

Food, Drug, and Cosmetic Act, and the implementing regulations that are administered by FDA.

Required Quantities of Malted Barley and Hops to Qualify as a Malt Beverage Under the FAA Act

TTB and its predecessor agency have previously provided guidance on the minimum quantities of malted barley and hops required to be used in the production of malt beverages. In 1994, the Bureau of Alcohol, Tobacco and Firearms (ATF) issued ATF Compliance Matters 94–1, which provided that beers fermented from at least 25 percent malted barley (calculated as the percentage of malt, by weight, compared to the total dry weight of all ingredients contributing fermentable extract to the base product) and made with at least 7½ pounds of hops (or the equivalent thereof in hop extracts or hop oils) per 100 barrels were “malt beverages” under the FAA Act. Because neither the FAA Act nor the implementing regulations in 27 CFR part 7 prescribe minimum standards for the amount of malted barley used in the production of a malt beverage, we are now reconsidering this guidance.

Pending a decision on whether to engage in rulemaking on this issue, TTB will continue to address inquiries from brewers regarding the classification of fermented beverages that contain hops and malted barley, but are made from less than 25 percent malted barley or less than 7½ pounds of hops per 100 barrels. For example, we recently determined that a neutral malt beer base containing a much lower amount of malted barley (one percent of the total dry weight of all ingredients contributing fermentable extract to the product) conformed to the definition of a “malt beverage.”

Brewers and importers should contact the Assistant Director, Advertising, Labeling and Formulation Division, if they have a question as to whether a particular product falls within the definition of a “malt beverage” and therefore is subject to the certificate of label approval and other requirements under the FAA Act.

TTB Holding

Held, in order for a brewery product to fall within the definition of a “malt beverage” under the FAA Act, it must be a fermented beverage made from both malted barley and hops, or their parts, or their products. A fermented beverage that qualifies as a “beer” under the IRC (other than saké or similar products) but that is made without both malted barley and hops is not subject to the requirements of the FAA Act.

Dated: July 7, 2008.

John J. Manfreda,
Administrator.

Dated: July 14, 2008.

John J. Manfreda,
Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[USCG–2008–0220]

RIN 1625–AA00

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending special local regulations for annual regattas and marine parades in the Captain of the Port Detroit zone. This rule is intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after regattas or marine parades. This rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after regattas or marine parades.

DATES: This rule is effective July 18, 2008.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2008–0220 and are available online at www.regulations.gov. This material is also available for inspection or copying at two locations: The 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and the U.S. Coast Guard, Sector Detroit, 110 Mt. Elliot Ave., Detroit, MI 48207 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call CDR Joseph Snowden, Prevention, U.S. Coast Guard Sector Detroit at (313) 568–9580. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 25, 2008, we published a notice of proposed rulemaking (NPRM) entitled Regattas and Marine Parades; Great Lakes Annual Marine Events, in the **Federal Register** (73 FR 22303). We received 0 letters commenting on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety and security of the spectators and participants during this event and immediate action is necessary to prevent possible loss of life or property.

Background and Purpose

This rule will remove the specific entries from table 1 found in 33 CFR 100.901, Great Lakes annual marine events that apply to regattas and marine parades in the Captain of the Port Detroit zone and list each regatta or marine parade as a subpart. This rule will also add several regattas and marine parades not previously listed in 33 CFR Part 100 and remove several events that no longer occur annually or are not regattas or marine parades.

Discussion of Comments and Changes

No comments were received and no changes were made to this rule.

Regulatory Analyses

We developed this 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 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.

The Coast Guard’s use of these special local regulations will be periodic in nature, of short duration, and designed to minimize the impact on navigable waters. These special local regulations will only be enforced immediately before and during the time the marine events are occurring. Furthermore, these special local regulations have been designed to allow vessels to transit

unrestricted through portions of the waterways not affected by the special local regulations. The Coast Guard expects insignificant adverse impact to mariners from the activation of these special local regulations.

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 would not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the areas designated as special local regulations in paragraphs (4) through (13) during the dates and times the special local regulations are being enforced.

These special local regulations would not have a significant economic impact on a substantial number of small entities for the following reasons: The special local regulations in this rule would be in effect for short periods of time, and only once per year; and the special local regulations have been designed to allow traffic to pass safely around the zone whenever possible and vessels will be allowed to pass through the zones with the permission of the Captain of the Port.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM 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 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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard. We did not receive any comments for this section.

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.

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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will 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. We did not receive any comments for this section.

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 create an environmental risk to health or risk to safety that may disproportionately affect children. We did not receive any comments for this section.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these regulations and fishing rights protection need not be incompatible. We have also determined that 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. Nevertheless, Indian Tribes that have questions concerning the provisions of this Rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this 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. We did not receive any comments for this section.

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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards. We did not receive any comments for this section.

Environment

We have analyzed this rule under Commandant Instruction M16475.ID and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (35)(h) of the Instruction, from further environmental documentation. This event establishes a regulated area for marine events, therefore paragraph (35)(h) of the Instruction applies.

A final environmental analysis checklist and a final categorical exclusion determination are available in the docket where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 100

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

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Amend § 100.901 by removing the entry “Group Detroit, MI” from Table 1 and adding paragraph (f) to read as follows:

§ 100.901 Great Lakes annual marine events.

* * * * *

(f) Patrol Commander means a Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to monitor a regatta area, permit entry into the regatta area, give legally enforceable orders to persons or vessels within the regatta area, and take other actions authorized by the Captain of the Port.

§ 100.902 [Removed and Reserved]

■ 4. Remove and reserve § 100.902.

■ 5. Add § 100.911 to read as follows:

§ 100.911 Bay City Airshow, Bay City, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Saginaw River bound on the south by a line extending from a point of land on the western shore at position 43°32.2' N; 083°53.3' W, east to a point of land on the eastern shore located at position 43°32.2' N; 083°53.2' W, and bounded on the north by a line extending from a point of land on the western shore at position 43°33.4' N; 083°54.5' W, east to a point of land on the eastern shore located at position 43°33.4' N; 083°54.3' W. (NAD 83). This area is south of Middle Ground Island near Clements Municipal Airport.

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* Two days during the second week in August. The exact dates and times for this event will be determined annually.

■ 6. Add § 100.912 to read as follows:

§ 100.912 Detroit Bell Isle Grand Prix, Detroit, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Detroit River near Belle Isle, bounded by a line extending from a point of land on the southern shore of Belle Isle located at position 42°20'00" N; 082°59'45" W, to 50 yards offshore at position 42°19'57"; 082°59' 43", and continuing at a distance of 50 yards around the western end of Belle Isle to the Belle Isle Bridge, maintaining a constant distance of 50 yards from the shoreline and terminating at position 42°20'28"; 082°59'43" on the northern side of Belle Isle, adjacent to a point on land at position 42°20'24" N; 082°59'48" W (NAD 83). This area wraps around the downstream end of Belle Isle.

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The last weekend in August. The exact dates and times for this event will be determined annually.

■ 7. Add § 100.913 to read as follows:

§ 100.913 ACORA Garwood Classic Offshore Race, Algonac, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of St. Clair River's North Channel, Algonac, Michigan, bounded by a north/south line beginning at a point of land adjacent to Allen Boats, Algonac, MI

(position 42°37'05" N, 082°33'34" W) extending to a point of land on Harsens Island (position 42°36'49" N, 082°33'34" W) extending east along the shoreline of Harsens Island to north/south line beginning at position 42°37'16" N, 082°31'11" W (approx. 500 ft west of the Russell Island buoy) extending north to a point at position 42°37'28" N, 082°31'11" W (approx. 300 ft offshore from the Russell Boat Club), then west along the shoreline of Algonac, MI stopping at the point of origin. (NAD 83).

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The first weekend in August. The exact dates and times for this event will be determined annually.

■ 8. Add § 100.914 to read as follows:

§ 100.914 Trenton Rotary Roar on the River, Trenton, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Detroit River, Trenton, Michigan, bounded by an east/west line beginning at a point of land at the northern end of Elizabeth Park in Trenton, MI, located at position 42°8.2' N; 083°10.6' W, extending east to a point near the center of the Trenton Channel located at position 42°8.2' N; 083°10.4' W, extending south along a north/south line to a point at the Grosse Ile Parkway Bridge located at position 42°7.7' N; 083°10.5' W, extending west along a line bordering the Grosse Ile Parkway Bridge to a point on land located at position 42°7.7' N; 083°10.7' W, and along the shoreline to the point of origin. (NAD 83). This area is in the Trenton Channel between Trenton and Grosse Isle, MI.

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The third week in July. The exact dates and times for this event will be determined annually.

■ 9. Add § 100.915 to read as follows:

§ 100.915 St. Clair River Classic Offshore Race, St. Clair, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the St. Clair River, St. Clair, Michigan, bounded by latitude 42°52'00" N to the north; latitude 42°49'00" N to the south; the shoreline of the St. Clair River on

the west; and the international boundary line on the east (NAD 83).

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The last week in July. The exact dates and times for this event will be determined annually.

■ 10. Add § 100.916 to read as follows:

§ 100.916 Chris Craft Silver Cup Races, Algonac, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the St. Clair River, North Channel, Algonac, Michigan, bounded on the north by a line starting at the northern end of Russel Island at position 42°37.0' N; 082°31.4' W extending across the channel to Algonac to a point at position 42°37.4' N; 082°31.5' W, and bounded on the south by a line starting north of Grande Point Cut on Russel Island at position 42°36.3' N; 082°32.5' W extending across the channel to Algonac to a point at position 42°36.5' N; 082°32.6' W. (NAD 83).

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The third week in August. The exact dates and times for this event will be determined annually.

■ 11. Add § 100.917 to read as follows:

§ 100.917 The Old Club Cannonade, Harsens Island, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of Lake St. Clair in an area bound by the coordinates starting at the cannon firing position located at 42°32.5' N; 082°40.1' W extending west to the Old Channel Light located at position 42°32.5' N; 082°41.6' W angling northeast to position 42°33.5' N; 082°40.6' W then angling southeast to the point of origin creating a triangle shaped safety zone. (NAD 83). This area is near the southern end of Harsens Island in Muscamoot Bay.

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The third week in October. The exact dates and times for this event will be determined annually.

■ 12. Add § 100.918 to read as follows:

§ 100.918 Detroit APBA Gold Cup, Detroit, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Detroit River, Belle Isle, Michigan, bound on the west by the Belle Isle Bridge (position 42°20'20" N, 083°00'00" W to 42°20'24" N, 083°59'45" W), and on the east by a north-south line drawn through Waterworks Intake Crib Light (Light List Number 8350; position 42°21'06" N, 082°58'00" W) (NAD 83).

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The first or second week in June. The exact dates and times for this event will be determined annually.

■ 13. Add § 100.919 to read as follows:

§ 100.919 International Bay City River Roar, Bay City, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Saginaw River bounded on the north by the Liberty Bridge, located at 43°36.3' N, 083°53.4' W, and bounded on the south by the Veterans Memorial Bridge, located at 43°35.8' N, 083°53.6' W. (NAD 83).

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The third or fourth week in June. The exact dates and times for this event will be determined annually.

■ 14. Add § 100.920 to read as follows:

§ 100.920 Tug Across the River, Detroit, MI.

(a) *Regulated Area.* A regulated area is established to include all waters of the Detroit River, Detroit, Michigan, bounded on the south by the International boundary, on the west by 083°03' W, on the east by 083°02' W, and on the north by the U.S. shoreline (DATUM: NAD 83). This position is located on the Detroit River in front of Hart Plaza, Detroit, MI.

(b) *Special Local Regulations.* The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) *Enforcement Period:* The third or fourth week in June. The exact dates and times for this event will be determined annually.

(d) Vessel operators desiring to enter or operate within the regulated area shall contact the Coast Guard Patrol Commander to obtain permission to do so. Vessel operators given permission to enter or operate in the regulated area must comply with all directions given to them by the Coast Guard Patrol Commander.

Dated: July 1, 2008.

F.M. Midgette,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

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DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

United States Marine Corps Restricted Area and Danger Zone, Neuse River and Tributaries, Marine Corps Air Station Cherry Point, NC

AGENCY: United States Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Corps of Engineers is amending its regulations to designate an existing rifle range fan as a danger zone. The military exercise area is located within the Rifle Range of Marine Corps Air Station Cherry Point, North Carolina, along the Neuse River. The danger zone will only be activated by the Marine Corps Air Station Cherry Point during range operational hours. The Marine Corps will advise residents in the vicinity of the range fan thus ensuring their safety by alerting them to temporary potential hazardous conditions which may exist as a result of small arms exercises. There will be no change in the use of the existing exercise area. The area will be marked on navigation charts to ensure security and safety for the public. Entry points into the danger zone will be prominently marked with signage indicating the boundary of the danger zone. The placement of aids to navigation and regulatory markers will be installed in accordance with the requirements of the United States Coast Guard. If the proposed signage exceeds nationwide permit and/or regional general permit conditions, the Commander, United States Marine Corps, Marine Corps Air Station Cherry Point, North Carolina, will seek additional Department of the Army authorizations.