

the animals covered by the order, the ability to appeal an order, and any other conditions on quarantine, re-export, or destruction. CDC officials ordinarily will not themselves quarantine, re-export, or destroy an animal. Instead, CDC officials will order that the animal be quarantined, re-exported, or destroyed, and the individual receiving the order will be responsible for placing the animal in quarantine or having it re-exported or destroyed and be responsible for any costs associated with quarantining, re-exporting, or destroying the animal. CDC has issued guidance to animal health officials on the disposition of animals.

CDC emphasizes that there may be instances where it is difficult to identify an animal as belonging to a particular species. Some species may resemble another, and juvenile animals may look different from adult animals. Thus, if you import any rodent, CDC strongly advises you to take steps to accurately and reliably identify the species involved. Accurate and reliable identification will reduce the potential for disagreements as to whether an animal is or should be subject to an order and avoid potential, unfortunate instances where animals that cannot be readily identified or whose species identification is in dispute are included in an order to cause their destruction.

#### 4. Can You Appeal an Order? (42 CFR 71.56(c))

If you received a written order to cause an animal to be placed in quarantine, re-exported, or destroyed, 42 CFR 71.56(c) 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 2 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.

#### D. When Does the Rule Become Effective?

For the effective date of the interim final rule see the DATES section of this document.

#### E. Will We Revoke Or Amend the Rule if Monkeypox Is Eradicated in the United States?

Monkeypox is endemic in parts of Africa. Therefore, we do not anticipate revoking the prohibition on import of African rodents and any other animals that the Director of CDC has specified under 42 CFR 71.56(a)(1)(i). However,

FDA will revoke or amend, as warranted, all or parts of 21 CFR 1240.63 if FDA concludes that monkeypox is eradicated or adequately controlled so that the virus does not become established in the United States. FDA's decision would depend on scientific principles for controlling zoonotic diseases. For example, if the incubation period is known, then it would be prudent to continue the restrictions for a time period that is double the incubation period to ensure that there is little further risk of infection or restarting the monkeypox outbreak. CDC tests on some animals involved in the original April 9, 2003, shipment from Ghana suggest that, insofar as dormice are concerned, the incubation period may be as long as 2.5 months. If FDA rounds this time frame up to 3 months, and then doubles the incubation period, there would appear to be little further risk of infection after 6 months had passed with no further evidence of monkeypox identified, and FDA would be able to take actions to revoke or amend 21 CFR 1240.63. The last infected animal from the April 9, 2003, shipment that died from monkeypox died on July 20, 2003. There have been no identified monkeypox cases in animals or people in the United States since that date. If no further monkeypox cases are identified in the United States, and if there is no new information warranting an extension of the 6-month time period, FDA intends to revoke or amend 21 CFR 1240.63 as early as January 20, 2004, which will be 6 months after July 20, 2003. At that time, if FDA decided to revoke or amend 21 CFR 1240.63, it would publish an appropriate document (such as a proposed rule or direct final rule) in the **Federal Register**. FDA invites comments on this approach.

We emphasize that any possible revocation or amendment of 21 CFR 1240.63 may also depend on new data or new developments. For example, various animal studies are being conducted to learn more about the incubation period and transmission dynamics of monkeypox. If those studies suggest that the period for incubation and transmission may be longer than 2.5 months, FDA could decide to recalculate the date on which it might revoke or amend 21 CFR 1240.63. Studies are also underway to determine whether certain species that may be infected with the virus, but not display any symptoms, can infect other species. To illustrate how the virus could spread from an asymptomatic animal, assume that an animal can carry the monkeypox virus, but that the

animal does not develop monkeypox. If that animal later comes into contact with prairie dogs, a species which is already known to be susceptible to monkeypox, then the prairie dogs could become infected, and another monkeypox outbreak in prairie dogs could erupt. Again, if studies suggest that species can be asymptomatic, but still infectious, those results could cause FDA to recalculate the date on which it could revoke or amend 21 CFR 1240.63.

#### F. What Actions Can be Taken to Prevent Outbreaks of Other Zoonotic Diseases?

If another outbreak of a different zoonotic disease occurred in the United States, we would take actions comparable to those we have taken to address monkeypox, modifying those actions as appropriate to the new circumstances. However, we believe that the introduction of monkeypox into the United States shows that we need to develop measures to prevent or minimize the likelihood of other zoonotic disease introductions or outbreaks. As noted in section IV of this document, section 361 of the PHS Act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see *State of Louisiana v. Mathews*, 427 F. Supp. 174 (E.D. La. 1977)). We may, therefore, publish a document in the **Federal Register** that would discuss possible regulatory approaches, such as:

- Banning the import into the United States, as well as the capture, sale and distribution within the United States, of certain categories of: Animals (e.g., rodents, marsupials, and bats), or animals captured in the wild, or animals captured in the wild from certain regions of the world, including regions within the United States (e.g., prairie dogs in the United States due to their potential to carry plague or tularemia); or

- Requiring health certifications and subsequent quarantine and health examination and/or testing prior to import or domestic distribution of certain categories of animals; or

- Requiring assessments of potential disease risks prior to import or domestic distribution of certain categories of animals, with the imposition of conditions or restrictions depending on the level of risk presented.

If we decide to publish a document in the **Federal Register** that addresses the