

System.<sup>3</sup> We recognize that AZA has an accreditation process for institutions such as zoological parks, and a separate certification process for related facilities, such as wildlife refuges, conservation research facilities, survival or rehabilitation centers, breeding farms, and educational organizations (Ref. 34). AZA accreditation requires that institutions follow the guidelines of the American Association of Zoo Veterinarians regarding medical programs and zoo hospitals.

Data on the sale and imports of the other rodents that would be prohibited with this interim rule are limited. Data from the U.S. International Trade Commission show that about \$38,000 worth of live African animals that could reasonably be expected to include these specific rodents were imported into the United States in 2002. Information from the Fish and Wildlife Service indicates that, in 2002, nearly 8,000 African rodents were imported into the United States. We do not have information that confirms that these separate database measurements relate to the same animals, but suggest that African rodent imports appear to be relatively small. Retail sales of such animals as pets would be expected to be somewhat higher than the value shown above due to retailer price markups. Further, we are unable to confidently estimate the number of other listed animals (except for prairie dogs) from either domestic or imported origin that are sold each year as pets in the United States. A recent American Pet Products Manufacturers Association survey does not list any of the animals listed in this interim final rule in its section on small animals (Ref. 35). Accordingly, we conclude that the number of such animals is relatively small.

The interim final rule would allow for persons wishing to seek exemptions from the rule's prohibitions by requesting written permission from FDA or CDC. We have tentatively estimated that about 60 such requests would be made annually to FDA. We would expect these requests to be made by animal relocation specialists or others involved in biological research or

conservation efforts. These requests are estimated to take 2 hours to complete. We cannot confidently estimate an average wage for those seeking permission to transport listed animals, but at a total annual burden of about 120 hours, we would expect the total cost burden to range from \$3,000 to \$6,000. FDA resource costs to process and respond to each request are estimated to total about 6 hours distributed across various staff levels. We estimate that the average pay level of these staff positions at about \$37 per hour. The administrative effort to process these requests would result in about \$13,300 (60 requests x 6 hours per request x \$37 per hour = \$13,320) in costs to FDA.

Similar costs would be incurred by those that would request written permission from CDC to import a listed animal. We estimate that CDC would receive about 12 requests annually, resulting in a cost burden of about \$500 to these individuals. CDC would also be expected to incur administrative costs to process and respond to these requests that would be similar to those incurred by FDA. We estimate that those costs may total to about \$3,000.

This interim final rule may result in the quarantine and/or destruction of an unknown number of listed animals if we determine that such action is necessary to prevent the further spread of monkeypox in the United States. We do not have an estimate of the marginal cost to quarantine, destroy or dispose of an individual animal. Further, the uncertainty surrounding the total number of animals that would be affected by this provision of the rule makes it difficult to estimate a total cost for such circumstances. We believe that facilities for such purposes are available and would not be expected to impose substantial costs to the Government.

#### 1. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities if that rule may have a significant impact on a substantial number of small entities.

a. *Objective of the rule.* The implementation of this interim final rule would ensure the safety of the human and animal populations in the United States from the monkeypox virus. The objective of this interim final rule is to reduce the risk to public health from the spread of the monkeypox virus throughout the United States.

b. *Small entity definitions and impacts.* A regulatory flexibility analysis (RFA) is required to estimate the number of small entities to which the interim final rule would apply. This rule would affect importers of African

rodents, trappers and distributors of prairie dogs, other small animal distributors, as well as retail pet stores.

The Small Business Administration (SBA) sets criteria by which it qualifies businesses as small entities. The SBA limit for small pet and pet supply stores is \$6 million in revenues. Census Bureau data shows that about 6,500 retail pet store companies operate about 8,300 establishments in the United States. A substantial number of these firms (about 94%) have a single establishment with average annual revenues of about \$356,000, thereby qualifying them as small businesses. We believe it is unlikely that the total sales of all of the listed animals would represent a significant portion of total pet store sales. However, due to the lack of data on total sales of these animals, as well as the possibility that some pet stores may specialize in the small animals that are listed in this rule, we cannot rule out the possibility that the rule may have a significant impact on a substantial number of these small entities.

The SBA limit for small business qualification for trappers is \$3.5 million or less in revenues. Prairie dog trappers, as described previously, would surely qualify as small businesses under this definition (Ref. 32). For at least some of these trappers, the loss of their profits from the effects of this rule would likely represent a significant impact on their businesses.

The SBA limit for all small business wholesale activities is set at 100 employees. We lack the data to determine the extent to which wholesalers and distributors of all small animals listed in this interim final rule (including those that import animals and those that handle domestic animals) would be affected by this rule. That being the case, we allow for the possibility that a substantial number of those that are affected may be small entities, and in some instances may incur significant impacts due to this rule.

We request public comment on the size and structure of those firms or persons involved in the trade of all animals listed in this interim final rule and the rule's effects on such firms and persons. The incompleteness of data, as described previously, precludes us from developing quantitative estimates of the costs of this rule for each type of small entity.

#### 2. Analysis of Alternatives

As stated previously, one alternative is a "sunset" provision ending the prohibitions on prairie dogs or other animals at some point in the future,

<sup>3</sup> The International Species Information System (ISIS) maintains a computer-based information system for wild animal species held in captivity. The database contains information on ten thousand species held in 586 institutions in 72 countries on 6 continents. Roughly 250 of these institutions are professionally managed United States zoos, most of which have been accredited by AZA. The ISIS Web site allows web-based searches by species and is updated weekly (see International Species Information System (ISIS); conversation with Mr. Nate Flesness, ISIS director; ISIS Web site information ([www.ISIS.org](http://www.ISIS.org))). ISIS is located in Apple Valley, Minnesota.