

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Centers For Disease Control

Requirement for a Special Permit to
Import Cynomolgus, African Green, or
Rhesus Monkeys Into the United
StatesAGENCY: Centers for Disease Control
(CDC), Public Health Service, HHS.ACTION: Notice of CDC Requirement for
Special Permit to Import Cynomolgus,
African Green, and Rhesus Monkeys
into the United States.

SUMMARY: Effective immediately, no person may import into the United States, nor distribute out of quarantine, any cynomolgus (*Macaca fascicularis*), African green (*Cercopithecus aethiops*), or rhesus (*Macaca mulatta*) monkeys unless accompanied by a special permit issued in advance by the Director, CDC. This special permit requirement is separate from, and in addition to, continued compliance with existing regulations pertaining to the importation of nonhuman primates which are contained in 42 CFR 71.53, including the isolation and quarantine measures made mandatory on March 15, 1990.

This special permit procedure, authorized under Sections 381 to 368 of the Public Health Service Act and 42 CFR 71.54, is based upon the current determination by the Director, CDC, that these three species of monkeys are capable of being an animal host or vector of human disease. In order to receive a special permit to import any of these three species of primates, at least thirty days prior to proposed importation, a registered importer of nonhuman primates must submit to the Director, CDC, a written plan which specifies the steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates. Importation cannot occur until receipt of written approval of the plan by the Director, CDC.

BACKGROUND: Beginning in November 1989, a number monkeys imported into the United States were found to have been infected with a filovirus related to Ebola virus from Africa. This virus has been isolated directly from cynomolgus monkey blood and tissues and antibody to the virus has been detected in cynomolgus, African green, and rhesus monkeys.

On January 19, 1990, CDC published in the *Morbidity and Mortality Weekly Report* (MMWR) interim guidelines for handling nonhuman primates during transit and quarantine (MMWR

1990;39:22-4,29-30). Based upon additional developments during the next two months, CDC notified all importers by letter of March 15, 1990, that compliance with these isolation and quarantine standards was made a mandatory condition for continued registration as an importer of nonhuman primates under 42 CFR part 71. On March 23, 1990, an announced public meeting (55 FR 10288) was held in Atlanta, Georgia, to allow all interested parties to comment concerning (1) actions taken to date to prevent the importation of filoviruses into the United States and their transmission to animal handlers; (2) potential impact of the imposition of a temporary ban on the importation into the United States of cynomolgus monkeys; and (3) additional disease control measures.

On April 4, 1990, CDC reported that four animal handlers at a quarantine facility in the United States had demonstrated serologic evidence of recent infection with the strain of this virus isolated from infected cynomolgus monkeys (MMWR 1990;39:30).

Recent serologic evidence indicates that approximately 5-10% of cynomolgus, African green, and rhesus monkeys coming into the United States have previously been infected with a filovirus—this is true irrespective of their origins in Africa or Asia (Philippines, Indonesia, and China).

Considering information currently available, CDC concludes that these three species are capable of being an animal host or vector of human disease. Until further information can be obtained about the risk of human illness following infection and about the means of transmission of filoviruses from monkeys to humans, public health practice requires that more stringent precautions now be applied with respect to the importation of these three species.

IMPLEMENTATION PROCEDURES: Under the authority of section 362 of the Public Health Service Act (42 U.S.C. 265) and 42 CFR 71.54, and in addition to the provisions of 42 CFR 71.53 for registration of importers of nonhuman primates, effective immediately, no person may import into the United States, nor distribute out of quarantine, any cynomolgus, African green, or rhesus monkeys unless accompanied by a special permit issued in advance by the Director, CDC.

In order to receive a special permit to import any of these three species, no less than thirty days in advance of proposed importation, a registered importer must submit to the Director, CDC, a written plan which specifies the steps that the importer will take to

prevent filovirus exposure of persons and animals during the entire importation and quarantine process. CDC will review all special permit plans on a case-by-case basis and will grant approvals in accordance with prudent public health practice at the time of evaluation. Importation cannot occur until receipt of written approval of the plan by the Director, CDC.

The United States Customs Service will not allow entry into the United States of any shipments of these three species of monkeys not accompanied by a copy of the special permit issued by CDC.

SPECIAL PERMIT PLANS: Any plan submitted to CDC by a registered importer for the importation and quarantine of monkeys covered under this special permit arrangement must address disease prevention procedures to be carried out in every step of the chain of custody of such monkeys, from the time of embarkation at the country of origin until delivery of these animals safely out of quarantine.

The elements (referenced by number) to be addressed by any special permit plan must include, at a minimum:

A. Basic Information

1. Number and species of monkeys
2. Origin of monkeys (country, exporter, address)
3. Anticipated use of monkeys—scientific, educational, or exhibition
4. Name and exact location of quarantine facility
5. Means of individually identifying monkeys

B. Transit Information

1. Specific itinerary with names, dates, flights, and responsible parties to contact at every step of travel, including all ground transportation
2. Description of caging
3. Procedures to protect and train transport workers
4. Procedures to prevent contamination of other articles and cargo during transit, including physical separation of cages from other cargo
5. Procedures to decontaminate aircraft, vessel, and/or vehicles following transport
6. Proposed use, if any, of transit holding facilities and steps to be taken to protect workers, as well as animals, from disease exposure at each holding facility to be used en route

C. Isolation and Quarantine Precautions

1. Worker protection plan to include:
 - a. Written infection-prevention program
 - b. Hazard evaluation and worker communication procedures
 - c. Training requirements for workers
 - d. Infection-prevention methods (e.g., personal protective equipment, work practices, housekeeping)
 - e. Medical surveillance and medical assessment and treatment of workers

2. Physical security procedures of quarantine area
3. Disinfection procedures for apparel, supplies, equipment, waste, etc., and disposal of remains of dead animals
4. Description of caging and room arrangement
5. Description of procedures to be used to assure the integrity of the isolation of each lot of animals in the quarantine unit
6. Record-keeping and reporting procedures
- D. Procedures for testing of quarantined animals
 1. Testing at entry into quarantine
 2. Testing prior to release from quarantine
 3. Record-keeping and reporting procedures
 4. Description of laboratory methodology and laboratory to be used
 5. Quarantine decision logic if positive serology or seroconversion occurs
 6. Post mortem procedures for animals dying during quarantine
- E. Such additional information as the importer feels will be useful in reviewing the plan

The Director, CDC, may request clarification or additional information, if

needed. CDC anticipates that initial approvals of special permits will be made on a shipment-by-shipment basis. As this process evolves and more experience develops, CDC may subsequently grant special permits on a broader basis for multiple shipments and/or specific intervals of time.

In submitting plans for approval, registered importers should indicate to CDC any specific information that CDC should consider proprietary pertaining to origins of monkeys, customer lists, and similar proprietary information. However, applicants should be aware that CDC intends generally to share publicly large portions of the application in order to expedite dialogue pertaining to the developing technical issues on appropriate quarantine and disease prevention methodology.

CDC recognizes that the lack of current knowledge about certain aspects of the present situation make risk assessment and risk management

decisions particularly difficult. Interested parties should realize that as new information becomes available, appropriate disease prevention practices may be altered to reflect such additional input. Since this special permit procedure may also have to be changed to reflect unanticipated developments CDC will make every effort to provide timely communication to the public of pertinent data.

EFFECTIVE DATE: Immediately.

FOR FURTHER INFORMATION OR TO REQUEST SPECIAL PERMITS, CONTACT: Mr. Charles R. McCance (404-639-1458), Director, Division of Quarantine, Centers for Disease Control, Atlanta, Georgia 30333.

Dated: April 17, 1990.
William L. Roper,

Director, Centers for Disease Control.
[FR Doc. 90-8428 Filed 4-19-90; 12:22 pm]
BILLING CODE 4160-12-M