

broader issues of zoonotic diseases and exotic species, that document will provide an opportunity for public comment on those issues.

IV. What Is the Legal Authority for This Rulemaking?

Because the public health objective is to prevent the spread of communicable disease, we are issuing the rule under section 361 of the Public Health Service Act (PHS act) (42 U.S.C. 264). Section 361 of the PHS act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see *State of Louisiana v. Mathews*, 427 F. Supp. 174 (E.D. La. 1977)).

Section 361 of the PHS act also provides for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to humans, and other measures, as may be deemed by the Secretary to be necessary.

We have invoked section 361 of the PHS act to regulate various activities and articles. FDA has invoked this authority, for example, to prevent the transmission of communicable disease through certain shellfish, turtles, certain birds, and human tissue intended for transplantation (see 21 CFR 1240.60 (molluscan shellfish), 1240.62 (turtles), 1240.65 (psittacine birds), and 1270.1 through 1270.43 (human tissue)). CDC has invoked section 361 of the PHS act to control the importation of dogs and cats, turtles, nonhuman primates, etiological agents, and dead bodies (see 42 CFR 71.51 through 71.55, respectively). CDC has also regulated the interstate shipment of etiologic agents under this authority (see 42 CFR part 72).

Section 368 of the PHS act (42 U.S.C. 271) provides the authority to enforce section 361 of the PHS act. Under section 368(a) of the PHS act, any person who violates a regulation prescribed under section 361 of the PHS act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 per violation if death has not resulted from the violation or up to \$250,000 per violation if death has resulted (18 U.S.C. 3559, 3571(b)). Organizations may be fined up to \$200,000 per violation not resulting in death and \$500,000 per violation resulting in death (18 U.S.C. 3559,

3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. You should also note that if we add more animals under 21 CFR 1240.63(a)(1)(i)(H) or 42 CFR 71.56(a)(1)(i), any violation involving those additional animals would be considered to be a violation of a regulation prescribed under section 361 of the PHS act.

We are proceeding without notice and comment rulemaking because we need to have regulations in place immediately to address the monkeypox situation. Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B), we find for good cause that prior notice and comment on this rule are impracticable and contrary to the public interest. It is imperative that we act quickly to clarify and maintain restrictions on the African rodents, prairie dogs, and other animals to prevent the monkeypox virus from spreading and becoming established in the United States.

V. What Is the Environmental Impact?

FDA has determined under 21 CFR 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR part 70 will not have a significant impact on the human environment. This determination is consistent with the FDA determination that the provisions in 21 CFR part 1240 are covered by a categorical exclusion.

VI. What Is the Result of the Analysis of Impacts?

We have examined the impacts of the interim final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act,

as amended by the Small Business Regulatory Flexibility Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). We have conducted analyses of the rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

The interim final rule is not a significant regulatory action as defined by the Executive Order. This regulatory action is also not a major rule under the Congressional Review Act. However, the Regulatory Flexibility Analysis concludes that the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require us to prepare a statement of costs and benefits for the interim final rule because the rule is not expected to result in any one-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation-adjusted statutory threshold is about \$110 million.

A. Objectives and Basis for the Action

Incomplete data preclude us from developing a quantitative estimate of the economic benefits or costs of this rule. However, we believe that the rule is necessary to minimize the risk of establishing and spreading the monkeypox virus. The rule formalizes an administrative ban on trade, transport, and import of certain animals and sets forth a process to obtain exemptions. In particular, the interim final rule prohibits the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release into the environment of prairie dogs and other specific animals, and it prohibits importation of African rodents. The interim final rule supersedes the June 11, 2003, order and allows permits for exemptions in cases that pose little risk of establishing or spreading the monkeypox virus.

B. The Nature of the Impacts

This rule has several impacts. It continues and clarifies the prohibition of the import of African rodents, as well as the capture, offer to capture,