



January 9, 2004

FDA
Dockets Management Branch (HFA -305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

5710 04 JAN 21 03:41

**ANIMAL
PROTECTION
INSTITUTE**

Sent via U.S. Mail and E-mail www.fda.gov/dockets/ecomments

RE: Interim Rule to Prevent Transmission of Monkeypox

To Whom It May Concern:

On behalf of the Animal Protection Institute (API) and our members and supporters, and the undersigned organizations, I am pleased to offer these comments on the Interim Rule to Prevent Transmission of Monkeypox.

First, we commend the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) for taking swift and appropriate action in reaction to the monkeypox outbreak by prohibiting the transportation or sale of prairie dogs in both the emergency rule and this interim final rule. While we support the FDA and CDC's action, we would be remiss in failing to point out potential shortcomings in this interim final rule that we hope will be addressed in the final rule.

Specifically, we urge the FDA and CDC to 1) work toward a phase out of the private possession of prairie dogs as pets by requiring permits for private possession, specific housing requirements, and mandatory sterilization of all privately held prairie dogs, 2) ban the importation of *all* bush meat from Africa, and 3) ban the importation of all products containing parts or products from listed animals regardless of processing claim.

1)Phase out prairie dogs as "pets."

We ask the FDA and CDC to clarify and define the rules governing the private possession of prairie dogs as pets and to adopt regulations that will serve to phase out the private possession of prairie dogs and to ensure the responsible and humane care of those currently held.

In the interim final rule the FDA/CDC state that, "We do not intend to permit pet sales (or barter or exchange) because the monkeypox outbreak developed in the pet industry, and exposure to infected animals intended as pets led to infections in prairie dogs. The infected prairie dogs, in turn, infected humans." This indicates that the keeping of prairie dogs as pets will be discouraged and disallowed but the FDA/CDC also makes an exception for transportation of prairie dogs to allow for veterinary care, "21 CFR 1240.63(a)(2) allows you to: Transport a listed animal to a veterinarian or animal control official for veterinary care, quarantine, or destruction purposes," thus indicating that the private possession of prairie dogs as "pets" is allowed. While we support the exemption to allow listed animals to be transported

API Headquarters
Mailing Address:
P.O. Box 22505
Sacramento, CA
95822

Street Address:
1122 S Street
Sacramento, CA
95814

916-447-3085
1-800-348-7387
Fax 916-447-3070
info@api4animals.org
www.api4animals.org

API Affiliate
TEXAS
SNOW MONKEY
SANCTUARY
Dilley, TX
www.snowmonkeys.org



2003N-0400

C61 1

for veterinary care we ask that special provisions also be made to allow the transport of unwanted "pet" prairie dogs prairie dog rescues/sanctuaries to protect the welfare of captive prairie dogs and reduce the possibility that unwanted "pet" prairie dogs will be released into the wild. We also ask that the policy on keeping prairie dogs as "pets" in the absence of sale, barter, or trade be clarified and sufficiently regulated to accomplish an eventual phase-out of privately held prairie dogs.

To accomplish this, we encourage the FDA/CDC to ban specifically the keeping of prairie dogs as pets while providing a grandfather clause to allow existing "pet" prairie dogs to remain with their caretakers or to be placed in a prairie dog rescue/sanctuary if their caretakers/rescues acquire permits to possess the animals and adhere to specific care standards. Caretakers should also have the option to place prairie dogs in a prairie dog rescue/sanctuary with appropriate permits. Mandatory sterilization of all prairie dogs in private possession should also be required to prevent future generations of captive prairie dogs and with them a continued regulatory burden.

To protect public health and safety and to ensure the humane care of prairie dogs, our suggested requirements for a permit to possess a prairie dog acquired prior to the interim or final rule are as follows:

(b) Food:

(i) Each animal shall be given access to adequate, wholesome, palatable food that is of nutritional value sufficient to maintain the animal in good health and that is free of contamination.

(ii) Food shall be given to each animal at least once every twenty-four hours except as otherwise necessary to maintain each animal in good health.

(iii) Food containers shall be positioned in each animal enclosure to allow each animal adequate access and to minimize contamination from excreta.

(c) Water:

(i) Potable water must be accessible to each animal at all times except as otherwise required to keep the animal in good health.

(ii) Water containers shall be positioned in each animal enclosure to allow each animal adequate access and to minimize contamination from excreta.

(d) Enclosure:

(i) Any enclosure in which an animal is housed or exercised must be constructed and maintained so as to prevent injury to the animal and to promote the health and safety of the animal and the public.

(ii) Any enclosure in which an animal is housed must provide sufficient space for the animal to experience normal body movements without having to make contact with the sides or top of the enclosure and without obstruction, interference, or impediment by the presence of food and water bowls. "Normal bodily movements" shall include the ability to stand up, sit down, turn about freely and relax in a natural position.

(iii) Enclosures must measure at least 3 square feet, 18 inches high per animal. For each additional animal, increase the cage space by 25 percent of original floor area. Each enclosure shall have gnawing items and a hide box.

Lastly, while the interim final rule prohibits “capture, offers to capture, transport, offers to transport, sale, barter, or exchange, offers to sell, barter, or exchange distribution, offers to distribute, or release of a listed animal into the environment regardless of whether the activity is interstate or intrastate,” the rule also uses a confusing example later in the document to describe what activities constitute “capture.” The example states that “if a prairie dog escaped from its cage in a pet store, catching the prairie dog to put it back in its cage would not constitute ‘capture’ within 21 CFR 1240.63(a)(1)(i).” This leads to confusion because, if it is illegal to sell, barter, or exchange a prairie dog, then a pet store possessing a prairie dog (presumably to sell) would be in violation of this rule regardless of whether the animal escapes from the cage and is later captured and returned. We urge the FDA/CDC rephrase or replace this example with one that is consistent with the intent of the entire rule.

2) Ban all bush meat from Africa

While the interim final rule recognizes the threat posed by the importation of dead animals and the ability of monkeypox and other infectious agents to remain viable in the flesh of animals even after preparation including salting, smoking, or brining, the prohibition on the importation of bushmeat applies only to African rodents. We question how the CDC will enforce the prohibition on the importation of bushmeat of rodent origin given the difficulty in distinguishing the species of processed flesh.

The interim final rule notes that “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.” Clearly, if individuals have already demonstrated a propensity to conceal bushmeat from listed species, this activity will continue under the proposed rule especially given the difficulty of distinguishing processed flesh of rodents from the flesh of non-rodents. We suggest that a more effective control would be to prohibit the importation of all bushmeat from Africa.

3) Ban imports of all products containing parts or products from listed animals.

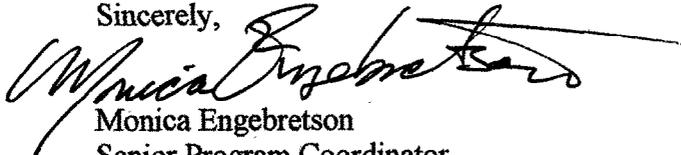
The interim final rule states that parts and products derived from African rodents known to carry the monkeypox virus can pose a disease risk based on the fact that, “variola virus, a related pox virus, has been shown to remain viable in proteinaceous exudates for as long as 1 year (Ref. 22).” The document notes, however, that if these products are properly processed to render them noninfectious, they pose no disease risk, and therefore allows for the import of products that purportedly have undergone one of the very specific and detailed processes outlined in the interim final rule. We question how the CDC will enforce this provision given that there seems to be no way to assure that a product has undergone one of the defined procedures and therefore the importation of rodent products would depend wholly on the claim of

the individual wishing to import the said product – a clear conflict of interest. We suggest that a more effective and enforceable policy would be to enact a complete ban on all products derived from listed African species.

Once again, we thank the FDA and CDC for its actions to protect human and animal health by restricting the import of rodent species and prohibiting the trade in prairie dogs as “pets.” We encourage the agencies to further clarify and strengthen the restrictions as explained above.

Thank you for your consideration.

Sincerely,



Monica Engebretson
Senior Program Coordinator
Animal Protection Institute

Stephanie Nichols-Young
President
Animal Defense League of Arizona

Laurie Crawford Stone
President
Animal Advocates of Iowa

Paula Martin
Director
Prairie Ecosystems, New Mexico

Richard Farinato
Director, Captive Wildlife Program
The Humane Society of the United States

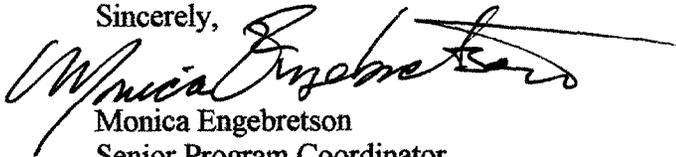
Andrea Lococo
Rocky Mountain Coordinator
The Fund for Animals

the individual wishing to import the said product – a clear conflict of interest. We suggest that a more effective and enforceable policy would be to enact a complete ban on all products derived from listed African species.

Once again, we thank the FDA and CDC for its actions to protect human and animal health by restricting the import of rodent species and prohibiting the trade in prairie dogs as “pets.” We encourage the agencies to further clarify and strengthen the restrictions as explained above.

Thank you for your consideration.

Sincerely,



Monica Engebretson
Senior Program Coordinator
Animal Protection Institute

Stephanie Nichols-Young
President
Animal Defense League of Arizona

Laurie Crawford Stone
President
Animal Advocates of Iowa

Paula Martin
Director
Prairie Ecosystems, New Mexico

Richard Farinato
Director, Captive Wildlife Program
The Humane Society of the United States

Andrea Lococo
Rocky Mountain Coordinator
The Fund for Animals