

**QUESTIONS AND ANSWERS****Interim Questions and Answers on Interim Final Rule Prohibiting Importation of African Rodents and Prairie Dogs****What does the Interim Final Rule do?**

The interim final rule creates two complementary regulations. First, for African rodents that are being imported or offered for import to the United States, the interim final rule adds 42 CFR § 71.56 that is entitled "African rodents and other animals that may carry the monkeypox virus." CDC will enforce 42 CFR § 71.56. Second, with respect to certain animals that are in the United States, the interim final rule adds 21 CFR § 1240.63 entitled "African rodents and other animals that may carry the monkeypox virus." FDA will enforce 21 CFR § 1240.63. Together, 21 CFR § 1240.63 and 42 CFR § 71.56 are intended to prevent the establishment and spread of the monkeypox virus in the United States.

When does the Interim Final Rule become effective?

The rule becomes effective on November 3, 2003. CDC and FDA are proceeding without notice and comment rulemaking because of the need to have regulations in place immediately to address the monkeypox situation. This interim final rule supersedes the June 11, 2003, order. As appropriate, CDC and FDA may amend the interim final rule in response to comments and to any new developments in the monkeypox outbreak.

What is CDC and FDA's legal authority for the Interim Final Rule?

Section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264) serves as the principal legal authority for both the CDC and FDA Rules. Section 361 of the PHS Act gives the Secretary of Health and Human Services the authority to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or from one State to another State. CDC's portion of the rule focuses on imported animals while FDA's portion focuses on animals moving between and within States.

What must I do to comply with CDC's portion of the Interim Final Rule?

You must not import or offer to import any rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, whether dead or alive, any products derived from such rodents, or any other animal, whether dead or alive, whose importation the Director of CDC has prohibited by order, or any products derived from such animals.

Does the CDC rule apply to African rodents that do not come directly from Africa?

Yes, the rule covers any rodents that were caught in Africa and then shipped directly to the United States or shipped to other countries before being imported to the United States. The prohibition also applies to rodents whose native habitat is in Africa, even if those rodents were born elsewhere. A broad import ban on African rodents is necessary because there is no quick, practical method for determining whether a specific animal was born in a particular geographic region.

Does the CDC rule apply to dead animals and animal products?

Yes, the monkeypox virus can remain infectious in bushmeat (a term used to describe meat obtained from animals taken in the wild or the "bush") and CDC is unaware of data demonstrating the safety of raw or even prepared bushmeat. Preparation methods such as smoking, salting, or brining bushmeat may slow

Interim Questions and Answers on Interim Final Rule Prohibiting Importation of African Rodents

(continued from previous page)

down bushmeat's decay, but may not render bushmeat free of infectious agents. Therefore, CDC's rule applies to live and dead African rodents and also to products derived from such animals.

What actions may CDC take under the rule?

To prevent the monkeypox virus from spreading and becoming established in the United States, the rule authorizes CDC to (1) issue an order causing an imported animal to be placed in quarantine; (2) issue an order causing an imported animal to be re-exported; (3) issue an order causing an imported animal to be destroyed; or (4) take any other action necessary to prevent the spread of the monkeypox virus.

The Director of CDC can also use other authorities to help prevent the spread of monkeypox. For example, under existing regulations, if the Director has reason to believe that there is an article (including an animal) arriving at a United States port and that article is or may be infected with a communicable disease, the Director may require such actions as detention, disinfection, or other related measures necessary to prevent the introduction, transmission, or spread of communicable disease. Consequently, the rule recognizes that the Director may use other authorities and states that the authority to issue orders or to take other action is "in addition to any other authorities under this part."

May I appeal an order issued by CDC under the rule?

If you received a written order to cause an imported animal to be placed in quarantine, re-exported, or destroyed, the rule explains that you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within two business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. CDC will issue a written response to the appeal which will constitute final agency action.

Are there criminal penalties for not complying with an order issued by CDC under the rule?

Yes, the rule states that you must not prevent or attempt to prevent CDC from causing an imported animal to be quarantined, re-exported, or destroyed pursuant to a written order for that animal's quarantine, re-export, or destruction. Therefore, if you prevent or attempt to prevent CDC from causing an imported animal to be quarantined, re-exported, or destroyed, you may be subject to criminal penalties.

What are those criminal penalties?

Under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 per violation if death has not resulted from the violation or up to \$250,000 per violation if death has resulted (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)).

Are there any exceptions to the CDC rule?

Yes, the rule recognizes that there are limited circumstances warranting exemptions from some prohibitions, such as the need to transport an animal for scientific, exhibition, or educational purposes. Consequently, under the CDC rule, an individual may seek written permission from CDC to import any rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or any other kind of animal whose importation the Director has prohibited by order. The interim final rule describes the procedures for seeking written permission from CDC and the information that should be submitted with any request and also states that the request must be limited to scientific, exhibition (such as exhibition of an animal at a zoo), or educational purposes. CDC will respond, in writing, to all requests.

Interim Questions and Answers on Interim Final Rule Prohibiting Importation of African Rodents

(continued from previous page)

Are there any exceptions for processed products, such as taxidermied animals or animal trophies?

Yes, some individuals have asked whether they could import taxidermied animals or animal trophies, while other questions have involved products derived from animals, such as brushes that use animal hair and animal skins. If these products are properly processed to render them non-infectious, they pose no disease risk. Such processes would include: (1) inactivation by Heat (heated to an internal temperature of 70°C or placed in boiling water for a minimum of 30 minutes); (2) 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); or (3) the use of hypertonic salt. Products derived from African rodents, if treated using one of these methods, are not subject to the import prohibition at § 71.56(a)(1) and may be imported without written permission from CDC. Similarly, fully taxidermied African rodents and completely finished trophies present no disease risk and therefore may be imported without written permission from CDC.

For more information, visit www.cdc.gov/ncidod/monkeypox or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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Page 3 of 3