Briefing Memorandum

To: Mr. Richard L Revesz

Administrator of the Office of Information and Regulatory Affairs

The Office of Management and Budget

Washington, D.C. 20503

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Subject: RIN 0920-AA82, Foreign Quarantine Importation of Dogs and Cats

Executive Order 12866 Teleconference with Soi Dog Foundation

Teleconference

Date:

February 27, 2023

Attachments: 1) Revised and Updated "Action Item 4," from January 4, 2022, APA Section 553(e) Submission

2) Revised and Updated "Action Item 5," from January 4, 2022, APA Section 553(e) Submission

Introduction

The Soi Dog Foundation completely and unequivocally supports the CDC's objective of keeping the United States free of the canine rabies virus, and minimizing the risk to humans or animals possibly posed by the importation of dogs from high-risk rabies countries.

Soi Dog also supports replacing the CDC's decades-old import regulations, which simply aimed at administratively recording vaccinations, with new measures like those the CDC employed during the Temporary Suspension. New regulations based on these measures, and derived from internationally recognized scientific standards and recommendations, should focus instead on verifying the actual presence of rabies antibodies that protect against the disease in imported dogs by requiring rabies serology titer tests.

Soi Dog also appreciates the opportunity to comment upon the CDC's efforts to move towards a new rabies import control regulatory system, based upon its experience with the various measures the CDC imposed during the Temporary Suspension of imports which began in July 2021.

Soi Dog Foundation Background



Soi Dog Foundation was established in 2003.

The Soi Dog Foundation was established in Phuket, Thailand in 2003 by John and Gill Dalley from the U.K., along with Dutch retiree Margo Homburg, to help the street dogs and cats who had no one else to care for them. Its mission is "To improve the welfare of dogs and cats in Asia, resulting in better lives for both the animal and human communities, to create a society without homeless animals, and to ultimately end animal cruelty".

Soi Dog is the largest domestic animal welfare and rescue organization in Southeast Asia

Soi Dog Foundation is a not-for-profit, legally registered charitable organization in: Thailand: Phor.Gor. 39/2548; the USA: 27-1600444; Australia: 58982568831; Holland: 37120202; France: W332011412; the United Kingdom: 1176305; Canada: 981179-6; and in Switzerland: CHE-393.768.679.

Soi Dog prides itself on spending donor's funds wisely and being transparent.

Our founders have never taken a dime in salary. We are dedicated to making sure that the maximum amount of donations go directly toward helping the animals. Soi Dog received Guidestar's Platinum Seal of Transparency, a 4-star rating on Charity Navigator and is a Top-Rated charity on Great Nonprofits.

Soi Dog provides life-saving care at our sanctuary and throughout Thailand.

The Soi Dog Sanctuary houses and cares for nearly 1,800 animals, on-site.

Our Emergency Response Team helps Thai communities affected by natural disasters. This began with the Asian tsunami in 2004, and has continued with providing assistance, hundreds of tons of food, and animal shelters to areas of Bangkok as well as southern and central Thailand as they experienced flooding in recent years. This past year Soi Dog helped support the more than 40,000 dogs and cats displaced by the war in the Ukraine with 325 tons of food and specially insulated dog enclosures.

Moreover, our state-of-the-art hospital, the only one in Asia specifically for street animals, sees an average monthly intake of between 350 and 400 dogs and cats, all from dire situations. Soi Dog's extremely well-equipped dog and cat hospitals are staffed by twenty-eight full-time veterinarians. The dog hospital is capable holding up to 170 "patients" simultaneously. The cat hospital can accommodate over 140 cats at any one time. In addition to our veterinarians in Phuket, we have two more working in our small clinic in Bangkok and a further thirty-two devoted to the 13 mobile CNVR clinics. Soi Dog anticipates having seventy-four veterinarians on staff by the end of this year.

In 2021, Soi Dog treated 15,186 sick or injured animals. 4,764 of the most severe cases in the Phuket dog and cat hospitals, 219 in the clinic in Bangkok, 365 on our mobile CNVR clinics, and 9,838 on location by the Community Outreach teams.

We also receive vets from other countries who spend time learning from our own vets, who encounter a far more varied and complex range of surgical and medical situations than most vets anywhere in the world. Soi Dog has provided training and experience not only to practitioners from Myanmar, Cambodia and Vietnam, but also from Europe.

Soi Dog works to reduce animal suffering through massive catch/neuter/vaccinate/return (CNVR) initiatives.

Soi Dog sterilizes and vaccinates more stray animals than any other organization in the world.

Soi Dog has spayed/neutered and vaccinated more than 870,000 street dogs and cats since 2003, and now sterilizes and vaccinates more than 200,000 animals annually. This not only prevents the birth of millions of puppies and kittens who would have been born into a life of suffering and starvation, but significantly contributes to reducing the prevalence of rabies.

Vaccinating a minimum of 70% of strays in an area contributes to establishing herd immunity and provides indirect protection from this serious disease. Soi Dog's CNVR work in Bangkok has contributed to a marked reduction in reported rabies cases in the city since 2015. Additionally, the province of Phuket has been recognized by the Thai government as Thailand's first rabies-free province, in significant part due to Soi Dog's efforts with its CNVR program.

Soi Dog initiated a Humane Education program in Thai schools.

Over 4,600 children were reached last year with lessons about compassion and empathy towards animals. The next generation is our only hope for a sustainable end to animal cruelty. The Soi Dog Sanctuary also includes a Humane Education Centre, the first of its kind in Thailand, aimed at incorporating animal welfare into Thailand's national curriculum and encouraging people to adopt rescue dogs rather than buying puppies from pet stores.

Soi Dog fights the Asian dog meat trade.

Soi Dog virtually ended the illegal dog meat trade in Thailand, saving an estimated 500,000 lives annually. But there's much more to do; it is estimated that 20 million dogs and cats are consumed in Asia every year. We are now embarking on a full-scale campaign to end the dog meat trade throughout Asia and the Philippines.

Soi Dog finds loving homes for carefully selected animals.

Most dogs are returned to where they came from, if it is safe to do so, once they fully recover from their CNVR or other treatments. Local and international adoptions remain an adjunct, albeit an important adjunct, to Soi Dog's other animal welfare and rescue activities. However, Soi Dog has found forever homes for thousands of dogs and cats in Thailand, Europe, and North America, who otherwise likely would have perished on the streets. Soi Dog's International Partner Rescue Program (IPRP) was created in 2017 and aided the rehoming of many more. In 2021, 714 animals were adopted through Soi Dog's national and international rescue programs, as shown in the chart below.



The majority of Soi Dog's adoptions are placed in Thailand. However, Soi Dog records show that, to-date, more than 1,600 dogs have found new homes in the United States. Prior to the CDC's Temporary Suspension on imports in July 2021, Soi Dog would typically send approximately 300 carefully selected dogs to the U.S. annually. Soi Dog does not charge adoption fees for the dogs it rehomes.

Soi Dog has never had any of the dogs it exported denied entry into the United States, nor has there been a positive case of rabies in any of the dogs sent to the United States for adoption.

A short video of one of our many international adoption success stories involving a placement in the United States is available at https://www.youtube.com/watch?v=vYiqUrADvcU (1:33 minute video).

Soi Dog Foundation USA represents Soi Dog in the United States

The Soi Dog Foundation USA supports and promotes Soi Dog's various animal welfare activities, and specifically focuses on fund raising and facilitating imports of suitable dogs with carefully selected partner rescue organizations or adopters in the United States.

Soi Dog Year-End 2022 Video

Soi Dog's most recent annual re-cap video for its supporters is available at https://www.youtube.com/watch?v=r7u0cjs-yRk (5:22 minute video), and provides a visual overview of the Sanctuary facilities; Soi Dog's rescue, treatment, and adoption activities; as well as touching upon the impact of the revisions to the CDC Temporary Suspension and imposition of the new Canadian import ban.

Soi Dog's Experience with the CDC Rabies Import Controls

The Soi Dog International Adoption Process

The Soi Dog Sanctuary staff carefully selects those dogs who may be considered for its international adoption program. Only dogs that are healthy and free of behavioral issues are candidates for overseas adoptions. The staff then coordinates with the International Partner Rescue organization in the receiving country (and with the Soi Dog Foundation USA in appropriate cases) to ensure that the potential adopters are also carefully selected and a good match for the individual dog. In a minority of cases, a "direct adoption" may occur without the participation of an IPR . Additionally, Soi Dog does not charge for adoptions.

Administratively, the Soi Dog Foundation's international export process is overseen by its International Logistics Coordinator, who is IATA (International Air Transport Association) and LAR (Live Animal Regulation) accredited. A video describing the Soi Dog's logistics process is available at https://www.youtube.com/watch?v=oGSXcDF-F9U (9:20 minute video).

The in-house International Logistics Coordinator's role is to ensure that all overseas exports are managed to the highest standards of animal welfare and regulatory compliance. This focuses Soi Dog's processes on the following points:

- Satisfying compliance standards in line with IATA and LAR guidelines.
- Protecting the safety and welfare of animals on the ground and in the air.
- Constantly reviewing special routings and animal behaviors.
- Identifying and implementing procedures to handle emergency situations.
- Understanding the container design principles for live animals.
- Ensuring strict compliance to destination countries' documentation and import requirements.
- Liaising with both governmental and internal veterinarians to ensure each animal is well prepared for travel, with the necessary medical treatments. This includes microchip certification, rabies vaccinations, rabies titer testing certification, parasitic treatments, and all necessary endorsements for any import and export permits.
- Liaising with destination country brokers to ensure all import information is electronically processed with Customs, in a timely and accurate manner.

Each of the Soi Dog exports to the United States, both before the Temporary Suspension, and after the new CDC "pathways" were created, were conducted in compliance with all applicable regulations, including advance USDA APHIS Live Dog Import Permits, and utilizing the services of an accredited import broker.

As Soi Dog exports dogs to other countries which already required post-vaccination pre-entry serology testing, such as the members of the European Union or the U.K., Soi Dog has for many years had dogs that were strong candidates for international adoption routinely tested, to ensure they met the strict requirements of those countries. This meant that many of the dogs that were sent to the United States prior to the current controls were already in possession of a valid rabies serology test, even though not required. Soi Dog uses a fully-accredited laboratory in Germany for carrying out the tests.

Accordingly, Soi Dog was titer testing dogs destined for the United States even before the CDC's Temporary Suspension.

Soi Dog Experience with the Temporary Suspension Import Rules

Based upon Soi Dog's experience and observations:

• More advance thought, planning, and especially staffing, would have been beneficial at the outset of the Temporary Suspension.

The sudden imposition of the CDC Temporary Suspension and the new CDC Dog Import Permit process clearly had a "bumpy" rollout, with significant confusion over what the process actually required and inadequate communication/coordination among the various parties involved, i.e. CDC, CBP, USDA/APHIS, foreign and domestic (US) airlines, and various categories of applicants. Although Soi Dog, as a rescue organization, was initially deemed "ineligible" to apply for a Dog Import Permit (until the June 1, 2022, Extension announcement) like many in the regulated community we were well aware of the multitude of problems airlines, brokers, and applicants initially encountered.

Insufficient staffing resources continues to be an issue even today, and presumably contributes to unduly long delays in designating additional approved ports-of-entry (both for air and land or sea arrivals); for processing permits under "Option B," and the appointment of additional Approved Animal Care Facilities under "Option C".

- It still remains unclear "who is in charge" (e.g. CDC, CBP, USDA/APHIS) particularly when there is an issue which needs to be resolved for a problematic import.
- The system would benefit if the government's requirements were properly found on a single, easier to use, website.

Responsible exporters and importers want to comply with the applicable governmental requirements.

However, the CDC website is confusing, lacks a reliable index or table of changes, sometimes provides information which conflicts with other website information or that was contained in the various Federal Register notices. Additionally, the information is spread over too many constantly changing webpages.

Entirely apart from the question of the legal sufficiency of promulgating the rules in this manner, as a practical matter, it makes it difficult for both individual government officials and the public to find what is truly required.

Specifically, a more user-friendly online portal for the management of applications would be helpful.

The APHIS eFile portal worked well in this respect, it allowed a centrally accessible portal for both parties to use. Erroneous documents and data were able to be changed in situ without the need for lengthy to-and-fros on email.

However, we are also aware that the use of the eFile portal was probably far below the CDC permit applications level. The APHIS Veterinary team were able to manage cases more proactively as a result, errors were pointed out and could be changed within a day of submission. permits were typically issued no more than 7 days after submission.

With the current lead times from submission to granted CDC permits being 7 or more weeks, one can see the size of the problem faced by the CDC teams.

- In the long term a single agency should take the lead as the primary point of contact for the public.
- There is a clear need for additional Approved Animal Care Facilities for "Option C".

Presumably the majority of imports will be conducted through "Option C" which currently requires the use of one of the five existing ACFs (JFK, IAD, ATL, MIA and LAX). That prohibits entry at several other import airports, such as Chicago (ORD) and Seattle (SEA) or San Francisco (SFO) on the West Coast.

Additionally, the lack of more ACFs means there is little to no competition currently for their services and, as a direct result, pricing models have been somewhat arbitrarily applied.

Beyond appointing additional Animal Care Facilities, other alternatives should be considered.

From the user perspective "Option C" works well for a capable and responsible organization like Soi Dog, except in terms of cost. All the complexity and onerousness of dealing with the USDA and CBP is undertaken by the ACF, They are effectively a costly middleman, in a process we are more than capable of doing ourselves. Perhaps equally effective mechanisms could be created for a subset of vetted and government approved responsible exporters or importers which does not require the use of an ACF.

• The post-arrival booster/revaccination requirements under "Option B" and "Option C," for dogs who already have successful titer tests, are an additional cost item which does not appear to be scientifically justified.

Dogs with titer in excess of the required threshold, from government approved laboratories, are already protected against rabies and scientifically pose no risk. Accordingly, the booster revaccination requirement is not justifiable and should be removed going forward.

This is different from the revaccination, retesting, and quarantine requirements for dogs arriving without a successful titer test, where there is a scientific justification for the additional measures may be made.

• The instructions for a CDC Dog Import Permit under "Option B" need to be updated to reflect other changes the CDC has made to its controls.

Firstly, in "Section F: Request Details," Field 35, still asks applicants to identify the purpose of the import, although the CDC no longer imposes such restrictions on permit applicants – and scientifically the "purpose" of the import (unlike the presence or absence of rabies antibodies) was never relevant to the scientific risk posed by importing the animal.

Secondly, in the instructions to "Section B: Permit Holder", it still states that "Flight Parents may not serve as Permit Holders" and that should be removed. Logically, it conflicts with the immediately preceding statement that Applicants may designate others to be Permit Holders and, moreover, the identify of someone travelling with a dog under a permit (unlike the presence or absence of rabies antibodies) was never relevant to the scientific risk posed by importing the animal.

Soi Dog's Perspective

On January 4, 2022, in response to the CDC's imposition of its "Temporary Suspension" of dogs from 113 countries, Soi Dog – along with eleven other non-profit animal rescue organizations – made a submission to both HHS and the CDC under Section 553(e) of the Administrative Procedure Act recommending five specific actions. Although neither HHS nor the CDC acknowledged the receipt of our document, nor responded to various requests to discuss the matter, the CDC did modify the rules of the initial Temporary Suspension in postings on its various webpages in the ensuing months.

Accordingly, we were pleased to see the agency update its 1950s era, "paper-based," rabies import controls, to reflect the internationally recognized scientific standards adopted and implemented by many other countries. Those international standards recommend modern post-vaccination serology testing, prior to arrival, to verify that imported animals do not pose a rabies risk to either humans or other animals in the importing country. We were also especially gratified when the agency removed its initial prohibition on imports by animal rescue organizations, and now provide a pathway – albeit an expensive and complicated pathway – for international dog rescues to continue. Now, with the pending proposal to incorporate all these various import rules into a Notice of Proposed Rulemaking published in the Federal Register, the CDC has essentially addressed and adopted three out of the five "Action Items" we proposed in our January 2022 submission.

The two remaining recommended Action Items were to properly and formally incorporate the controls the CDC was posting under the Temporary Suspension into its regulations ("Action Item 4 in the January 2022 submission), and to establish an Advisory Committee to facilitate ongoing engagement with stakeholders and the regulated community to continually improve its regulatory controls (Action Item 5 in the January 2022 submission). Updated and revised detailed versions of those two recommendations, reflecting the intervening changes the CDC made to its rabies import controls since our §553(e) submission last year, are attached to this Briefing Memorandum.

Soi Dog's Regulatory Proposal

The attached revision to Action Item 4 from our §553(e) submission attempts to incorporate the updated version of the CDC's rabies import controls into the agency's regulations. Among the details noted in the attached revision you will notice we did introduce and propose, however, four significant changes.

- 1. Under "Option A," the requirement that a rabies vaccination by a U.S. licensed veterinarian must also be administered within the United States is removed. The logic being that if U.S. licensed veterinarians are entitled to special consideration or trust when completing rabies vaccination certificates, as compared to foreign practitioners, that special consideration should not be affected by where the U.S. licensed veterinarian is located when he or she administers the vaccination. See proposed § 71.51(e)(2)(ii).
- 2. The one-time application and three dog maximum limits on applying for a CDC Dog Import Permit under "Option B" are removed, and the permit is restyled as a *Single-Transaction CDC Dog Import Permit*, and the entry option is restyled as "Option B1". See proposed § 71.51(e)(2)(iii)(A).
- 3. A new entry option is proposed, for "CDC Registered Importers" who could apply for a new "CDC Multi-Entry Dog Import Permit," under a new entry pathway styled as "Option B2". See proposed § 71.51(e)(2)(iii)(B).
 - This expands the existing "Option B" pathway, permitting vetted and pre-approved importers, who commit to additional governmental checks and requirements, to make multiple shipments. In effect it blends that added security and control the

- government has with approved partners under "Option C" with the added flexibility (and ports-of-entry) available to importers under "Option B" but without requiring the CDC to extensive additional permit processing. And, as noted in Action Item 4, the CDC already has experience with a roughly similar licensing scheme dealing with importers of non-human primates. See 42 CFR § 71.53.
- 4. The concept of "approved" ports of entry is expanded to include other airports or other types of entry points where additional non-governmental quarantine or isolation facilities may be available which, in the CDC Director's opinion, are satisfactory in the event an animal needs to be detained. This would be particularly useful with Registered Importers who have the appropriate facilities themselves. See proposed § 71.51(e)(3)(iii).

Soi Dog's Additional Recommendation

Our primary recommendation is that it is in the CDC's long-term interest to engage with the regulated community in order to better achieve the agency's control objectives and to improve the efficiency and ongoing operation of its rabies import control program. Establishing an Advisory Committee, comprised of responsible stakeholders in addition to health specialists, would greatly assist the CDC in dealing with the multiplicity of issues associated with dog importation.

Responsible members of the regulated community, such as Soi Dog, completely and unequivocally support the CDC's efforts to keep the country free from canine rabies. However, numerous interested parties, rescue organizations, and other significant stakeholders, were neither involved with the formulation of the Temporary Suspension nor consulted regarding the various subsequent changes. Indeed, many of the dealings among the interested public, the regulated community, and the agency, were characterized by an unnecessary and unfortunate adversarial tone and an actual refusal to communicate.

Those of us engaged in international dog rescue recognize that we are partly responsible for that state of affairs, as international rescues generally have not done a good job of explaining how seriously we regard the health risks posed by international animal transport, the lengthy and extensive steps we take to address those risks, and the fact that various import regulations have actually long held rescues to higher health standards than are applied to non-commercial importers, such as those dealing with privately owned pets. In the absence of conveying what responsible importers are actually doing, the government, of course, focused on the problems caused by supposed (and misnamed) "retail rescues," puppy traffickers, fraudsters, and scammers, and erroneously assumed that they represented the wider rescue community – as can still be seen on some CDC webpage entries.

However this state of affairs came to be, we would submit that it was this lack of involvement with the regulated community, those who are actually conducting the imports the CDC sought to address, which significantly contributed to the bumpy roll-out of the new import rules and the many issues encountered with the structure of the program. A different approach, recognizing that responsible rescue organizations and the wider regulated community are partners with the government in controlling the risks associated with living in the global era, would contribute to a more effective efficient rabies import control program.

As we wrote in Action Item 5 in our §553(e) submission:

"Tackling the broader issues associated with dog importation is an ideal area in which an Advisory Committee, comprised of responsible representatives from the importing, brokerage, and airline communities, in addition to health specialists, would be of assistance to the agency going forward. As CDC representatives have publicly acknowledged, "[r]evision of current CDC dog importation policies should be considered" not only to promote "enhanced and coordinated screening by U.S. government agencies for all live dog importations," but also to leverage governmental resources with those of the regulated community to "stop the transportation of animals that do not meet U.S. entry requirements ... in the departure country" rather than upon arrival." [Citations omitted.]

Our understanding is that there are roughly 250 Advisory Committees active at HHS, including 21 which are responsible for advising the CDC. Other agencies with similar controls, such as Commerce's Bureau of Industry and Security and State's Directorate of Defense Trade Controls, for example, make good use of Advisory Committees with membership drawn from their regulated communities to help achieve their respective control objectives as efficiently and effectively as possible. The CDC could benefit from this approach as well.

Accordingly, we would encourage HHS/CDC to establish a permanent Advisory Committee drawn from responsible members of the regulated community to help with ongoing monitoring and improvements to its dog import controls. Some of the issues and tasks such an Advisory Committee could address are outlined in the revised text of Action Item 5 from our earlier submission, which is attached to this memo for your convenience.

Examples of important additional issues an Advisory Committee on Rabies Import Controls might address or explore, among others, include:

- The need to harmonize inter-agency controls and develop a "single face" for the public and stakeholders.
- Eliminating non-scientific distinctions (such as commercial vs non-commercial) among different imports or importers.
- Reestablishing rabies vaccination, and possibly imposing titer testing, requirements for all importers for all purposes.

Conclusion

ATTACHMENTS:

<u>Updated and Revised Excerpts from January 4, 2022, APA §553(e) Petition</u> Submitted to HHS/CDC by Soi Dog and Eleven Other Rescue Organizations

Action Item 4: Update and revise Code of Federal Regulations, Title 42, Chapter 1, Subchapter F, Part 71 with the rules associated with the import ban and the new CDC Dog Import Controls.

Petitioners urge the CDC to revise and update the agency's importation regulations in the CFR as shown below.

The *Code of Federal Regulations* (CFR), is the official codification of the general and permanent rules published in the Federal Register.¹ Title 42, which contains the CDC's regulations is updated and published annually on October 1st and supplemented in the interim by the daily Federal Register.²

Since 1957, the CDC has had regulations in place governing the importation dogs from rabies endemic countries, and the current regulations are found at 42 CFR 71.51.³ Those pre-Suspension regulations are still "on the books," and were not amended or revised by the Federal Register Notices the agency issued in June, 2021, June 2022, and in January 2023. Nor have the CDC's regulations changed as a result of any of agency's website postings.

Therefore, the following markup incorporates the basic provisions of the Temporary Suspension, as of the January 24, 2023, website Update, into the regulations.

However, while moving as much content as possible into the text of the regulations, the markup does not reflect a redesigned/restructured website as suggested in **Action Item 2**. So, for example, pointers to the lists on various webpages remain, and should be readjusted when the website redesign is accomplished.

Notably the markup:

¹ 44 U.S.C. § 1510.

² National Archives, "About the Code of Federal Regulations" https://www.archives.gov/federal-register/cfr/about.html.

³ See, 42 CFR 71.154(c) and (d) in "Codification Guide Title 42, Chapter I, Part 71", 22 FR 6460, at 6463 (August 13, 1957). https://archives.federalregister.gov/issue_slice/1957/8/13/6457-6464.pdf#page=4; and 42 CFR 71.51(c) and (d) (2022).

- Adds a clarification to the definition of "Person" in § 71.50(b);
- Adds a standard definition of "US Person" to § 71.51(a);
- Incorporates the definitions of "Certified Translation," "Valid Rabies Serologic Titer Test" and "Valid Rabies Vaccination Certificate" found on the CDC's webpages into § 71.51(a);
- Updates the "Rabies Vaccination Requirements for Dogs" in § 71.51(c)(1)-(3),
 - o to reflect the CDC's updated new requirements for imports from high-risk countries,
 - o and to delete the now obsolete confinement agreement provisions previously found in the old version of § 71.51(c)(2);⁴
- Deletes the reference to "confinement", and adds a reference to "testing" in § 71.51(d);
- Adds the updated basic provisions of the CDC Dog Import Permit program ("Option B") to § 71.51(e)(2)(iii)(A),
 - o Without the limited categories of eligible applicants,
 - Without the one-time application, and three-dog-maximum restrictions,
 - o *But With* the 6 months minimum age, vaccination, Rabies Vaccination Certificate, and Serology Testing, and other application information requirements from the CDC webpages,
 - And With the requirement to use of approved Ports of Entry in § 71.51(e)(3);
- Bolsters the general requirement of § 71.51(b)(2) to appear healthy upon arrival with an additional reference in § 71.51(e)(2)(i), and the cross reference to that same provision is corrected in § 71.51(f)(1);
- And incorporates the provisions for dogs vaccinated by US-licensed veterinarians (aka "Option A") into § 71.51(e)(2)(ii),
 - Without also requiring that the US vaccination is documented by a "US-issued" Rabies Vaccination Certificate (i.e. even a vaccination by a US-licensed veterinarian who completes the Rabies Vaccination Certificate overseas would qualify under this provision).

Particular attention should also be given to two entirely new provisions Petitioners urge the CDC to adopt.

⁴ In 2019 the CDC announced that Confinement Agreements under 42 CFR 71.51(c)(2) are no longer available for dogs arriving from high-risk countries that are inadequately vaccinated against rabies, but confinement of dogs that do not appear healthy upon arrival is still possible under 42 CFR 71.51(b)(2). See, CDC, "Guidance Regarding Agency Interpretation of "Rabies Free" as it Relates to the Importation of Dogs into the United States", 84 FR 724 at 726 (January 31, 2019) https://www.govinfo.gov/content/pkg/FR-2019-01-31/pdf/2019-00506.pdf.

Firstly, in § 71.51(e)(3)(iii) Petitioners urge the CDC to expand the concept of "approved" ports of entry beyond the 18 airports with CDC quarantine facilities currently listed on the CDC's website,⁵ to include additional airports and other types of ports of entry, based upon the availability of other quarantine or isolation facilities which, in the Director's opinion, afford the necessary protection against disease in the event a dog needs to be detained.

This provision builds upon the old, and now obsolete, confinement agreement concepts, and attempts to provide the agency the express flexibility to selectively adapt to some importers' need to use land crossings or other ports of entry where governmental quarantine facilities may not be available, particularly where state authorities may rigorously regulate such private facilities.⁶ This flexibility might be

(1) General Facilities

* * *

(2) Quarantine Room. In addition to complying with 330 CMR 30.05(1), each Facility shall:

- (a) Provide a room to be used exclusively for the purposes of Quarantining sick or diseased Animals; and
- (b) Ensure that the room, in addition to complying with the requirements of 330 CMR 30.05(1) and (5), is:
 - 1. Physically separated from rooms used to maintain other Animals;
 - 2. Completely enclosed by walls that extend from floor to ceiling;
 - 3. Constructed with floors and walls made of Impervious surfaces;
 - 4. Equipped with an exhaust fan that serves to efficiently remove air from the room to an area outside the building and adequately ventilates to allow fresh air to circulate into the room;
 - 5. Equipped with a sink having hot and cold running water used exclusively for the cleaning and maintenance of the Quarantine Room, all equipment and utensils used therein, and Animals housed within the room;
 - 6. Not used to house or maintain other Animals, for storage, as an employee restroom, as a public access area, or any other such purpose;
 - 7. Thoroughly Cleaned and Disinfected immediately after Animals have been removed from the room and prior to the placement of other Animals into the room; and
 - 8. Maintained in such a manner that all equipment and utensils used within the room are thoroughly Cleaned and Disinfected before being taken out of the room.
- (3) <u>Isolation Room</u>. In addition to providing a Quarantine Room as required by 330 CMR 30.05(2), each Licensee holding an Import License shall:
 - (a) Provide an Isolation Room for the exclusive purpose of isolating newly acquired Dogs and Cats;
 - (b) Ensure that the Isolation Room complies with the requirements of 330 CMR 30.05(1), (2)(b), and (5);
 - (c) Ensure that Quarantined sick or diseased Animals and Isolated newly-acquired Dogs and Cats are not maintained in the same Quarantine/Isolation Room simultaneously; and

⁵ See CDC, "What Your Dog Needs to Enter the United States," https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/dog-origin.html.

⁶ See, e.g., Massachusetts Department of Agricultural Resources, "Animal Rescue and Shelter Organization Regulations," 330 CMR 30.05, "Facility Requirements" which mandates:

particularly useful with "CDC Registered Importers" who hold "Multi-Entry Dog Import Permits," which are discussed next.

Secondly, Petitioners urge the CDC to create and adopt a new "Multi-Entry Dog Import Permit", for use by "CDC Registered Importers", as proposed in § 71.51(e)(2)(iii)(B) below. This would be a variation of the current Option B CDC Dog Import Permit rules and might be considered as either a subset of that provision, or perhaps as an "Option B2".

While an application process would need to be established for Registered Importers, as well as for the multi-transactional permit or license, the CDC already has experience with a roughly similar scheme in its regulations for Importers of Non-Human Primates.⁷

US Persons with a demonstrated record of compliance with all applicable live dog import regulations could apply in advance, and would commit to, for example, making their facilities, vehicles, equipment, and business records, available to the CDC for inspection as part of the approval and vetting process. Additionally, Registered Importers would also commit using CBP registered Customs Brokers and pre-clearing all imports prior to shipment. Steps such as these would simultaneously help alleviate the CDC's concerns over irresponsible importers such as puppy traffickers and others who create unnecessary risks by disregarding or abusing the government's import controls, and the occasional instances of CDC and Customs officials being surprised at various ports of entry by unanticipated arrivals at odd hours as could happen under the old regulations.

The Multi-Entry Dog Import Permit would be analogous to the current single transaction Dog Import Permit under "Option B," and have the same basic requirements. The principal difference would be that, once the Registered Importer is approved and received its basic Multi-Entry Permit authorization, the specific

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⁽d) If maintaining the Isolation Room for Isolation Upon Import, provide a separate entrance through which the Imported Dog or Cat can enter without passing through any area where other Animals are housed, handled, or cared for.

^{(4) &}lt;u>Protective Clothing for Quarantine and Isolation Rooms.</u> Each Licensee shall ensure that each person who enters a Quarantine or an Isolation Room or otherwise feeds, waters, cleans, treats, or handles Quarantined or Isolated Animals showing signs of infectious or contagious disease or disease-contaminated equipment or material shall wear clean protective outerwear, gloves and shoe covers, or take equivalent biosecurity measures while so doing, and shall remove and adequately clean or dispose of the protective outerwear, gloves, and shoe covers, or equivalent, and thoroughly wash their hands with soap and water immediately upon leaving such room.

⁷ 42 CFR 71.53

details regarding the particular dog(s) in each shipment, including their vaccination and serology testing information, would be provided closer to the actual time of shipment. For example, the proposed regulation suggests seven days, rather than six weeks in advance as under the current permit application scheme. The information would then be provided to the government in advance of the shipment as part of the pre-clearance process handled by the CBP approved customs broker. We also arbitrarily propose that the Multi-Entry Dog Import Permit be valid for a period of three years. The multi-entry process would reduce the time the CDC would otherwise need to spend processing individual permit applications and create a more efficient process for known responsible importers who otherwise engage in multiple import transactions over time.

REGULATORY MARKUP

(Additions are <u>underlined</u>, and deletions are <u>struck through</u>)

Title 42 - Public Health

CHAPTER I - PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES.

SUBCHAPTER F - QUARANTINE, INSPECTION, LICENSING.

PART 71 - FOREIGN QUARANTINE.

Subpart A—Definitions and General Provisions

§ 71.1 Scope and definitions.

- (a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or territories (also known as possessions) of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR parts 1240 and 1250 and 42 CFR part 70.
- (b) As used in this part the term:

* * * *

Communicable disease means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected

person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

* * * *

Director means the Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative.

* * * *

Subpart F—Importations

§ 71.50 Scope and definitions.

- (a) The purpose of this subpart is to prevent the introduction, transmission, and spread of communicable human disease resulting from importations of various animal hosts or vectors or other etiological agents from foreign countries into the United States.
- (b) In addition to terms in § 71.1, the terms below, as used in this subpart, shall have the following meanings:

Animal product or Product means the hide, hair, skull, teeth, bones, claws, blood, tissue, or other biological samples from an animal, including trophies, mounts, rugs, or other display items.

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Exhibition purpose means use as part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely schedule for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

In transit means animals that are located within the United States, whether their presence is anticipated, scheduled, or not, as part of the movement of those animals between a foreign country of departure and foreign country of final destination without clearing customs and officially entering the United States.

Isolation when applied to animals means the separation of an ill animal or ill group of animals from individuals, or other animals, or vectors of disease in such a manner as to prevent the spread of infection.

Licensed veterinarian means an individual who has obtained both an advanced degree and valid license to practice animal medicine.

Person means any individual or partnership, firm, company, corporation, association, organization, including a not-for-profit organization such as a rescue organization, sanctuary, or shelter, or other legal entity. or similar legal entity, including those that are not-for-profit.

Quarantine when applied to animals means the practice of separating live animals that are reasonably believed to have been exposed to a communicable disease, but are not yet ill, in a setting where the animal can be observed for evidence of disease, and where measures are in place to prevent transmission of infection to humans or animals.

Render noninfectious means treating an animal product (e.g., by boiling, irradiating, soaking, formalin fixation, or salting) in such a manner that renders the product incapable of transferring an infectious biological agent to a human.

Scientific purpose means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products. *You* or *your* means an importer, owner, or an applicant.

§ 71.51 Dogs and cats.

(a) Definitions. As used in this section the term:

Cat means all domestic cats.

<u>Certified translation</u> means a signed statement on professional letterhead issued by a licensed translator declaring that the translation is an accurate and true representation of the original document. The translation must include the name, address, and contact information of the translator and have a signatory stamp or elevated seal with the translator's license number.

Confinement means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

Dog means all domestic dogs.

Owner means owner or agent.

<u>U.S. Person</u> means any United States citizen or alien admitted for permanent residence in the United States, and any corporation, partnership, or other organization organized under the laws of the United States.

<u>Valid rabies serologic titer test</u> means a laboratory test used to detect the presence of rabies antibodies in blood.

- (1) The titer must be collected in accordance with the WOAH "Manual of Diagnostic Tests and Vaccines for Terrestrial Animals", Chapter 3.1.17, (https://www.woah.int/fileadmin/Home/eng/Health standards/tahm/3.01.17 R ABIES.pdf) a minimum of 30 days after an initial rabies vaccination and at least 45 days before US entry. Dogs due to receive rabies vaccination boosters may have their titers drawn at any time, but titers are most easily detected at least 30 days after vaccination;
- (2) Results from an approved laboratory must show rabies antibody levels equal to or greater than 0.5IU/ml. The list of approved testing laboratories is found at the CDC "Approved Rabies Serology Laboratories for Testing Dogs" webpage https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/approved-labs.html, or may be requested by email to cdcanimalimports@cdc.gov.
- (3) Rabies serology test results are valid for one year and must be in English or accompanied by a certified translation.

Valid rabies vaccination certificate means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which: documents a dog's vaccination against rabies, and must include all of the following information:

- (1) Name and address of the dog's owner;
- (2) The dog's breed, sex, date of birth (or approximate age if date of birth is unknown), color, and markings;
- (3) The dog's iso-compatible microchip number;
- (4) The date of rabies vaccination and vaccine product name, manufacturer, lot number and product expiration date;
 - (i) Puppies must *not* be vaccinated *before* they are 12 weeks (84 days) of age;
 - (ii) Adult dogs (15 months or older) must show a history of previous rabies vaccination with at least one vaccine given after three months of age and one current booster rabies vaccination;
 - (iii) All dogs vaccinated against rabies for the first time must be vaccinated at least 4 weeks (28 days) before traveling. Adult dogs with boosters who meet the requirements immediately above do not need to wait 4 weeks before traveling.

- (1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.
- (2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.
- (5) (3) The certificate must specify a vaccine expiration date Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.
- (4) Bears the signature of a licensed veterinarian.
- (6) Provides the name, license number or official seal, address, telephone or email address, date and signature of the veterinarian who administered the vaccination.
- (7) The certificate must be in English or accompanied by a certified translation.

Health certificates or pet passports without proof of rabies vaccination, veterinarian exemption letters, or rabies antibody titer values or serologic test results are not acceptable as proof of vaccination in lieu of a valid rabies vaccination certificate.

- (b) General requirements for admission of dogs and cats—
 - (1) *Inspection by Director*. The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.
 - (2) Examination by veterinarian and confinement of dogs and cats. When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.
 - (3) Record of sickness or death of dogs and cats and requirements for exposed animals.

- (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.
- (ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph § 71.51 (b)(2) of this section shall be applicable to the examination or tests.
- (4) Sanitation. When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.
- (c) Rabies vaccination requirements for dogs.
 - (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a <u>live</u> dog <u>from any country which the Director has designated as a high-risk country for dog rabies. A current list of high-risk countries for dog rabies may be found at the CDC "High-Risk Countries for Dog Rabies" webpage https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/high-risk.html or requested by email to cdcanimalimports@cdc.gov.</u>
 - (2) A valid rabies vaccination certificate is *not* currently required at a U.S. port for admission of a live dog if the dog is imported from a rabies-free country (a current list of rabies-free countries may be found at the CDC, "Rabies Status: Assessment by Country" webpage, http://cdc.gov/rabies/resources/countries-risk.html or requested by email to cdcanimalimports@cdc.gov.), and the if owner submits evidence satisfactory to the Director that:
 - (i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free; or (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333); or
 - (ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free.
 - (iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

- (3) Regardless of the provisions of this paragraph addressing dog imports from rabies-free countries, vaccination against rabies and possession of a valid rabies vaccination certificate is strongly recommended and encouraged for *all* dogs imported into the United States. Importers should also be aware that dogs imported for commercial purposes (adoption, resale, or transfer of ownership) from any country are subject to additional requirements from the US Department of Agriculture, which require the provision of a valid rabies vaccination certificate as described in these regulations, or its substantial equivalent. Importers must comply with all applicable USDA and State regulations, in addition to these CDC regulations.
- (2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:
 - (i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;
 - (ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;
 - (iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in confinement for at least 30 days after the date of vaccination.
- (3) When a dog is admitted under paragraph (c)(2), the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.
- (d) *Certification requirements*. The owner shall submit such certification regarding confinement and vaccination and testing prescribed under this section as may be required by the Director.
- (e) Additional requirements for the importation of dogs and cats. Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.
 - (1) Dog from Countries Without High Risk of Dog Rabies

Dogs that have NOT been in a high-risk country in the past 6 months may enter the United States through any port of entry, and importers are NOT required by CDC to present rabies vaccination documentation. However, when your dog enters the United States, you must provide a written or verbal statement your dog has only been in a

country NOT at high risk for at least 6 months or since birth if under 6 months of age. There is no limit to the number of dogs.

- (2) Dogs from High-Risk Countries for Dog Rabies
 - (i) All dogs imported from high-risk countries must:
 - (A) Appear healthy on arrival.
 - (B) Be at least 6 months old;
 - (C) Have a valid *CDC Rabies Vaccination and Microchip Record* or rabies vaccination certificate which meets the requirements of § 71.51(a) issued by a U.S. licensed veterinarian.
 - (D) Have an ISO-compatible microchip for identification listed on their rabies vaccination certificate or CDC Rabies Vaccination and Microchip Record.
 - (E) Meet the requirements of either Option A, B1, B2, or C below.
- (ii) Dog Imports from High-Risk Countries Option A
 - (A) Dog imports accompanied with a rabies vaccination certificate which meets the requirements of § 71.51(a) issued by a U.S. licensed veterinarian, and which otherwise meet the requirements of § 71.51(e)(2)(i), may enter the country at any airport with a CDC quarantine station.
 - (B) While not required, use of the *CDC Rabies Vaccination and Microchip Record* form is strongly encouraged to facilitate entry clearance.
 - (C) The importer must also comply with all applicable USDA or State import regulations.
- (iii) Dog Imports from High-Risk Countries Options B1 and B2
 - (A) Option B1. Single Transaction CDC Dog Import Permit for dogs imported from high-risk rabies countries.

Three or fewer dogs may be imported from one or more high-risk rabies countries in a single trip under a *Single Transaction CDC Dog Import Permit*. Applications may be obtained, and submitted electronically, at the CDC, "How to Apply for a CDC Dog Import Permit" webpage, https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/apply-dog-import-permit.html; or requested by email to cdcanimalimports@cdc.gov.

The completed Permit application must include the following:

Applicant Information:

- (1) The name, address, and contact information for the applicant and any designated permit holder intending to import the dog(s) into the United States, including a copy of the photo page of the applicant's (and holder's) passport, visa, or US Citizenship and Immigration Services number, as applicable; and,
- (2) The purpose of the importation.

<u>Information Regarding Dog(s) to be Imported:</u>

- (3) The most recent country of origin, and length of time the dog(s) were present in a high-risk country; and,
- (4) Each dog's date of birth, showing that the dog is at least six months old, as verified by accompanying current photographs of its teeth; and,
- (5) Each dog's microchip number, as well as their breed, color, and sex, and other identifying markings as appropriate; and,
- (6) A properly completed *CDC Rabies Vaccination and Microchip Record* for each dog; and,
- (7) The date of each dog's most recent valid rabies serologic titer test, and a certificate of the results, which meets all the requirements of § 71.51(a), and includes the dog's microchip number.

Travel Information:

- (8) The port of embarkation and the mode of transportation; and,
- (9) The proposed port of entry in the United States; and,
- (10) The proposed date of arrival in the States.

Dogs entering under a Single Transaction CDC Dog Import Permit, and otherwise meet the requirements of § 71.51(e)(2)(i), may enter the country at any airport with a CDC quarantine station.

- (B) Option B2: CDC Multi-Entry Dog Import Permit for dogs imported from high-risk rabies countries.
- U.S. Persons with a demonstrated record of compliance with all applicable live dog import regulations may apply to become CDC Registered Importers, eligible to use a

CDC Multi-Entry Dog Import Permit in lieu of the standard CDC Dog Import Permit or other Options described in § 71.51(e)(2)

A CDC Multi-Entry Dog Import Permit provides advance written authorization for the CDC Registered Importer to import dogs, which are at least six months old, from high-risk rabies countries for a period of up to [three] years.

- (1) When applying to become a CDC Registered Importer and receive a CDC Multi-Entry Dog Import Permit, the US person must provide Applicant Information analogous that detailed in § 71.51(e)(2)(iii)(A)(1) & (2). That includes providing its name, address, and contact information as the prospective permit holder intending to import the dogs into the United States; as well as providing a copy of the photo page of the applicant's passport, visa, or US Citizenship and Immigration Services number, or organizational corporate registration, as applicable; and,
- (2) The specific high-risk rabies country or countries from which the dogs will be imported; and,
- (3) The purpose of the importation.
- (4) The Information Regarding Dogs to be Imported, and their Travel Information, analogous to that detailed in § 71.51(e)(2)(iii)(A)(3) to (10) and specifically including both a CDC Rabies Vaccination and Microchip Record and a certificate of the results of a valid rabies serologic titer test matched to each dog's microchip number must be provided to the CDC at least [seven] days in advance of arrival of each and every shipment under the Multi-Entry Dog Import Permit.

(5) CDC Registered Importers also must:

(i) commit to using an individual or organizational Customs Broker, licensed by U.S. Customs and Border Protection, who provides the government with advance notice of each import under the CDC Multi-Entry Dog Import Permit; and,

(ii) make their facilities, vehicles, equipment, and business records, available to the CDC for inspection during operating business days and hours, and at other necessary and reasonable times, to enable CDC to ascertain compliance with the regulations in this section.

(6) Applications for a CDC Multi-Entry Dog Import Permit and to become a CDC Registered Importer, may be obtained, and submitted electronically, at the CDC, "[insert]" webpage, http://cdc.gov/[insert].html; or requested by email to cdcanimalimports@cdc.gov

- (iv) Option C: Dog Imports from High-Risk Countries, without an accompanying rabies vaccination certificate which meets the requirements of § 71.51(a) issued by a U.S. licensed veterinarian, or a CDC Single or Multi-Transaction Dog Import Permit
 - (A) Imports of dogs which do not meet the requirements of either Option A or Option B may still proceed if they meet the following:
 - (1) Arrivals are limited to designated airports with CDC Approved Animal Care Facilities (ACF), and advance reservations are required;
 - (2) The importer is responsible for the ACF fees;
 - (3) The dog(s) must be accompanied by a valid CDC Rabies Vaccination and Microchip Record and a valid serologic titer test;
 - (4) The ACF will determine if the CDC Rabies Vaccination and Microchip Record and serologic rabies titer test are valid.
 - (B) If the CDC Rabies Vaccination and Microchip Record is invalid, the dog will be denied entry
 - (C) If the serologic rabies titer test and results:
 - (1) are valid, each dog must be examined and re-vaccinated with a USlicensed rabies vaccine by a USDA-accredited veterinarian at the CDCapproved animal care facility upon arrival at the importer's or owner's expense;
 - (2) are invalid or missing, each dog must have a reservation for revaccination and quarantine at the ACF for 28 days after the exam at the importer's or owner's expense.
- (3) All dogs imported from a high-risk rabies country under this paragraph, § 71.51(e), must enter the United States either:
 - (i) at a CDC approved US port-of-entry which has a live animal care facility that meets USDA Animal Welfare Act standards, (a list of approved ports-of-entry is available on the CDC "How to Apply for a CDC Dog Import Permit: Approved Ports of Entry" webpage at https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/apply-dog-import-permit.html#approved-ports); or,
 - (ii) if being imported in accordance with § 71.51(e)(2)(iv), "Option C", through the services of a CDC approved Animal Care Facility; or,

(iii) at any U.S. port-of-entry, if the importer has State approved isolation or quarantine facilities, or other isolation and quarantine facilities which in the judgment of the Director, will afford protection against any communicable disease in the event it is necessary to detain a dog pending determination of its admissibility. Use of such isolation or quarantine facilities shall be subject to conditions specified by the Director to protect the public health.

- (4) Even though a CDC Dog Import Permit or a CDC Multi-Entry Dog Import Permit has been issued for the importation of a dog from a high-risk rabies country, or entry occurred at an Approved Animal Care Facility, dogs may only be imported if all applicable requirements of this subpart and any other applicable regulations of this subchapter and any other statute or regulation of any State or of the United States are met. All dogs, whether or not entering under a CDC Dog Import Permit or a CDC Multi-Entry Dog Import Permit, or through an Animal Care Facility, must appear healthy upon arrival and meet the general entry requirements of § 71.51(b).
- (f) Requirements for dogs and cats in transit. The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:
 - (1) Dogs and cats that appear healthy but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph § 71.51(b)(2) (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.
 - (2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.
- (g) Disposal of excluded dogs and cats. A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

<u>Updated and Revised Excerpts from January 4, 2022, APA §553(e) Petition</u> Submitted to HHS/CDC by Soi Dog and Eleven Other Rescue Organizations

Action Item 5: Acting pursuant to the Federal Advisory Committee Act, HHS and the CDC should establish an Advisory Committee drawn from the regulated community to help evaluate and improve the agency's CRVV import control system and regulations on an ongoing basis.

The Federal Advisory Committee Act (FACA)¹ governs the operation of committees or groups which involve the public consulting with executive agencies. The Act emphasizes openness and reporting of meetings between Federal agencies and groups established for the purpose of obtaining advice and recommendations regarding the agency's operations or activities. It is implemented across the government by regulations and guidance issued by the General Services Administration (GSA).² HHS currently has nearly 250 active Advisory Committees, including 21 which advise the CDC.³

Tackling the broader issues associated with dog importation is an ideal area in which an Advisory Committee, comprised of responsible representatives from the importing, brokerage, and airline communities, in addition to health specialists, would be of assistance to the agency going forward. As CDC representatives have publicly acknowledged, "[r]evision of current CDC dog importation policies should be considered" not only to promote "enhanced and coordinated screening by U.S. government agencies for all live dog importations," but also to leverage governmental resources with those of the regulated community to "stop the transportation of animals that do not meet U.S. entry requirements ... in the departure country" rather than upon arrival.

In assessing how to improve the dog import control system, there are several subjects which the Advisory Committee should consider at the outset.

Firstly, the multiplicity of agencies and regulations governing dog importations is a longstanding source of confusion and frustration among importers and government officials alike, which was exacerbated by the announcement of the Temporary Suspension. Long before the new CDC Dog Import Permit program was created, there was a complex interaction between the CDC's rabies regulatory vaccination requirements, and the USDA APHIS' import permit regulations for dogs that were intended for "adoption, resale or transfer of ownership". Additionally, the CDC assumes that a good portion of the faulty Rabies Vaccination Certificates it encounters reflect attempts by puppy traffickers and others to manipulate the differences in the various regulations to their advantage or use their complexity to evade the controls altogether.

Measures in Congress such as the proposed Healthy Dog Importation Act in the last Congress (H.R. 4239; S. 2597)¹⁰ recognize the need for harmonization and greater simplicity, but not the full scope of the issue, as they were largely based upon similar measures drafted in 116th Congress before the Temporary Suspension further complicated matters. Senator Grassley has just reintroduced the measure in the 118th Congress.¹¹

The following chart, which has been updated since the original 553(e) submission, attempts to summarize the confusing complexity of the interrelationships among these regulatory provisions and requirements, and the impact of the CDC's various changes since July 2021.

Import Purpose	At Least 4 Months Old	At Least 6 Months Old	Advance APHIS Permit	APHIS Health & Rabies Cert.	Advance CDC Permit aka now "Option B"	CDC Commercial Entry Pathway aka now "Option C"	Rabies Vaccination Certificate & Microchip	Pre-Departure Rabies Antibody Titer Test	Appear Healthy Upon Arrival	Entry thru Designated Airport or Approved Animal Care Facility	Post Arrival Revaccination and Quarantine
					PRE-TEMPORARY SUSPENSION Import from Rabies-Free Country						
Pet [CDC Regs]					N/A	N/A		N/A	х	N/A	N/A
Rescue/Resale [APHIS Regs]		х	х	х	N/A	N/A		N/A	Х	N/A	N/A
					PRE-TEMPORARY SUSPENSION Import from High-Risk Country						
Pet [Old CDC Regs]	х				N/A	N/A	х	N/A	х	N/A	N/A
Rescue/Resale [APHIS Regs]		х	х	х	N/A	N/A		N/A	х	N/A	N/A
					Import	FEMPORARY SUSPE (7/21-6/22) from High-Risk Oreign Rabies Vac	Country				
Pet [New CDC Rules]		х			X Max 3 Pets	N/A	x	х	х	18 Designated Airport Ports of Entry	N/A
Rescue/Resale [New CDC Rules]	NO CDC PERMITS AVAILABLE due to ELIGIBILITY RESTRICTIONS NO APHIS PERMITS AVAILABLE as APHIS defers to CDC import prohibition										
					POST-TEMPORARY SUSPENSION & COMMON & CO						
Pet [New CDC Rules]		х					X CDC RVC Form Recommended		х	18 Designated Airport Ports of Entry	N/A
Rescue/Resale [APHIS Regs*]		x	х	X			CDC RVC Form Recommended		x	18 Designated Airport Ports of Entry	N/A

^{*}APHIS Regs apply because dogs imported with U.S. rabies vaccination are outside the scope of the CDC Temporary Suspension (apart from 6 month minimum age, and arrival at approved port of entry, requirements) so APHIS no longer needs to defer to CDC import prohibition.

					EXTENDED TEMPORARY SUSPENSION Import from High-Risk Country With Foreign Rabies Vaccination						
Pet [New CDC Rules]		x			Option B, CDC Permit, Available Max 2 Dogs	Option C, Commercial Pathway, also available if importing 3 or more dogs No Eligibility Restrictions	X CDC RVC FORM REQ'D	х	х	18 Designated Airports if arriving under CDC Permit, Option B ACF clearance only, if arriving under Option C	Booster within 10 days of arrival Under CDC Permit, Option B Under Option C: Veterinary Exam and Booster at ACF OR Veterinary Exam, Vaccination, and 28 Day Quarantine
Rescue/Resale [APHIS Regs]		x	x	x	Option B, CDC Permit, Available Max 2 Dogs Option B Eligibility Restrictions On Rescues Removed	Option C, Commercial Pathway, Presumed Default Entry Path	X CDC RVC FORM REQ' D	x	х	18 Designated Airports if arriving under CDC Permit, Option B ACF clearance only, if arriving under Option C	Booster within 10 days of arrival Under CDC Permit, Option B Under Option C: Veterinary Exam and Booster at ACF OR Veterinary Exam, Vaccination, and 28 Day Quarantine

Harmonizing or consolidating the dog importation controls into a single agency and providing a "single face" to the regulated community – whether or not that is the CDC – should be an essential long-term goal.

Secondly, obviously, more can and should be done to help minimize or contain disease risks. All imports for adoption, resale, or transfer of ownership must go through the APHIS Live Dog Import Permit process, irrespective of where the dogs originate. That means rescue organizations – such as YGRR, Soi Dog, and the other Petitioners – are already held to higher standards than are applied to non-commercial importers such as those dealing with privately owned pets. As noted earlier, the pet versus resale distinction was also incorporated into the CDC Temporary Suspension, arguably without proper foundation, as a means of limiting applications under the CDC Dog Import Permit program. In either case, the Advisory Committee should explore eliminating the distinction altogether, ¹² so that *all* dog imports, for any purpose, are treated alike within a harmonized framework.

Thirdly, the Advisory Committee and the CDC should reevaluate whether some sort of Rabies Vaccination Certificate requirement for dogs imported from rabies-free countries is appropriate and should be re-instated. The CDC eliminated the need to provide a Rabies Vaccination Certificate for dogs entering from "rabies-free" countries in 2019,¹³ and made the United States virtually the only rabies-free country in the world without such a requirement. When it abandoned the previous 60+ years' practice, and dropped the Rabies Vaccination Certificate requirement (albeit for imports from rabies-free countries), the agency expressly authorized the legal entry of unvaccinated dogs – even though the CDC also recognized that its actions might cause state and local governments, "to increase efforts to educate their populations about their [own local] dog vaccination requirements."¹⁴

Part of the justification for dispensing with the certificate requirement was that imports from other rabies-free countries were viewed as presenting an "extremely low" risk of importing a dog with CRVV.¹⁵ Interestingly, the agency stated that a low – but non-zero – level of risk was entirely acceptable. The CDC wrote, "[t]he 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."¹⁶

The contrast with the zero-tolerance approach the CDC uses to justify its Temporary Suspension, only seventeen months later, is striking. In announcing the Temporary Suspension, the CDC asserted that, "[t]he 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 health."¹⁷

Most likely, an approach that is somewhere in the middle is perhaps most appropriate. A proper risk analysis is certainly useful in addressing rabies prevention and, for example, supports Petitioners' proposed regulatory revisions opening up the basic CDC Dog Import Permit program to *any* importer, for any purpose, whose dogs can meet the permit program's vaccination and antibody testing requirements. Adding the post-vaccination verification of rabies antibody results by an approved lab tied to the animal's microchip means the risk posed by an import of that particular dog is indeed very low. However, it also is prudent not to completely abandon documenting rabies vaccinations from imported animals altogether. Indeed, the WHO recommends the "presentation of a valid international veterinary certificate for all imported animals, whether coming from rabies-free or rabies endemic countries." For example, the State of Hawaii not only requires microchipping and health and rabies vaccination certificates, but also a rabies titer test even when arriving from a "rabies-free" jurisdiction (such as the mainland U.S.), with exceptions only for the British Isles, Australia, Guam, or New Zealand.²⁰

The Advisory Committee could help explore how, irrespective of origin, Rabies Vaccination Certificates could still be used with imports that do not require an import permit. For example, a personal pet under the

current CDC regulations could be checked upon arrival with minimal effort or, ideally, entered in advance no later than the time of departure.

- ¹⁰ H.R. 4239, https://www.congress.gov/bill/117th-congress/house-bill/4239?q=%7B%22search%22%3A%5B%22healthy+dog+importation+act%22%2C%22healthy%22%2C%22dog%2 2%2C%22importation%22%2C%22act%22%5D%7D&s=2&r=1.
- ¹¹ See, Press Release, *Grassley, Smith Reintroduce Legislation to Prevent Spread of Foreign Animal Diseases,* https://www.grassley.senate.gov/imo/media/doc/healthy_dog_importation_act_of_2023.pdf
- ¹² Eliminating the distinction as it applies to the USDA APHIS import controls may well require amending the Animal Welfare Act, but in a manner which is different from that envisioned in the proposed Healthy Dog Importation Act.
- See, CDC, "Guidance Regarding Agency Interpretation of 'Rabies-Free' as It Relates to the Importation of Dogs Into the United States" 84 FR 724 (January 31, 2019) https://www.govinfo.gov/content/pkg/FR-2019-01-31/pdf/2019-00506.pdf.
 Id. at 730.

¹ 5 U.S.C. App. https://www.govinfo.gov/content/pkg/USCODE-2011-title5/pdf/USCODE-2011-title5-app.pdf.

² See, GSA, "Federal Advisory Committee Act Management Overview", https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-act-faca-management-overview.

³ See, GSA FACA Database, "Agency Reports: Department of Health and Human Service"s, https://www.facadatabase.gov/FACA/apex/FACA/apex/FACAPublicAgencyReports?id=001t000000DCAp5AAH.

⁴ Emily Pieracci, et al, "US dog importations during the COVID- 19 pandemic: do we have an emerging problem?" PLOS ONE, September 7, 2021 (hereafter "DOG IMPORTATIONS DURING THE PANDEMIC") https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0254287.

⁵ E.G. Pieracci *et al*, "*Risk factors for death and illness in dogs imported into the United States, 2010–2018,"* TRANSBOUNDARY AND EMERGING DISEASES (pre-publication submission, 2021).

⁶ DOG IMPORTATIONS DURING THE PANDEMIC, note 4, supra.

⁷ 42 CFR 71.51.

^{8 9} CFR 2.150 et sea.

⁹ See e.g., CDC Health Alert, "Imported Dogs with Questionable Documentation" (May 27, 2014) http://www.naiaonline.org/uploads/Main_Upload_Directory/healthAlertQuestionableDocs.pdf, which states, "CDC has learned of several instances when importers have provided inaccurate rabies vaccine certificates for puppies arriving into the United States. These documents state that the puppies are older than 4 months of age and fully immunized against rabies. However, upon examination, these animals were found to be less than 4 months old and sometimes as young as 4-8 weeks of age. Documentation has also included falsification of birth location and breed registration." The CDC's Health Alert was issued just three months before the USDA/APHIS Importation of Live Dogs Regulations were published which require, among other things, that dogs intended for "resale" must be at least 6 months old. APHIS, "Animal Welfare; Importation of Live Dogs" 79 FR 48653 (August 18, 2014) https://www.govinfo.gov/content/pkg/FR-2014-08-18/pdf/2014-19515.pdf.

¹⁵ *Id.* at 729.

¹⁶ *Id.* at 726. Moreover, the CDC hypothesized in a "break-even" cost analysis that "if fewer than 26 dogs per year with CRVV are imported from countries classified as CRVV-free or low-risk under the new guidance," then, "[e]ven in the worst case scenario, it is extremely unlikely that the costs will exceed the benefits as a result of this clarification in guidance." *Id.* at 729-730. The CDC also used a similar "break-even" cost analysis with its Temporary Suspension. CDC, "*Temporary Suspension of Dogs Entering the United States from High-Risk Rabies Countries*", 86 FR 32041 at 32047 (June 16, 2021) https://www.govinfo.gov/content/pkg/FR-2021-06-16/pdf/2021-12418.pdf.

¹⁷ *Id.* at 32042.

¹⁸ *Id.* at 32045; CDC, "How To Apply for a CDC Dog Import Permit" https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/apply-dog-import-permit.html

¹⁹ See, "Prevention and Control Of Rabies In Dogs: International Movement of Animals" Chapter 9.3, WHO Expert Consultation on Rabies, Third Report (2018) https://apps.who.int/iris/bitstream/handle/10665/272364/9789241210218-eng.pdf.

²⁰ State of Hawaii, Animal Quarantine Information Page (Updated) https://hdoa.hawaii.gov/ai/aqs/aqs-info/, and Checklist No. 1 https://hdoa.hawaii.gov/ai/files/2022/01/Checklist-1-7.1.2021.pdf.