following proportions are used: (3) CRVV low-risk countries under the new guidance, including Mexico and Israel (23%), (4) CRVV high-risk countries (20%).

^c For the upper bound estimate, it was assumed that a larger proportion of dogs arrive from countries that will be considered low-risk in the new guidance, which would result in more benefits (reduced costs) from the clarification in guidance. For the upper bound the following proportions are used: (3) CRVV low-risk countries under the new guidance, including Mexico and Israel (33%), (4) high-risk countries (10%).

Estimated costs and benefits (reduced costs) associated with clarification in guidance

Under the new guidance, each dog would be screened at U.S. ports of entry. However, DHS/CBP field officers at U.S. POEs will no longer need to review rabies immunization documents, review permits for unimmunized dogs, issue dog confinement agreements for dogs allowed to enter the United States without rabies vaccination certificates or permits or deny entry for dogs from CRVV-free or low-risk countries (due to lack of valid rabies vaccination certificate) unless these dogs had traveled from a high-risk country to the CRVV-free or low-risk country within the previous six months.

The range of estimated annualized benefits (reduced costs) associated with the clarification in guidance are about \$2.6 million to \$11.0 million, most likely estimate \$6.1 million (Table 2). The largest potential benefits (reduced costs) accrue to federal agencies (DHS/CBP and HHS/CDC), which would spend less time reviewing permit requests and reviewing immunization documents or permits at ports of entry (\$2.0 million to \$8.3 million) per year. For more information on the model used to estimate costs and benefits (reduced costs) for DHS/CBP and HHS/CDC, refer to Sections 4 and 5 of the supplemental appendix. Importers/owners from CRVV-free or low-risk countries would spend less time applying for a Permit to Import a Dog Inadequately Immunized against Rabies (OMB No. 0920-0134), providing documentation at POEs, and confining

dogs. As a result, they would save an estimated \$470,000 to \$2.3 million per year. For more information on the model used to estimate costs and benefits (reduced costs) for importer/owners, refer to Section 3 of the supplemental appendix. Potential state and local governments' benefits (reduced costs) will depend on the amount of effort spent enforcing dog confinement agreements after importation from CRV-free countries or countries under the previous guidance that now will be classified as low-risk under the new guidance. With limited data on enforcement, state and local governments are estimated to save between \$120,000 and \$350,000 annually in reduced costs of monitoring confinement of unimmunized dogs. For more information on the model used to estimate benefits (reduced costs) for state and local health departments, refer to Section 6 of the supplemental appendix. Airlines would also have some benefits (reduced costs) associated with transporting dogs denied entry and abandoned by importers/owners or their agents. Refer to Table A9 in Section 3 of the supplemental appendix for additional details.

The estimated costs associated with this clarification in guidance result from a one-time increase in DHS/CBP training costs during the first year of implementation (\$700,000, range: \$430,000 to \$2.6 million). When annualized over a 10 year period with a 3% discount rate, this would correspond to

\$80,000 (range: \$49,000 to \$300,000). More information is available in Appendix Table A15 of the supplemental appendix. Importers/owners, who bring dogs from high-risk countries, were estimated to spend more time at airport and land border POEs (3-10 minutes per dog for importers and 3-17 minutes per dog for CBP staff) because CBP staff reported that they would spend more time on dogs from high-risk countries. This additional time was estimated to correspond to an opportunity cost of \$120,000 to \$480,000 per year (Tables A7b and A8b of the supplemental appendix).

Table 2: Summary Table (in \$ 2017 dollars, over a 10-year time horizon)				
Benefits				
Category	Most Likely Estimate	Lower Bound Estimate	Upper Bound Estimate	Source Citation
Annualized monetized benefit to importers/owners (3% discount rate) ^a	\$1,478,057	\$469,678	\$2,300,409	RIA (Appendix Section 3)
Annualized	\$22,680	\$4,536	\$61,236	RIA

monetized benefit to airlines (3% discount rate)				(Appendix Section 3, Table A9)
Annualized monetized benefit to DHS/CBP	\$4,007,188	\$1,849,245	\$7,441,556	RIA (Appendix Section 4)
Annualized monetized benefit to HHS/CDC	\$391,982	\$115,893	\$829,398	RIA (Appendix Section 5)
Annualized monetized benefit to States and local PHDs	\$218,511	\$116,633	\$349,479	RIA (Appendix Section 6)
Total annualized monetized benefits (3% discount rate)	\$6,118,418	\$2,555,984	\$10,982,077	RIA
Annualized quantified, but unmonetized,	The estimated response costs estimate associated with a dog imported while infected with CRVV			RIA (Appendix Sections

benefits	are \$213,833, range \$171,066 to \$256,599. If the additional time spent screening dogs from high-risk countries leads to a reduced risk of the importation of a dog with CRVV, future response costs may decrease.			7 and 8)
Costs				
Category	Most Likely Estimate	Lower Bound Estimate	Upper Bound Estimate	Source Citation
Annualized monetized costs to Importers/owners (3% discount rate) ^b	\$375,450	\$121,172	\$479,487	RIA (Appendix Section 3, Tables A7b and A8b)
Annualized monetized costs to DHS/CBP (3% discount rate) ^c	\$79,154	\$49,278	\$295,666	RIA (Appendix Section 4, Table A15)
Total annualized	\$454,604	\$170,449	\$775,053	RIA

monetized costs (3% discount rate)				
Annual quantified, but unmonetized, costs	The estimated response costs estimate associated with a dog imported while infected with CRVV are \$213,833, range \$171,066 to \$256,599. If eliminating the rabies vaccine certificate requirement for dogs from CRVV-free or low-risk countries leads to an increased risk of the importation of a dog with CRVV, future response costs may increase.			RIA (Appendix Section 7)
Qualitative (unquantified costs)	State and local governments may have to increase efforts to educate their populations about dog vaccination requirements in the absence of the HHS/CDC requirement for rabies vaccination certificates for dogs to enter from CRVV-free or low-risk			NA

	countries under the previous guidance.	
<p>Notes: ^a Importers/owners who bring dogs from CRVV-free or low-risk countries.</p> <p>^b Importers/owners who bring dogs from high-risk countries.</p> <p>^c Costs for DHS/CBP training is one-time costs during the first year of implementation.</p>		

Over a 10-year time horizon, the total benefits (reduced costs) associated with this clarification in guidance depend on the discount rate selected (3%) to value future benefits (reduced costs). The 10-year time horizon was chosen because countries may become CRVV-free or revert to being high-risk over time. Because limited data exist to estimate the number of dogs imported to the United States at present, HHS/CDC did not attempt to project future dog imports, but instead applied estimates of imported dogs in 2017 to future years. If the number of imported dogs would instead increase in future years, the benefits (reduced costs) from this clarification in guidance would be underestimated.

The most likely estimate of the present value of the 10-year benefits (reduced costs) is \$52.2 million at a 3% discount rate (Table 3). The lower bound estimate is \$21.8 million and the upper bound estimate is \$93.7 million. In

comparison, the 10-year costs are estimated at \$3.9 million, range \$1.5 million to \$6.6 million. The 10-year net benefits (i.e. benefits - costs) are estimated at \$48.3 million, range (\$20.3 million to \$87.1 million).

Table 3: Present value summary table (in \$ Million 2017 dollars, over a 10-year time horizon, 3% discount rate)			
	Most Likely estimate	Lower bound	Upper bound
Present value of cost savings			
Importers/owners ^a	\$12.6	\$4.0	\$19.6
Airlines	\$0.2	\$0.04	\$0.5
DHS/CBP	\$34.2	\$15.8	\$63.5
HHS/CDC	\$3.3	\$1.0	\$7.1
Sates and local health departments	\$1.9	\$1.0	\$3.0
Total (A)	\$52.2	\$21.8	\$93.7
Present value of costs			
Importers/owners ^b	\$3.2	\$1.0	\$4.1
DHS/CBP ^c	\$0.7	\$0.4	\$2.5

Total (B)	\$3.9	\$1.5	\$6.6
Present value of net cost savings			
Total (A) - (B)	\$48.3	\$20.3	\$87.1
Notes: ^a Importers/owners who bring dogs from CRVV-free or low-risk countries.			
^b Importers/owners who bring dogs from high-risk countries.			
^c Costs for DHS/CBP training is a one-time cost during the first year of implementation.			

Comparison of costs and benefits

As discussed above, HHS/CDC believes the risk of an importation of a dog with CRVV from a country defined as low-risk under the new guidance is extremely low. As noted previously, during the past 15 years, six CRVV-infected dogs were imported into the United States and all of these imports were from high-risk countries. HHS/CDC notes that if dogs travel from a high-risk country to a CRVV-free or low-risk country within six months of U.S. entry, the dogs would still have to present a certificate of rabies vaccination at entry. State and local governments would face the greatest costs to mount responses in the event of an importation of a dog with CRVV. In addition, individuals or their insurance companies may face costs associated with post-exposure prophylaxis if they are exposed to the imported dog.

A threshold analysis was performed to compare the potential annualized costs and benefits of the clarification to the guidance to the potential cost of an importation of a dog with CRVV. To perform the threshold analysis, HHS/CDC compared the most likely estimate, lower bound, and upper bound of the annual net benefits (reduced costs) of the new guidance to the potential costs of an importation and calculated the annual risk of importation necessary for costs to equal benefits (reduced costs).

HHS/CDC rabies subject matter experts estimate that the public health response would require about 800 hours per event for investigation, providing post-exposure prophylaxis to about 16 people exposed to the infected dog after importation, and addressing 30 animal exposures per importation. The net benefits (reduced costs) estimate can be compared to the estimated response costs associated with a dog imported while infected with CRVV (\$213,833, range \$171,066 to \$256,599). See Section 7 of the supplemental appendix for additional details on this cost estimate. This response cost does not include the small risk that a person could die after becoming infected with the rabies virus in the absence of receiving post-exposure prophylaxis. Although U.S. residents have died after exposure to rabid dogs in other countries, no such deaths have resulted from exposures to U.S. dogs since CRVV

was eliminated in the United States in 2007. The probability of such a death cannot be quantified, but is expected to be very low under either scenario.

Expected net benefits (reduced costs) would exceed the potential costs associated with the importation of a dog with CRVV if fewer than 26 dogs per year with CRVV are imported from countries classified as CRVV-free or low-risk under the new guidance using the most likely estimates. In the worst case scenario, the lower bound estimate of annualized benefits (reduced costs, \$2.6 million) minus the upper bound estimate of annualized costs (\$780,000) results in an annualized net benefit of about \$1.8 million. This worst case annualized net benefit can be compared to the upper bound cost estimate associated with the importation of a dog with CRVV (\$256,599 per event) to estimate a worst case scenario threshold (6.9 dogs per year).

This threshold analysis can be compared to surveillance data from Mexico, a country that is considered low-risk. Mexico only identified 11 dogs over the previous 2 years in which surveillance data were available.¹⁰ Thus, even if all of the dogs found with CRVV in Mexico over the past two years had been imported to the United States, the response costs would

¹⁰ Ma, X., et al. (2018). "Rabies surveillance in the United States during 2016." JAVMA 252(8): 945-957.

have fallen under the threshold result. Even in the worst case scenario, it is extremely unlikely that costs will exceed benefits as a result of this clarification in guidance. As noted above, HHS/CDC also believes that any increased risk of importation from a CRVV-free or low-risk country may be offset by allowing DHS/CBP officers to spend more time evaluating dogs entering the United States from high-risk countries. DHS/CBP officers reported that they expected to increase the amount of time spent on dogs from high-risk countries by 3-17 minutes per dog under the new guidance. By refocusing screening effort at U.S. POEs from dogs from CRVV-free or low-risk countries to dogs from high-risk countries, the overall risk of importation of a dog with CRVV may be reduced.

Possible additional activities by state or local governments

As noted throughout this FRN, importers should continue to check with state and local government officials regarding requirements of the final destination prior to entry or re-entry into the United States; this new federal policy is not intended to invalidate or supersede such requirements. State and local governments may also have to increase efforts to educate their populations about their dog vaccination requirements in the absence of the HHS/CDC requirement for proof of rabies vaccination for dogs to enter from CRVV-free or low-risk countries under the previous guidance. However,

HHS/CDC was not able to estimate any costs associated with these efforts.

V. Paperwork Reduction Act

This clarification does not institute a new collection of information. The collection of information, 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 number: Foreign Quarantine: OMB Control No. 0920-0134, expiration date 5/31/2019.

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