

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Plant and Dairy Food Safety/ Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1493.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of July 9, 2009 (74 FR 33030), we issued a final rule requiring shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. This final rule became effective September 8, 2009. In the **Federal Register** of July 13, 2011 (76 FR 41157), we made available a draft guidance entitled “Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” and gave interested parties an opportunity to submit comments by September 12, 2011. We have reviewed and evaluated these comments and have modified the guidance where appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on how to interpret the requirements in the final rule, including questions and answers on compliance dates; coverage; definitions; SE prevention measures; sampling and testing for SE; registration; and compliance and enforcement. It does not create or confer any rights for or on any person and does not operate to bind

FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

##### **III. Comments**

Interested persons may submit written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: August 13, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-20383 Filed 8-20-12; 8:45 am]

**BILLING CODE 4160-01-P**

#### **DEPARTMENT OF THE TREASURY**

##### **Internal Revenue Service**

##### **26 CFR Part 1**

[TD 9597]

**RIN-1545-BF34**

##### **Deductions for Entertainment Use of Business Aircraft; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to final regulations.

**SUMMARY:** This document corrects the final regulation (TD 9597) that was published in the **Federal Register** on Wednesday, August 1, 2012, (77 FR

45480), relating to the use of business aircraft for entertainment.

**DATES:** *Effective Date:* This correction is effective on August 21, 2012 and is applicable on August 1, 2012.

**FOR FURTHER INFORMATION CONTACT:** Michael Nixon (section 274), (202) 622-4930; or Lynne A. Camillo (section 61), (202) 622-6040 (not toll-free numbers).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The final regulation (TD 9597) that is the subject of this correction is under section 274 of the Internal Revenue Code.

##### **Need for Correction**

As published, TD 9597 contains an error that may prove to be misleading and is in need of clarification.

##### **Correction of Publication**

Accordingly, the publication of the final regulation (TD 9597) that was the subject of FR Doc. 2012-18693, is corrected as follows:

On page 45480, column 1, under the caption **DATES:** line five, the language “1.274–9(e), and 1.274–10(h)” is corrected to read “1.274–9(e), and 1.274–10(g)”.

**LaNita Van Dyke,**

*Chief, Legal Processing Division, Associate Chief Counsel, Procedure and Administration.*

[FR Doc. 2012-20436 Filed 8-20-12; 8:45 am]

**BILLING CODE 4830-01-P**

#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Coast Guard**

##### **33 CFR Parts 100 and 165**

[Docket No. USCG-2011-0551]

**RIN 1625-AA00; 1625-AA08**

##### **Special Local Regulation and Safety Zone; America’s Cup World Series Regattas, San Francisco Bay; San Francisco, CA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard has established a special local regulation and a safety zone for sailing events scheduled to occur on the waters of San Francisco Bay adjacent to the City of San Francisco waterfront in the vicinity of the Golden Gate Bridge and Alcatraz Island. This rule will revise the start time for enforcement on August 26, 2012, to 11:30 a.m. instead of noon. This

change will protect mariners transiting the area from the dangers associated with the sailing events. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative.

**DATES:** This rule is effective from August 21, 2012, until August 26, 2012.

**ADDRESSES:** Documents mentioned in this preamble are part of docket USCG–2011–0551. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit 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.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or email Lieutenant DeCarol Davis, U.S. Coast Guard Sector San Francisco; telephone (415) 399–7443 or email at [D11-PF-MarineEvents@uscg.mil](mailto:D11-PF-MarineEvents@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Acronyms**

APA Administrative Procedure Act  
ACRM America’s Cup Race Management  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

##### **A. Regulatory History and Information**

On July 17, 2012, the Coast Guard published a temporary final rule regulating the on-water activities associated with the “2012 America’s Cup World Series” regatta scheduled to occur August 21–26, 2012 (77 FR 41902). That rule created a special local regulation and safety zone to be enforced from noon until 5 p.m. on those days.

On August 11, 2012, the Coast Guard received notification from America’s Cup Race Management (ACRM) that the race scheduled to occur on August 26, 2012, would begin 30 minutes earlier in order to maintain schedules for television coverage and broadcasting. Regulating on-water activities associated with the regatta during those 30 minutes is necessary to protect the public from

the dangers posed by the high speeds of the sailing vessels operating during this media coverage. The time remaining before the scheduled August 26th race does not allow for public comment on this change. Publishing a rule is in the public’s interest, however, to provide for the safety of mariners transiting the area and to notify the public of planned on-water activities. The timing of enforcement also was addressed in public comments the Coast Guard received and considered in development of the rule published on July 17, and based on those comments the Coast Guard believes that starting enforcement 30 minutes earlier on one day will not interfere with other waterway uses.

Accordingly, the Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” For the reasons described above, the Coast Guard finds under 5 U.S.C. 553(b)(B) that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be contrary to the public interest.

Similarly, 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**. For the reasons stated above, delaying the effective date would be contrary to the public interest.

##### **B. Basis and Purpose**

Under 33 CFR 100.35, the Coast Guard District Commander has authority to promulgate certain special local regulations deemed necessary to ensure the safety of life on the navigable waters immediately before, during, and immediately after an approved regatta or marine parade. The Commander of Coast Guard District 11 has delegated to the Captain of the Port (COTP) San Francisco the responsibility of issuing such regulations. The COTP also has the authority to establish safety zones under 33 CFR 1.05–1(f) and 165.5.

From August 21–26, 2012, the City of San Francisco plans to host America’s Cup World Series regattas as part of a circuit of sailing events being conducted at other U.S. and international venues. On July 17, 2012, the Coast Guard published a temporary final rule establishing a special local regulation

and temporary safety zone to govern these events from noon to 5 p.m. (77 FR 41902); however, the events on August 26, 2012, will start earlier to maintain the event’s television broadcast schedule. To protect the public during this media coverage, the Coast Guard is revising the enforcement provisions of the July 17 rule to provide for enforcement from 11:30 a.m. until 5 p.m. on August 26, 2012. This change is necessary to ensure the safety of mariners transiting the area from the dangers associated with the sailing events.

##### **C. Discussion of the Temporary Final Rule**

The location and restrictions of the special local regulation established at 33 CFR 100.T11–0551A and the safety zone established at 33 CFR 165.T11–0551 remain as they were published on July 17, 2012, and are not changed by this rule. The enforcement periods of both the special local regulation and the safety zone are revised to reflect enforcement from 11:30 a.m. until 5 p.m. on August 26, 2012, instead of from noon until 5 p.m. as originally established. Enforcement on the other program days in 2012 and 2013 is not affected by this rule.

The effect of the special local regulation and temporary safety zone will be to restrict navigation in the vicinity of the America’s Cup sailing events. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep mariners and vessels away from the immediate vicinity of the high-speed sailing vessels participating in America’s Cup. Movement within marinas, pier spaces, and facilities along the City of San Francisco waterfront is not regulated by this rule.

##### **D. Regulatory Analyses**

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

###### **1. Regulatory Planning and Review**

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive

Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

Although this rule restricts navigation on San Francisco Bay, these restrictions will only be in place for an additional 30 minutes on one day, and are limited to a narrowly tailored geographic area. In addition, although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

## 2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 may affect the following entities, some of which may be small entities: Owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing, if these facilities or vessels are in the vicinity of the special local regulation and safety zone at times when they are being enforced. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This rule will encompass only a small portion of the waterway for a limited period of time; (ii) vessel traffic may pass safely around the area; (iii) vessel traffic may pass through the area with COTP approval; (iv) recreational vessel operators may use spaces outside of the affected areas; and (v) the maritime public will be advised in advance via Broadcast Notice to Mariners. These measures have been implemented during similar marine events such as Fleet Week and have been successful.

## 3. 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 rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION**

**CONTACT**, above. 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.

## 4. 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).

## 5. 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.

## 6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

## 7. 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 (adjusted for inflation) 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.

## 8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and

Interference with Constitutionally Protected Property Rights.

## 9. 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.

## 10. 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.

## 11. 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.

## 12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

## 13. Technical Standards

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

## 14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, 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 this action does not individually or cumulatively have a significant effect on the human environment. A copy of the environmental assessment is available in the docket.

## List of Subjects

### 33 CFR Part 100

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

### 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Parts 100 and 165 as follows:

## PART 100—REGATTAS AND MARINE PARADES

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

**Authority:** 33 U.S.C. 1233.

■ 2. Revise paragraph (b) of § 100.T11–0551A to read as follows:

### § 100.T11–0551A Special Local Regulation; 2012 America's Cup World Series.

\* \* \* \* \*

(b) *Enforcement Period.* The regulations in this section will be enforced between the hours of noon and 5 p.m. on designated program days between August 21, 2012, and August 25, 2012, and between 11:30 a.m. and 5 p.m. on August 26, 2012. The enforcement period may be curtailed earlier by the Captain of the Port (COTP) or Patrol Commander. Notice of the specific program dates and times will be issued via Broadcast Notice to Mariners and published by the Coast Guard in the Local Notice to Mariners and in the **Federal Register**.

\* \* \* \* \*

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 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.

■ 4. Effective from August 21, 2012, until August 26, 2012, suspend paragraph (b) of § 165.T11–0551 and add paragraph (d) to read as follows:

### § 165.T11–0551 Safety Zone; America's Cup Sailing Events.

\* \* \* \* \*

(d) *Location and enforcement period.* A safety zone extends 100 yards around America's Cup Racing Vessels from noon until 5 p.m. on program days between August 21, 2012, and August 25, 2012; from 11:30 a.m. until 5 p.m. on August 26, 2012; and from 11 a.m. until 4 p.m. on program days between July 4, 2013, and September 23, 2013. The enforcement period may be curtailed earlier by the Captain of the

Port (COTP) or Patrol Commander. Notice of the specific program dates and times will be issued via Broadcast Notice to Mariners and published by the Coast Guard in the **Federal Register**.

\* \* \* \* \*

Dated: August 14, 2012.

**Cynthia L. Stowe,**

*Captain, U.S. Coast Guard, Captain of the Port San Francisco.*

[FR Doc. 2012–20465 Filed 8–17–12; 4:15 pm]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

[Docket No. USCG–2012–0193]

**RIN 1625–AA09**

### Drawbridge Operation Regulation, Atlantic Intracoastal Waterway (AIWW); Wrightsville Beach, NC; Cape Fear and Northeast Cape Fear River; Wilmington, NC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is modifying the operating schedule that governs three North Carolina Department of Transportation (NCDOT) bridges: The S.R. 74 Bridge, across the AIWW, mile 283.1 at Wrightsville Beach, NC; the Cape Fear Memorial Bridge across the Cape Fear River, mile 26.8; and the Isabel S. Holmes Bridge across the Northeast Cape Fear River, mile 1.0; both in Wilmington, NC. The modification will alter the dates and times these bridges are allowed to remain in the closed position to accommodate the time and route change of the annual YMCA Tri Span 5K & 10K races.

**DATES:** This rule is effective September 20, 2012.

**ADDRESSES:** Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0193 and are available online by going to <http://www.regulations.gov>, by inserting USCG–2012–0193 in the “Keyword” box, and then clicking “Search”. This material is also available for inspection or copying at 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.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Terrance A. Knowles, Environmental Protection Specialist, Fifth Coast Guard District; telephone (757) 398–6587, email [terrance.a.knowles@uscg.mil](mailto:terrance.a.knowles@uscg.mil). 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:

#### Table of Acronyms

DHS Department of Homeland Security  
FR **Federal Register**  
NPRM Notice of Proposed Rulemaking

#### A. Regulatory History and Information

On May 1, 2012 we published a notice of proposed rulemaking (NPRM) entitled “Drawbridge Operation Regulation; Atlantic Intracoastal Waterway (AIWW), at Wrightsville Beach, NC; Cape Fear and Northeast Cape Fear River, at Wilmington NC” in the **Federal Register** (77 FR 25652). We received no comments on the published NPRM. No public meeting was requested, and none was held. The current operating schedule for the S.R. 74 Bridge at Wrightsville Beach, NC, the Cape Fear Memorial Bridge and the Isabel S. Holmes Bridge both at Wilmington, NC are located at 33 CFR 117.821(a)(4), 33 CFR 117.822, and 33 CFR 117.829(a), respectively. All three operating regulations were last amended on May 27, 2011 regarding an unrelated issue. There have been no other publications or efforts to reach out to the public in the development of this rule modification because these races are annual races that mariners are familiar with and this rule makes minor adjustments to the times the bridges will be unable to open.

#### B. Basis and Purpose

The YMCA Tri Span 5K and 10K races are annual events that are held in the Wrightsville Beach and Wilmington, NC areas. Recently, the Wilmington Family YMCA made a permanent change to both the time and route of the events. The races will continue to be held on the second Saturday of July of every year; however, the events will now begin and end an hour earlier (7 a.m. to 9 a.m.) and the race routes will now include the S.R. 74 Bridge. As a result, the Wilmington Family YMCA, on behalf of NCDOT, requested a change to the operating regulations for the S.R. 74 Bridge, the Cape Fear Memorial Bridge, and the Isabel S. Holmes Bridge. This final rule allows the bridges to