

Questions and Answers for Importers about the Proposed Updates to the Regulations for the Importation of Nonhuman Primates (42 CFR Part 71.53)

The Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC) published a Notice of Proposed Rulemaking (NPRM) on January 5, 2011 detailing proposed changes to the regulations for importation of nonhuman primates (NHPs) into the United States. This NPRM outlines the proposed requirements for the importation of NHPs into the United States to prevent the spread of communicable disease from NHPs to humans. The public will have 60 days after publication to comment on the NPRM. HHS and CDC will review all comments and determine if changes to the NPRM are necessary.

Why are the NHP regulations being updated?

CDC regulations for the importation of NHPs were developed to address the health risk they pose to humans. Over time, various measures have been implemented to prevent the spread of disease from NHPs to humans. The purpose of the proposed update is to consolidate and formalize the many measures that have been used to manage the importation of NHPs.

Who is affected by these regulations?

The proposed regulations apply to any person importing a live NHP into the United States, including existing registered importers, any person applying to become a registered importer, and any person importing NHP products such as trophies or biological samples.

What is CDC's role in carrying out NHP regulations?

HHS delegates to CDC's Division of Global Migration and Quarantine (DGMQ) the responsibility for administering the regulation of importation of NHPs in its foreign quarantine regulations (42 Code of Federal Records [CFR] Part 71). Since 1975, section 71.53 has prohibited the importation of NHPs except for scientific, educational, or exhibition purposes. DGMQ regulates the importation of NHPs at major US ports of entry with help from federal partners and state and local health departments.

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

Yes, the proposed rule continues the general prohibition on importing live NHPs except for science, education, or exhibition purposes. NHPs may not be imported as pets under any circumstances.

What are considered "scientific, educational, or exhibition" purposes for importing NHPs?

For the purpose of importing NHPs:

- Educational purpose means the use of NHPs in the teaching of a defined educational program at the university level or equivalent.
- Scientific and educational purposes are as those conducted at the university level or equivalent (e.g., use in breeding colonies and the advancement of medicine).
- Exhibition purposes are 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 by a comparable accrediting agency.

In addition to consolidating current requirements, are there any new or changed requirements in the NPRM for the importation of NHPs?

Yes, the proposed regulations simplify zoo-to-zoo and laboratory-to-laboratory transfers if additional criteria are met; describe designated ports of entry through which NHPs must enter; require brokers to notify CDC about in-transit shipments; incorporate the special permit requirements into the registration process; and remove the requirement that a separate special permit be renewed every 180 days (all registrations are to be renewed every 2 years).

What are the changes to the regulations for importation of NHPs?

Below is a summary table showing each of the changes in the proposed regulations. Click on a specific requirement for more information about that proposed requirement. The requirements marked “Current” are ones that importers are already following and are now incorporated into the NPRM. The requirements marked “Revised” are ones that have been modified in the NPRM. The ones marked “New” are new practices required of importers.

NPRM	Requirement	Current	Revised	New	Details of proposed regulations
71.53 (A) and 71.53 (b)(3)	Record inspection	√			Importers must make NHP records available for inspection by CDC during scheduled site visits or within 1 hour of unscheduled visits.
71.53 (D)	Special permits		√		Under the new ruling, importer registration will be simplified by eliminating the need for a category of importer that must request special permits.
71.53 (D) and 71.53 (g)(1)	Becoming a registered importer with CDC	√			In order for potential NHP importers to become registered, they must submit an application to CDC.

71.53 (G) and 71.53 (i)(3)	Employee illness reporting	√			An importer must contact CDC immediately by telephone to report any suspected zoonotic illness among employees and must develop procedures for contacting CDC in the worker protection plan.
71.53 (G) and 71.53(i)(6)	Worker protection plans	√			Registered importers must have a written worker protection plan.
71.53 (I) and 71.53(f)	Ports of Entry into the United States			√	Entry of NHPs into the United States is restricted to those ports of entry where CDC Quarantine Stations are located, except in limited circumstances approved in advance by CDC.
71.53 (H) and 71.53 (l)(1)	TB testing	√			Tuberculin skin testing is required for all imported NHPs to decrease the risk for human exposure to TB.
71.53 (H) and 71.53(l)	31-day quarantine	√			Importers must quarantine all NHPs for at least 31 days after arrival at a US quarantine facility.
71.53 (H) and 71.53 (l)(2)	Design and operation of animal-holding facilities	√			Animal-holding facilities must meet specific requirements for airflow and disinfection.

71.53 (I) and 71.53 (j)	Crating, caging, and transporting NHPs	√			Importers must meet specific requirements for crating, caging, and transporting NHPs.
71.53 (J) and 71.53 (k)	Ground transportation vehicles	√			An importer must establish, implement, maintain, and adhere to standard operating procedures (SOPs) for vehicles transporting NHPs.
71.53 (K) and 71.53 (m)(6)	Illness reporting requirements for NHPs	√			An importer must report to CDC any instances of severe illness or death in NHPs or if more than 5% of NHPs in a shipment die during the quarantine period.
71.53 (L) and 71.53 (n)(2)	Shipment pre-notification	√			An importer must notify CDC in writing at least 7 days before importing a shipment of NHPs.
71.53 (M) and 71.53 (o)(1)	Foreign-based animal acts	√			All foreign-based animal acts entering the United States that include an NHP must be registered with CDC; the registrant shall provide detailed information about the animal's identification, housing, transport, medical history and performance activities.

71.53 (M) and 71.53 (o)(2)	Domestic animal acts	√			US-based animal acts with NHPs that leave and re-enter the United States are considered to be imports and therefore must meet all of the same requirements for foreign-based animal acts.
71.53 (M) and 71.53(p)(q)	Zoo-to-zoo and laboratory-to-laboratory transfers			√	Quarantine requirements are removed for zoo-to-zoo and laboratory-to-laboratory transfers that meet certain criteria.
71.53 (N) and 71.53 (r)	In-transit shipments			√	For NHPs not intended for import into the US, brokers must notify CDC of all scheduled in-transit shipments and must adhere to new infection control requirements while the NHPs are in the United States.
71.53 (O) and 71.53 (s)	Revocation and reinstatement of importer's registration		√		An importer's registration can be recalled if requirements are not met and can be reinstated by following specific procedures.
71.53 (P) and 71.53 (t)(1)	NHP trophies, skins, or skulls rendered non-infectious		√		NHP trophies, skins, or skulls may be imported without obtaining a permit if they are

					accompanied by documentation describing the treatment that rendered them noninfectious.
71.53 (P) and 71.53(t)(2)	NHP blood, skulls, skins, bodies or tissue that has not been rendered non-infectious				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 certain circumstances.

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What are the proposed record inspection requirements for importers?

Importers must make their facilities, vehicles, equipment, and business records used in the importation of NHPs available to CDC during operating business hours and at other “necessary and reasonable times,” to enable CDC to determine whether importers are in compliance with the regulations in this section. These “necessary and reasonable times” may include during an outbreak or other public health event that requires immediate and unobstructed access to importer records.

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What is the special permit for importing NHPs?

On April 20, 1990, CDC published a notice in the *Federal Register* requiring importers to have a special permit for importing cynomolgus macaques, rhesus macaques, and African green monkeys. This special permit requirement was established in response to the potential risk of filovirus infections associated with these species.

What are the proposed changes to the special permit in terms of renewal?

The current special permit notice in the *Federal Register* requires importers of cynomolgus macaques, African Green monkeys, and rhesus macaques to renew their special permits every 180 days.

If adopted as proposed, importer registration will be simplified by eliminating the need for a category of importer that must request special permits (i.e., those that import cynomolgus macaques, rhesus macaques, and African green monkeys) and change the need for renewal from every 180 days to every 2 years.

What are the proposed changes to the special permit as it relates to filovirus and NHPs?

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 for NHPs

that exhibit signs consistent with a filovirus infection during quarantine. Testing must be done at the end of the quarantine period and before the cohort of NHPs are released from quarantine.

Under the new proposed regulations, filovirus testing will be expanded to all Old World NHPs (NHPs native to Asia or Africa) in quarantine. These changes will require antigen capture testing for filovirus infection in any Old World NHPs that die during the quarantine period from anything other than trauma. Additionally, antibody testing will be required for all Old World NHPs that exhibit signs consistent with a filovirus infection during quarantine; this testing must be done at the end of the quarantine period and before the cohort of NHPs is released from quarantine.

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What documentation is required to become a registered NHP importer with CDC?

To register as an importer, an individual must submit to CDC a completed application form, a 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 (SOPs) (as specified in the NPRM), a copy of any current registrations, licenses, and/or permits that may be required from the United States Department of Agriculture (USDA) and United States Fish and Wildlife Service (USFWS), 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.

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What are the requirements for a worker protection plan and personal protection equipment (PPE)?

Under the new proposed provision, importers must have a written worker protection plan for anyone who may be exposed to NHPs while at work. The proposed protection plan is designed to ensure that individuals who work with or around NHPs are educated on the risks and are protected from exposure to zoonotic diseases (diseases that can spread from animals to humans).

Employee illness reporting

Also, an importer must contact CDC immediately by telephone to report any suspected communicable illness in an employee and must develop procedures for contacting CDC in its worker protection plan.

What is “exposure”?

For the purposes of this regulation, “exposure” refers to an employee in direct contact with or close enough to an NHP (≤ 5 feet) that NHP body fluids or respiratory pathogens could be transferred between the NHP and the worker (e.g., through splashing or aerosol). Using the concept of a performance-based standard, 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.

What additional protection is proposed for individuals who work with and are exposed to NHPs?

The proposed regulations require the importer to develop a worker protection plan, to provide exposed workers with direct and rapid access to a medical consultant, and to document the frequency and type of worker training and education provided on potential risks for exposure to NHPs. As part of the worker protection plan, an importer must establish, implement, and maintain

hazard evaluation and worker communication procedures. These procedures shall include but not be limited to:

- a thorough hazard assessment of all work procedures, potential routes of exposure (e.g., bites, scratches, or mucosal exposures), and potential adverse health outcomes and assurance that workers have quick and direct access to a medical consultant,
- a description of the known zoonotic disease and injury hazards of handling NHPs,
- the need for personal protective equipment (PPE) in handling NHPs, training in proper use of PPE, and re-training and reinforcement of use,
- steps for monitoring workers for signs of zoonotic illness, and
- steps for disinfection of garments, supplies, equipment, and waste.

The importer must comply with the proposed requirements of this section and continue to comply with all relevant federal and state occupational health and safety requirements.

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What are the proposed port of entry (POE) requirements for importation of NHPs?

The updated regulations propose to restrict entry of NHPs into the United States to those where CDC Quarantine Stations are located, except in limited circumstances approved in advance by CDC. These circumstances may involve ground transport across the US border and charter aircraft transport arriving at airports that do not have quarantine stations. The current list of operational CDC Quarantine Stations at POEs and border crossings is available at: <http://www.cdc.gov/quarantine/QuarantineStationContactListFull.html>

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What are the tuberculosis (TB) testing requirements for NHPs?

CDC considers all NHPs to be susceptible to TB. In July 1993, CDC published a review of TB in imported NHPs over a 3-year period. Because TB was found to be both an animal and a human health problem, NHP importers must routinely conduct tuberculin skin tests (TSTs) for NHPs according to the Institute of Laboratory Animal Research (ILAR) guidelines and require tuberculosis screening for NHP workers.

The TB testing requirements included in the NPRM mandate that each NHP in quarantine must complete a series of at least three negative TSTs before any are released. An importer must consider any NHP with a positive TST during import as infectious and a high risk for disease transmission. Therefore, when an importer identifies a quarantined NHP as TST-positive, the standard practice is to attempt laboratory confirmation of TB. While maintaining quarantine, the importer should repeat tuberculin skin testing of all other exposed NHPs at 2-week intervals until five consecutive negative TSTs are completed for all quarantined NHPs.

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What is the required time 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 United States. The 31-day quarantine may be extended if

- the NHPs are infected with communicable diseases (such as tuberculosis, measles, *Campylobacter*), or
- the importer or CDC suspects an NHP may be infected with communicable diseases, or

- the importer or CDC determines that there is a need for additional diagnostic testing.

Each NHP will remain in quarantine until the CDC determines that it no longer poses a threat to human health. These requirements help prevent a potentially infected NHP from premature release from quarantine, minimizing risk of human exposure.

In addition, the proposed ruling requires an importer to:

- establish, implement, and maintain documentation and standard operating procedures for the importation of NHPs,
- make the records available to CDC for inspection during the life of the NHP,
- maintain records electronically or in a location near the quarantine facility and in an organized manner,
- maintain direct and immediate access to both a veterinarian in the care of NHPs and a qualified (i.e., licensed or certified) laboratory, and
- maintain written protocols for the evaluation and diagnostic testing of suspect cases of communicable disease in NHPs.

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What are the requirements for the design and operation of animal holding facilities?

An importer must maintain an adequate quarantine facility for holding NHPs during the required quarantine period. The quarantine facility must be easy to disinfect; have equipment and space for discarding and disinfecting all equipment, clothing, and caging; adhere to specific requirements for airflow, airflow indicators, and disinfection; and meet the following physical security requirements:

- The facility must be locked and secure, with access limited to authorized, trained, and knowledgeable personnel.
- Access to NHP quarantine must be limited to authorized personnel who are responsible for the transport, study, care, or treatment of the NHPs.

In addition, 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.

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What are the proposed requirements for standard operating procedures and equipment for crating, caging, and transporting NHPs?

In the proposed regulations, it is the importer's responsibility to ensure that all infection control measures are in place throughout transportation, 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). 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 NHP shipping conditions. This provision is considered to be part of the performance-based approach, and the intent is for CDC to work with the importers to identify procedures and develop standard operating procedures that are effective in preventing the spread of communicable disease.

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What are the requirements for ground transport vehicles?

When a shipment of NHPs arrive at a US port of entry by aircraft, special vehicles must be used to transport the NHPs safely to a quarantine facility and to 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 destined for a quarantine facility enters the United States through a land border crossing. To ensure vehicles contain proper safeguards, the proposed regulations require that an importer establish, implement, maintain, and adhere to standard operating procedures for ground transport vehicles transporting NHPs.

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What are the illness reporting requirements for NHPs?

In the proposed regulations, an importer would have to ensure that CDC is notified within 24 hours of the occurrence of any of the following events:

Event	Notification Procedures
More than 5% of NHPs in a shipment die during the period from when the shipment leaves the country of origin to the release of the shipment of animals from quarantine	The report must include the cause of death of each NHP. This report may be made by telephone. Include a copy or summary of the deceased NHP’s health records.
Severe illness or death of NHPs in a quarantine facility	By email, text, or phone. Include a copy or summary of the deceased NHP’s health records.
Illness in an NHP that the importer reasonably suspects is yellow fever, monkey pox, or filovirus disease	By email, text, or phone
An NHP testing positively for filovirus antigen or antibody	By email, text, or phone
Any positive or suspicious tuberculin skin test results, necropsy findings, or laboratory results	By telephone, text or phone

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What are the requirements for shipment pre-notification?

At least 7 calendar days before importing a shipment of NHPs, an importer must notify CDC in writing or by email of the impending shipment and provide CDC information including the type and number of NHPs being imported, information about shipping, the type of animal identification being used, names and addresses of all persons/companies involved in the shipment, and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permit..

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What are the requirements for registering NHP animal acts?

Foreign animal acts

Under the proposed regulations, an importer must register with CDC all foreign-based animal acts that include an NHP. This provision requires 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 and all performance activities. Other requirements include documentation signed by a licensed veterinarian documenting the results of routine, yearly NHP

physical examinations. The exams must address routine elements and tests for conditions specified in the regulations, including a yearly tuberculosis test.

Domestic animal acts

All US-based animal acts including an NHP that leave the United States are considered to be “imports” upon re-entry and therefore must meet the requirements listed above for foreign-based animal acts.

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What is the proposed requirement for zoo-to-zoo and laboratory-to-laboratory transfers?

For those NHPs entering the United States through zoo-to-zoo or laboratory-to-laboratory transfer, the proposed regulations would eliminate the CDC-required 31-day quarantine period *if* the following criteria are met:

For zoos to qualify:

- The recipient zoo must be registered with CDC and must submit veterinary medical records documenting the NHPs’ current and past health history, including a history of testing for tuberculosis.
- Both the recipient and transferring zoos must be accredited by the Association of Zoos and Aquariums (AZA) or by a comparable accrediting agency.
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For laboratories to qualify:

- The laboratory must have both a foreign-based and a US-based facility, and NHPs must be part of an ongoing research project that has been approved by the Institutional Animal Care and Use Committee (IACUC).
- The recipient laboratory must be registered with CDC and must submit veterinary medical records documenting the NHPs’ current and past health history, including a history of testing for tuberculosis.
- US- based laboratories must be licensed by the USDA. Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International is desirable.
- The foreign-based laboratory must be accredited by a comparable accrediting agency.
- Justification must be provided to CDC describing the reason a transfer to a US laboratory is necessary (e.g., diagnostic equipment only available in the US-based laboratory).

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

The NPRM proposes that United States in-transit shipments be housed and cared for in a manner consistent with requirements for NHPs intended for import into the United States.

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What procedures are being proposed for revocation and reinstatement of an importer’s registration?

Under the proposed regulations, procedures have been added for revoking and reinstating an importer’s registration. Under these proposed procedures, a registration may be revoked upon notice to the importer if the Director of CDC or his/her designee determines that the importer has failed to comply with any of the applicable provisions of the regulation. The importer may request a

written record review by the Director by filing a response within 20 calendar days of receiving notice from CDC. The Director will review the written record and issue a decision in writing to confirm the recall 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.

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What are the requirements for importing NHP products that have been rendered non-infectious?

Under the NPRM provision, a permit is not required if the product has been rendered noninfectious by one of the approved methods. Suitable methods to render a product noninfectious include but may not be limited to the following:

- Gamma irradiation
- Ethylene oxide
- Heat (heated to an internal temperature of 70 degrees Celsius [158 degrees Fahrenheit] or placed in boiling water for a minimum of 30 minutes)
- Preservation in 2% formaldehyde
- Chemically treating in acidic or alkaline solutions (soaking in a solution below pH 3.0 or above pH 11.5 for 24 hours)
- Use of hypertonic salts
- Dry heat at 180°F (82.2°C) for 30 minutes
- Soaking in boiling water for 30 minutes
- Soaking for 2 hours in a 0.1% solution of chlorine bleach
- Soaking for 2 hours in a 5% solution of acetic acid
- Soaking for 2 hours in a 5% solution of hydrogen peroxide

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What are the requirements for importing NHP products such as skulls, skins, bodies, blood, or tissue that have not been rendered noninfectious?

Due to the risk to human health posed by untreated NHP products such as carcasses, trophies, blood, and other biological samples, a permit requirement has been added to the NPRM for importing these products. Non-living 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:

- The product must be accompanied by a permit issued by the Director of CDC or his/her designee. 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 of CDC or his/her designee will review the request for a permit, and accompanying materials, and issue a decision that shall constitute final agency action.
- The product may only be imported for scientific purposes.
- The product may only be received by a facility equipped to handle potentially infectious NHP materials.

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. To learn more, please review the [CDC select agent website](#).

What are the penalties for violation of these regulations?

Any person who violates these proposed regulations may be punished by a fine of up to \$100,000 if the violation did not result in the death of a person. The fine may be up to \$250,000 per violation if death of a person has resulted. Individuals may also be imprisoned for up to 1 year. Organizations may be fined up to \$200,000 per violation not resulting in death and \$500,000 per violation resulting in death. These penalties are criminal in nature and would thus be enforced by a court, and not administratively by HHS or CDC. These penalties are not new, but merely reflect changes in statute that have occurred since the regulations were first published in 1975.

Are these regulations available for public comment?

Yes. The NPRM will be publically available for comment for 60 days. HHS and CDC will carefully review all public comments it receives and decide whether to make any changes based upon those comments. HHS and CDC will then publish a final rule containing these changes. To make a comment on the proposed regulation, visit www.regulations.gov or email nhppubliccomments@cdc.gov.

Where can I find more information about these regulations?

For more information and to read the proposed regulations on importation of nonhuman primates, visit the [Notice of Proposed Rulemaking on the Regulations for the Importation of Nonhuman Primates website](#).