federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 872

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.2050 is added to subpart B to read as follows:

§ 872.2050 Dental sonography device.

(a) *Dental sonography device for monitoring*—(1) *Identification.* A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) *Classification.* Class I. The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Dental sonography device for interpretation and diagnosis*—(1) *Identification.* A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.''

■ 3. Section 872.2060 is added to subpart B to read as follows:

§ 872.2060 Jaw tracking device.

(a) *Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla*—(1) *Identification.* A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis*—(1) *Identification.* A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.''

Dated: October 23, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–29863 Filed 12–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[T.D. TTB–7; Re Notice No. 965]

RIN: 1513–AA68

Expansion of the Russian River Valley Viticultural Area (2002R–421P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: This final rule expands by 767 acres the eastern boundary of the Russian River Valley viticultural area in Sonoma County, California. The Alcohol and Tobacco Tax and Trade Bureau believes the use of viticultural area names as appellations of origin in wine labeling and advertising helps consumers identify the wines they may purchase. It also allows wineries to better designate the specific grape-growing area in which their wine grapes were grown.

EFFECTIVE DATE: This final rule is effective on February 2, 2004.

FOR FURTHER INFORMATION CONTACT: N.A. Sutton, Specialist, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau (TTB), 6660 Delmonico Drive, #D422, Colorado Springs, CO 80919; telephone 415–271–1254.

SUPPLEMENTARY INFORMATION:

Homeland Security Act Impact on Rule Making

Effective January 24, 2003, the Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms (ATF) into two agencies, the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury and the Bureau of Alcohol, Tobacco, Firearms and Explosives in the Department of Justice. Regulation of wine labeling, including viticultural area designations, is the responsibility of the new TTB. References to ATF in this document relate to events that occurred prior to January 24, 2003, or to functions that the Bureau of Alcohol, Tobacco, Firearms and Explosives continues to perform.

Background on Viticultural Areas

TTB Authority

The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's

identity, while prohibiting the use of misleading information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions. The Secretary has delegated this authority to the Alcohol and Tobacco Tax and Trade Bureau.

Regulations in 27 CFR Part 4, Labeling and Advertising of Wine, allow the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Title 27 CFR part 9, American Viticultural Areas, contains the list of approved viticultural areas for American wines.

Definition

Title 27 CFR 4.25a(e)(1) defines an American viticultural area as a delimited grape-growing region distinguishable by geographic features whose boundaries have been delineated in subpart C of part 9. These designations allow consumers and vintners to attribute a given quality, reputation, or other characteristic of wine made from grapes grown in an area to its geographic origin.

Requirements

Section 4.25(e)(2) outlines the procedure for proposing an American viticultural area. Anyone interested may petition TTB to establish a grape-growing region as a viticultural area. The petition must include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that the boundaries of the proposed viticultural area are as specified in the petition;
- Evidence that the proposed area's growing conditions, such as climate, soils, elevation, physical features, etc., distinguish it from surrounding areas;
- A description of the proposed viticultural area's specific boundaries, based on features found on United States Geological Survey (USGS)-approved maps; and
- Copies of the appropriate USGS-approved map(s) with the boundaries prominently marked.

Impact on Current Wine Labels

As appellations of origin, viticultural area names have geographic significance and, under the FAA Act, may not be used in a misleading manner on wine labels. Our 27 CFR part 4 label regulations prohibit the use of brand names with geographic significance on a wine unless the wine meets the appellation of origin requirements for the named area. The FAA Act and our regulations also prohibit the misleading use of a viticultural area name on a wine label in a context other than an appellation of origin. (*See* 27 CFR 4.33(b), 4.39(i), and 4.39(j).

Bottlers who use brand names, including trademarked names, similar to ''Russian River Valley'' must ensure that their existing products are eligible to use the viticultural area's name as an appellation of origin. For a wine to be eligible, at least 85 percent of the grapes in the wine must have been grown within the viticultural area, and the wine must meet the other requirements of 27 CFR 4.25(e)(3). If a wine is not eligible for the appellation, the bottler must change the brand name or other label reference and obtain approval of a new label. Different rules apply if a wine in this category has a brand name used prior to July 7, 1986. *See* 27 CFR 4.39(i) for details.

Russian River Valley Expansion Petition

ATF received a petition from Donald L. Carano of the Ferrari-Carano Vineyards and Winery in Healdsburg, California, in August 2002, proposing a 767-acre expansion of the established 96,000-acre Russian River Valley viticultural area (*see* 27 CFR 9.66). On January 8, 2003, ATF published a Notice of Proposed Rulemaking requesting comments on the expansion of the Russian River area. (See Notice No. 965, 68 FR 1020). TTB received six comments, which are described and evaluated in the Notice of Proposed Rulemaking section of this document.

Located approximately 55 miles north of San Francisco, the Russian River Valley expansion area fits into a 90° angle in the original eastern boundary at the village of Fulton, which is just northwest of the city of Santa Rosa in Sonoma County, California. The expansion area has the same climate and other characteristics as the originally established Russian River Valley viticultural area. The added land accounts for less than a one percent increase in the original size of the viticultural area. In the past, some winegrape growers in the expansion area erroneously believed their vineyards to be within the boundaries of the Russian River Valley viticultural area. The newly expanded boundaries include Fulton Road on the west, River Road on the north, U.S. Highway 101 on the east, and two locally known streets, Dennis Lane and Francisco Avenue, on the south. Within these boundaries approximately 365 acres are currently planted to grapes.

Name Evidence

The 767-acre expansion area was commonly considered to be part of the original Russian River Valley viticultural area. A Wine Country Living magazine map of viticultural areas, dated July 2002, shows the expansion area as being within the established Russian River Valley viticultural area's borders. A June 2002, Wine Spectator Online article states that the Vintners Inn hotel, which lies in the expansion area, is within the originally established boundaries. The Russian River Wine Road Web site (1998–2002) locates the Vintners Inn and Siduri Wines inside the Russian River viticultural area, although both are in the expansion area. In August 2002, the Russian River Valley Winegrape Growers Association Web site listed several members who are in the expansion area. Also, road signs indicate that the expanded boundary area is locally associated with the Russian River area.

Boundary Evidence

Historically, according to Mr. John Marcucci, whose family has owned thirty acres in the area for four generations, the land in the expansion area was used for prune orchards and vineyards. He recalls that, prior to 1918, the acreage was planted to Petite Syrah, Zinfandel, and Pinot Noir wine grapes. Mr. Marcucci and Mr. Henry Bisordi, both life long residents of the area, also recollect that years ago prune orchards were more profitable than vineyards, but when the market changed, some orchards were replaced with vineyards. The previous owner of the Vintners Inn land claims that approximately 50 acres were devoted to French Colombard wine grapes and orchards. The orchards were removed about 25 years ago for Chardonnay, Pinot Blanc, and Sauvignon Blanc wine grape plantings. Currently, 48 percent, or almost half of the 767-acre expansion area, is used for viticulture.

Growing Conditions

Treasury Decision ATF–159 of October 21, 1983, 48 FR 48813, established the Russian River Valley as a viticultural area. This Treasury Decision stated:

> The Russian River viticultural area includes those areas through which flow the Russian River or some of its tributaries and where there is a significant climate effect from coastal fogs. The specific growing climate is the principal distinctive characteristic of the Russian River Valley viticultural area. The area designated is a cool growing coastal area because of fog intruding up the Russian River and its tributaries during the early morning hours.

Climate

The term ''Russian River,'' as it applies to viticulture, refers to the cool temperatures and coastal fog that influence portions of the Russian River Valley. The expansion area has heavy fog, as noted on an undated map titled ''Lines of Heaviest and Average Maximum Fog Intrusion for Sonoma County.''

The petition and Treasury Decision ATF–159, which established the Russian River Valley viticultural area, both refer to the Winkler degree-day (accumulated heat units) system used to classify grape-growing climatic regions (see ''General Viticulture,'' Albert J. Winkler, University of California Press, 1975). As noted in Treasury Decision ATF–159, ''The Russian River Valley viticultural area is termed 'coastal cool' with a range of 2000 to 2800 accumulated heat units.''

The 767-acre expansion petition documented a degree-day study of three vineyards from April 2001 through October 2001, which coincides with Winkler's growing season. Two of these vineyards are within the original Russian River Valley viticultural area, while the other is in the newly approved expansion area. This study measured air temperature, wind speed, precipitation, and humidity at the three area vineyards. Documentation is provided in the following table:

Vineyard	Degree-Days (accumulated heat units)
In the *established* viticultural area:	
Vino Farms Vineyard	2,477
Storey Creek Vineyard	2,736
In the *proposed expansion* area:	
LeCarrefour Vineyards	2,636

The results from the three vineyards studied show that all three are within the 2,000 to 2,800 accumulated heat units range found in the Russian River Valley viticultural area, as stated in Treasury Decision ATF–159. We independently confirmed that LeCarrefour Vineyards, at 4350 Barnes Road, Santa Rosa, California, is within the approved expansion.

Elevation

Elevations in the expansion area range from 130 feet to 160 feet, with a gentle rise from southwest to northeast, according to the two USGS topographic maps covering the expansion area. These elevations are similar to those found in the portion of the established Russian River Valley viticultural area immediately adjacent to the expansion area.

Soil

The predominant soils of the expanded Russian River Valley viticultural area are Huichica Loam, Yolo Clay Loam, and Yolo Silt Loam, as depicted on the Sonoma County Soil Survey map (USDA, 1972), sheet 74. These soils are also found within the originally-established Russian River Valley viticultural area in vineyards to the north of the expansion area, as noted on pages 57 and 66 of the maps developed by the USDA's, Forest Service and Soil Conservation Service in May 1972. Treasury Decision ATF–159, which established the Russian River Valley viticultural area, does not identify any predominant soils or indicate unique soils of the viticultural area.

Watershed

Both the original Russian River Valley viticultural area and the expanded area are in the large Russian River Valley watershed, as noted on the (California) Department of Fish and Game Inland Fisheries Division's ''Russian River Watershed'' map of April 1, 1997. This watershed includes the Russian River and the tributaries noted in Treasury Decision ATF–159.

Notice of Proposed Rulemaking

Comments

The Notice of Proposed Rulemaking, Notice No. 965, requested comments from all interested persons concerning the expansion of the Russian River Valley viticultural area by March 10, 2003. TTB received six comments. Two comments supported the petitioned expansion, three opposed the expansion as petitioned, and one stated that this type of Government ruling is not in the public interest. These comments are posted on the TTB Web site under Notice No. 965 at *http://www.ttb.gov/alcohol/rules/index.htm.*

After careful evaluation of each comment, TTB has approved the 767-acre expansion of the Russian River Valley viticultural area in accordance with the August 2002 petition's proposed boundaries.

The first supporting comment, from a winemaker with 18 years of experience, states ''the area between Fulton road and Hwy 101, proposed for inclusion in the RRV [Russian River Valley] in Notice 965 is very true-to-type for the RRV [Russian River Valley].'' The commenter explains that the quality of grapes grown in the expansion area is on par with the nearby vineyards inside the boundaries of the originally established Russian River Valley viticultural area. This commenter notes that in the future he will not hesitate to buy winegrapes from the expansion area and include them in his Russian River Valley-labeled wines.

The second favorable comment requested approval of the proposed expansion and notes that the expansion area ''satisfies all the criteria outlined in Title 27 CFR 4.25a(e)(2) for proposing an American viticultural area (AVA).'' The commenter states that the expansion area satisfies the principal distinctive characteristic of the Russian River Valley viticultural area with its ''significant climatic effect from coastal fogs.''

A comment, neither in favor or opposed to the Russian River Valley viticultural area expansion petition, states that this type of ruling is ''not in the public interest and the government has no business in this.'' The comment continues that such rulings are for commercial purposes, do not directly benefit the public, and argues that the wine industry should be responsible for this action.

The FAA Act requires that alcohol beverage labels provide the consumer with adequate information regarding, among other things, a product's identity. TTB believes the use of viticultural area names as appellations of origin in wine labeling and advertising helps consumers identify the wines they may purchase.

The first opposing comment states, ''If anything, the Russian River Valley AVA should be made smaller to reflect the uniqueness of that area.'' The commenter adds that since the 767-acre

expansion area falls outside the original Russian River Valley viticultural area, the expansion's approval will mislead wine buyers. The commenter concludes that the petitioning winery should not be allowed to purchase land outside the established viticultural area's boundaries and then propose the area's expansion to include its purchased land.

In response, TTB notes that its 27 CFR part 9 regulations state that TTB shall receive and process petitions to establish viticultural areas and that such areas are found with the territorial extent of the entire United States, including the Russian River Valley. There is no regulatory provision to prohibit petitioners, who have purchased property outside the boundaries of an established American viticultural area, from proposing an expansion of the viticultural area's boundary line to include their property. We have also determined that the petition supports the requirements in 4.25a(e)(2) for the expansion of this viticultural area.

Two commenters oppose the Carano petition to expand the Russian River Valley viticultural area. Both argue that the expansion area does not comply with the American Viticultural Area regulations in 27 CFR part 9 because there is ''substantial acreage outside the proposed expanded boundaries that is not significantly different, and in many cases is identical, to land within the proposed area of addition.'' Also, they explain there is no difference in climate, soils, or elevation in the areas immediately beyond the Carano boundary line expansion. One of the commenters separately states the Carano petition is ''incomplete.''

Both comment letters indicate that on January 17, 2003, the Russian River Valley Winegrowers group submitted a petition to expand the Russian River Valley viticultural area boundaries by 30,200 acres. This group's expansion petition includes the subject area of this final rule and, as discussed in the two comments, other areas with similar climate, soil and elevation. Both commenters requested that Carano's August 2002 petition for the 767-acre expansion of the Russian River Valley viticultural area, which is approved by this ruling, be joined with the January 2003 expansion petition of the Russian River Valley Winegrowers group.

In response to the opposition to the Carano petition, TTB notes that the two comments do not disagree with the petitioned 767-acre expansion, but believe that the expansion should be larger. The petitioner provided convincing evidence that the expansion area complies with the 27 CFR part 9 and is similar to the established Russian River Valley area, with the same distinguishing cool, foggy climate. The Russian River Valley Winegrowers' January 2003 petition to expand the Russian River Valley viticultural area by 30,200 acres includes the 767-acre expansion area approved in this rule. Because of the five months between receipt of the 767-acre expansion petition in August 2002 and the winegrowers' expansion petition in January 2003, we will continue to process the January 2003 petition separately.

Therefore, through this final ruling, TTB incorporates the 767-acre expansion area into 27 CFR 9.66, Russian River Valley.

Regulatory Analyses and Notices

Paperwork Reduction Act

This rule imposes no requirement to collect information. Therefore, the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, and its implementing regulations, 5 CFR part 1320, do not apply.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires an agency to conduct a regulatory flexibility analysis on any proposed rule that may have a significant economic impact on a substantial number of small entities. We certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation imposes no new reporting, recordkeeping, or other administrative requirements.

The establishment of viticultural areas represents neither our endorsement nor approval of the quality of wine made from grapes grown in the areas. The use of viticultural names as appellations of origin merely allow vintners to better describe the origin of their wines to consumers and helps consumers identify the wines they purchase. Thus, any benefit derived from using a viticultural area name results from a proprietor's own efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This rule is not a significant regulatory action as defined by Executive Order 12866, 58 FR 51735. Therefore, it requires no regulatory assessment.

Drafting Information

The principal author of this document is N.A. Sutton (Oregon), Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau.

List of Subjects in 27 CFR Part 9

Wine.

Authority and Issuance

■ For the reasons discussed in the preamble, we amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

■ 2. Amend § 9.66, Russian River Valley viticultural area by removing ''Road'' and adding in its place ''Avenue'' at the end of paragraph (c)(9), by redesignating paragraphs (c)(12) through (c)(24) as (c)(14) through (c)(26), by revising paragraphs (c)(10) and (c)(11), and by adding new paragraphs (c)(12) and (c)(13) to read as follows:

Subpart C—Approved American Viticultural Areas

§ 9.66 Russian River Valley.

* * * * *

(c) * * *

(10) Proceed north on Wright Avenue, which becomes Fulton Road, for approximately 3.8 miles to an unnamed unimproved road running to the east in Section 5 of T7W, R8W, which becomes a light duty road locally known as Francisco Avenue, and continue generally east on Francisco Avenue for about 0.6 mile to its intersection with the eastern boundary line of Section 5 in T7W, R8W, at a point where Francisco Avenue makes a 90° turn to the south.

(11) Proceed north along that section line for about 500 feet to a point due west of the intersection of Barnes Road and an unnamed light duty road locally known as Dennis Lane.

(12) Proceed straight east 1.2 miles, following Dennis Lane to its end, and continuing straight east to U.S. Highway 101, passing onto the Santa Rosa map in the process.

(13) Proceed 1.3 miles straight northwest along U.S. Highway 101, passing onto the Sebastopol map, to its intersection with an unnamed medium duty road locally known as River Road west of U.S. Highway 101 and as Mark West Springs Road east of U.S. Highway 101.

* * * * *

Signed: September 3, 2003.

John J. Manfreda,

Acting Administrator.

Approved: September 24, 2003.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 03–29906 Filed 12–1–03; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–03–181]

RIN 1625–AA00

Safety Zone; Bogue Sound, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the Atlantic Intracoastal Waterway (AICW) in the vicinity of Marine Corps Base Camp Lejeune, NC. Naval gunfire will be conducted crossing the AICW from offshore in the vicinity of N–1/BT3 impact area and impacting areas in Camp Lejeune. This safety zone is needed to ensure the safety of persons and vessels operating on the AICW in this area during the specified periods. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative.

DATES: This rule is effective from 8 a.m. on December 4, to 6 p.m. on December 11, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–03–181 and are available for inspection or copying at Coast Guard Marine Safety Office Wilmington, 721 Medical Center Drive, Wilmington, NC 28401 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Chuck Roskam, Chief, Port Operations, USCG Marine Safety Office Wilmington, telephone number (910) 772–2207.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing an NPRM and delaying the effective date of this rule would be contrary to the public interest since immediate action is necessary to minimize potential danger to the public and required to ensure the safety of persons and vessels operating on the AICW in this area at the times specified.

Background and Purpose

Naval gunfire will be conducted crossing the AICW and impacting areas in Camp Lejeune from 8 a.m. to 12 p.m. and 2 p.m. to 6 p.m. on December 4, 5, 10 & 11, 2003. The Safety Zone is in effect to ensure the safety of persons and vessels operating on the AICW in this area.

Discussion of Rule

The safety zone will cover the AICW extending from Bogue Sound-New River Daybeacon 58 (LLNR 39210) southeast to Bogue Sound-New River Light 64 (LLNR 39230). This safety zone will be in effect to ensure the safety of persons and vessels operating on the AICW in this area. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative. A Coast Guard or U.S. Navy vessel will patrol each end of the Safety Zone to ensure that the public is aware that the firing exercises are in progress and that the firing area is clear of traffic before firing commences.

Regulatory Evaluation

This 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. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). This rule only affects a small portion, less than two miles, of the AICW in North Carolina for a limited time. The regulation is tailored in scope to impose the least impact on maritime interests, yet provide the level of safety necessary for such an event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the AICW from 8 a.m. to 12 p.m. and 2 p.m. to 6 p.m. on December 4, 5, 10 & 11, 2003. The Coast Guard expects a minimal economic impact on a substantial number of small entities due to this rule because little commercial traffic transits this area of the AICW.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small Entities requesting guidance or exemption from this rule may contact LCDR Chuck Roskam, Chief, Port Operations, USCG Marine Safety Office Wilmington at (910) 772–2207.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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