

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 1**

[Docket No. FDA-2007-N-0465]

Label Requirement for Food That Has Been Refused Admission Into the United States; Correction**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of Thursday, September 18, 2008 (73 FR 54106). The document issued a proposed rule that would require owners or consignees to label imported food that is refused entry into the United States. The preamble to the proposed rule inadvertently omitted a reference. This document corrects that error.

DATES: Effective October 27, 2008.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Preparedness (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

SUPPLEMENTARY INFORMATION: In FR Doc. E8-21813, appearing on page 54118, in the **Federal Register** of Thursday, September 18, 2008, the following correction is made:

1. On page 54118, in the first column, after reference number "6." and before the "List of Subjects in 21 CFR Part 1," reference "7." is added to read:

"7. Memorandum to the record from J. Bradley Brown, Food and Drug Administration, dated March 20, 2008."

Dated: October 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-25588 Filed 10-24-08; 8:45 am]

BILLING CODE 4160-01-S**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket No. USCG-2008-1001]

RIN 1625-AA00**Security Zone; Potomac and Anacostia Rivers, Washington, DC, Arlington and Fairfax Counties, VA, and Prince Georges County, MD****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary security zone encompassing certain waters of the Potomac and Anacostia Rivers in order to safeguard high-ranking government officials and the public-at-large before, during, and after scheduled activities associated with the 2009 Presidential Inauguration. This security zone will be in effect between January 14, 2009 and January 25, 2009.

DATES: Comments and related material must reach the Coast Guard on or before November 26, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2008-1001 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number 410-576-2674 or 410-576-2693. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Public Participation and Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2008-1001), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> at any time. Enter the docket number for this rulemaking (USCG-2008-1001) in the Search box, and click "Go >>." You may also visit either the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the Commander, U.S. Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Building 70, Waterways Management Division, Baltimore, Maryland 21226-1791, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard, as lead federal agency for maritime homeland security, has determined that the Coast Guard Captain of the Port must have the means to be aware of, deter, detect, intercept, and respond to asymmetric threats, acts of aggression, and attacks by terrorists on the American homeland while still maintaining our freedoms and sustaining the flow of commerce. This proposed security zone is part of a comprehensive port security regime designed to safeguard human life, vessels, and waterfront facilities against sabotage or terrorist attacks.

The Captain of the Port Baltimore is proposing to establish a security zone to address the aforementioned security concerns and to take steps to prevent the catastrophic impact that a terrorist attack against the large gatherings of high-ranking United States officials, the public at large, and surrounding waterfront areas and communities would have. The proposed security zone is necessary to safeguard life and property on the navigable waters before, during, and after scheduled activities associated with the 2009 Presidential Inauguration and will help the Coast Guard prevent vessels or persons from bypassing the security measures established on shore for the events and engaging in waterborne terrorist actions during the highly publicized events.

Discussion of Proposed Rule

On Tuesday, January 20, 2009, the U.S. Presidential Inauguration will take place at the U.S. Capitol in Washington, DC. Activities associated with the 2009 Presidential Inauguration in and near the District of Columbia will include several Inaugural balls, parades and receptions. The proposed zone will be

in effect from January 14, 2009 through January 25, 2009. The proposed zone will cover (1) all waters of the Potomac River, from shoreline to shoreline, bounded on the north by the Francis Scott Key (U.S. Route 29) Bridge, downstream to and bounded on the south from a position at latitude 38°46'42" N, longitude 077°02'55" W on the Virginia shoreline to a position at latitude 38°46'42" N, longitude 077°01'33" W on the Maryland shoreline, including the waters of the Georgetown Channel Tidal Basin; and (2) all waters of the Anacostia River, from shoreline to shoreline, bounded on the north by the New York Avenue (U.S. Route 50) Bridge, downstream to and bounded on the south by its confluence with the Potomac River.

This rule requires that entry into or remaining in this security zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor in the security zone at the time the security zone is implemented do not have to depart the zone. All vessels underway within this security zone at the time it is implemented are to depart the zone. However, the Captain of the Port may, in his discretion, grant waivers or exemptions to this rule, either on a case-by-case basis or categorically to a particular class of vessel that otherwise is subject to adequate control measures. To seek permission to transit the area, the Captain of the Port Baltimore can be contacted at telephone number 410-576-2693 or on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). The Coast Guard will issue Broadcast Notices to Mariners to further publicize the security zone.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. There is no vessel traffic associated with recreational boating and commercial fishing during the effective

period, and vessels may seek permission from the Captain of the Port Baltimore to enter and transit the zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate or transit on (1) all waters of the Potomac River, from shoreline to shoreline, bounded on the north by the Francis Scott Key (U.S. Route 29) Bridge, downstream to and bounded on the south from a position at latitude 38°46'42" N, longitude 077°02'55" W on the Virginia shoreline to a position at latitude 38°46'42" N, longitude 077°01'01" W on the Maryland shoreline, including the waters of the Georgetown Channel Tidal Basin; and (2) all waters of the Anacostia River, from shoreline to shoreline, bounded on the north by the New York Avenue (U.S. Route 50) Bridge, downstream to and bounded on the south by its confluence with the Potomac River. This security zone would not have a significant economic impact on a substantial number of small entities because vessels with compelling interests that outweigh the port's security needs may be granted waivers from the requirements of the security zone.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your

small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number (410) 576-2674 or (410) 576-2693. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520.).

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 proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically

significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 5100.1 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969

(NEPA)(42 U.S.C. 4321-4370f), and have made a preliminary determination under the Instruction that this action is not likely to have a significant effect on the human environment. An environmental analysis checklist supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05-1001 to read as follows:

§ 165.T05-1001 Security Zone; Potomac and Anacostia Rivers, Washington, DC, Arlington and Fairfax Counties, VA, and Prince Georges County, MD.

(a) *Location*. The following area is a security zone: (1) all waters of the Potomac River, from shoreline to shoreline, bounded on the north by the Francis Scott Key (U.S. Route 29) Bridge, downstream to and bounded on the south from a position at latitude 38°46'42" N, longitude 077°02'55" W on the Virginia shoreline to a position at latitude 38°46'42" N, longitude 077°01'33" W on the Maryland shoreline, including the waters of the Georgetown Channel Tidal Basin; and (2) all waters of the Anacostia River, from shoreline to shoreline, bounded on the north by the New York Avenue (U.S. Route 50) Bridge, downstream to and bounded on the south by its confluence with the Potomac River.

(b) *Definitions*. As used in this section:

Captain of the Port Baltimore means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

Designated representative means any Coast Guard commissioned, warrant, or

petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the security zone described in paragraph (a) of this section.

(c) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones found in 33 CFR 165.33.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor at the time the security zone is implemented do not have to depart the security zone. All vessels underway within this security zone at the time it is implemented are to depart the zone. The Captain of the Port Baltimore may, in his discretion, grant waivers or exemptions to this rule, either on a case-by-case basis or categorically to a particular class of vessel that otherwise is subject to adequate control measures.

(3) Persons desiring to transit the area of the security zone must first obtain authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410-576-2693 or on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Enforcement period.* This section will be enforced from 4 a.m. on January 14, 2009, through 10 p.m. on January 25, 2009.

Dated: October 6, 2008.

Brian D. Kelley,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. E8-25435 Filed 10-24-08; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 207, 235, and 252

RIN 0750-AF96

Defense Federal Acquisition Regulation Supplement; Protection of Human Subjects in Research Projects (DFARS Case 2007-D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to address requirements for the protection of human subjects involved in research projects. The proposed rule contains a clause for use in contracts that include or may include research involving human subjects.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before *December 26, 2008*, to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2007-D008, using any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* dfars@osd.mil. Include DFARS Case 2007-D008 in the subject line of the message.
- *Fax:* 703-602-7887.
- *Mail:* Defense Acquisition Regulations System, Attn: Mr. Mark Gomersall, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301-3062.

• *Hand Delivery/Courier:* Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202-3402.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Gomersall, 703-602-0302.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule addresses statutory and regulatory requirements for the ethical treatment of human subjects involved in research projects. The proposed rule contains a clause for use in contracts involving human subjects in research, to inform

contractors of their responsibilities for compliance with 32 CFR Part 219; DoD Directive 3216.02; applicable DoD component policies; 10 U.S.C. 980; and, when applicable, Food and Drug Administration policies and regulations.

This proposed rule was subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the proposed rule is a reinforcement of existing requirements and obligations that apply with regard to the protection of human subjects involved in research projects. Therefore, DoD has not performed an initial regulatory flexibility analysis. DoD invites comments from small businesses and other interested parties. DoD also will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 2007-D008.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because the proposed rule does not contain any new information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 207, 235, and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR Parts 207, 235, and 252 are proposed to be amended as follows:

1. The authority citation for 48 CFR Parts 207, 235, and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 207—ACQUISITION PLANNING

2. Section 207.172 is added to read as follows:

207.172 Human research.

Any DoD component sponsoring research involving human subjects—

(a) Is responsible for oversight of compliance with 32 CFR Part 219, Protection of Human Subjects; and