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42 CFR Part 71
Requirements for Importers of
Nonhuman Primates; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 171

[Docket No. CDC-2011-0001]

RIN 0920-AA23

Requirements for Importers of Nonhuman Primates

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: CDC is proposing to amend its regulations for the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of *Macaca fascicularis* (cynomolgus), *Chlorocebus aethiops* (African green), and *Macaca mulatta* (rhesus) monkeys to all NHPs. Filovirus testing will continue to be required only for Old World NHPs. CDC also is proposing to reduce the frequency at which importers of cynomolgus, African green, and rhesus monkeys are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address: NHPs imported as part of a trained animal act; NHPs imported or transferred by zoological societies; The transfer of NHPs from approved laboratories; and Non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

DATES: Submit written or electronic comments by March 7, 2011.

ADDRESSES: Written comments, identified by Docket No. xxx, may be submitted to the following address: Centers for Disease Control and Prevention, Division of Global Migration and Quarantine, ATTN: NHP Rule Comments, 1600 Clifton Road, NE., (E03), Atlanta, GA, 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road, NE., Atlanta, GA 30333. Please call ahead to 1-866-694-4867 and ask for a representative in the Division of Global Migration and Quarantine (DGMQ) to schedule your visit. Comments also may be viewed at <http://www.cdc.gov/ncidod/dq>. Written comments may be submitted electronically via the Internet at <http://www.regulations.gov> or via e-mail to NHPPublicComments@cdc.gov. All comments received will be posted

publicly without change, including any personal or proprietary information provided. To download an electronic version of the rule, access <http://www.regulations.gov>.

Mail written comments on the proposed information collection requirements to the following address: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for CDC.

FOR FURTHER INFORMATION CONTACT:

Ashley A. Marrone, J.D., U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Division of Global Migration and Quarantine, 1600 Clifton Road, NE., Mailstop E-03, Atlanta, GA 30333, Telephone, 404-498-1600.

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I. Background

A. What is the risk to human health from nonhuman primates?

Nonhuman primates (NHPs), particularly those recently captured in the wild, may harbor agents infectious to humans. Although such infectious agents, if present, are usually detectable in the NHP's blood, they also may be detected in secreted bodily fluids such as urine, feces, or saliva. Due to the nature of their work, persons working in temporary and long-term holding facilities and those involved in transporting NHPs (e.g., cargo handlers and inspectors) are especially at risk for infection. NHPs are a potential source of pathogens and communicable or zoonotic disease that may be fatal to humans, including filoviruses, hepatitis, herpes B virus, tuberculosis, and parasitic infections (1). A zoonotic disease is any infectious agent or communicable disease that is able to be transmitted from animals, both wild and domestic, to humans. A filovirus is a virus that can cause severe hemorrhagic fever in humans and nonhuman primates, such as Ebola virus and Marburg virus. Some *Macaca fascicularis* (cynomolgus), *Chlorocebus aethiops* (African green), and *Macaca mulatta* (rhesus) monkeys imported into the United States have been infected with a filovirus (2). An epidemiologic link between hepatitis A infections in NHPs, especially chimpanzees, and their caretakers has been demonstrated (3). Herpes B virus is a zoonotic agent that naturally infects only macaque monkeys. However, while Herpes B virus infection is generally asymptomatic or mild in macaque monkeys, it can cause fatal encephalomyelitis in humans. Previously reported cases of herpes B virus disease in humans usually have been attributed to NHP bites, scratches, or percutaneous (through the skin) inoculation with infected materials (4). NHPs, especially macaques, are highly susceptible to tuberculosis, and most are imported from areas of the world with a high prevalence of tuberculosis in humans and NHPs (5). NHPs may also be a source of yellow fever virus, which can be transmitted to humans by mosquitoes that have fed on an infected

NHP (6). In fact, transmission of yellow fever to humans in NHP research work has occurred in this manner (7). NHPs imported into the United States from foreign countries often have an uncertain health history, and may potentially harbor diseases infectious to humans. Quarantine requirements for imported NHPs are designed to reduce this communicable disease risk.

B. What is the legal authority for this rulemaking?

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) authorizes the Secretary of the Department of Health and Human Services (HHS) to make and enforce regulations as the Secretary deems necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one State or possession to another. Section 361 of the PHSA further provides that such regulations may provide for the carrying out and enforcement of measures to protect public health, including inspection and destruction of animals or articles found to be so infected or contaminated as to constitute dangerous sources of infection to humans. Section 361 of the PHSA serves as the primary legal authority for 42 CFR 71.53, regarding the importation of NHPs.

Section 368 of the PHSA (42 U.S.C. 271) sets forth penalties for violations of any regulations prescribed under section 361 of the PHSA. Under section 368(a) of the PHSA, any person who violates a regulation prescribed under section 361 of the PHSA may be punished by a fine up to \$1,000 or by imprisonment for up to 1 year, or both [42 U.S.C. 271(a)]. These penalties are strengthened under the sentencing classification provisions of 18 U.S.C. sections 3559 and 3571, which provide for more strict penalties for criminal violations that would otherwise be classified as Class A misdemeanors. Individuals may be punished by a fine of up to \$100,000 per violation if death of a person has not resulted from the violation or up to \$250,000 per violation if death of a person has resulted from the violation [18 U.S.C. 3559, 3571(b)]. Organizations may be fined up to \$200,000 per violation not resulting in death and \$500,000 per violation resulting in death [18 U.S.C. 3559, 3571(c)]. These penalties are criminal in nature and would be imposed by a court, and not administratively by HHS or CDC.

C. What is the history of this rulemaking?

CDC regulations regarding the importation of NHPs were developed to address the risk NHPs pose to humans. Since October 10, 1975, CDC, through 42 CFR 71.53, has prohibited the importation of NHPs except for scientific, educational, or exhibition purposes. For the purpose of importing NHPs, CDC has defined scientific and educational purposes as those conducted at the university level or equivalent (e.g. use in breeding colonies and the advancement of medicine). Exhibition purposes is defined as the use of NHPs as part of a public display open to the general public during routinely scheduled hours in a facility that meets or exceeds the accreditation standards of the Association of Zoos and Aquariums (AZA), or in a comparable facility. For example, if an importer or facility proposes to exhibit the NHPs for one day a month and only to friends and family, this would neither meet nor exceed AZA accreditation standards and therefore the facility would not qualify as an importer for exhibition purposes. However, if an importer or facility proposes to exhibit the NHPs to the general public at a zoo during routinely scheduled hours, that importer may qualify as an importer for exhibition purposes. Some institutions may fall under more than one category of importer. For example, if an established zoo applies for a permit to import a live NHP for display, it would be considered an importer for exhibition purposes. On the other hand, if the zoo employs researchers and requests a permit so that staff can perform behavioral psychology studies, for example, it would be considered an importer for scientific purposes.

Under this regulation, NHP importers are required to register with CDC; this registration must be renewed every two years. NHPs are required to be held in quarantine for at least 31 days following entry into the United States. This regulation also requires importers to maintain records on imported NHPs and to immediately report illness suspected of being communicable to humans. Importers must make their facilities, vehicles, equipment, and business records used in the importation of NHPs available to CDC 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. These "necessary and reasonable times" may include an outbreak or other threat to public health that requires immediate

and unobstructed access to an importer's facilities.

Additional requirements for importers of NHPs have been developed and implemented in response to specific public health threats. On January 19, 1990, in response to the identification of Ebola virus (Reston strain) in NHPs imported from the Philippines, CDC published interim guidelines for handling NHPs during transit and also during quarantine (2). Importers were informed by letter from the Director on March 15, 1990, that they must comply with specific isolation and quarantine standards for continued registration as an importer of NHPs under 42 CFR part 71 (8).

On March 23, 1990, CDC invited the public to comment on new guidelines for the importation of NHPs and the potential impact of a temporary ban on the importation of cynomolgus monkeys into the United States (9). After considering information received at this public meeting, coupled with an April 4, 1990, confirmation of asymptomatic Ebola virus infection in four NHP caretakers and serologic findings suggesting that cynomolgus, African green, and rhesus monkeys posed a risk for human filovirus infection, CDC concluded that these three species were capable of being an animal host or vector of human disease (10).

On April 20, 1990, CDC published a notice in the **Federal Register** requiring a special permit for importing cynomolgus, African green, and rhesus monkeys (11). To be granted a special permit, importers must submit a plan to CDC describing specific isolation, quarantine, and communicable disease control measures. The plan must detail the measures to be carried out at every step of the chain of custody, from embarkation at the country of origin, through delivery of the NHPs and the completion of the required quarantine period. Additional requirements include detailed testing procedures for all quarantined NHPs to rule out the possibility of filovirus infection. When importers demonstrate compliance with these special-permit requirements, CDC authorizes continued shipments under the same permit for a period of 180 days. Certain components of the special-permit requirement have changed slightly in response to surveillance findings and the development of improved laboratory tests. As indicated in the 1990 notice, importers were informed of these changes by letter from CDC (12). The current special-permit notice requires filovirus antigen testing on specimens from any NHP that dies during quarantine for reasons other than trauma. Antibody testing is also

required on surviving NHPs that exhibit signs of possible filovirus infection before the cohort is released from quarantine (13).

On July 30, 1993, CDC published guidelines in the Morbidity and Mortality Weekly Report (MMWR) for tuberculosis testing requirements for NHPs, following the recognition of tuberculosis in up to 2% of imported NHPs and the risk for infection posed to caretakers (5). These published guidelines include provisions for recordkeeping to track and trace nonhuman primates and use of personal protective equipment by NHP handlers to prevent transmission of tuberculosis (5). Since publication of the guidelines in the MMWR, importers have submitted a minimum of three negative tuberculin skin tests (TSTs) administered at two-week intervals on each imported NHP, before CDC has agreed to release of any NHPs from quarantine.

II. Proposed Rule Requirements

A. What is the scope of this proposed rule?

This proposed rule applies to any person importing a live NHP into the United States, including existing importers, any person applying to become a registered importer, and any person importing NHP products. Importers must make their facilities, vehicles, equipment, and business records used in the importation of NHPs available to CDC for inspection during operating business days and hours, and at other necessary and reasonable times, to enable CDC to ascertain compliance with these regulations. Nothing in this proposal supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

B. Does the proposed rule continue the general prohibition on importing live NHPs except for science, education, or exhibition purposes?

Yes, it does. In § 71.53(d), CDC would continue the long-standing general prohibition in the current regulation on importing live NHPs except for science, education, or exhibition purposes. This prohibition extends to the importation of non-human primates intended for use as service animals. On July 23, 2010, Attorney General Eric Holder signed final regulations revising U.S. Department of Justice regulations under the Americans with Disabilities Act (ADA), which included a revised definition of “service animal.” Effective February, 2011, these regulations limit the definition of service animals to dogs.

Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this definition. CDC has carefully considered the potential risks associated with the use of imported nonhuman primates as service animals and agrees with the position of the U.S. Department of Justice that nonhuman primates should not be recognized as service animals because of their potential for disease transmission and unpredictable aggressive behavior.

C. What new and revised definitions is CDC proposing in regard to importers of NHPs?

In this NPRM, CDC has developed a list of definitions specific to modern importation principles and practices for NHPs. These definitions either do not appear in the current 42 CFR 71.53, or have been revised, and are intended to add clarity to the provisions regulating the importation of NHPs. CDC is soliciting public comment on these definitions. Of particular importance to this proposal are the definitions for animal act, breeding colony, broker, cohort, importer, in transit, lab or laboratory, medical consultant, offspring, Old World NHP, permitted purpose, quarantine facility, quarantine room, trophy, zoo, and zoonotic disease.

D. What expanded requirements apply to importers of NHPs?

CDC is proposing to expand the isolation, quarantine, and worker protection requirements, as well as the registration process, currently described in the special-permit requirements for cynomolgus, African green, and rhesus monkeys to all importations of NHPs. The proposed changes will simplify importer registration procedures by eliminating the need for a separate category of importer that must request special permits (those that import cynomolgus macaques, Rhesus macaques, and African green monkeys). The proposed changes will also provide an enhanced measure of worker and NHP safety against known and emerging zoonotic diseases. Under proposed provision (g)(1), to register as an importer, an individual must submit to CDC a completed application form, a completed statement of intent describing the number and types of NHPs intended for import during the registration period, a copy of all written Standard Operating Procedures (as specified in the NPRM), a copy of any current registrations, licenses, and/or permits that may be required from the U.S. Department of Agriculture and U.S. Fish and Wildlife Service, and a signed, self-certification stating that the

importer is in compliance with the regulations contained in this section and agrees to continue to comply with these regulations. Upon receiving the above application and documentation required (as proposed in section (g)(2)), CDC will review the application and grant or deny the application for registration as an importer. The timeframe between acceptance of the application, and either approval or denial, will generally be 30 to 60 calendar days, during which time CDC may consult with the applicant regarding any element of the application or accompanying documentation.

E. What is a performance-based standard?

A performance-based standard states goals and objectives to be achieved and describes methods that can be used to demonstrate whether or not processes, products, and services meet the specified goals and objectives. In contrast, a prescriptive standard typically prescribes materials, design and construction methods without stating goals and objectives. A performance-based standard focuses on desired characteristics of the final product, service, or activity rather than requirements for the processes to produce it. Performance-based standards allow users flexibility in choosing materials (such as which products to use for disinfection), design (such as the use of squeeze-back cages for controlling animals), and services (such as the use of off-site, contractual occupational health services for workers). An example of a performance-based standard is the Occupational Safety and Health Administration's Hazard Communication Standard (HCS), 29 CFR 1910.1200. CDC proposes to primarily use a performance-based standard in reviewing and approving applications for individuals to become registered importers of NHPs into the United States and is soliciting public comments on this approach.

F. What documentation requirements apply to importers of NHPs?

The utility of the special permit requirements in quickly detecting and controlling filovirus was illustrated by the early and effective detection of Ebola virus in imported cynomolgus monkeys in 1996. The special permit and other disease control requirements were effective in promptly identifying the filovirus infection, minimizing NHP exposure, and preventing spread of the infection beyond the room housing the original infected NHP (14). For these reasons, CDC is also proposing that filovirus testing be expanded to include

all Old World NHPs (as defined in proposed provision (c)(2)) in quarantine that have illness consistent with filovirus or that die for any reason other than trauma. The proposed changes would allow for surveillance of filovirus infection in other Old World primates, such as chimpanzees, gorillas, baboons, drills, and mandrills, which are known to be susceptible to infection but are not addressed by the current special permit requirements (unpublished data, CDC; 15–18).

Consistent with the current special permit requirements, under proposed provision (h), an importer of NHPs must have a written policy that imported NHPs and their offspring will only be used and distributed for permitted purposes, as defined in proposed subsection (a), and document the intended purpose for the imported NHPs. An importer must also retain records documenting the identity of any recipients, the number of NHPs in each shipment or sale, and the dates of each shipment or sale. An importer must keep written certifications demonstrating that the NHPs and any offspring will continue to be used for permitted purposes. CDC is proposing to require the importer to maintain such documentation to ensure that these NHPs are not diverted into the pet trade and subsequently place individuals at risk of contracting zoonotic diseases. This record retention requirement would apply to any transfer of the NHP from the quarantine facility and any subsequent transfers. CDC is soliciting public comment on the proposed record retention requirement to learn whether the burden to importers outweighs the benefit to public health. Specifically, CDC is soliciting comment on how long records should be maintained by the importer, *e.g.*, for the expected life of the NHP.

Proposed subparagraph (h) also proposes to require the importer to maintain these records in an organized manner and either electronically or in a central location, at or in close proximity to the NHP facility, to allow CDC to inspect the records during CDC site visits during regular business hours or within one hour of such visits. Before distributing or transferring an imported NHP, an importer must communicate to the recipients of NHPs, in writing, the restrictions and definitions of permitted purposes and obtain written certifications from the intended recipient that the NHPs will be used and distributed for one of the permitted purposes before the NHPs are sent to them. CDC is soliciting public comments on these proposed requirements.

G. What are the requirements for a worker protection plan and personal protection equipment?

In accordance with good public health practice, HHS/CDC recommends that all workers who are at high risk of exposure to NHPs be current on routine vaccinations including but not limited to Hepatitis B, tetanus, and measles vaccines. As part of the NPRM, in provision (i), CDC is proposing to require that importers have a written worker protection plan for anyone whose duties may result in exposure to NHPs. The proposed protection plan is designed to ensure that individuals who work in close proximity to NHPs are educated on the risks and protected from exposure to zoonotic diseases. For the purposes of enforcement of this provision CDC considers “exposure” to be a well-understood term in the NHP importing community, generally meaning in direct contact or sufficiently close proximity to a NHP (≤ 5 feet) that NHP bodily fluids could be transferred between the NHP and the worker. “Exposure” also refers to worker exposure to respiratory pathogens (*e.g.*, *Mycobacterium tuberculosis*) for workers in proximity to a NHP (≤ 5 feet). However, CDC is soliciting public comment on provisions which use this term and welcomes input on ways which may add clarification to its meaning. Using the performance-based standard described above, CDC will evaluate the importer’s worker protection plan and determine whether the proposed worker protection program is sufficient to protect workers from exposure to zoonotic diseases.

Under proposed subsection (i) an importer must contact CDC immediately by telephone to report any instance of a worker contracting a potential zoonotic disease, and must include specific instructions for contacting CDC in its worker protection plan. Also included in the worker protection plan must be procedures to protect and train transport workers from exposures to communicable disease; hazard evaluation and worker communication procedures; personal protective equipment (PPE) requirements; tuberculosis requirements; if applicable, SOPs that adhere to requirements relating to macaques as described in paragraph (i)(7); an infection-prevention program; SOPs that include requirements for preventing workplace infection from potentially contaminated needles or other sharp instruments; SOPs requiring that used disposable sharp items are placed in puncture-resistant containers kept as close to the work site as practical; SOPs requiring

that removed, disposable PPE be disposed of as biohazardous waste; and that nondisposable clothing worn in the quarantine facility be disinfected on site before laundering. CDC is soliciting public comments on these provisions.

To further ensure worker safety from communicable disease, subsection (i) also includes certain specific post-exposure requirements to be included in the worker protection plan, such as an infection prevention program that requires NHP handlers to cleanse all bites, scratches, and/or mucosal surfaces or abraded skin exposed to blood or body fluids immediately and thoroughly.

The worker protection plan also places requirements upon the importer to provide exposed workers with direct and rapid access to a medical consultant, and to document the frequency of worker training and education on potential risks of exposure to NHPs. CDC is specifically soliciting comment on the appropriate frequency of such worker training and education programs. As part of the worker protection plan described in proposed subparagraph (i), an importer must establish, implement, and maintain hazard evaluation and worker communication procedures. Such procedures for employees working in the quarantine facility shall include the following: a description of the known zoonotic disease and injury hazards of handling NHPs; the need for PPE in handling NHPs and training in proper use of PPE, including re-training and reinforcement of appropriate use; procedures for monitoring workers for signs of zoonotic illness; and procedures for disinfection of garments, supplies, equipment, and waste (1–5, 7, 10, 11, 14, 19–21).

As part of the worker protection plan described in this subsection (i), an importer must identify the PPE required for each task or working. Proposed § 71.53(i)(5) describes requirements in the worker protection plans for PPE, including face shields or eye protection and respiratory protection (such as N95, or powered air-purifying respirator (PAPR)) that is compliant with OSHA 29 CFR § 1910.134 which requires a respiratory protection program. Face shields are important for preventing droplet splashes to the head from running down into the eyes and preventing mucous membrane exposure around the edges (sides, top, and bottom to below the chin).

For tuberculosis protection, CDC is proposing that an importer be required to ensure that workers in a facility housing NHPs have a baseline tuberculosis test prior to beginning work

with NHPs and, at least annually, a tuberculosis skin test. Tuberculosis is an illness which can potentially be transmitted either from NHP to human, or from human to NHP. The purpose of this requirement is to protect the NHPs from exposure to tuberculosis from the workers as well as to monitor potential exposure of the workers to tuberculosis from the NHPs. A baseline tuberculosis test is typically conducted before the employee begins working with NHPs to ensure that the employee does not already have active or latent tuberculosis. A Mantoux tuberculosis skin test is the most common diagnostic test used for humans to detect tuberculosis exposure.

Proposed § 71.53(i)(3)(xii) describes herpes B virus post-exposure procedures that would be required as part of worker protection plans for registered importers who import macaques. For protection against herpes B virus, CDC is proposing in this subsection that an importer must develop, implement, and adhere to a written PPE program to prevent herpes B virus transmission.

CDC is also proposing to require that the worker protection program include a thorough hazard assessment of all work procedures, potential routes of exposure (e.g., bites, scratches, or mucosal exposures), and potential adverse health outcomes. Workers must also be assured prompt and direct access to a medical consultant, defined in the proposed rule as an occupational health physician, physician's assistant or a registered nurse, who is knowledgeable about the risks to human health associated with NHPs. The medical consultant in this proposed provision may either be an employee of the quarantine facility or a contractor, but must be readily available and aware of the potential zoonotic risks involved in working with NHPs. CDC is seeking comment on this proposed requirement. Additionally, CDC is proposing to require all importers to maintain records of all serious febrile illnesses [fever greater than 101.3 degrees Fahrenheit (38.5 degrees Celsius) for more than 48 hours] in workers having been exposed to NHPs in transit or in quarantine. CDC is proposing to require that the record of febrile illnesses be kept indefinitely by the importer as part of the worker's medical records, and is soliciting public comment on whether this requirement would pose an undue burden upon the importer as to outweigh the benefit to public health and the health of the individual.

If macaques are being imported under this provision, the proposed worker protection requirements would also

include provisions related to exposure to herpes B virus (*Cercopithecine herpesvirus*) because of the unique risk of herpes B virus transmission associated with macaques. Most cases of herpes B virus disease in humans have been attributed to NHP bites, scratches, or percutaneous inoculation with infected materials. However, a report of a fatal case of herpes B virus infection caused by mucosal splash exposure occurred in 1998, lead to the development of CDC recommendations in 1999 for preventing and treating herpes B virus exposure (19).

In addition to complying with the proposed requirements of this section, an importer must continue to comply with all relevant Federal and State requirements relating to occupational health and safety. CDC is soliciting public comment on these additional proposed requirements.

H. What are the proposed requirements for NHP quarantine?

The proposed requirements state that importers must quarantine all NHPs for at least 31 days after arrival at a quarantine facility in the U.S. This time period may be extended in the event that the NHPs are infected with certain communicable diseases (such as tuberculosis, shigella, measles, campylobacter), the importer or CDC suspect a NHP may be infected with certain communicable diseases, or if the importer or CDC determines that there is a need for additional diagnostic testing. The NHP will remain in quarantine until the CDC determines that it no longer poses a threat to human health. These requirements minimize the risk to persons exposed to imported NHPs by preventing an infected NHP from premature release from quarantine.

The proposed rule directly addresses the two major reasons for quarantining recently imported NHPs. The first major reason is to provide the earliest recognition of the importation of a zoonotic disease with potential public health importance. The second is to prevent transmitting infectious agents between NHPs or from NHPs to humans. The proposed procedures and standards contained in § 71.53(l) are essential to minimize the risk of transmitting infectious agents between NHPs and from NHPs to humans in quarantine facilities. CDC has based these procedures and standards on National Research Council (NRC) guidelines, CDC biosafety guidelines, current knowledge of infectious agent transmission routes and, experience gained from investigating filovirus infection outbreaks (14, 22). These requirements are in addition to U.S.

Department of Agriculture (USDA) regulations in 9 CFR parts 1 through 3 on Animal Welfare, and Fish and Wildlife Service regulations in 50 CFR part 14 on Importation, Exportation, and Transportation of Wildlife. Section 71.53(l)(1)(ii) requires the use of commonly accepted industry standards for the design and operation of animal holding facilities and the care and use of laboratory animals. Examples of minimum acceptable industry standards include those found in the current editions of NRC's "Guide for the Care and Use of Laboratory Animals" (20) and the CDC/NIH's "Biosafety in Microbiological and Biomedical Laboratories" (21).

We have written the proposed facility and procedural requirements to apply to all NHP importers. We intend these requirements to protect NHPs, facility workers, and others from a variety of potential pathogens and to be adaptable to changing needs. We would further require importers to incorporate the essential features of each applicable proposed requirement into written policies and procedures for employees. Proposed § 71.53(g)(1) requires an importer to establish, implement, and maintain documentation and standard operating procedures (SOPs) associated with the importation of NHPs, and proposed § 71.53(b)(3) requires the importer to make the records available to CDC for inspection during the life of the NHP, so that we may ascertain compliance with the regulations. To facilitate inspection, records should be maintained electronically or in a location in close proximity to the quarantine facility and in an organized manner. CDC is specifically soliciting comment on these proposed record-keeping requirements.

Proposed § 71.53(i) and § 71.53(l) address routine veterinary medical care and screening for zoonotic diseases of NHPs in quarantine and management of illnesses and deaths of unknown etiology. Appropriate screening or diagnostic tests may differ by species, country of origin, clinical presentation of ill NHPs, and necropsy findings. Therefore, in these regulations, it is proposed that importers be required to maintain direct and immediate access to both a veterinarian experienced in the care of NHPs and a qualified (i.e., licensed or certified) laboratory. CDC is soliciting public comments on this provision. Specifically, we hope to obtain feedback on what factors should be taken into consideration in the determination of whether a veterinarian is sufficiently "experienced" in the care of NHPs and what factors constitute a "qualified" laboratory. This provision

also proposes to require that importers maintain written protocols for the evaluation and diagnostic testing of suspect cases of zoonotic disease in NHPs. At a minimum, an importer's written protocols must include diagnostic testing for the infectious agents for which reporting is required under these regulations and a plan for evaluating unusually high morbidity or mortality rates in a shipment of NHPs.

Proposed section 71.53(l)(1) of the quarantine requirements addresses monitoring and testing NHPs for tuberculosis (TB). In July 1993, CDC published in the *MMWR* a review of TB in imported NHPs over a three-year period (5). Because TB in captive NHPs is both an animal and a human health problem, NHP importers routinely provide a tuberculin skin test (TST) for NHPs and workers. According to the *MMWR*, an importer must consider any NHP with a positive TST during import quarantine as infectious and as representing a high risk for disease transmission. Therefore, when an importer identifies a quarantined NHP as TST-positive, the standard practice according to the *MMWR* recommendation is to euthanize the NHP, attempt laboratory confirmation of TB, and reinstitute tuberculin skin testing of all other exposed NHPs at two-week intervals, with quarantine until five consecutive negative TSTs are completed in the quarantined NHPs.

CDC considers all NHPs to be susceptible to TB; virtually all are imported from areas of the world with high prevalence of TB in humans and NHPs. Close confinement of these and other NHPs in holding facilities (including quarantine) and shipping crates fosters conditions where one infected NHP might infect many others. Therefore, each NHP in a cohort in quarantine must complete negative TSTs before any are released.

Because there is the potential for transmitting TB and other pathogens among NHPs and humans, improved surveillance and testing procedures are essential in NHP quarantine and research facility settings. Paragraphs § 71.53(i)(6) and (l)(2) of the proposed rule include worker protection and quarantine requirements regarding TB. Proposed § 71.53(l)(2)(ix) requires an importer to conduct three TSTs, with at least two weeks between tests, before releasing NHPs from import quarantine. If any NHP in the cohort has a positive or suspicious TST reaction (as defined by Institute of Laboratory Animal Resources [ILAR] standards [25]), the importer must keep the cohort in quarantine and must administer at least five additional TSTs following removal

of the last affected NHP. Proposed § 71.53(l)(5)(iv) provides that for any necropsy of an NHP dying during quarantine, the importer must ensure that the necropsy is performed under biosafety level 3 (BSL3) or biosafety level 2 (BSL2) with enhanced protective equipment and procedures to protect against exposure to highly infectious agents.

Proposed § 71.53(m)(6) requires an importer to report to CDC within 48 hours any positive or suspicious TST results, necropsy findings, or laboratory results.

I. What are the proposed requirements for SOPs and equipment for crating, caging, and transporting NHPs?

In this proposed provision, the importer bears responsibility for ensuring that all infection control measures are in place throughout the transportation of the cohort, not just after the NHPs reach a licensed quarantine facility in the United States. Physical custody of NHPs may be transferred several times during transportation (e.g., from exporter to airline to importer). However, because the registered importer selects the supplier at the country of origin and arranges for transportation to the United States, CDC expects the importer to exert control over the conditions under which the NHPs are shipped. CDC considers this provision to be part of the performance-based approach and the intent is for CDC to work with the importer to identify procedures that are effective in preventing communicable disease spread. Proposed § 71.53(j) outlines the requirements that the importer must meet, either directly or by contractual or other arrangement, to ensure safe handling of NHPs during transportation. In the combined proposed requirements for crating, caging, and transporting, we emphasize the infection control-related aspects of shipping NHPs, including procedures to prevent contamination of other articles and cargo during transportation, to provide physical separation of crates from other cargo, and to decontaminate aircraft, ships, vehicles, and related equipment following transport. An importer must meet these requirements in combination with all applicable sections of other Federal and international regulations and guidelines, such as the International Air Transport Association "Live Animal Regulations," which have been adopted by U.S. Fish and Wildlife Service (23) and the World Health Organization's "Transport of Infectious Substances" (24). Certain procedures such as planeside transfers and expedited clearances may require

oversight and/or inspection by CDC to ensure implementation of CDC's requirements and guidelines. Therefore, in § 71.53(f), CDC proposes to restrict entry of NHPs into the United States to those ports of entry where CDC quarantine stations are located, except in limited circumstances approved in advance by CDC. These circumstances may include situations involving ground transport across the U.S. border and charter aircraft transport arriving through airports that do not have quarantine stations. CDC is working with the stations to enhance the training and response capability of the staff. The CDC quarantine stations operational at ports of entry and border crossings are currently listed at: http://www.cdc.gov/ncidod/dq/quarantine_stations.htm. This listing will be updated if more stations are added in the future.

J. What are the requirements for ground transport vehicles?

When a shipment of NHPs arrive at a U.S. port of entry via aircraft, special vehicles must be used to transport the NHPs safely to a quarantine facility and ensure that these pre-quarantined NHPs do not pose a risk to human health. Likewise, a specialized ground transportation vehicle should be used when a shipment of NHPs enters the U.S. via a land border crossing, destined for a quarantine facility. To ensure vehicles contain proper safeguards, in proposed subparagraph (k), CDC is proposing that an importer be required to establish, implement, maintain, and adhere to SOPs for ground transport vehicles transporting NHPs. CDC is soliciting public comments on these proposed requirements.

K. What are the health reporting requirements for NHPs?

Under proposed § 71.53(m), an importer would have to ensure that CDC is notified of the occurrence of any of six events listed in the paragraph. An importer must report to CDC within 24 hours of discovering the severe illness or death of NHPs in a quarantine facility; an illness in an NHP that the importer reasonably suspects is yellow fever, monkey pox, or filovirus disease; or of an NHP testing positively for filovirus virus antigen or antibody. An importer must report to CDC within 48 hours, any positive or suspicious tuberculin skin test results, necropsy findings, or laboratory results. These reports may be by telephone.

An importer must report promptly to CDC if the mortality for a shipment exceeds 5 percent. The period runs from the time of embarkation from the country of origin to the release of the

shipment's animals from quarantine. The report must include the cause of death of each NHP. This report may be by telephone. Finally, the importer must ensure that CDC receives a written report from the quarantine facility's licensed veterinarian of the health status of a shipment after the quarantine period is complete, but before the importer releases any NHP, cohort, or mixed cohort.

Any report CDC requires in this section must include a copy or summary of the individual NHP's health records.

L. What are the requirements for recordkeeping and reporting?

In addition to the NHP health reporting requirements in § 71.53(m), CDC proposes 19 general reporting and recordkeeping requirements in § 71.53(n), with which the importer must comply in writing at least 7 days before it imports a shipment of NHPs. Among these requirements is supplying information that will help authorities identify named individuals, businesses, shippers, and carriers importing NHPs who are responsible for the NHPs at every leg of the transportation process from the time a shipment leaves the country of origin to the time the animals arrive at a licensed quarantine facility.

CDC also will require importers to provide information to identify the specific vehicles or aircraft used to transport these animals, the quarantine facility for which the animals are destined, methods of identifying individual NHPs, and similar information. CDC is soliciting comment on these proposed requirements.

M. What are the requirements for animal acts; zoo-to-zoo transfers; and lab-to-lab transfers?

Under proposed § 71.53(o)(1), an importer must register with CDC all foreign-based animal acts that include a NHP. This provision would require the importer to provide information and documentation to help identify the individual animal and to describe the conditions under which the NHPs are housed in the United States. Other requirements include documentation signed by a licensed veterinarian attesting to the results of physical examinations of NHPs. The exams must address routine elements and tests for conditions specified in the regulations. Under proposed § 71.53(o)(2), an importer must meet specified requirements for U.S.-based animal acts containing NHPs when the animal re-enters the United States after export. The requirements in § 71.53(o) are in addition to those documentation requirements in proposed § 71.53(g).

For those NHPs entering the U.S. under the zoo-to-zoo and laboratory-to-laboratory transfers exception, proposed § 71.53(p) and (q) require the recipient zoo or laboratory within the United States to submit veterinary medical records documenting a NHP's current and past health history. To qualify for these exemptions, both the recipient and transferring zoos must be accredited by the Association of Zoos and Aquariums (AZA) (or equivalent if outside of the U.S.) and the labs or laboratories must both be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or licensed by USDA. In addition to the requirement itself, CDC is soliciting public comment on these provisions to ascertain what standards or factors should be considered in reaching the determination that a zoo located outside of the U.S. is "equivalent" to an AZA accredited facility for it to qualify for an exemption under this provision. Further, § 71.53(q) is available only to those NHPs from a lab that has both a foreign-based and United States-based facility and that are part of an ongoing, institutionally approved research project. Adequate justification must also be provided to CDC describing the reason a transfer to a U.S. laboratory is necessary (e.g., diagnostic equipment only available in the U.S.-based laboratory).

N. What are the requirements for in-transit shipments of NHPs?

Under § 71.53(r), CDC is proposing to add requirements for brokers in the U.S. regarding the handling of in transit shipments of NHPs that have a layover or are detained or delayed at a U.S. airport. Because there is the potential for human exposure or other cargo contamination from NHPs with diseases of public health concern while located in the United States, in transit shipments must be housed and cared for in a manner consistent with requirements for NHPs intended for import into the United States as specified in paragraphs 71.53(j) and 71.53(k) of this section. CDC is soliciting comment on these new proposed requirements for brokers.

O. What procedures are being proposed for revocation and reinstatement of an importer's registration?

Under § 71.53(s), CDC is proposing new procedures for revocation and reinstatement of an importer's registration. Under these procedures, a registration may be revoked upon notice to the importer if the Director determines that the importer has failed

to comply with any of the applicable provisions of this section. The importer may request a written record review by the Director by filing a response within 20 calendar days of receiving our notice. The Director will review the written record and issue a decision in writing to affirm the revocation or reinstate the importer's registration. As a condition of reinstating the registration, the Director may require inspection of facilities, examination of records, and other assurances of compliance with CDC's requirements. The Director's written decision shall constitute final agency action.

P. What are the requirements for importing NHP products?

Because of the risk to human health of untreated NHP products such as carcasses, trophies, blood, and other biological samples, CDC is also adding a permit requirement under proposed § 71.53(t) for importing these products. Under this provision, a permit is not required if the product has been rendered non-infectious by one of the approved methods. HHS/CDC has selected this prescribed manner of rendering a product non-infectious because it has proven to be efficient and effective in protecting public health. However, a permit will be required if the product is untreated. An untreated product without an accompanying permit will be considered a potential health hazard and may be seized for destruction upon arrival at the port of entry. This permit requirement applies to individuals importing trophies for their own personal use as well as businesses importing trophies for a commercial purpose, with the intent to resell to the public.

Q. Is there an appeal process for a denied application to import?

Yes. HHS/CDC proposes new subsection (u) to provide importers with an opportunity for a written appeal in the event that the Director denies a request for a permit to import a NHP for bona fide scientific, exhibition, or educational purposes, NHP products that have been rendered noninfectious, or an application to become an importer. Under the proposal, a person who wishes to make such an appeal would have two business days after receiving the denial to submit the appeal. CDC would issue a written response, which would constitute final Agency action. HHS/CDC invites comments on this process.

III. Regulatory Analyses

A. Economic Analysis

CDC has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity. Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in expenditure by State, local, and Tribal governments in the aggregate or by the private sector of \$100 million in any one year (adjusted annually for inflation). CDC has analyzed the rule and has determined that it is consistent with the principles set forth in the Executive Order and these statutes.

This proposed rule is not a significant regulatory action as defined by the Executive Order. This regulatory action is not a major rule under the Congressional Review Act. In our screening analysis under the Regulatory Flexibility Act, CDC also concludes that the rule will not have a significant economic impact on a substantial number of small entities. UMRA does not require CDC to prepare a statement of costs and benefits for this proposed rule because we do not expect the rule to result in any one-year expenditure that would exceed \$100 million adjusted for inflation.

1. Objectives and Basis for the Action

Our principal objectives in this proposed rule are to consolidate and codify requirements for infection control and worker safety procedures to prevent transmitting pathogens from NHPs to humans. The proposed requirements for developing an operating plan and SOPs will ensure that facility-specific documents outlining quarantine and other operations, personnel training, and

worker health programs are in place before NHPs are imported into the United States.

2. The Nature of the Impacts

The proposed rule would consolidate CDC's import requirements into one regulatory section thus easing the burden on importers. The rule would expand the requirements for importing cynomolgus, rhesus, and African green monkeys to all NHPs, with the exception of filovirus testing, which would be required only for Old World NHPs, but allow importers of those three species to renew their registrations every two years, rather than every 180 days. CDC proposes to incorporate into the rule, our interim NHP guidelines, requirements for NHP imports as part of a circus or trained animal act or a zoo-to-zoo or laboratory-to-laboratory transfer, as well as restrictions on which ports of entry an NHP may be imported into the United States.

3. Baseline

Economic analysis of a regulatory action requires as a first step identifying a baseline, which is a depiction of the world in the absence of any action. CDC uses this baseline to calculate the effects of new regulation. In this action, CDC proposes to codify guidelines, registration requirements, notices, and permitting procedures that have been in effect since 1990. In January 1990, CDC published interim guidelines for handling NHPs during transit and quarantine (2). In March 1990, CDC notified all importers that their compliance was required with the transit, isolation, and quarantine standards for continued registration and that CDC would subject registered importers to unannounced inspections of quarantine facilities. In April 1990, CDC implemented a special permitting procedure for importing cynomolgus, African green, and rhesus monkeys (9).

These administrative requirements differ only slightly from the requirements CDC proposes today; the proposed rule merely formalizes, clarifies, and makes minor changes in existing administrative requirements. Therefore, the proposed rule has little impact on costs and benefits relative to the baseline of existing practices. In this analysis, CDC estimates incremental costs and benefits relative to that baseline, and also provides background on the health benefits that motivated the administrative actions taken in 1990.

In general, CDC intends that the proposed rule will preserve the health benefits of current practices, while reducing some costs for the regulated community. Specifically, the proposed

rule would reduce costs in two ways. First, CDC proposes to reduce the frequency of registration renewal for importers of cynomolgus, rhesus, and African green monkeys from every 180 days to every 2 years, consistent with registration requirements for importers of other NHPs. This change would reduce administrative cost burdens for importers of cynomolgus, rhesus, and African green monkeys.

Second, CDC proposes to eliminate the 31-day quarantine requirement for transfers of NHPs into the United States between accredited zoos, such as those accredited by the Association of Zoos and Aquariums (AZA) (or its equivalent) (*i.e.*, "zoo-to-zoo transfers"), and transfers of those NHPs from laboratories that are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) (or its equivalent) that have a foreign based and a United States based facility and the NHP is part of an ongoing research project. In such circumstances, CDC would require zoos and laboratories to maintain detailed records regarding NHPs. Because domestic AZA-accredited zoos and established research labs are regulated by USDA's Animal Welfare Act, and if receiving Public Health Service (PHS) funds are bound by the PHS Policy for Humane Care and Use of Laboratory Animals, and may additionally be accredited by AAALAC, to meet strict guidelines regarding husbandry and medical care for animals and occupational health and safety, CDC believes that a records requirement for these zoo collections and research laboratories effectively provides the same health and safety assurance as a 31-day quarantine. Additionally, since zoos are placing imported animals into their existing collections, they require a quarantine facility for all new NHPs. The records requirement will document the health of the NHPs over a specified period of time, in a monitored setting, before the NHPs are transferred between zoo collections or research facilities, thereby providing the same health and safety assurance that quarantine provides for other NHP imports. The transportation of NHPs for a zoo-to-zoo or laboratory-to-laboratory transfer would be in accordance with the transportation guidelines listed in proposed paragraphs (j) and (k). In the event that zoo collections or research laboratories are unable to comply with the requirements regarding proper veterinary medical records, all other aspects of the importation and quarantine requirements will apply.

The proposed rule could increase costs for a small set of importers by

requiring that all live NHP imports enter through ports of entry where CDC quarantine stations are located, except in limited circumstances approved in advance by CDC. This change could increase transportation costs for a small number of shipments currently driven across the Mexican or Canadian borders. Restricting the ports of entry should not increase costs for importers shipping by air, since currently all shipments are to airports with CDC quarantine stations. Further, CDC believes the nominal cost of this requirement is warranted by the health and safety value of ensuring proper loading of the NHPs on a flight, proper handling of the crates as they are unloaded, and adequate disinfection of the plane.

4. Alternatives

The key alternative to the proposed rulemaking would be to not adopt these proposed regulations. If the provisions described above are not adopted, importers of cynomolgus, rhesus, and African green monkeys would continue to bear an additional administrative burden when importing. CDC believes that the reductions in administrative burden and costs proposed through these regulations can be achieved without compromising or reducing the health and safety benefits of current practices. The registration process that all importers must complete, detailed in subsection (g), will include the development of detailed standard operating procedures designed to protect both the NHPs and the individuals at each facility, a signed statement of intent, the review and approval of these SOPs by the Director, and an inspection by CDC. Regular, unscheduled site visits ensure that facility operations are adequately maintained in a manner to prevent the transmission of infectious agents from NHPs to humans.

5. Benefits

In November 1989, a shipment of cynomolgus monkeys imported into the United States was found to be infected with a previously unrecognized Ebola-like filovirus (22). In the 1990 guidelines, registration requirements and permitting procedures were established specifying transit, isolation, and quarantine standards for importers of African green, cynomolgus, and rhesus monkeys. These guidelines were established to reduce the risks to public health that could result from the importation of monkeys carrying a filovirus. The 1990 CDC actions also provided the related benefit of avoiding an economic disruption of the NHP

import market associated with the threat of an Ebola-like filovirus.

Although we propose few changes to the existing baseline, this rule would provide some further assurance of health and safety by requiring that most imports of live NHPs arrive at a port of entry with a CDC quarantine station, where qualified personnel are present to monitor the arriving shipments.

By removing the regulatory cost barrier of the quarantine requirement for zoos accredited by AZA and laboratories accredited by AAALAC or licensed by USDA, the proposed rule is expected to yield an additional public benefit by facilitating transfers from zoo-to-zoo and laboratories-to-laboratories. The proposed rule would remove obstacles to the movement of highly endangered NHPs for preservation of a species. Additionally, it would allow the controlled entry of long-term research NHPs for public health studies that could only be performed in a U.S.-based laboratory.

6. Costs

It is difficult to calculate the regulatory costs of our 1990 actions because the threat of an Ebola-like filovirus in the United States may have sharply reduced the future importation of NHPs. Assuming no complications, CDC estimates that the cost for keeping an NHP in quarantine for 31 days is roughly \$500–\$600 per NHP, which includes the cost of recordkeeping, monitoring and testing NHPs for TB. These costs are in addition to registration and permitting costs per importer. However, absent CDC action, the economic disruption associated with the threat of an Ebola-like filovirus could have resulted in higher industry costs. From FY 2000 through FY 2007, NHP imports increased from 15,433 NHPs to 26,714 NHPs, indicating that CDC's transit, isolation, and quarantine standards for NHP imports have provided for an orderly, growing market while protecting public health.

As noted above, the proposed rule would have three cost impacts relative to the baseline of current practices: (1) An administrative cost reduction for importers of cynomolgus, rhesus, and African green monkeys resulting from a 2-year registration renewal cycle rather than the current 180-day registration renewal cycle; (2) a reduction in quarantine costs for zoos and laboratories that are able to maintain detailed records of zoo-to-zoo and laboratory-to-laboratory transfers; and (3) an increase in transportation costs for NHP shipments customarily driven across borders that will have to enter through ports of entry with CDC

quarantine facilities or obtain advance approval and enter the U.S. by an alternate port of entry.

Based on recent estimates from the American College of Laboratory Animal Veterinarians and the Bureau of Labor Statistics, CDC estimates that the average wage for NHP importers is \$112.00 per hour. Thus, the estimated cost of registration renewal is \$56.00 (30 minutes at \$112.00 per hour). In late 2005, eight active commercial importers were subject to the 180-day renewal cycle for cynomolgus, rhesus, and African green monkey importers. The change to a 2-year renewal cycle will reduce annual regulatory costs for each of these importers by \$84.00 per year (\$56.00 per renewal times 3 fewer renewals every two years), reducing total costs for these eight importers by \$672.00 per year (\$84.00 × 8). Other registered importers (e.g., zoos) import very infrequently and will continue to renew their registration once every two years, resulting in no net change in costs.

By eliminating quarantine requirements for zoo-to-zoo and laboratory-to-laboratory NHP transfers for zoos and labs that maintain detailed records of such transfers, we expect to reduce annual regulatory costs by about \$550 to \$1800 per transfer. CDC estimates that only one or two zoo-to-zoo or laboratory-to-laboratory transfers occur each year under current requirements, so eliminating the quarantine requirement for these transfers would yield no substantial regulatory cost reduction.

Requiring importers to send all live NHPs through ports of entry with CDC quarantine stations could increase transportation costs for any NHP shipment that might be driven across the Mexican or Canadian borders. However, we estimate that only three or four such overland shipments occur per year (or about 2% of all shipments), and alternate ports of entry may be allowed if approved in advance by CDC. CDC expects the total cost to be insignificant because of the small number of imports affected.

7. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities if that rule may have a significant economic impact on a substantial number of small entities.

Objective of the Rule. The implementation of the proposed rule would preserve the health benefits of current practices and standards, while yielding net regulatory cost reductions for the NHP importers.

Small Entity Impacts. A regulatory flexibility analysis (RFA) is required to estimate the number of small entities to which a proposed rule would apply, unless a screening analysis shows that the rule will not have a significant economic impact on a substantial number of small entities. A screening analysis is adequate for this proposed rule because it will yield administrative cost reductions for most NHP importers, because the 2-year registration renewal cycle will replace the 180-day registration renewal cycle, and because this proposed rule will eliminate quarantine costs for zoo-to-zoo and laboratory-to-laboratory NHP transfers that maintain detailed records. The only change from current practices that could increase costs is an increase in transportation costs for the small number of shipments currently driven across the Mexican or Canadian borders. If approved in advance by CDC, these imports may be allowed to enter through alternate ports of entry. Thus, CDC expects this change to affect a very small number of NHP importers of any size (a few shipments per year). CDC estimates that there are at most only three or four such overland shipments per year. CDC does not expect the increase in cost for these imports to represent a significant portion of any NHP importer's total sales. Any additional costs are likely to be low, in part because there are several CDC quarantine stations near the Canadian border (Boston, Chicago, Detroit, Minneapolis, New York, and Seattle) and near the Mexican border (El Paso, Houston, and San Diego). Thus, CDC does not expect the proposed rule either to have a significant impact on any small entity or to have a significant economic impact on a substantial number of small entities.

Analysis of Alternatives. As stated previously, the key alternative of the proposed rule is not to adopt each of the provisions that affect regulatory costs, including the provision that would increase costs by requiring NHP importation through ports of entry with CDC quarantine stations for shipments currently imported overland across the Mexican or Canadian borders. CDC did not accept this alternative because CDC believes that the small additional cost is warranted by the health and safety value of assuring that NHP shipments arrive at a port of entry with a CDC quarantine station.

B. Paperwork Reduction Act Analysis

HHS/CDC has determined that this proposed rule contains data collection and record keeping requirements that are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3420). HHS/CDC already has approval from OMB for the collection of registration information from importers and record keeping requirements under OMB Control No. 0920–0134: Foreign Quarantine Regulations (expiration date June 30, 2012).

In addition, HHS/CDC currently has approval from OMB under OMB Control No. 0920–0263: Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (expiration date June 30, 2011) to collect data from importers who wish to apply for a special permit to import non-human primates. HHS/CDC plans to submit an extension request to OMB for OMB Control No. 0920–0263 for approval to continue the special permit program until HHS/CDC promulgates its final rule on non-human primates. HHS/CDC requests comment from the public on the proposed data collection and record keeping requirements in the rule.

C. Federalism Impact

Under Executive Order 13132, if the contemplated rule would limit or preempt State authorities, then a Federalism analysis is required. The agency must consult with State and local officials to determine whether the rule would have a substantial direct effect on State or local governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance.

In accordance with section 361(e) of the PHSA [42 U.S.C. 264(e)], nothing in this proposed rule would supersede any provisions of State or local law except to the extent that such a provision conflicts with this rule. For example, the rule would not prevent a State from taking stronger measures to deal with infected or possibly infected NHPs or to cover additional species. Further, our proposed rule will not supersede State requirements not in conflict with the Federal rule's provisions. However, in accordance with section 361(e) of the PHSA, any State or local law that would permit any activity prohibited under this rule would conflict with this rule and, therefore, would be superseded. The rule would not have a substantial direct effect on State or local governments or impose a substantial direct cost of compliance on them.

D. Environmental Impact

In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR 71.53 will not have a

significant impact on the human environment.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector of \$100 million or more (adjusted for inflation) in any given year. This proposed rule is not expected to result in any one-year expenditure that would exceed this amount.

F. Executive Order 12988

This Notice of Proposed Rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. This notice of Proposed Rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Would preempt all State and local laws and regulations that are inconsistent with this rule; (2) would have no retroactive effect; and (3) would not require administrative proceedings before parties may file suit in court challenging this rule.

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List of Subjects in 42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention proposes to amend 42 CFR part 71 as follows:

PART 71—FOREIGN QUARANTINE

1. The authority citation for 42 CFR part 71 continues to read as follows:

Authority: Sec. 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 243), secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

2. Revise § 71.53 to read as follows:

§ 71.53 Requirements for importers of nonhuman primates.

(a) *Purpose.* The purpose of this section is to prevent the transmission of communicable disease, including pathogens, from nonhuman primates (NHPs) imported into the United States, or their offspring, to humans. These regulations are in addition to other regulations promulgated by the Secretary to prevent the introduction, transmission, and spread of communicable diseases under 42 CFR part 71, subpart A and 42 CFR part 70.

(b) *Scope.* This section applies to any person importing a live NHP into the United States, including existing importers, any person applying to become a registered importer, and any person importing NHP products.

(1) Importers must make their facilities, vehicles, equipment, and business records used in the importation of NHPs available to CDC for inspection during operating business days and hours, and at other necessary and reasonable times, to enable CDC to ascertain compliance with these regulations.

(2) Nothing in this section supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

(c) *Acronyms, Initialisms, and Definitions.* (1) For the purposes of this section:

AAALAC means the Association for Assessment and Accreditation of Laboratory Animal Care International.

AZA means the Association of Zoos and Aquariums.

CDC means the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative acting on its behalf.

CITES means the Convention on International Trade in Endangered Species.

ELISA means enzyme-linked immunosorbent assay, a type of laboratory test that measures antibodies or detects antigens for specific pathogens.

MOT means mammalian old tuberculin, a biological product used as a diagnostic tool in the evaluation for mycobacterial (tuberculosis and related bacteria) infections.

NIOSH means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

PPE means personal protective equipment, such as gloves, respirators, and other devices used in preventing the spread of communicable diseases.

SOPs means standard operating procedures. (2) For purposes of this section, the terms listed below shall have the following meanings:

Animal act means any use of NHPs for entertainment in which the NHPs are trained to perform some behavior or action and are part of a show, performance, or exhibition. Offspring of such NHPs are subject to the requirements of this section.

Breeding colony means a facility where NHPs are maintained for reproductive purposes. Offspring of such NHPs are subject to the requirements of this section.

Broker means a person within the United States that acts as an official agent of, or intermediary between, an exporter and an importer of NHPs.

Cohort means a group of NHPs imported together into the United States.

Director means the Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative.

Educational purpose means the use of NHPs in the teaching of a defined educational program at the university level or equivalent. Offspring of such NHPs are subject to the requirements of this section.

Exhibition purposes means the use of NHPs as part of a public display open to the general public during routinely scheduled hours in a facility that meets or exceeds AZA accreditation standards. Offspring of such NHPs are subject to the requirements of this section.

Importer means any person importing, or attempting to import, a live NHP into the United States, including an applicant to become a registered importer. Within the meaning of this section, *importer* includes any person maintaining a facility or institution housing NHPs during quarantine. Within the meaning of this section, *importer* also includes the agent of any animal act, laboratory, or zoo that is subject to or carries out responsibilities in accordance with these regulations.

In transit means NHPs located within the United States that are not intended for import, whether scheduled or not as part of the movement of those NHPs between a foreign country of departure and foreign country of final destination.

Lab or laboratory means a facility accredited by AAALAC or licensed by USDA, conducting research using NHPs, having foreign and/or United States based facilities, and intending to transfer or transferring one or more NHPs that were originally part of an institutionally approved, ongoing protocol, into the United States facility for purposes related to that specific research project.

Medical consultant means an occupational health physician, physician's assistant, or registered nurse, who is knowledgeable about the risks to human health associated with NHPs.

Nonhuman primate or NHP means all nonhuman members of the Order Primates, including animals commonly known as chimpanzees, gorillas, monkeys, macaques, gibbons, orangutans, baboons, marmosets, tamarins, lemurs, and lorises.

Offspring means the direct offspring of any live NHPs imported into the United States and the descendants of any such offspring.

Old World Nonhuman Primate means all nonhuman primates endemic to Asia or Africa.

Pathogen means any organism or substance capable of causing a communicable disease, including herpes B virus.

Permitted Purpose means the use of NHPs for scientific, education, or exhibition purposes as defined in this section.

Person means any individual or partnership, firm, company, corporation, association, organization, or similar legal entity.

Quarantine means the practice of isolating live NHPs for at least 31 days after arrival in a U.S. quarantine facility where the NHPs are observed for evidence of infection with communicable disease, and where measures are in place to prevent transmission of infection to humans or NHPs, including other NHPs within the cohort.

Quarantine facility means a facility used by a registered importer of NHPs for the purpose of quarantining imported NHPs.

Quarantine room means a room in a registered import facility for housing imported NHPs during the quarantine period.

Scientific purposes means the use of NHPs for research following a defined protocol and other standards for research projects as normally conducted at the university level. Offspring of such NHPs are subject to the requirements of this section.

Trophy means a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of a nonhuman primate.

Zoo means:

(A) Within the United States, an AZA accredited and professionally maintained park, garden, or other place in which animals are kept for public exhibition and viewing; or

(B) Outside of the United States, a professionally maintained park, garden, or other place in which animals are kept for public exhibition and viewing that meets or exceeds the accrediting standards of the AZA.

Zoonotic Disease means any infectious agent or communicable disease that is capable of being transmitted from other animals to humans or from humans to animals.

(d) *General Prohibition of Excluded Nonhuman Primates.* (1) A person may not import live NHPs into the United States unless the person is registered with CDC as a NHP importer in accordance with this section. (2) A person may not import live NHPs into the United States or maintain, sell, resell, or otherwise distribute imported NHPs except for:

(i) Permitted purposes; or

(ii) Use in breeding colonies, provided that all offspring will be used only as replacement breeding stock or for permitted purposes.

(3) A person may not import live NHPs into the United States or maintain, sell, resell, or otherwise distribute imported NHPs or their offspring for use as pets, as a hobby, or as an avocation with occasional display to the general public.

(e) *Disposal of Prohibited or Excluded NHPs.* (1) CDC may seize, examine, isolate, quarantine, export, treat, or destroy any NHP if:

(i) It is imported through a location other than an authorized port of entry;

(ii) It is imported for purposes other than permitted purposes;

(iii) It is maintained, sold, resold, or distributed for purposes other than permitted purpose;

(iv) It is imported by a person who is not a registered importer; or

(v) It is otherwise deemed to constitute a public health threat by the Director.

(2) For any NHP arriving in the United States through an unauthorized location, for other than the permitted purposes, or by a person who is not a registered importer, the person attempting to import that NHP, must, at the person's own expense, do one of the following:

(i) Export or arrange for destruction of the NHP, or

(ii) Donate the NHP to a scientific, educational, or exhibition facility as approved by the Director.

(3) If the importer fails to dispose of the NHP by one of the options described in paragraph (e)(2) of this section, the Director will dispose of the NHP at the importer's expense.

(4) Pending disposal of any NHPs arriving into the United States, the NHP will be detained at the importer's expense at a location approved by the Director.

(f) *Authorized ports of entry for live NHPs.* (1) An importer may import live NHPs into the United States only through a port of entry where a CDC quarantine station is located. Currently, the list of CDC quarantine stations can be found at <http://www.cdc.gov/quarantine/QuarantineStations.html>.

(2) In the event that the importer is unable to provide for entry at a port where a CDC quarantine station is located, the importer may only import live NHPs into the United States if advance written approval has been obtained from the Director.

(3) If prior written approval is not obtained from the Director, the importer and excluded NHPs will be subject to the provisions of paragraph (e) of this section.

(g) *Registration of Importers.* Before importing any live NHP into the United States, including those that are part of an animal act or those involved in zoo-to-zoo or laboratory-to-laboratory transfers, an importer must register with and receive written approval from the Director.

(1) To register as an importer, a person must submit the following documents to CDC:

- (i) A completed application form;
- (ii) A completed statement of intent describing the number and types of NHPs intended for import during the registration period;
- (iii) A copy of all written Standard Operating Procedures (SOPs) that include all elements required in paragraphs (h) through (n) of this section;
- (iv) A copy of any current registrations, licenses, and/or permits that may be required from the U.S. Department of Agriculture and U.S. Fish and Wildlife Service;
- (v) A signed, self-certification stating that the importer is in compliance with the regulations contained in this section and agrees to continue to comply with these regulations.

(2) Upon receiving the documentation required by this section, the Director will review the application and either grant, in whole or in part, or deny the application for registration as an importer. CDC may consult with the importer regarding any element of the application or accompanying documentation.

(i) Before issuing a registration, the Director may inspect any business record, facility, vehicle, or equipment to be used in importing NHPs.

(ii) Unless revoked in accordance with paragraph (t) of this section, a registration certificate issued under this section is effective for two years beginning from the date CDC issues the registration certificate.

(iii) An importer must apply to CDC for renewal of the registration certificate not less than 30 days and not more than 60 days before the existing registration expires.

(3) All importers must comply with the requirements of paragraphs (h) through (n) of this section.

(h) *Documentation.* An importer must have a written policy that imported NHPs and their offspring will only be used and distributed for permitted purposes.

(1) An importer must document the intended purpose for each imported NHP and the purpose must comply with one of the permitted purposes.

(2) An importer must retain records documenting the identity of any recipients, the number of NHPs in each shipment or sale, and the dates of each shipment or sale.

(3) An importer must maintain these records in an organized manner and either electronically or in a central location that is at or in close proximity to the NHP facility to allow CDC to

inspect the records during CDC site visits during regular business hours or within one hour of such visits.

(4) Before distributing or transferring an imported NHP, an importer must:

- (i) Communicate to the recipients of NHPs, in writing, the restrictions and definitions of permitted purposes; and
- (ii) Obtain written certifications from the intended recipient that the NHPs will be used and distributed for one of the permitted purposes.

(5) An importer must keep written certifications demonstrating that the NHPs and any offspring will continue to be used for permitted purposes.

(i) *Worker Protection Plan and Personal Protective Equipment.* (1) In addition to complying with the requirements of this section, an importer must comply with all relevant Federal and State requirements relating to occupational health and safety.

(2) Importers must have a written worker protection plan for anyone whose duties may result in exposure to NHPs. An importer must adhere to the plan and SOPs and must ensure that each worker covered under the plan also adheres to it and SOPs.

(3) An importer must contact CDC immediately by telephone to report any instance of a worker exposed to a zoonotic illness and must include instructions for contacting CDC in its worker protection plan.

(4) A worker protection plan must include the following:

(i) Procedures to protect and train transport workers in how to avoid and respond to zoonotic disease exposures associated with NHPs;

(ii) Hazard evaluation and worker communication procedures that adhere to those in paragraph (i)(4) of this section;

(iii) Personal protective equipment (PPE) requirements that adhere to those in paragraph (i)(5) of this section;

(iv) SOPs that adhere to tuberculosis requirements in paragraph (i)(6) of this section;

(v) If applicable, SOPs that adhere to requirements relating to macaques as described in paragraph (i)(7) of this section;

(vi) An infection-prevention program, including infection-prevention methods requiring, at a minimum, PPE and workplace practices for preventing infection among workers whose duties may result in exposure to NHPs;

(vii) SOPs that include requirements for preventing workplace infection from potentially contaminated needles or other sharp instruments and that, at a minimum, prohibit workers from recapping used needles by hand; removing needles by hand; or otherwise

bending, breaking, or manipulating used needles by hand;

(viii) SOPs requiring that used disposable syringes and needles, scalpel blades, and other sharp items be placed in puncture-resistant containers kept as close to the work site as practical;

(ix) SOPs requiring that removable, disposable PPE be autoclaved, incinerated, or otherwise disposed of as biohazardous waste. Nondisposable clothing worn in the quarantine facility must be disinfected on site before laundering;

(x) An infection prevention program that requires NHP handlers to cleanse all bites, scratches, and/or mucosal surfaces or abraded skin exposed to blood or body fluids immediately and thoroughly;

(xi) Infection prevention procedures that require workers to immediately flush their eyes with water for at least 15 minutes following an exposure of blood or body fluids to the eye;

(xii) Post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant including:

(A) Procedures ensuring that exposed workers have direct and immediate access to a medical consultant who has been previously identified in the SOPs to CDC.

(B) For potential exposures to B virus, post-exposure procedures that require the routing of diagnostic specimens to the National B Virus Resource Center located at Georgia State University in Atlanta, Georgia, or another location as specified by CDC.

(xiii) Procedures for documenting the frequency of worker training, including for those working in the quarantine facility.

(5) As part of the worker protection plan described in this subparagraph, an importer must establish, implement, and maintain hazard evaluation and worker communication procedures that include the following:

(i) A description of the known zoonotic disease and injury hazards of handling NHPs;

(ii) The need for PPE in handling NHPs and training in proper use of PPE, including re-training and reinforcement of appropriate use;

(iii) Procedures for monitoring workers for signs of zoonotic illness, including procedures that ensure reporting to CDC by telephone within 24 hours of the occurrence of illness in any worker suspected of having a zoonotic disease acquired from an NHP; and

(iv) Procedures for disinfection of garments, supplies, equipment, and waste.

(6) As part of the worker protection plan described in this paragraph, an importer must identify the PPE required for each task or working area. Additionally, in this part of the worker protection plan, an importer must ensure the following:

(i) Any required PPE must be available to workers when needed;

(ii) Workers in direct contact with NHPs must wear the following:

(A) Gloves of sufficient thickness to reduce the risk of cuts, scratches, and punctures;

(B) Disposable NIOSH-approved N95 or equivalent respirators, in compliance with OSHA 29 CFR § 1910.134 which requires respiratory protection program;

(C) Face shields or eye protection; and

(D) Outer protective clothing when opening crates, removing foreign materials from crates, feeding NHPs, removing dead NHPs, or handling bedding materials.

(iii) Workers handling crates or pallets containing NHPs must wear the following:

(A) Elbow-length, reinforced leather gloves or equivalent gloves that prevent penetration of splinters, other crating materials, or debris;

(B) Long-sleeved shirts and trousers that resist minor tears and are appropriate for the weather;

(C) Waterproof shoes or boots;

(D) NIOSH-approved respiratory protection that is compliant with OSHA 29 CFR § 1910.134, and

(E) Face shields or eye protection that protect the eyes.

(iv) Workers whose faces may come within 5 feet of an NHP must wear disposable NIOSH-approved N95 or equivalent respirators and either face shields or eye protection to protect against aerosol or droplet transmission of pathogens;

(v) Workers must remove disposable PPE and discard as a biohazard; and

(vi) Workers must not drink, eat, or smoke while physically handling NHPs or cages, crates, or other materials from such NHPs.

(7) For tuberculosis protection, an importer must ensure the following:

(i) Workers in a facility housing NHPs must have a baseline tuberculosis skin test prior to working with NHPs and, at least annually, a tuberculosis skin test;

(ii) Prompt and direct access to a medical consultant who reads tuberculin skin tests and maintains records for such tests;

(iii) If an NHP is found to have laboratory-confirmed tuberculosis, any worker who had previously entered any room where a confirmed NHP has been housed must promptly undergo a post-exposure tuberculin skin test and

(A) If that test is negative, the worker must undergo another tuberculin skin test 3 months after exposure, and

(B) If that test is reactive, the worker must be referred for medical evaluation; and

(C) The CDC must be immediately notified of the results by telephone, SMS text, or e-mail as specified in the importer's standard operating procedures.

(iv) Compliance with exposure control planning elements under 29 CFR 1910.1030 for workers who will have parenteral and other contact with blood or other potentially infectious material from NHPs and compliance with the respiratory protection requirements in 29 CFR 1910.134.

(8) An importer must develop, implement, and adhere to a written PPE program to prevent herpes B virus transmission. The program must be based on a thorough hazard assessment of all work procedures, potential routes of exposure (e.g., bites, scratches, or mucosal exposures), and potential adverse health outcomes.

(9) An importer must keep records of all serious febrile illnesses [fever greater than 101.3 degrees Fahrenheit (38.5 degrees Celsius) for more than 48 hours] in workers having exposure to NHPs in transit or in quarantine. The record must be kept by the importer as part of the worker's administrative records. The importer must promptly notify CDC by telephone if such an illness occurs. An importer must ensure that the medical consultant providing care is informed that the patient works with and/or has been exposed to NHPs.

(j) *SOP Requirements and Equipment Standards for Crating, Caging, and Transporting Live Nonhuman Primates. Equipment standards for crating, caging, and transporting live NHPs must be in accordance with USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3), and an importer must establish, implement, maintain, and adhere to SOPs that ensure the following requirements are met:*

(1) Any crate used to transport NHPs must be free of sharp projections that could scratch or otherwise injure workers.

(2) Glass items must not be used for feeding or watering NHPs during transport.

(3) NHPs must only be removed from crates in an approved quarantine facility under the supervision of a licensed, qualified veterinarian. NHPs must not be removed during transport.

(4) Whenever possible, workers must not handle live NHPs directly.

(5) Upon arrival into the U.S., only an importer or an authorized representative

may receive the NHPs from a conveyance (i.e., airplane, ship, etc).

(6) All reusable items must be decontaminated between uses.

(7) At all times during transport, crates containing NHPs must be separated by a physical barrier from workers, other individuals, and all other animals and cargo, or by a spatial barrier greater than 5 feet, that prevents contamination of cargo or individuals with bodily fluids, feces, or soiled bedding.

(8) At all times during transport, ventilation systems must direct airflow away from individuals and toward the compartment housing NHPs to prevent the transmission of zoonotic diseases to individuals traveling with the shipment; any recirculated air must be HEPA-filtered.

(9) If traveling by plane, crates containing NHPs must be loaded in the cargo hold last and removed first, must be placed on plastic that prevents spillage onto the deck of the plane, and must be placed on pallets or double crated to ensure separation from other cargo.

(10) Workers, as well as NHPs, must be protected from communicable disease exposures at any facility used en route, including transportation holding facilities. An importer must maintain a description of any transportation holding facilities and document the communicable disease prevention measures taken to protect workers at facilities used en route.

(11) Documentation must be made of the communicable disease-prevention procedures carried out in every step of the chain of custody, from the time of embarkation of the NHPs at the country of origin until arrival at the quarantine facility.

(12) Procedures to ensure that aircraft, ship, vehicles, and related equipment are decontaminated following transport.

(13) PPE, bedding, or other biohazardous waste must be disposed of following transport.

(k) *Ground Transport Vehicles.* An importer must establish, implement, maintain, and adhere to SOPs for ground transport vehicles transporting NHPs that meet the following requirements.

(1) Ground transport vehicles must have a separate cargo compartment with separate heating, ventilation, and air-conditioning systems.

(2) The interior surfaces of ground transport vehicle cargo compartments must be of smooth construction, easily cleaned and disinfected.

(3) PPE, bedding, or other biohazardous waste must be disposed of following ground transport.

(4) Ground transport vehicle cargo compartments must be large enough to allow safe stowage of NHP crates in a manner that allows ready access to each NHP during transit without unloading any crates.

(5) After transport of the NHP shipment from the port of entry to the quarantine facility, the importer must notify CDC in writing within 48 hours of the time the shipment arrived at the quarantine facility.

(6) As part of the notification of arrival in paragraph (k)(4) of this section, an importer must inform CDC whether suspected or confirmed transmission or spread of communicable disease occurred during transport, including notification of NHPs that died or became ill during transport or malfunctions associated with disease mitigation procedures or equipment.

(l) *Quarantine Facilities.* (1) The requirements of this paragraph relating to quarantine facilities does not apply to laboratory-to-laboratory transfers or zoo-to-zoo transfers that are in compliance with paragraphs (p)(2) and (q)(2) of this section, respectively.

(2) An importer must maintain a quarantine facility for holding a cohort during the required quarantine period. NHPs must be quarantined for 31 days after arrival at the importer's quarantine facility. CDC may extend the quarantine period if an importer or CDC finds or suspects that an NHP is infected with, or has been exposed to, a zoonotic disease, or if an importer or CDC finds a need for additional diagnostic testing.

(i) For any quarantine facility established or maintained under this section, an importer must establish, implement, maintain, and adhere to SOPs that meet the following physical security requirements:

(A) The facility must be locked and secure, with access limited to authorized, trained, and knowledgeable personnel.

(B) An importer must limit access to NHP quarantine areas to authorized personnel who are responsible for the transport, study, care, or treatment of the NHPs.

(ii) An importer must keep the number of workers involved in the care, transport, and inspection of NHPs to the minimum necessary to perform these functions.

(iii) The facility must be designed and operated in such a manner as to allow for adequate disinfecting.

(iv) The facility must have adequate equipment and space for discarding and disinfecting all equipment, clothing, and caging.

(v) Each quarantine room must have a separate air-handling system and

remain under negative air pressure in relationship to the common hallway or anteroom(s) adjacent to the quarantine room.

(vi) Each quarantine room must have air flow indicators that are affixed outside the quarantine room that indicate the direction of airflow into or out of quarantine rooms and adjoining common hallways and anterooms.

(3) An importer must establish, implement, maintain, and adhere to SOPs for handling, monitoring, and testing NHPs in quarantine that meet the following requirements:

(i) An importer must ensure that all NHPs are identified individually with a unique number or alphanumeric code permanently applied to the NHP by tattoo, microchip, or other permanent identifier before importation or after the 31-day quarantine. Tattoos, microchips, or other permanent identifiers must not be applied during the quarantine period because such procedures pose a risk of needle sticks or aerosol exposures to employees.

(ii) Health certificates, shipping documents, and NHP health records must include the number or code required in paragraph (l)(2)(i) of this section, as well as the age, sex, and species of the NHP.

(iii) An importer must ensure NHPs are confined in a squeeze-back cage whenever possible and that any individual NHP is anesthetized or tranquilized before handling.

(iv) For any procedure involving the use of a syringe, a separate, disposable needle and syringe must be used, including a sterile needle and syringe for withdrawing medication from any multidose vials (e.g., ketamine).

(v) Before any contaminated item is removed from a quarantine facility an importer must ensure all NHP waste, bedding, uneaten food, or other possibly contaminated items are disinfected, autoclaved, or double-bagged for disposal as biomedical waste by a licensed facility.

(vi) All cages, feeding bottles, reusable items, and other contaminated items must be disinfected between uses and before disposal.

(vii) Any equipment used for infusion of NHPs must be autoclaved or incinerated, as appropriate.

(viii) During the quarantine period, an importer must monitor NHPs for signs of any zoonotic illness, including signs consistent with yellow fever, monkeypox, or filovirus disease.

(A) If any NHP appears ill during quarantine, an importer must monitor that NHP for signs of zoonotic illness, including filovirus disease, and ensure appropriate treatment.

(B) If an Old World NHP displays signs suggestive of filovirus infection (e.g., diarrhea with melena or frank blood, bleeding from external orifices or petechiae, or suffusive hemorrhage), and survives, an importer must collect serum samples on day 31 of quarantine and test these samples for antibodies to filovirus while the entire cohort remains in quarantine. An importer must test the serum for Immunoglobulin G (IgG) antibodies to Ebola viruses by using an ELISA methodology, or other method approved by CDC.

(C) An importer must not request a release from CDC of any NHP from quarantine under paragraph (l)(3) of this section, if the importer knows or has reason to suspect that the NHP is infected with or has been exposed to a zoonotic disease.

(ix) For each NHP in a quarantine facility, an importer must administer at least three tuberculin skin tests on the eyelid using old mammalian tuberculin (MOT), with at least 2 weeks between tests, before the NHP is released from import quarantine. Tuberculin skin tests must be read and recorded at 24, 48, and 72 hours, and a grading scale for interpretation of these tests must be listed in an SOP for tuberculosis testing.

(A) An importer must ensure that any cohort with positive or suspicious tuberculin reactions remains in quarantine and receives at least five additional tuberculin skin tests (each administered at least two weeks apart) following removal of the last NHP with a positive TST.

(B) The validity of tuberculosis test results may be compromised if during quarantine an NHP contracts a viral illness, including measles; a severe illness; is treated with steroids; or is immunized. An importer must document such occurrence(s) and hold the NHPs until they have recovered from the illness or are no longer on treatment, and for a recommended time after recovery (to be determined in consultation with CDC, depending on the illness or treatment in question) before tuberculosis tests are performed.

(C) An importer must retain records of all tuberculin skin tests performed during the lifetime of each NHP at the facility housing the NHP until the NHP is transferred to another facility. These records must accompany the NHP during moves to other facilities.

(x) An importer must ensure that different cohorts of NHPs are quarantined in separate quarantine rooms.

(A) If mixing of cohorts should occur, an importer must treat the mixed cohort as a single cohort.

(B) All NHPs within that mixed cohort must remain in quarantine until each NHP in that mixed cohort has completed the minimum 31-day quarantine period.

(C) Quarantined NHPs must be housed in such a manner that they at all times will not expose non-quarantined NHPs to non-filtered air and other potentially infectious materials, including soiled bedding, caging, and other potentially contaminated items.

(4) Before releasing an NHP from quarantine, an importer must obtain written permission from CDC. CDC may permit the release of a cohort from quarantine when all the following conditions have been met:

(i) The 31-day quarantine period, including any required extension of quarantine, has been completed.

(ii) CDC has confirmed receipt of written notification of the health status of the NHPs in the shipment from the quarantine facility's licensed veterinarian as required by paragraph (m)(4) of this section.

(iii) CDC confirms that the importer has addressed and resolved to CDC's satisfaction any NHP or worker communicable disease issues that were reported to CDC during shipment.

(5) If CDC notifies an importer of any evidence that NHPs have been exposed to a zoonotic disease, the importer must, at the importer's expense, implement or cooperate in the CDC's implementation of additional measures to rule out the spread of suspected zoonotic disease before releasing a shipment from quarantine, including examination, additional diagnostic procedures, treatment, detention, isolation, seizure, or destruction of exposed animals.

(6) An importer must establish, implement and adhere to SOPs for safe handling and necropsy of any NHP that dies in quarantine. The SOPs must ensure the following:

(i) The carcass of the NHP must be placed in a waterproof double-bag and properly stored for necropsy, specimen collection, autoclaving and/or incineration, and disposal;

(ii) A necropsy must be performed by a State-licensed veterinary pathologist or State-licensed veterinarian under biosafety level 3 containment. Each necropsy report must address all major organ systems and incorporate clinical history and laboratory findings;

(iii) Necropsy and appropriate laboratory testing of the NHP must document the cause of death and/or rule out zoonotic illness;

(iv) Necropsy must be performed under biosafety level 3 or biosafety level 2 to protect against exposure to highly infectious agents;

(v) Any samples of tissues, blood, serum, and/or transudates (bodily fluid) collected during necropsy must be retained until the NHP shipment has been released from quarantine by CDC, in case other testing is required by CDC;

(vi) Fresh and formalin-fixed tissue specimens, including tracheobronchial lymph node, liver, lung, and spleen, regardless of necropsy findings must be collected for laboratory examination;

(vii) Any granulomatous lesions found in any NHP at necropsy, regardless of whether tuberculosis in the NHP was previously suspected, must be submitted to a laboratory for laboratory examination for acid-fast bacilli and for mycobacterial culture; and

(viii) In the event that an Old World NHP dies or is euthanized for any reason other than trauma during quarantine, liver tissue for filovirus antigen by using the antigen-capture ELISA method must be submitted to a laboratory for testing

(m) *Health Reporting Requirements for Nonhuman Primates.*

(1) An importer must notify CDC of the events listed in this paragraph by telephone or as otherwise specified in this paragraph.

(2) An importer must notify CDC within 24 hours of the occurrence of severe illness or death of NHPs in quarantine facilities.

(3) An importer must report to CDC within 24 hours of the occurrence of any illness in NHPs that an importer has reason to suspect is yellow fever, monkey pox, or filovirus disease.

(4) If mortality for a cohort exceeds 5 percent, calculated from time of embarkation from country of origin to release from CDC quarantine, an importer must report the circumstances to CDC promptly, including the cause of death for each NHP.

(5) Upon completion of the quarantine period and before an importer releases any NHP, cohort, or mixed cohort from quarantine, the importer must ensure that the quarantine facility's licensed veterinarian notifies CDC in writing of the health status of the shipment.

(6) An importer must notify CDC within 24 hours if any NHP tests positive for filovirus virus antigen or antibody.

(7) An importer must report to CDC within 48 hours, any positive or suspicious tuberculin skin test results, necropsy findings, or laboratory results. Any report required under this section must include a copy or summary of the individual NHP's health records.

(n) *Recordkeeping and Reporting Requirements for Importing NHPs.*

(1) Before authorizing the import of any NHPs, an importer must be in

compliance with all applicable elements of the importer's SOPs.

(2) At least seven days before importing a shipment of NHPs, an importer must notify CDC in writing of the impending shipment and provide the following information:

(i) The importer's name and address;

(ii) Number and species of NHPs being imported;

(iii) Description of crates;

(iv) Means of individually identifying NHPs;

(v) Origin of NHPs, including the country, the exporter, and the exporter's address;

(vi) Use of NHPs as described by the recipient under paragraph (i)(2) of this section;

(vii) Specific itinerary with names, dates, flights, times, airports, sea ports, and responsible parties to contact at every step of travel, including all ground transportation;

(viii) Port of entry;

(ix) If arriving by flight, the name of the airline and its flight number;

(x) If arriving by vehicle, the name of the vehicle's owner and its license plate number;

(xi) If arriving by ship, the name of the ship and its vessel number;

(xii) Name and address of the destination quarantine facility;

(xiii) Name, address, and contact information for shipper, if other than the importer;

(xiv) Name, address, and contact information for broker in the United States;

(xv) Name, address, and contact information for person responsible for off-loading NHPs in the United States;

(xvi) Name, address, and contact information for any party responsible for ground transportation from port of entry to quarantine facility;

(xvii) Expected quarantine facility, if different from the importer;

(xviii) Master air waybill number for shipment;

(xix) CITES permit number and expiration date.

(o) *Animal Acts.* (1) All foreign-based animal acts that include a NHP must be registered with CDC in accordance with this section prior to entry into the U.S.

In addition to the requirements in paragraph (g) of this section, an importer must provide:

(i) A description of the animal act that includes the NHP.

(ii) Brochures, advertising materials, and/or documentation of recent or planned animal act performances.

(iii) A current list of all NHPs in the animal act, indicating each NHP's name, species, sex, age, distinguishing physical description, and unique identifier such as a tattoo or microchip.

(iv) A description, diagram, and photographs of the facilities where the importer houses the NHPs in the animal act in the United States, including illustrations of the primate caging and/or enclosures; the relationship of these cages or enclosures to other structures on the property and adjoining properties; whether the primate facilities are open to the air or fully enclosed; and the physical security measures of the facility.

(v) Documentation signed by a licensed veterinarian describing the physical exam performed on each NHP in the animal act. Such examinations must be performed at least once a year. The physical exam must include the following:

(A) Routine complete blood counts, clinical chemistries, fecal exams, and any additional testing indicated by the physical exam.

(B) At least once a year, tuberculosis testing with MOT and interpreted as stated in paragraph (l)(2)(ix);

(C) NHPs with positive tuberculin skin test results must be treated with antituberculosis chemotherapy after consultation with CDC.

(D) If the NHP is a chimpanzee, serology and antigen testing for hepatitis B, serology for hepatitis C, and any additional titers as indicated by clinical history or exam. A chimpanzee found serologically positive for hepatitis B and/or hepatitis C is ineligible for entry or re-entry into the U.S., unless confirmatory evidence signed by a licensed veterinarian shows that there is no hepatitis B or hepatitis C virus present in the NHP.

(vi) SOPs for transporting the NHPs internationally, including the shipping crates or enclosures, the type of conveyance, and measures to minimize human exposure to the NHPs.

(vii) A copy of a negative tuberculosis test conducted within the past 12 months, or medical documentation that the individual is free of clinically active tuberculosis, for each trainer and/or handler.

(viii) A copy of each SOP for dealing with suspected zoonotic diseases.

(ix) If macaques are in the animal act, a procedure for dealing with potential herpes B-virus exposures.

(2) Requirements for U.S.-based animal acts containing NHPs to re-enter the United States after export.

(i) An importer must ensure that the NHP contains the unique identifier, such as a tattoo or microchip, obtained prior to export.

(ii) Each NHP must be included on an approved list of performing NHPs that are cleared by CDC to travel outside of and return to the U.S.

(iii) Before re-entry, an importer must ensure that CDC receives the itinerary as described in paragraph (n)(2).

(p) *Zoo-to-Zoo Transfers.* (1) Persons who will only be importing live NHPs into the United States through transfer from one zoo to another must comply with all the elements listed in paragraphs (g), (h), (i), (j), (k), (m), (n) of this section.

(2) If a zoo is receiving one or more NHPs into the United States from another AZA zoo (or AZA-equivalent outside of the U.S.), the recipient zoo must, before the transfer, submit the following information for approval by CDC:

(i) A copy of each NHP's veterinary medical records regular testing for tuberculosis from the previous zoo for approval by CDC, including a method of positive identification such as a tattoo, microchip or photograph, and

(ii) A copy of a current health certificate, including documentation of a negative tuberculosis test, signed by a licensed qualified veterinarian within 14 days of the transfer documenting that the NHP appears healthy and free from communicable diseases, and

(iii) Documentation which verifies that the recipient zoo is registered in accordance with this section, and

(iv) Specific itinerary with names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel, including all ground transportation.

(3) Persons importing live NHPs that are transferred from one zoo to another, who are not able to meet the requirements listed in paragraphs (p)(2)(i) and (ii) of this section must comply with all the elements in paragraphs (g), (h), (i), (j), (k), (l), (m), and (n) of this section.

(q) *Laboratory-to-Laboratory Transfers.* (1) Persons who will only be transferring NHPs on established research protocols from a laboratory outside of the U.S. to laboratory within the U.S. must comply with all the elements listed in paragraphs (g), (h), (i), (j), (k), (m), and (n) of this section.

(2) If a lab is receiving one or more NHPs for purposes related to an ongoing research project from another established research facility outside the United States, the recipient facility must, before the transfer, submit the following to CDC for approval:

(i) A copy of each NHP's veterinary medical records, including regular testing for tuberculosis from the previous lab for CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.

(ii) A copy of a current health certificate stating that the NHP(s) appear healthy and are free from communicable diseases, including documentation of a negative tuberculosis test. The certificate must be signed by a State licensed veterinarian within 14 days of the transfer; and

(iii) Documentation of the ongoing research project and the reason the NHP needs to be transported to the U.S. laboratory facility.

(iv) Specific itinerary with names, dates, flights, times, airports, sea ports, and responsible parties to contact at every step of travel, including all ground transportation.

(3) Persons importing live NHPs that are transferred from one lab to another, who are not able to meet the requirements listed in paragraph (q)(2)(i),(ii), and (iii) of this section must comply with all the elements in paragraphs (g), (h), (i), (j), (k), (l), (m), and (n) of this section.

(r) *In Transit Shipments of NHPs.*

(1) Before arrival into the United States, brokers of in transit shipments must notify CDC of all scheduled in transit shipments of NHPs not intended for import into the United States and provide the following information:

(i) Number and species of NHPs in the shipment;

(ii) Origin of NHPs, including the country, the exporter, and the exporter's address;

(iii) Name and full address of the final destination quarantine facility in the importing country;

(iv) Means of individually identifying NHPs, if required by the importing country;

(v) Specific itinerary while in the United States including names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel within the United States, including all ground transportation;

(vi) Description of crates;

(vii) Established SOPs to protect and train transport workers from exposure to communicable disease while handling NHPs;

(viii) SOPs describing procedures to prevent contamination of other articles and cargo during transit, including physical separation of crates from other cargo;

(ix) SOPs describing procedures to decontaminate aircraft, ships, vehicles, and related equipment following transport; and

(x) Proposed use, if any, of in transit holding facilities and steps to be taken to protect workers, as well as NHPs, from communicable disease exposure at each facility to be used en route.

(2) While located in the United States, in transit shipments must be housed and cared for in a manner consistent with requirements for NHPs intended for import into the United States as specified in paragraphs (j) and (k) of this section.

(s) *Revocation and Reinstatement of an Importer's Registration.* (1) If the Director determines that an importer has failed to comply with any applicable provisions of this section, including the importer's SOPs, the Director may revoke the importer's registration.

(2) CDC will send the importer a notice of revocation stating the grounds upon which the proposed revocation is based.

(i) If the importer wishes to contest the revocation, the importer must file a written response to the notice within 20 calendar days after receiving the notice.

(A) As part of the response, an importer may request that the Director review the written record.

(B) If an importer fails to file a response within 20 calendar days, all of the grounds listed in the proposed revocation will be deemed admitted, in which case the notice shall constitute final agency action.

(3) If an importer's response is timely, the Director will review the registration, the notice of revocation, and the response, and make a decision in writing based on the written record.

(4) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency action. The Director will serve the importer with a copy of the written decision.

(5) The Director may reinstate a revoked registration after inspecting the

importer's facility, examining its records, conferring with the importer, and receiving information and assurance from the importer of compliance with the requirements of this section.

(t) *Nonhuman primate products.*

(1) NHP trophies, skins, or skulls may be imported without obtaining a permit under this section if accompanied by documentation demonstrating that the products have been rendered noninfectious using one of the following methods:

(i) Boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers, or teeth is removed; or

(ii) Gamma irradiation at a dose of at least 20 kilo Gray at room temperature (20° C or higher); or

(iii) Soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate, Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours; or

(iv) Soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 liters water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

(v) In the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate, Na₂CO₃).

(2) Non-live NHP products (including skulls, skins, bodies, blood, or tissue) that have not been rendered noninfectious are considered to pose a potential human health risk and may only be imported under the following circumstances:

(i) The product must be accompanied by a permit issued by the Director. Requests for permits should be

accompanied by an explanation of the product's intended use and a description of how the product will be handled to ensure that it does not pose a zoonotic disease threat to humans. The Director will review the request for a permit, and accompanying materials, and issue a decision that shall constitute final agency action.

(ii) The product may only be imported for bona fide scientific purposes.

(iii) The product may only be received by a facility equipped to handle potentially infectious NHP materials.

(iv) The product must comply with any other applicable Federal requirements, including those relating to packaging, shipping, and transport of potentially infectious, biohazardous substances as well as those for Select Agents pursuant to 42 CFR part 73.

(u) *Appeal of denial for a permit to import.* (1) If the CDC denies your request for a permit under 42 CFR 71.53, you may appeal that denial to the CDC Director.

(2) You must submit your appeal in writing to the CDC Director, stating the reasons for the appeal and showing that there is a genuine and substantial issue of fact in dispute.

(3) You must submit the appeal within 2 business days after you receive the denial.

(4) CDC will issue a written response to the appeal, which shall constitute final Agency action.

Dated: December 15, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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