

were born elsewhere. For example, 42 CFR 71.56(a)(1)(i) would apply to a Gambian giant pouched rat even if that animal was born outside Africa. 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. The import restriction complements efforts taken by the U.S. Fish and Wildlife Service to prevent the importation of infected animals (Ref. 20).

Similarly to 21 CFR 1240.63, 42 CFR 71.56 applies to dead animals. Some individuals have attempted to conceal "bushmeat" (a term used to describe meat obtained from animals taken in the wild or the "bush") from Federal authorities since the June 11, 2003, order was issued and others have attempted to import preserved specimens of listed species. The monkeypox virus can remain infectious in bushmeat (Refs. 1, 21, and 38), 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 down bushmeat's decay, but may not render bushmeat free of infectious agents. Therefore, 42 CFR 71.56(a)(1) applies to live and dead African rodents.

42 CFR 71.56(a)(1)(ii) states that you must not prevent or attempt to prevent CDC from causing an animal to be quarantined, re-exported, or destroyed pursuant to a written order for that animal's quarantine, re-export, or destruction. (For purposes of this rule, "quarantine" means that the animal is held or stored in an isolated area, and all further movement has been restricted so as not to expose other animals.) Most individuals will cooperate with a written order to quarantine, re-export, or destroy an infected animal, but some individuals may attempt to avoid those consequences by releasing the animal instead. Releasing an infected or potentially infected animal would create a serious risk to animal and human health because the monkeypox virus could then spread to native animal species and become established in the United States. Therefore, if you prevent or attempt to prevent us from causing an animal to be quarantined, re-exported, or destroyed, you may be subject to criminal penalties. (For more information on penalties, section IV of this document.)

Similarly to 21 CFR 1240.63(a)(2), 42 CFR 71.56(a)(2) recognizes that there are limited circumstances warranting exemptions from some prohibitions. Consequently, under 42 CFR 71.56(a)(2), 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 is limiting the request to scientific, exhibition, or educational purposes because it recognizes the important contributions that these rodents may make to science, education, and conservation. CDC will respond, in writing, to all requests, and it also may impose conditions in granting an exemption. If CDC decides against granting written permission, that decision may be appealed by writing to the CDC official whose office denied the request. The appeal must state the reasons for the appeal and show 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.

42 CFR 71.56(a)(3) represents another exemption from the import restrictions. 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. Products derived from rodents, such as products that use rodent hair, quills, bones, and skins, may contain viable monkeypox virus if the animal from which they are derived was infected with monkeypox. This is based on the fact that variola virus, a related pox virus, has been shown to remain viable in proteinaceous exudates for as long as 1 year (Ref. 22). If these products are properly processed to render them noninfectious, they pose no disease risk. Such processes would include inactivation by:

- Heat (heated to an internal temperature of 70 °C or placed in boiling water for a minimum of 30 minutes);
- Preservation in 2 percent 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
- The use of hypertonic salts.

Vaccinia virus, a related pox virus, was shown to be inactivated after heating in neutral salt buffer solution for 90 minutes at 50 °C or after heating for 60 minutes at 55 °C (Ref. 23). Support for

these methods can be found in the pox virus material safety data sheet compiled by Health Canada, <http://www.hc-sc.gc.ca/pphb-dgsp/msds-ftss/msds160e.html>, which states that pox viruses are rendered nonviable by 2 percent formaldehyde, and heating to ≤ 60 °C. Procedures for alkaline and acid inactivation are based on the OIE 2003 Terrestrial Animal Code procedures for food and mouth disease (Article 3.6.2.1) (http://www.oie.int/eng/normes/MCode/A_00144.htm). (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Products derived from African rodents, if treated using one of these methods, are not subject to the import prohibition at 42 CFR 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. Products imported under the exception in 42 CFR 71.56(a)(3) are subject to inspection to ensure that they do meet the conditions set forth in 42 CFR 71.56(a)(3).

3. What Actions Can CDC Take? (42 CFR 71.56(b))

To prevent the monkeypox virus from spreading and becoming established in the United States, 42 CFR 71.56(b) gives CDC the authority to:

- Issue an order causing an animal to be placed in quarantine;
- Issue an order causing an animal to be re-exported;
- Issue an order causing an animal to be destroyed; or
- 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 42 CFR 71.32(b), 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, 42 CFR 71.56(b) 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."

Any orders issued by CDC, similar to those issued by FDA, will be in writing and will contain other details, such as