

September 16, 1994, is amended as follows:

Paragraph 6002—Class E airspace areas designated as a surface area for an airport

**AEA NJ E2 Trenton, NJ [New]**

Merger County Airport, Trenton, NJ  
[Lat. 40°16'36" N., long. 74°48'49" W.]  
Yardley VORTAC

[Lat. 40°15'12" N., long. 74°54'27" W.]  
That airspace extending upward from the surface to and including 2,700 feet MSL within a 4.1-mile radius of Mercer County Airport and within 2.2 miles north of the Yardley VORTAC 064° radial and within 1.8 miles south of the Yardley VORTAC 070° radial extending from the 4.1-mile radius to the VORTAC. This Class E airspace is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Airport/Facility Directory.

Issued in Jamaica, New York, on August 19, 1994.

John S. Walker,

Manager, Air Traffic Division.

[FR Doc. 94-21981 Filed 9-6-94; 8:45 am]

BILLING CODE 4910-13-M

**14 CFR Part 73**

[Airspace Docket No. 92-AWP-6]

**Alteration and Subdivision of Restricted Area R-2503 and Revocation of R-2533; California**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

**SUMMARY:** This action modifies Restricted Area R-2503, Camp Pendleton, CA, and subdivides the area into three separate areas designated as R-2503A, R-2503B, and R-2503C. R-2503A will incorporate part of the existing Restricted Area R-2533, Oceanside, CA. R-2533 will be removed concurrent with this action. This action will allow Marine Corps Base Camp Pendleton to accomplish required training.

**EFFECTIVE DATE:** 0901 UTC, October 13, 1994.

**FOR FURTHER INFORMATION CONTACT:** Paul Gallant, Military Operations Program Office (ATM-420), Office of Air Traffic System Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone: (202) 267-9361.

**SUPPLEMENTARY INFORMATION:**

**History**

On November 23, 1993, the FAA proposed to amend part 73 of the

Federal Aviation Regulations (14 CFR part 73) by subdividing Restricted Area R-2503, Camp Pendleton, CA, into three separate areas designated as R-2503A, R-2503B, and R-2503C and by removing R-2533, Oceanside, CA (58 FR 61854). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. This action also corrects an inadvertent error that was published in the notice concerning the base commander's name listed in the using agency.

"Commanding Officer" should have been "Commanding General." Except for the change noted above, this amendment is the same as that proposed in the notice. Section 73.25 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8B dated March 9, 1994.

**The Rule**

This amendment to part 73 of the Federal Aviation Regulations subdivides Restricted Area R-2503, Camp Pendleton, CA, into three separate areas designated as R-2503A, R-2503B, and R-2503C. Camp Pendleton has found that having two restricted areas with similar sounding, but different numbers is confusing, and has requested that R-2533 be removed and modified under the designation of R-2503A. R-2503A is smaller in size than the current R-2533. The southwestern boundary of R-2503A will be 2 miles closer to the shoreline so that the distance that nonparticipating aircraft will need to fly offshore to avoid the area will be reduced. Additionally, the boundary on the northwestern side of R-2503A will be adjusted to return airspace near San Clemente to the public. R-2503B is a slightly enlarged version of the existing R-2503. The southwestern boundary will be moved 1 mile toward the shoreline to enable the Marine Corps to provide requisite training. R-2503C is new airspace which will extend from 15,000 to 27,000 feet and will overlie approximately three-fourths of R-2503B. The Marine Corps has requested this additional airspace to accomplish required training, such as high angle, high altitude artillery firing, and has indicated that its use will typically be less than 40 hours per year. A change to the using agency to standardize format is also included in this action.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under

Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

An Environmental Assessment (EA) of this action, resulting in a Finding of No Significant Impact (FONSI), was completed by the Environmental and Natural Resources Management Office, Marine Corps Base Camp Pendleton, CA. The FAA has reviewed the EA, and adopts the EA/FONSI, as supplemented by the Marine Corps. The FAA concludes that this action will have no significant impact on the environment.

**List of Subjects in 14 CFR Part 73**

Airspace, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510, 1522; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

**§ 73.25 [Amended]**

2. § 73.25 is amended as follows:

**R-2503 Camp Pendleton, CA [Removed]**

**R-2503A Camp Pendleton, CA [New]**

Boundaries. Beginning at lat. 33°22'42" N., long. 117°36'45" W.; to lat. 33°27'13" N., long. 117°34'17" W.; to lat. 33°18'41" N., long. 117°23'58" W.; to lat. 33°17'30" N., long. 117°16'43" W.; to lat. 33°14'09" N., long. 117°26'38" W.; to the point of beginning by following a line 1 NM from and parallel to the shoreline.

Designated altitudes. Surface to 2,000 feet MSL.

Time of designation. 0600-2400 local time daily; other times by NOTAM.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding General, MCB Camp Pendleton, CA.

**R-2503B Camp Pendleton, CA [New]**

Boundaries. Beginning at lat. 33°24'23" N., long. 117°15'18" W.; to lat. 33°18'00" N., long. 117°16'11" W.; to lat. 33°17'30" N., long. 117°16'43" W.; to lat. 33°18'41" N., long. 117°23'58" W.; to lat. 33°27'13" N., long. 117°34'17" W.; to lat. 33°30'13" N., long. 117°29'16" W.; to the point of beginning.

Designated altitudes. Surface to 15,000 feet MSL.

Time of designation. 0600-2400 local time daily; other times by NOTAM.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding General, MCB Camp Pendleton, CA.

**R-2503C Camp Pendleton, CA [New]**

Boundaries. Beginning at lat. 33°24'23" N., long. 117°15'18" W.; to lat. 33°18'41" N., long. 117°23'58" W.; to lat. 33°27'13" N., long. 117°34'17" W.; to lat. 33°30'13" N., long. 117°29'16" W.; to the point of beginning.

Designated altitudes. 15,000 feet MSL to FL 270.

Time of designation. Intermittent by NOTAM at least 24 hours in advance, and with the concurrence of the controlling agency, not to exceed 40 hours annually.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding General, MCB Camp Pendleton, CA.

**R-2533 Oceanside, CA [Removed]**

Issued in Washington, DC, on August 29, 1994.

Nancy B. Kalinowski,

Acting Manager, *Airspace-Rules and Aeronautical Information Division.*

[FR Doc. 94-21982 Filed 9-6-94, 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 177

[Docket No. 91F-0449]

#### Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of hydrogenated butadiene/acrylonitrile copolymers in repeated use food-contact articles. This action is in response to a petition filed by Polysar Rubber Corp.

**DATES:** Effective September 7, 1994; written objections and requests for a

hearing by October 7, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 177.2600(c)(4)(i), effective September 7, 1994.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of December 19, 1991 (56 FR 65907), FDA announced that a food additive petition (FAP 2B4299) had been filed by Polysar Rubber Corp., 1265 South Vidal St., Sarnia, Ontario, Canada N7T 7M1. The petition proposed that the food additive regulations be amended in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) to provide for the safe use of hydrogenated butadiene/acrylonitrile copolymers in repeated use food-contact articles.

FDA, in its evaluation of the safety of this additive, reviewed the safety of the additive and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted acrylonitrile, a carcinogenic reactant used in the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as acrylonitrile, are commonly found as contaminants in chemical products, including food additives.

#### I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The anticancer or Delaney clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal.

Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive (*Scott v. FDA* 728 F.2d 322 (6th Cir. 1984)).

#### II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, hydrogenated butadiene/acrylonitrile copolymer, will result in exposure to the additive of no greater than 7 parts per trillion (ppt) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from acute toxicity studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by acrylonitrile, a carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of acrylonitrile has two aspects: (1) Assessment of the exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

#### A. Acrylonitrile

FDA has estimated the worst-case exposure to acrylonitrile from the petitioned use of the additive in the manufacture of repeated use food-contact articles to be 0.02 ppt of the daily diet (3 kilograms) or 0.06 nanogram (ng) per person per day (Ref. 1). The agency used data from two carcinogenicity studies on acrylonitrile monomer fed to rats to estimate the upper-bound limit of lifetime human risk from exposure to this chemical stemming from the proposed use of hydrogenated butadiene/acrylonitrile copolymers and the level of acrylonitrile that may be present in the additive (Ref. 3). The results of the bioassays on acrylonitrile monomer demonstrated that the material was carcinogenic for

rats under the conditions of the studies. The test material caused significantly increased incidences of carcinogenic tumors at many tissue sites.

Based on the estimated worst-case exposure of 0.06 ng per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from the use of the hydrogenated butadiene/acrylonitrile copolymers is  $8 \times 10^{-11}$  or 8 in 100 billion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime averaged individual daily exposure to acrylonitrile is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to acrylonitrile would result from the proposed use of hydrogenated butadiene/acrylonitrile copolymers.

#### B. Conclusion on Safety

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive in repeated use food-contact articles is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 177.2600 should be amended as set forth below.

#### C. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of acrylonitrile impurity in the food additive. The agency finds that a specification is not necessary for the following reasons: (1) Because of the low level at which acrylonitrile may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely small levels; and (2) the upper-bound limit of lifetime risk from exposure to this impurity, even under worst-case assumptions, is very low, less than 8 in 100 billion.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

### III. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 7, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch (HFS-247) to the Indirect Additives Branch, FDA (HFS-216), concerning FAP 2B4299 (Polysar Rubber Corp.) and exposure to the food additive and its component (acrylonitrile), November 24, 1992.

2. Kososki, C. J., "Regulatory Food Additive Toxicology," in *Chemical Safety Regulation and Compliance*, edited by F.

Homburger, J. K. Marquis, and S. Karger, New York, NY, pp.24-33, 1985.

3. Memorandum of the Cancer Assessment Committee, Center for Food Safety and Applied Nutrition, FDA, on "Acrylonitrile Risk Assessment," dated November 24, 1981.

4. Memorandum from the Quantitative Risk Assessment Committee, Center for Food Safety and Applied Nutrition, FDA, concerning acrylonitrile (FAP 2B4299), dated April 19, 1993.

### List of Subjects in 21 CFR Part 177

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 177 is amended as follows:

### PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.2600 is amended in paragraph (c)(4)(i) by alphabetically adding a new entry to read as follows:

#### § 177.2600 Rubber articles intended for repeated use.

\* \* \* \* \*

(c) \* \* \*

(4) \* \* \*

(i) \* \* \*

Hydrogenated butadiene/acrylonitrile copolymers (CAS Reg. No. 88254-10-8) produced when acrylonitrile/butadiene copolymers are modified by hydrogenation of the olefinic unsaturation to leave not more than 10 percent *trans* olefinic unsaturation and no  $\alpha$ , $\beta$ -olefinic unsaturation as determined by a method entitled "Determination of Residual  $\alpha$ , $\beta$ -Olefinic and *Trans* Olefinic Unsaturation Levels in HNBR," developed October 1, 1991, by Polysar Rubber Corp., 1256 South Vidal St., Sarnia, Ontario, Canada N7T 7M1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

\* \* \* \* \*

Dated: August 24, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94-21900 Filed 9-6-94; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 117

[CGD05-94-072]

RIN 2115-AE47

#### Drawbridge Operations Regulations; Pamunkey River, West Point, VA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

**SUMMARY:** The Coast Guard is changing the regulations governing the operation of the Eltham drawbridge, SR 33, across Pamunkey River, mile 1.0, located in West Point, Virginia, by restricting commercial fishing and crabbing vessels and recreational vessels from opening the bridge between the hours of 7 a.m. to 9 a.m., 12 noon to 1 p.m. and 4 p.m. to 6 p.m. The remaining times those vessels are restricted to opening the bridge on the hour, Monday through Friday, except Federal holidays.

This is intended to provide for regulatory scheduled drawbridge openings to help reduce motor vehicle traffic delays and congestion on the roads and highways linked by this drawbridge, while still providing for the reasonable needs of navigation.

**EFFECTIVE DATE:** This rule is effective on October 7, 1994.

**FOR FURTHER INFORMATION CONTACT:** Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, (804) 398-6222.

#### SUPPLEMENTARY INFORMATION:

##### Drafting Information

The principal persons involved in drafting this document are Bill H. Brazier, Project Officer, and LT Monica L. Lombardi, Project Attorney, Fifth Coast Guard District.

##### Regulatory History

On May 20, 1994, the Coast Guard published a Supplemental Notice of Proposed Rulemaking entitled Pamunkey River, West Point, Virginia, in *Federal Register* (59 FR 25474). The comment period ended July 19, 1994. The Coast Guard received three letters commenting on the proposal. Prior to publishing the Supplemental Notice of Proposed Rule, the Coast Guard also published Public Notice 5-818 and the

original Notice of Proposed Rulemaking entitled Pamunkey River, West Point, Virginia, in *Federal Register* (58 FR 62303). The comment period ended January 10, 1994. The Coast Guard received 66 letters commenting on the proposal.

##### Background and Purpose

The original Notice of Proposed Rule announced that a proposal was being considered to restrict openings of the Eltham Bridge to all vessels during morning, noon, and evening rush hours, between the hours of 7 a.m. to 9 a.m., 12 noon to 1 p.m. and 4 p.m. to 6 p.m., Monday through Friday; except Federal holidays.

As a result of the proposed rule and the public notice, comments were received from the maritime community and the motoring public. The motorists all were in favor of the proposed restrictions during peak traffic hours to reduce traffic disruption, delays, congestion and minor accidents. The commercial marine industry was opposed to restricting the openings, based on economic impact concerns, safety and tidal navigational requirements.

Following further investigation by the Coast Guard, it was determined that the major cause of traffic congestion due to bridge lifts for the Eltham Bridge was contributed by commercial fisherman, crabbers and recreational boaters requesting frequent bridge lifts during rush hour traffic periods. These mariners, for the most part, could pass through without a bridge lift, by lowering their antennae. The remainder of the maritime industry, consisting of piloted vessels and large tugs and barges, passing through this bridge is very sporadic. The bridge tender's logs only reflected 4 or 5 bridge lifts per month for these vessels.

The Virginia Department of Transportation, in an effort to improve this situation, has requested these revised regulations. It agreed to changing the original request by excluding larger classes of maritime vessels from the restrictions, and to placing new restrictions on commercial fishing and crabbing vessels and recreational vessels which create most of the problem.

##### Discussion of Comments and Change

The three comments received as a result of the Supplemental Notice of Proposed Rule issued by the District Commander are all in favor of the new restrictions for the Eltham Bridge. No new or additional changes are being made to the regulatory language of this final rule.

##### Regulatory Evaluation

This action is not considered a significant regulatory action under Executive Order 12866 and is not significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary.

This opinion is based on the fact that the regulations will not unduly cause a hardship on commercial/military vessels who will be able to plan their vessel transits around the hours of restriction.

##### Small Entities

No comments were received concerning small entities or on the economic impact this rule would have on small entities. Since the impact on these regulations is expected to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C. et seq.), that this final rule will not have a significant economic impact on a substantial number of small entities.

Even though commercial crabbers and small fishing vessel operators would be restricted under the proposed regulations, the Coast Guard believes the proposed opening schedule for these operators is not unduly restrictive. These vessel operators can still crab and fish, but they will have to time their requests for openings of the bridge to coincide with the proposed new schedule. This should not cause any economic hardship. Because it expects the impact of this proposal to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

##### Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

##### Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

##### Environment

The Coast Guard considered the environmental impact of this proposal and concluded that under section 2.B.2.g.(5) of Commandant Instruction M16475.1B, this rule is categorically