

40 CFR Part 97

Environmental protection, Air pollution control, Electric utilities, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: July 18, 2007.

Bharat Mathur,

Acting Regional Administrator, Region 5.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 71

RIN 0920-AA03

Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal-Importation Regulations

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) is issuing this Advance Notice of Proposed Rulemaking (ANPRM) to begin the process of revising the regulations that cover the importation of dogs and cats (42 CFR 71.51), including by extending these regulations to cover domesticated ferrets. This ANPRM will also address the importation of African rodents (42 CFR 71.56) into the United States. HHS/CDC is also considering the need for additional regulations to prevent the introduction of zoonotic diseases into the United States.

The input received from stakeholders and other interested parties via the ANPRM process will lead to a Notice of Proposed Rulemaking (NPRM), with the aim of improving HHS's ability to prevent importation of communicable diseases into the United States. The scope of this ANPRM does not include the non-human primate regulations (42 CFR 71.53).

DATES: To be assured consideration, written comments must be received on or before October 1, 2007.

ADDRESSES: You may submit written comments to the following address: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Division of Global

Migration and Quarantine, ATTN: Animal Importation Regulations, 1600 Clifton Road, N.E., (E03), Atlanta, GA 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, N.E., Atlanta, GA 30333. Please call ahead to 1-866-694-4867 and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit.

You may also submit written comments electronically via the Internet at <http://www.regulations.gov> or via e-mail to

animalimportcomments@cdc.gov.

Electronic comments may be viewed at <http://wwwn.cdc.gov/publiccomments/>. CDC's general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change, including any personal identifiers or contact information.

You can download an electronic version of the ANPRM at <http://www.regulations.gov>. CDC has also posted the ANPRM and related materials to its Web site at <http://www.cdc.gov/ncidod/dq>.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Mullan, (404) 639-4537.

SUPPLEMENTARY INFORMATION: Zoonoses are diseases that are transmissible from animals to people. The prevention of zoonoses in humans poses special challenges, and requires consideration of the role of animals in disease transmission. For example, domesticated animals such as dogs and cats can carry rabies, and wild exotic animals can carry a variety of known and emerging zoonotic pathogens. Under Section 361 of the Public Health Service Act (42 U.S.C. 264), HHS/CDC is responsible for regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States, and from one U.S. State or possession into another. HHS/CDC recently published a Notice of Proposed Rulemaking to revise its foreign and interstate quarantine regulations in 42 CFR, Parts 70 and 71. Under its statutory authority, HHS/CDC may regulate the importation of animals into the United States that pose a health risk to humans. The Food and Drug Administration (FDA) within HHS also has regulatory authority under the Public Health Service Act to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases. Within the U.S. Department of Agriculture (USDA), the

Animal and Plant Health Inspection Service (APHIS) has the authority to regulate the importation of animals; its focus is primarily on animal-welfare issues and diseases of veterinary and agricultural importance. In addition, the Office of Law Enforcement within the U.S. Fish and Wildlife Service (FWS) of the U.S. Department of the Interior (DOI) regulates the entry of some shipments of animals to ensure compliance with U.S. laws and international agreements that protect endangered species.

HHS/CDC currently regulates the importation of dogs and cats into the United States to prevent the entry of zoonotic diseases through 42 CFR 71.51. Dogs and cats are subject to inspection at ports of entry for evidence of infectious diseases transmissible to humans. If a dog or cat appears to be ill, inspectors may require further examination by a licensed veterinarian.

In addition, HHS/CDC provides additional restrictions on the importation of dogs to prevent the entry of rabies. Rabies is a virus that causes a fatal disease in humans and animals, especially dogs. In the United States, widespread mandatory vaccination of dogs has eliminated canine strains of rabies, and dramatically reduced the number of human cases in this country. However, canine strains of rabies remain a serious health threat in many other countries, and preventing the entry of animals infected with this strain of rabies into the United States is an important public-health priority. HHS/CDC currently regulates the importation of dogs into the United States by requiring rabies vaccination and the confinement of most dogs for up to 30 days after vaccination, principally to prevent the importation of rabies. Recently, HHS/CDC has received reports of large-volume shipments of puppies intended for immediate re-sale. These animals often appear younger than the age on their accompanying documents, and their vaccination status is questionable. Although a veterinary examination can assess many common zoonotic diseases of dogs, current regulations do not require dogs to be accompanied by a standard international health certificate signed by a licensed veterinary authority in the country of origin or means of unique identification for these animals. In addition, current regulations do not require rabies vaccination for cats, which are highly susceptible to canine strains of rabies virus, and can also transmit the infection to humans. Furthermore, current regulations do not require rabies vaccination or inspection for ferrets, which are domesticated pet

carnivores that are also highly susceptible to canine strains of rabies. Thus, the current regulations might not be sufficient to prevent the entry of canine strains of rabies into the United States.

Zoonotic pathogens are important not only because of the known illnesses they cause, which can move to new parts of the world, but also because of new human diseases that can arise from animal sources. In 2003, an outbreak of Severe Acute Respiratory Syndrome (SARS) in humans spread worldwide, and the initial transmission to humans was linked to civet cats sold for food in marketplaces in China. The emergence of SARS in humans following exposure to wild animals is an example of how a previously unrecognized zoonotic disease can quickly cause unexpected illness in human populations.

HHS/CDC believes many animals imported into the United States for the commercial pet trade represent a risk to human health. In 2003, an outbreak of monkeypox occurred in the United States, and involved 37 confirmed human cases. HHS/CDC ultimately traced back the outbreak of monkeypox, through infected prairie dogs, to the importation of African rodents. However, our investigators could not identify many potentially infected animals associated with this outbreak, because no accurate records were available to trace their movements. This outbreak eventually led to publication of 42 CFR 71.56, which prohibited the importation of all African rodents into the United States, except as approved by the Director of HHS/CDC for scientific, exhibition, or educational purposes. This outbreak illustrates the possibility of animals as sources of human infections, and the special risk associated with keeping wild animals as pets.

The importation of wild animals poses a health risk because most shipments involve a high volume of animals, most of which are wild-caught and not captive-raised. Many shipments also include different species co-mingled or kept in close proximity in confined spaces, conditions ideal for the transmission of disease. For most species, there is no screening for the presence of infectious diseases prior to shipment, and no holding or testing is required on entry into the United States, which creates an opportunity for the widespread exposure of humans to pathogens these animals could be harboring. High mortality rates among some animals, such as rodents, are common, and current U.S. statutes and regulations do not require importers to have diagnostic necropsies performed to

determine whether the mortality is from a pathogen that could have an adverse effect on public health. Some imported animals are also known reservoirs or vectors of communicable diseases of public-health significance.

HHS/CDC has taken actions to prevent the introduction, transmission, and spread of specific communicable diseases into the United States, including monkeypox, SARS, and avian influenza. 42 CFR 71.56 prohibits the importation of African rodents, except as approved by the Director of HHS/CDC for scientific, exhibition, or educational purposes. HHS/CDC has issued an order to ban the importation of civets, because of concerns over the importation of SARS-coronavirus. HHS/CDC has also issued orders to ban the importation of birds and bird products from specific countries with highly pathogenic avian influenza H5N1; these orders mirror similar regulatory actions taken by USDA/APHIS to prevent the importation of birds with avian influenza H5N1. These actions might not be sufficient to fully prevent the introduction of zoonotic diseases into the United States, because they are limited to specific species and regions.

HHS/CDC believes a number of approaches could further limit the transmission of zoonotic diseases. Potential solutions to this problem include screening animals with reliable laboratory tests, treating the animals empirically for known diseases, or quarantining the animals upon entry into the United States for the duration of an incubation period or duration of transmissibility. Many of those solutions, however, are currently not feasible or practical to employ on the large volume of imported animals. In addition, the control measures cannot prevent new or emerging pathogens or infections for which no laboratory tests or no empiric treatments exist, when practical experiences regarding a species' susceptibility are lacking, when incubation periods are unknown, or when the infections are subclinical. In these instances, import restrictions of a wider range of species than currently regulated could be the only effective means of preventing the introduction of exotic infections into this country.

On May 18, 2006, HHS/CDC hosted a public meeting on the subject of infectious-disease threats associated with the importation and trade of exotic animals. Stakeholders submitted a variety of positions and views to the public meeting. Of the 22 statements received for consideration, seven indicated a measure of support for increased restrictions on the importation and sale of exotic species,

while 15 expressed support for alternatives to regulatory or legal restrictions, or opposition to possible restrictions. HHS/CDC posted a summary of this meeting in the **Federal Register** of August 7, 2006 (71 FR 44,698).

Advance Notice of Proposed Rulemaking for Animal Importations

Before considering whether to engage in rulemaking, HHS/CDC is seeking input and background information from stakeholders, including pet owners, veterinarians, animal breeders and importers, retailers and distributors, U.S. State agricultural and public-health veterinarians, medical epidemiologists, infectious-disease internists, animal-welfare and conservation groups, research facilities, zoological societies, animal transporters, and other Federal, State, and local agencies on various issues relating to the potential application of revisions to the current rules. This process will allow HHS/CDC to consider the scope of any proposed changes.

HHS/CDC is requesting comments from stakeholders on the issues and questions below, pertaining to regulations on the importation into the United States of dogs, cats, and ferrets, as well as other animals. We request input on the economic, regulatory, management, social, health, and political impact any changes would have on the various stakeholder groups. We also request stakeholder groups to provide data to substantiate their claims of any positive or negative impact of any changes in the regulation. In addition, HHS/CDC solicits any additional comments from interested parties that could meaningfully inform the process of adjusting the current regulations.

Dog, Cat, and Ferret Regulations

Should HHS/CDC extend the regulations that currently cover dogs and cats to also cover domesticated ferrets?

Should HHS/CDC establish a minimum age for the importation of dogs, cats, and ferrets into the United States? If so, at what age and why? Should the minimum age differ for cats, dogs, and ferrets? Should HHS/CDC establish a requirement for the estimation of age by a licensed veterinarian?

Should rabies vaccination be a requirement for entry into the United States for all dogs, cats, and ferrets? What documentation would suffice as proof of vaccination? Should HHS/CDC require serologic evidence of immunity? What timeframe of vaccination would be appropriate? Should dogs, cats, and

ferrets imported for research purposes be considered exempt from rabies vaccination requirements if vaccination would interfere with the intended research?

Should HHS/CDC require each dog, cat, and ferret to have a valid international health certificate signed by a veterinary authority in the country of origin as a condition for entry into the United States? Are there particular international health certificates that should be used as a model? Would such a requirement be financially feasible for the importer? What diseases should a health examination and issuance of a health certificate cover? What are the perceived benefits or shortcomings of health certificates with respect to accurately reflecting a dog, cat, or ferret's true health status? How can these certificates be made difficult to falsify? Are there other methods that can demonstrate the health of the animal?

Would a requirement for all dogs, cats, and ferrets imported into the United States to have a unique identifier, such as a tattoo or microchip, as endorsed by the American Veterinary Medical Association, reduce the likelihood of fraudulent vaccination claims and health certificates? Would identifiers unique to each animal assist officials in locating and tracking dogs, cats, and ferrets during public-health investigations? How might the uniqueness of identifiers be assured if they are administered in other countries? What are some possible difficulties associated with requiring a unique identifier for each dog, cat, or ferret? Who would read the identifier? Should a database of identifiers for imported dogs, cats, and ferrets be maintained, and if so, who would maintain it? What is the impact of the cost of identification measures? Are there alternative identification methods?

To facilitate the implementation of these regulations, should HHS/CDC restrict the importation of dogs, cats, and ferrets to only those ports of entry staffed by HHS/CDC personnel? These quarantine stations are located in Atlanta, GA; Miami, FL; Chicago, IL; New York City, NY; Honolulu, HI; San Francisco, CA; Los Angeles, CA; Seattle, WA; Newark, NJ; Washington, DC; Dallas, TX; El Paso, TX; Houston, TX; Anchorage, AK; Boston, MA; Detroit, MI; Minneapolis, MN; San Diego, CA; Philadelphia, PA; and San Juan, PR. What impact would limiting the importation of dogs, cats, and ferrets to certain ports potentially have on pet owners and the pet industry?

Many countries allow dogs, cats, and ferrets with appropriate documentation and vaccination history to accompany

travelers. Is there a need for possible exemptions to importation requirements for dogs, cats, and ferrets that are traveling with their owners abroad and returning to the United States? Is there a need for other types of exemptions for dogs, cats, and ferrets?

Should HHS/CDC consider additional requirements that might reduce the risk of importing communicable diseases from dogs, cats, and ferrets into the United States, and make the implementation of these regulations more feasible and effective at ports of entry?

For firms and other entities potentially affected by the options discussed in the ANPRM, what types of negative (or positive) impacts could occur? What types of businesses and other entities would the options affect? What provisions would have the greatest impact? How would the revenues and costs of affected businesses change under the various approaches discussed in the ANPRM? For example, what percent of revenues are these options likely to affect in the short, medium, and long term (e.g., one year, 10 years, and 30 years)? How could HHS/CDC reduce or avoid the impact on small entities, and how would any changes to reduce impact on small entities affect the potential effectiveness of the rules?

Other Animal Regulations (Including African Rodents Currently Regulated Under 42 CFR 71.56)

HHS/CDC's current approach to controlling zoonotic disease threats has been to issue emergency orders or rules prohibiting importation of implicated animals. These actions are usually taken after an outbreak occurs, rather than to proactively prevent outbreaks from known high-risk animals. Given that this approach might not be sufficient to prevent fully the introduction of many zoonotic diseases, should HHS/CDC establish a regulation that maintains a list of species or categories of high-risk animals for which importation is restricted (e.g. either prohibited from entry, or subject to certain entry and permitting requirements)? If so, how would the types of animals included on such a list be determined? Should these regulations be based on broad taxonomic groupings (e.g., all rodents), or should they list individual species? Should HHS/CDC consider issuing these restrictions on a limited geographical basis (i.e., certain countries or regions), or more broadly?

If HHS/CDC were to prohibit certain subsets of animals from entry, how would personnel at ports of entry accurately identify animals, considering

that many species of concern are difficult to identify or distinguish from each other?

Should the revised rules focus on restricting the importation of diseases not already present in the United States, or should they also cover enzootic diseases that may pose a health risk (ex. salmonellosis)? What data sources should HHS/CDC use to determine a prioritized list of covered diseases?

Should HHS/CDC require shipments of restricted animals to enter a port staffed with HHS/CDC personnel? These quarantine stations appear in the above section on the regulations that cover dogs, cats, and ferrets. What impact would limiting the importation of restricted animals to certain ports potentially have on pet owners, the pet industry, and the scientific research community?

What impact will changing these regulations to include other species of animals have on the U.S. market for rearing these animals domestically? What impact will changing the regulations have on the illegal trade of restricted animal species?

Should HHS/CDC subject restricted animals to a quarantine period to cover the risks of diseases that have established incubation periods, as well as to allow assessment of the animals' general health status? Should there be quarantine exemptions for laboratory animals certified as being free of pathogens of concern? If a quarantine period is permitted, should animals that become ill or die during quarantine be required to have diagnostic tests or necropsies conducted to rule out communicable diseases of human health concern? Should such a requirement be mandatory, or should diagnostic tests or necropsies be ordered at the discretion of HHS/CDC? Who should bear the costs of the required diagnostic tests or necropsies?

How might changes to these regulations affect current practices regarding the tracking and handling of animals? What are ways to improve record-keeping for these animals to allow more rapid tracking during public-health investigations?

For firms and other entities potentially affected by the options discussed in the ANPRM, what types of negative (or positive) impacts could occur? What types of businesses and other entities would the options affect? What provisions would have the greatest impact? How would their revenues and costs change under the various approaches discussed in the ANPRM? For example, what percent of revenues are these options likely to affect in the short, medium, and long

term (e.g., one year, 10 years, and 30 years)? Please provide suggestions about how HHS/CDC could reduce or avoid the impact on small entities, and how those changes would affect the potential effectiveness of the rules.

References

1. Regulations on the importation of dogs and cats (42 CFR 71.51): http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr_2003/octqtr/42cfr71.51.htm.

2. Other animal-importation regulations (42 CFR 71.56) and orders:

a. <http://edocket.access.gpo.gov/2003/03-27557.htm>

b. <http://www.cdc.gov/ncidod/monkeypox/animals.htm>

c. <http://www.cdc.gov/flu/avian/outbreaks/embargo.htm>

d. <http://www.cdc.gov/ncidod/sars/civetembargo.htm>

Dated: April 16, 2007.

Michael Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on July 25, 2007.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AV25

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Devils River Minnow

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the Devils River minnow (*Dionda diaboli*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 73.5 stream kilometers (km) (45.7 stream miles (mi)) are within the boundaries of the proposed critical habitat designation. The proposed critical habitat is located along streams in Val Verde and Kinney Counties, Texas.

DATES: We will accept comments from all interested parties until October 1, 2007. We must receive requests for public hearings, in writing, at the address shown in the **ADDRESSES** section by September 14, 2007.

ADDRESSES: If you wish to comment on the proposed rule, you may submit your

comments and materials by any one of several methods:

1. You may mail or hand-deliver written comments and information to Adam Zerrenner, Field Supervisor, U.S. Fish and Wildlife Service, Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758.

2. You may send comments by electronic mail (e-mail) to fw2_drm@fws.gov. Please see the Public Comments Solicited section below for file format and other information about electronic filing.

3. You may fax your comments to the attention of Adam Zerrenner at 512-490-0974.

4. You may go to the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758; telephone 512-490-0057.

FOR FURTHER INFORMATION CONTACT:

Adam Zerrenner, Field Supervisor, Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758; telephone 512-490-0057; facsimile 512-490-0974. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339, 7 days a week and 24 hours a day.

SUPPLEMENTARY INFORMATION:

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) The reasons habitat should or should not be designated as critical habitat under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether the benefit of designation would outweigh any threats to the species caused by designation such that the designation of critical habitat is prudent;

(2) Specific information on the amount and distribution of Devils River minnow habitat, what areas should be

included in the designation that were occupied at the time of listing that contain the features that are essential for the conservation of the species and why, and what areas that were not occupied at the listing are essential to the conservation of the species and why;

(3) Information on the status of the Devils River minnow in Sycamore Creek and Las Moras Creek watersheds and information that indicates whether or not these areas should be considered essential to the conservation of the species;

(4) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(5) Any foreseeable economic, national security, or other potential impacts resulting from the proposed designation and, in particular, any impacts on small entities and information about the benefits of including or excluding any areas that exhibit those impacts; and

(6) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

You may submit comments and materials concerning this proposal by one of several methods (see **ADDRESSES**). Please include "Attn: Devils River minnow" in your e-mail subject header and your name and return address in the body of your message. If you do not receive a confirmation from the system that we have received your message, contact us directly by calling our Austin Ecological Services Field Office at 512-490-0057. Please note that comments must be received by the date specified in the **DATES** section in order to be considered and that the e-mail address fw2_drm@fws.gov will be closed out at the termination of the public comment period.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat in this proposed rule. For more information on