expenditures of this magnitude, such statements are not necessary.

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis of the potential impact of the proposed rule on small entities and permits agency heads to certify that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. CDC also addressed these concerns in the NPRM published on October 28, 1999-Packaging and Handling of Infectious Substances and Select Agents (42 CFR part 72). CDC requested comments on the economic burden from a number of small entities. It also requested recommendations on other possible less burdensome approaches. No comments were received.

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that this rule does not have implications for federalism.

Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes.

Energy Effects

This rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulation Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order.

Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the Department will report to Congress promulgation of this rule prior to its effective date. The report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more.

List of Subjects in 42 CFR Part 72

Biologic, Incorporation by reference, Packaging and containers, Transportation.

Text of the Rule

For the reasons stated in the preamble, part 72 is amended as follows:

PART 72—[AMENDED]

1. The authority section for part 72 continues to read as follows:

Authority: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

2. Amend § 72.6 by revising paragraphs (a)(5) and (c)(1) to read as follows:

§ 72.6 Additional requirements for facilities transferring or receiving select agents.

(a) * * *

(5) The biosafety standards and requirements for BSL-2, 3, and 4 operations are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition, May 1999 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C.

552(a) and 1 CFR part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop A–13 Atlanta, Georgia, or at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. The manual is also available on the CDC web site at www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm.

(c) * * *

(1) the Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition.

Dated: August 16, 2001.

Jeffrey Koplan,

Director, Centers for Disease Control and Prevention.

Dated: August 29, 2001.

Tommy G. Thompson,

 $Secretary, Department\ of\ Health\ and\ Human\ Services.$

[FR Doc. 01–22128 Filed 8–30–01; 8:45 am] BILLING CODE 4163–18–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 356

[Docket No. MARAD-2001-10518] RIN 2133-AB45

Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length To Obtain a Fishery Endorsement to the Vessel's Documentation

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Interim final rule and request for comments.

SUMMARY: The Maritime Administration ("MARAD," "we," "our," or "us") is publishing this interim final rule amending our regulations implementing the new U.S. citizenship requirements set forth in the American Fisheries Act of 1998 ("AFA"). MARAD's regulation,

at 46 CFR Part 356, contains the substantive requirements mandated by the AFA and procedural requirements established by MARAD for administration of the AFA. We are promulgating an amendment which provides us with the ability to waive any procedural requirement, if there is good cause to do so and the waiver would not be inconsistent with the AFA and the intent of this part. The waiver provision is effective upon publication, but we are inviting comments on the provision.

DATES: The effective date of this final rule is August 31, 2001. Submit comments on or before October 1, 2001. ADDRESSES: Comments should refer to docket number MARAD-2001-Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. DOT Dockets, Room PL-401, Department of transportation, 400 7th St., SW. Washington, D.C. 20590-0001. You may send comments electronically via the Internet at http://dmses.dot.gov/ submit/. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Murray A. Bloom, Citizenship Approval Officer, Maritime Administration, MAR–222 Room 7228, 400 7th Street, SW, Washington, DC 20590. Telephone: (202) 366–5320.

SUPPLEMENTARY INFORMATION: The AFA imposes new citizenship requirements for the owners of vessels of 100 feet or greater in registered length which hold a fishery endorsement or for which a fishery endorsement is sought and for entities holding a preferred ship mortgage on such vessels. We are required by the AFA to "rigorously" scrutinize any transfer of ownership and control over fishing vessels, fish processing vessels and fish tender vessels. In so doing, we must pay particular attention to leases, charters, financing arrangements, mortgages, and other documents to determine if they constitute an impermissible conveyance of control to persons not eligible to own a vessel with a fishery endorsement.

MARAD's detailed regulations, 46 CFR Part 356, were published in the **Federal Register** on July 19, 2000 (65 FR 44860), following notice and opportunity for submission of comments. The new citizenship requirements become effective on October 1, 2001. Vessel owners were directed to submit citizenship affidavits and other documents to us by June 1, 2001. We have provided information on the new requirements on MARAD's web site, http://marad.dot.gov/afa.html, mailed information to owners of fishing industry vessels and conducted briefings open to the public.

Nevertheless, because the new regulations apply for the first time to a population of individuals who have not yet had the opportunity to communicate or work with MARAD, we are concerned that we may face circumstances in which issues that were not anticipated by us or the public can not be resolved in the short period of time before October 1, 2001. In addition, some confusion may arise for the public because the U.S. Coast Guard will administer the AFA's citizenship requirements with regard to vessels under 100 feet in registered length under its own procedures. Our concerns are based on actual contacts between MARAD staff and the public that have brought to our attention the potential for certain inequitable results that could stem from the implementation of the regulations if MARAD does not have the ability to waive certain procedural requirements. We expect to review about 500 affidavits along with underlying articles of incorporation, bylaws, charters, management agreements, sales agreements and other documents.

In the course of reviewing this large number of complicated business arrangements it has become apparent that circumstances will arise, often not the fault of the vessel owner, that prevent us from making a complete citizenship finding by October 1, 2001. Our regulations provide the opportunity for the applicant to work with us to resolve matters prior to issuing a determination whether the applicant qualifies as a U.S. citizen. However, the AFA rule would cause the vessel owner's fishery endorsement to be deemed invalid on October 1, 2001. Thus, there will be times when a waiver of our procedures will be appropriate to avoid this result. Accordingly, MARAD is promulgating this amendment to 46 CFR Part 356, which allows us to waive procedural provisions of the rule not mandated by the AFA. The waiver provision would not be applicable to the substantive requirements set out in the AFA and the rule. In addition, any waiver must be supported by good cause shown.

We expect to issue decisions by October 1, 2001, on the bulk of the citizenship applications that we have received; however, the waiver provision will provide MARAD with the necessary

flexibility to ensure that vessel owners do not suffer harsh consequences such as the loss of their ability to fish or the loss of the vessel's fishery endorsement if MARAD is unable to make a citizenship determination by that date. Vessel owners are advised that we intend to process citizenship affidavits as expeditiously as possible and that the waiver provision is not intended to provide a mechanism that can be used by vessel owners to circumvent the requirements of the American Fisheries Act or to delay its implementation. Accordingly, we expect to complete decisions on any remaining applications by December 31, 2001.

The waiver provision will be effective as an interim measure immediately upon publication so that it will be in place before October 1, 2001, the date when MARAD must determine the U.S. citizenship status of 500-700 vessel owners and operators. The need to fairly administer the new and intricate requirements of the AFA within the stringent time constraints fully supports a finding of good cause, under the Administrative Procedure Act, 5 U.S.C. § 553(b) and (d), that the interim final rule should be effective upon publication and that prior notice and opportunity for public comment is not practicable and would not be in the public interest. However, we will consider public comment on the waiver provision before making the provision a permanent final rule.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review)

After discussing compliance requirements with interested vessel owners, operators and mortgagees, we became aware of a need to have a waiver provision in the AFA regulations so that non-material discrepancies in a vessel's documentation would not arbitrarily cause a vessel owner to lose their fishery endorsement. The waiver provision will not entail any cost to vessel owners, mortgagees, charterers, or other parties regulated by 46 CFR part 356.

This final rule is not a significant regulatory action under § 3(f) of Executive Order 12866. Consequently, it was not reviewed by the Office of Management and Budget. The economic impact, if any, should be minimal; therefore, no further analysis is necessary. This proposed rule is not significant according to the Regulatory Policies and Procedures of the Department of Transportation, 44 FR 11034 (February 26, 1979) as it merely

allows waiver of administrative and procedural requirements.

Federalism

We analyzed this rulemaking in accordance with the principles and criteria contained in E.O. 13132 ("Federalism") and have determined that it does not have sufficient federalism implications to warrant consultation with State and local officials. The regulations have no substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials.

Executive Order 13175

MARAD does not believe that this final rule will significantly or uniquely affect the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13175 ("Consultation and Coordination with Indian Tribal Governments"). Therefore, the funding and consultation requirements of this Executive Order would not apply.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires us to consider whether our proposals will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under § 3 of the Small Business Act (15 U.S.C. 632). This rulemaking may reasonably be expected to affect small businesses or entities that currently own documented fishing vessels, fish processing vessels, or fish tender vessels, that have financed such vessels, or that are engaging in the fisheries of the United States with such vessels. The Small Business

Administration defines businesses within the fishing industry that have annual receipts of \$3 million or less as small businesses, 13 CFR 121.201. We do not believe that there will be any cost to small business entities to comply with this interim final rule. Therefore, MARAD certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact Statement

We have analyzed this rule for purposes of compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and have concluded that under the categorical exclusions provision in section 4.05 of Maritime Administrative Order 600-1, "Procedures for Considering Environmental Impacts," 50 FR 11606 (March 22, 1985), the preparation of an Environmental Assessment, and an Environmental Impact Statement, or a Finding of No Significant Impact for this rulemaking is not required. This rulemaking involves administrative and procedural regulations that clearly have no environmental impact.

Paperwork Reduction Act

This rulemaking does not establish any new requirement for the collection of information.

Unfunded Mandates Reform Act of 1995

This final rule will not impose an unfunded mandate under the Unfunded Mandates Reform Act of 1995. It will not result in costs of \$100 million or more, in the aggregate, to any of the following: State, local, or Native American tribal governments, or the private sector. This proposed rule is the least burdensome alternative that achieves the objective of the rule.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action

listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 46 CFR Part 356

Citizenship and naturalization, Fishery endorsement, Fishing vessels, Mortgages, Mortgage trustee, Penalties, Preferred mortgages, Reporting and recordkeeping requirements, Vessels.

For the reasons discussed in the preamble, MARAD amends 46 CFR Part 356 as follows:

PART 356—REQUIREMENTS FOR VESSELS OF 100 FEET OR GREATER IN REGISTERED LENGTH TO OBTAIN A FISHERY ENDORSEMENT TO THE VESSEL'S DOCUMENTATION

1. The authority citation for 46 CFR Part 356 continues to read as follows:

Authority: 46 App. U.S.C. § 12102; Public Law 105–277, Division C, Title II, Subtitle I, § 203 (46 App. U.S.C. 12102 note), § 210(e), and § 213(g), 112 Stat. 2681; 46 CFR 1.66.

2. Amend 46 CFR Part 356 by adding a new § 356.2 to read as follows:

§ 356.2 Waivers.

In special circumstances and for good cause shown, we may waive the procedures prescribed in this part, provided the waiver is consistent with the requirements of the AFA and with the intent of this part.

Dated: August 28, 2001.

By Order of the Acting Deputy Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.
[FR Doc. 01–22039 Filed 8–30–01; 8:45 am]
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