

West Nile virus was unknown in the United States before 1999. The virus apparently arrived in the eastern United States and quickly spread, via mosquitoes, to domestic bird species, other animal species (such as horses), and to humans. In 1999, the virus was reported in 4 States; by October 2003, 45 States had reported cases of the West Nile virus activity in humans or other animals. The virus's continued spread in the United States suggests that it is now permanently established in the United States.

To prevent the monkeypox virus from spreading and becoming established in the United States, 21 CFR 1240.63(b)(1) authorizes FDA to take the following actions:

- Issue an order causing an animal to be placed in quarantine. An order causing an animal to be placed in quarantine could extend to kinds of animals not named in this interim final rule. For example, if a potentially infected prairie dog had been in contact with a ferret, it would be reasonable to quarantine the ferret to ensure that it was not infected with the monkeypox virus;

- Issue an order causing an animal to be destroyed; and

- Take other actions as necessary to prevent the spread of the monkeypox virus.

For example, if a pet store were going out of business, FDA could, under the interim final rule, make arrangements with the appropriate Federal, State, local and tribal authorities to take temporary possession of the animals.

21 CFR 1240.63(b)(1) also states that the authority to issue these orders or to take any other action is "in addition to any other authorities in this part." The reference to other authorities includes, for example, 21 CFR 1240.30, which allows FDA to take measures to prevent the spread of communicable disease, "including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection."

FDA will issue all orders in writing. The order will contain other details, such as the animals covered by the order, your ability to appeal the order (including instructions on filing an appeal), and any other conditions on quarantine or destruction. FDA officials ordinarily will not themselves quarantine or destroy an animal. Instead, FDA officials will order that the animal be quarantined or destroyed, and the individual receiving the order will be responsible for placing the animal in quarantine or having it destroyed and any costs associated with quarantining

or destroying the animal. CDC has issued guidance to animal health officials on the disposition of animals (Refs. 18 and 19).

Additionally, 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 capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, or offer to distribute any rodent, FDA 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 or group of animals 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.

If a person violates 21 CFR 1240.63, that person may be subject to fines, imprisonment, and inspections. Penalties for violating the rule are discussed in section IV of this document.

4. Can You Appeal an Order? (21 CFR 1240.63(c))

If you receive a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed, 21 CFR 1240.63(c) allows you to appeal that order. Your appeal must be in writing and be submitted to FDA within 2 business days after you receive the order. As part of your appeal, you may request an informal hearing, and your appeal must include specific facts showing there is a genuine and substantial issue of fact that requires a hearing. For example, if the order was to cause the destruction of prairie dogs, and you have beavers instead of prairie dogs, a genuine and substantial issue of fact (i.e., whether you have the animals described in the order) would exist. In contrast, if the order was to cause the destruction of prairie dogs, and you simply disagreed with the idea of destroying any animal, there would be no genuine and substantial issue of fact, and FDA would not conduct a hearing for your appeal. The interim final rule instructs you to send your appeal to the FDA District Director whose office issued the order.

If FDA grants your request for an informal hearing, FDA will follow the regulatory hearing requirements at 21 CFR part 16, except that the written order will serve as notice of opportunity

for a hearing for purposes of initiating the hearing under 21 CFR 16.22(a). Additionally, 21 CFR 1240.63(c)(3) states that the presiding officer will issue a decision instead of issuing a report and a recommended decision as would normally be required under 21 CFR 16.60(e) and (f). (Under pre-existing FDA regulations, the Commissioner of Food and Drugs may delegate the authority to an FDA employee to serve as the presiding officer (see 21 CFR 16.42(a).) The interim final rule gives the presiding officer the authority to issue a decision so that the agency may deal with infected or potentially infected animals quickly; otherwise, if the presiding officer were to issue reports and recommendations, final action on an animal's status would be delayed, and this would increase the possibility that the animal, if infected, could escape or otherwise transmit the monkeypox virus to humans or other animals.

FDA has also amended 21 CFR 16.1(b)(2) to add 21 CFR 1240.63 to the list of regulatory provisions for which a part 16 regulatory hearing is available.

C. What Does CDC's Rule Say?

1. Where Is the Rule Codified? (42 CFR 71.56)

The interim final rule creates a new 42 CFR 71.56 titled, "African rodents and other animals that may carry the monkeypox virus."

2. What Does the Rule Prohibit? (42 CFR 71.56(a))

42 CFR 71.56(a) contains only two general prohibitions. In brief, under 42 CFR 71.56(a)(1)(i), you must not import or offer to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa; any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director of CDC has prohibited by order, or any products derived from such animals. This provision is intended to prevent the further importation of infected and potentially-infected rodents and represents a slight modification from the import restriction that appeared in the June 11, 2003, order. The June 11, 2003, order barred importation of "all rodents from Africa." The rule's import prohibition is intended to make clear that it 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