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# federal register

Monday
December 18, 1995

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[Two Sessions]

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**New Feature in the Reader Aids!**
Beginning with the issue of December 4, 1995, a new listing will appear each day in the Reader Aids section of the Federal Register called ''Reminders''. The Reminders will have two sections: ''Rules Going Into Effect Today'' and ''Comments Due Next Week''. Rules Going Into Effect Today will remind readers about Rules documents published in the past which go into effect ''today''. Comments Due Next Week will remind readers about impending closing dates for comments on Proposed Rules documents published in past issues. Only those documents published in the Rules and Proposed Rules sections of the Federal Register will be eligible for inclusion in the Reminders.
The Reminders feature is intended as a reader aid only. Neither inclusion nor exclusion in the listing has any legal significance.
The Office of the Federal Register has been compiling data for the Reminders since the issue of November 1, 1995. No documents published prior to November 1, 1995 will be listed in Reminders.

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 906

**[Docket No. FV95–906–3–FIR]**

### Oranges and Grapefruit Grown in the Lower Rio Grande Valley in Texas; Final Rule To Temporarily Relax Size Requirements for Texas Grapefruit

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Department of Agriculture (Department) is adopting as a final rule, without change, the provisions of an interim final rule which temporarily relaxed the minimum size requirements for Texas grapefruit for the entire 1995–96 season. This interim final rule is designed to help the Texas citrus industry successfully market the 1995–96 season grapefruit crop.

**EFFECTIVE DATE:** January 17, 1996.

**FOR FURTHER INFORMATION CONTACT:** Charles L. Rush, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456; telephone: 202–690–3670; or Belinda G. Garza, McAllen Marketing Field Office, USDA/AMS, 1313 East Hackberry, McAllen, Texas 78501; telephone: 210–682–2833.

**SUPPLEMENTARY INFORMATION:** This final rule is issued under Marketing Agreement and Marketing Order No. 906 (7 CFR Part 906) regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas, hereinafter referred to as the order. This order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is not intended to have retroactive effect. This final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 15 citrus handlers subject to regulation under the order covering oranges and grapefruit grown in Texas, and approximately 1,500 producers of these citrus fruits in Texas. Small agricultural service firms, which includes grapefruit handlers, have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those whose annual receipts are less than $500,000. A majority of these handlers and producers may be classified as small entities.

This rule finalizes the temporary relaxation of the minimum size requirements for grapefruit as prescribed under the Texas citrus marketing order. The rule provides that pack size 112 grapefruit may be shipped throughout the entire 1995–96 season if such grapefruit grade at least U.S. No. 1. This relaxation is similar to the relaxations which were issued for the 1993–94 and 1994–95 seasons. This relaxation was unanimously recommended by the Texas Valley Citrus Committee (TVCC).

The interim final rule was issued on October 17, 1995, and published in the October 23, 1995, Federal Register (60 FR 54291), providing a 30-day comment period ending November 22, 1995. No comments were received.

Minimum grade and size requirements for fresh grapefruit grown in Texas are in effect under § 906.365 (7 CFR 906.365). This rule amends § 906.365 by revising paragraph (a)(4) to permit shipment of grapefruit measuring at least 3 5/16 inches in diameter (pack size 112) and grading at least U.S. No. 1 for the entire 1995–96 season ending June 30, 1996.

Section 906.365 establishes minimum size requirements for Texas grapefruit. During the period November 16 through January 31 each season, grapefruit must be at least pack size 96, that is the minimum diameter for the grapefruit in any lot is 3 9/16 inches. At other times, grapefruit that is pack size 112, except that the minimum diameter for grapefruit in any lot is 3 5/16 inches, may be shipped if it grades at least U.S. No. 1. The minimum grade requirement for grapefruit is Texas Choice.

Permitting shipments of pack size 112 grapefruit grading at least U.S. No. 1 for the remainder of the 1995–96 season will enable Texas grapefruit handlers to meet market needs and compete with similar sized grapefruit expected to be shipped from Florida.

The relaxation is expected to help the Texas citrus industry successfully market its 1995–96 season grapefruit crop and have a positive effect on producer returns. Permitting shipments of pack size 112 grapefruit grading at least U.S. No. 1 for the entire 1995–96

season will enable Texas grapefruit handlers to meet market needs. This final rule is based on the current and prospective crop and market conditions for Texas grapefruit. Fresh Texas grapefruit shipments began in late September this season.

Based on the above, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the TVCC and other available information, it is found that finalizing this rule without change, as published in the Federal Register (60 FR 54291, October 23, 1995) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 906 is amended as follows:

## PART 906—ORANGES AND GRAPEFRUIT GROWN IN THE LOWER RIO GRANDE VALLEY IN TEXAS

Accordingly, the interim final rule amending 7 CFR part 906 which was published at 60 FR 54291 on October 23, 1995, is adopted as a final rule without change.

Dated: December 12, 1995.

Sharon Bomer Lauritsen,

*Deputy Director, Fruit and Vegetable Division.*

[FR Doc. 95–30672 Filed 12–15–95; 8:45 am]

**BILLING CODE 3410–02–P**

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## 7 CFR Part 984

**[Docket No. FV95–984–2FIR]**

## Walnuts Grown in California; Expenses and Assessment Rate

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Department of Agriculture (Department) is adopting as a final rule, without change, the provisions of an interim final rule that authorized expenses and established an assessment rate that generated funds to pay those expenses. Authorization of this budget enables the Walnut Marketing Board (Board) to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

**EFFECTIVE DATE:** August 1, 1995, through July 31, 1996.

**FOR FURTHER INFORMATION CONTACT:** Martha Sue Clark, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, PO. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone 202–720–9918, or Mark A. Hessel, California Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, Suite 102B, 2202 Monterey Street, Fresno, CA 93721, telephone 209–487–5901.

**SUPPLEMENTARY INFORMATION:** This rule is issued under Marketing Agreement and Order No. 984, both as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the provisions of the marketing order now in effect, California walnuts are subject to assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable walnuts handled during the 1995–96 marketing year, which began August 1, 1995, and ends July 31, 1996. This final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling not later than 20 days after the date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 5,000 producers of California walnuts under this marketing order, and approximately 65 handlers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. The majority of California walnut producers and handlers may be classified as small entities.

The budget of expenses for the 1995–96 marketing year was prepared by the Walnut Marketing Board, the agency responsible for local administration of the marketing order, and submitted to the Department for approval. The members of the Board are producers and handlers of California walnuts. They are familiar with the Board's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the Board was derived by dividing anticipated expenses by expected merchantable certifications of California walnuts. Because that rate will be applied to the actual quantity of certified merchantable walnuts, it must be established at a rate that will provide sufficient income to pay the Board's expenses.

The Board met September 8, 1995, and unanimously recommended a 1995–96 budget of $2,280,175, $109,403 more than the previous year. Budget items for 1995–96 which have increased compared to those budgeted for 1994–95 (in parentheses) are: Field travel and relates expenses, $17,000 ($13,000), general insurance, $6,800 ($6,400), social security and hospital insurance taxes, $9,286 ($8,129), audit, $8,900, ($8,700), group life, retirement, and medical, $45,861 ($44,370), office

salaries, $41,740 ($40,740), office rent, $27,168 ($26,419), office supplies and miscellaneous, $20,000 ($15,000), postage, $7,000 ($5,000), furniture, fixtures, and automobiles, $25,000 ($5,000), domestic market research and development, $998,000 ($953,000), walnut production research, $718,420 ($718,302), crop estimate, $67,000 ($60,000), and $30,000 for the reserve for contingencies, for which no funding was recommended last year. Items which have decreased compared to the amount budgeted for 1994–95 (in parentheses) are: Administrative salaries, $99,000 ($101,712), and production research director, $34,000 ($40,000). All other items are budgeted at last year's amounts.

The Board also unanimously recommended an assessment rate of $0.0116 per kernelweight pound of merchantable walnuts certified, $0.0005 more than the previous year. This rate, when applied to anticipated shipments of 1,980,000 kernelweight pounds of merchantable walnuts, will yield $2,296,800 in assessment income, which will be adequate to cover budgeted expenses. Unexpended funds may be used temporarily during the first five months of the subsequent marketing year, but must be made available to the handlers from whom collected within that period.

An interim final rule was published in the Federal Register on October 30, 1995 (60 FR 55178). That interim final rule added § 989.346 to authorize expenses and establish an assessment rate for the Committee. That rule provided that interested persons could file comments through November 29, 1995. No comments were received.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived by the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register (5 U.S.C. 553) because the Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis. The 1995–96 fiscal period began on August 1, 1995. The marketing order requires that the rate of assessment for the fiscal period apply to all assessable walnuts handled during the fiscal period. In addition, handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and published in the Federal Register as an interim final rule.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR part 984 is amended as follows:

## PART 984—WALNUTS GROWN IN CALIFORNIA

Accordingly, the interim final rule amending 7 CFR part 984 which was published at 60 FR 55178 on October 30, 1995, is adopted as a final rule without change.

Dated: December 12, 1995.

Sharon Bomer Lauritsen,

*Deputy Director, Fruit and Vegetable Division.*

[FR Doc. 95–30673 Filed 12–15–95; 8:45 am]

BILLING CODE 3410–02–P

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## 7 CFR Part 1212

**[FV–95–703]**

## Lime Research, Promotion, and Consumer Information Order

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule; termination order.

**SUMMARY:** This document removes the Lime Research, Promotion, and Consumer Information Order (Order) in its entirety. A referendum was conducted in November 1995 to determine whether continuance of the Order was favored by a majority of the producers, producer-handlers, and importers voting in the referendum. A majority of the persons voting in the referendum did not favor continuance of the Order.

**EFFECTIVE DATE:** December 18, 1995.

**FOR FURTHER INFORMATION CONTACT:** Richard B. Schultz, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, Box 96456, Room 2535–S, Washington, D.C. 20090–6456, telephone (202) 720–5976.

**SUPPLEMENTARY INFORMATION:**

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This termination order has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this termination order.

This action is governed by section 1960 of the Lime Research, Promotion, and Consumer Information Act of 1990, as amended (Act). Section 1960 of the Act provides that the Secretary of Agriculture (Secretary) shall conduct a referendum not later than 30 months after the date on which the collection of assessments begins to determine whether the issuance of the Order is favored by a majority of the producers, producer-handlers, and importers voting in the referendum. Paragraph (b) of section 1960 of the Act requires that the Order continue in effect only if favored by such majority.

Background

The Lime Research, Promotion, and Consumer Information Act of 1990 (1990 Act) (Pub. L. 101–624, 7 U.S.C. 6201–6212) was enacted on November 28, 1990, for the purpose of establishing an orderly procedure for the development and financing of an effective and coordinated program of research, promotion, and consumer information to strengthen the domestic and foreign markets for limes. The Order required by the 1990 Act became effective on January 27, 1992 (57 FR 2985), after notice and comment rulemaking.

In March 1992 the Department conducted nomination meetings to nominate lime producers and importers for appointment to the Lime Board (Board). The Board members were appointed by the Secretary in September 1992 and the Board conducted its first meeting at the Department in Washington, D.C. in October 1992. During the course of this meeting, the Board and the Department concluded that a technical amendment to the 1990 Act was needed before an order could be implemented. Consequently, full implementation of the Order was delayed until the enactment of such technical amendment.

The Lime Research, Promotion, and Consumer Information Improvement Act (1993 Act) (Pub. L. 103–194, Dec. 14, 1993) contained the necessary technical amendment to properly cover the regulated commodity. The 1993 Act also provided for increasing the exemption level from less than 35,000

pounds annually to less than 200,000; terminating the initial Board; changing the size and composition of the Board; and delaying the initial referendum date.

A proposed rule was published in the April 7, 1994, issue of the Federal Register (58 FR 3446) inviting comments on amending the Order to reflect the provisions of the 1993 Act. A final rule was published in the February 8, 1995, issue of the Federal Register (60 FR 7435).

In March 1995, as a result of terminating the initial Board under the 1993 Act, the Department conducted nomination meetings to nominate lime producers and importers for appointment to the new Board. The Board members were appointed by the Secretary in June 1995 and the newly constituted Board met at the Department in Washington, D.C. in August 1995. At this meeting, amid concern over the changing character of the lime industry, the Board voted that a referendum be conducted before the Order is fully implemented to determine industry support.

Since the enactment of the 1990 Act, the character of the lime industry has significantly changed. As a result of the extensive damage to lime orchards in Florida by Hurricane Andrew in August 1992, domestic production has plummeted and the volume of imports has increased dramatically. Domestic production is not expected to reach pre-Hurricane Andrew levels for several more years because Florida accounted for a majority of domestic production. Imports currently represent roughly 94 percent of lime shipments in the United States.

In response to the Board's vote, an interim final rule with request for comments containing a referendum order and procedures was published in the October 11, 1995, issue of the Federal Register (60 FR 52835). No comments were received.

A representative period from September 1, 1994, through August 31, 1995, was established to determine voter eligibility in the referendum. Persons who produced, produced and handled, or imported 200,000 more pounds of limes for the fresh market during this period were eligible to vote. A voting period from November 1, 1995, through November 15, 1995, was established to allow eligible persons an opportunity to vote.

Continuance of the Order was favored by only 28 percent of the producers, producer-handlers, and importers casting valid ballots in the referendum. Thus, it is found and determined that a majority of persons casting valid ballots in the referendum do not favor continuance of the Order. Accordingly, it is found and determined that the Order does not tend to effectuate the declared policy of the Act. For these reasons, in accordance with the provisions of the Act, this action will terminate 7 CFR 1212 in its entirety.

It is also found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register because: (1) A continuance referendum was conducted in November 1995 and a majority of persons voting in the referendum did not favor continuance of the Order; (2) it has been determined that the Order does not tend to effectuate the declared policy of the Act; and (3) no useful purpose would be served in delaying the effective date of the termination order.

Termination Order

*It is, therefore, ordered,* That 7 CFR part 1212 is hereby terminated effective on December 18, 1995.

List of Subjects in 7 CFR Part 1212

Administrative practice and procedure, Advertising, Limes, Marketing agreements, Reporting and recordkeeping requirements.

## PART 1212—[REMOVED]

For the reasons set forth in the preamble, and under the authority of 7 U.S.C. 6201–6212, 7 CFR Part 1212 is removed.

Dated: December 12, 1995,

Lon Hatamiya,

*Acting Assistant Secretary, Marketing and Regulatory Programs.*

[FR Doc. 95–30671 Filed 12–15–95; 8:45 am]

BILLING CODE 3410–02–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Airspace Docket No. 95–AWP–29]**

## Amendment of Class E Airspace; Bullhead City, AZ

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends the Class E airspace area at Bullhead City, AZ. Additional controlled airspace is required for aircraft executing instrument approach procedures at Laughlin/Bullhead International Airport. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Laughlin/Bullhead International Airport, Bullhead City, AZ.

**EFFECTIVE DATE:** 0901 UTC February 29, 1996.

**FOR FURTHER INFORMATION CONTACT:** Scott Speer, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6533.

**SUPPLEMENTARY INFORMATION:**

History

On October 20, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Bullhead City, AZ (60 FR 54205).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at Bullhead City, AZ. The intended effect of this action is to provide adequate Class E Airspace for aircraft executing the Standard Instrument Approach Procedure at Laughlin/Bullhead International Airport, Bullhead City, AZ.

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. Therefore, this regulation—(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 10034; 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.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

## PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

AWP CA E5 Bullhead City, AZ [Revised]

Laughlin/Bullhead International Airport, AZ
(lat. 35°09′27″ N, long. 114°33′34″ W)
Needles VORTAC, CA
(lat. 34°45′58″ N, long, 114°28′27″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the Laughlin/Bullhead International Airport and within 3 miles each side of the Needle VORTAC 350° radial extending from the 6-miles radius to 10 miles south of the Laughlin/Bullhead International Airport. That airspace extending upward from 1,200 feet above the surface within the area bounded by a line beginning a lat. 34°55′00″ N, long. 114°36′00″ W; to lat. 35°07′00″ N, long. 115°00′00″ W; to lat. 35°16′00″ N, long, 115°10′00″ W; to lat. 35°30′00″ N, long. 114°47′00″ W, thence to the point of beginning.

* * * * *

Issued in Los Angeles, California, on December 1, 1995.

James H. Snow,

*Acting Manager, Air Traffic Division, Western-Pacific Region.*

[FR Doc. 95–30692 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF EDUCATION

## Office of Postsecondary Education

## 34 CFR Part 682

## Federal Family Education Loan Program eligible borrowers

*CFR Correction*

In Title 34 of the Code of Federal Regulations, part 400 to end, revised as of July 1, 1995, on page 680, second column, the text designated as § 682.201 (a)(8) is correctly designated as § 682.201 (b)(8) and should appear on page 681, in the second column before paragraph (c).

BILLING CODE 1505–01–D

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 93–174; RM–8263]**

## Radio Broadcasting Services; Owensville and Versailles, MO

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document substitutes Channel 236C3 for Channel 236A at Versailles, Missouri, and modifies the license for Station KLGS(FM), in response to a petition filed by Twin Lakes Communications, Inc. *See* 58 FR 35421, July 1, 1993. The coordinates for Channel 236C3 at Versailles are 38–23–27 and 92–38–06. We shall also make an editorial change in the FM Table of Allotments for Owensville, Missouri, deleting Channel 237C2 and adding Channel 237A in accordance with the Commission's Rules. *See* letter dated March 17, 1995, from the Chief, Audio Services Division, cancelling the construction permit for Station KLZE(FM), Channel 237C2. Public notice of this action was given on March 29, 1995. With this action, this proceeding is terminated.

**EFFECTIVE DATE:** January 25, 1996.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Report and Order,* MM Docket No. 93–174, adopted November 30, 1995, and released December 11, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC. 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

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

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 237C2 and adding Channel 237A at Owensville and by removing Channel 236A and adding Channel 236C3 at Versailles.

Federal Communications Commission.

John A. Karousos,

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Docs. 95–30616 Filed 12–15–95; 8:45 am]

BILLING CODE 6712–01–F

## 47 CFR Part 73

**[MM Docket No. 94–78; RM–8472; RM–8525]**

## Radio Broadcasting Services; Cloverdale, Montgomery and Warrior, AL

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document dismisses a petition for rule making to Channel 254A to Cloverdale, Alabama, as that locality's first local aural transmission service as requested by Pulaski Broadcasting, Inc. (RM–8472). The proposal is dismissed based upon the failure of the petitioner or any other interested party to demonstrate that Cloverdale constitutes a *bona fide* community for purposes of Section 307(b) of the Communications Act for allotment objectives. *See* 59 FR 36735, July 19, 1994. Additionally, in response to a mutually exclusive joint counterproposal, this document substitutes Channel 254C1 for Channel 254C3 at Warrior, Alabama, and modifies the license of North Jefferson Broadcasting Company, Inc. for Station WLBI(FM). Further, to accommodate the

Warrior allotment, Channel 255C1 is substituted for Channel 255C at Montgomery, Alabama, and the license of Deep South Broadcasting Company, Inc. for Station WBAM-FM is modified accordingly (RM–8525).

Coordinates used for Channel 254C1 at Warrior, Alabama, are 33–44–30 and 86–48–30. Coordinates used for Channel 255C1 at Montgomery, Alabama, are 32–14–45 and 86–07–30. With this action, the proceeding is terminated.

**EFFECTIVE DATE:** January 25, 1996.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Report and Order*, MM Docket No. 94–78, adopted November 30, 1995, and released December 11, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, located at 1919 M Street, NW., Room 246, or 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

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

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by removing Channel 255C and adding Channel 255C1 at Montgomery; and by removing Channel 254C3 and adding Channel 254C1 at Warrior.

Federal Communications Commission.

John A. Karousos,

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 95–30614 Filed 12–15–95; 8:45 am]

BILLING CODE 6712–01–F

# Proposed Rules

Federal Register
Vol. 60, No. 242
Monday, December 18, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Parts 1005, 1011, and 1046

**[Docket No. AO–388–A8 et al.; DA–94–12]**

### Milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville Marketing Areas; Decision on Proposed Amendments to Marketing Agreements and to Orders

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

| 7 CFR part | Marketing area | AO Nos. |
|---|---|---|
| 1005 | Carolina ..... | AO–388–A8 |
| 1011 | Tennessee Valley ... | AO–251–A39 |
| 1046 | Louisville-Lexington-Evansville. | AO–123–A66 |

**SUMMARY:** This final decision proposes to amend the pooling standards of the Tennessee Valley and Carolina orders; modifies the marketing areas of the Tennessee Valley and Louisville-Lexington-Evansville orders; changes the location adjustment under the Carolina order for plants located in the Middle Atlantic marketing area; and changes the base-paying months under the Carolina order. The decision is based upon industry proposals presented at a public hearing in Charlotte, North Carolina, on January 4, 1995.

**FOR FURTHER INFORMATION CONTACT:** Nicholas Memoli, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 690–1932.

**SUPPLEMENTARY INFORMATION:** This administrative action is governed by the provisions of Sections 556 and 557 of Title 5 of the United States Code and therefore is excluded from the requirements of Executive Order 12866.

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this rule will not have a significant economic impact on a substantial number of small entities. The amended orders will promote more orderly marketing of milk by producers and regulated handlers.

These proposed amendments have been reviewed under Executive Order 12778, Civil Justice Reform. This rule is not intended to have a retroactive effect. If adopted, this proposed rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law and requesting a modification of an order or to be exempted from the order. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Prior documents in this proceeding;

Notice of Hearing: Issued November 21, 1994; published November 25, 1994 (59 FR 60574).

Recommended Decision: Issued August 17, 1995; published August 24, 1995 (60 FR 43986).

Preliminary Statement

A public hearing was held upon proposed amendments to the marketing agreements and the orders regulating the handling of milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice (7 CFR Part 900), at Charlotte, North Carolina, on January 4, 1995. Notice of such hearing was issued on November 21, 1994, and published November 25, 1994 (59 FR 60574).

Upon the basis of the evidence introduced at the hearing and the record thereof, the Administrator, on August 17, 1995, issued a recommended decision containing notice of the opportunity to file written exceptions thereto. Two comments were received in response to the notice, both of which fully support the findings and conclusions of the recommended decision.

The material issues, findings and conclusions, rulings, and general findings of the recommended decision are hereby approved and adopted and are set forth in full herein, with no material modifications.

The material issues on the record of the hearing relate to:

1. Marketing area modifications to the Tennessee Valley and Louisville-Lexington-Evansville orders;
2. Where to regulate a distributing plant that meets the pooling standards of more than one order;
3. Supply plant pooling standards under the Tennessee Valley order;
4. Distributing plant pooling standards under the Carolina order;
5. Location adjustments under the Carolina order; and
6. Base-paying months under the Carolina order.

Findings and Conclusions

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

*1. Marketing Area Modifications to the Tennessee Valley (Order 11) and Louisville-Lexington-Evansville (Order 46) Orders*

Six now-unregulated Kentucky counties between the Order 11 and Order 46 marketing areas should be added to the Order 11 marketing area and one county that is now part of the Order 46 marketing area should be removed and added to the Order 11 marketing area.

A spokesman for Southern Belle Dairy Company, Inc., testified that the six unregulated counties—Clay, Jackson, Laurel, McCreary, Owsley, and Rockcastle—and the one Order 46

county—Pulaski—are in an area that is closely associated with the Tennessee Valley marketing area. He pointed out, for example, that two Order 11 pool plants—the Flav-O-Rich plant at London and the Southern Belle plant at Somerset—are in Laurel and Pulaski Counties, respectively.

The witness indicated that Southern Belle had sales in each of the counties proposed to be added to the marketing area. He also introduced data showing that 79 percent of the fluid milk sales in the seven-county area came from the Southern Belle and Flav-O-Rich plants. He said that a majority of the sales in Pulaski County also came from Order 11 plants.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The six now-unregulated Kentucky counties should be added to the Order 11 marketing area and Pulaski County should be removed from the Order 46 marketing area and added to the Order 11 marketing area. This seven-county area is closely associated with the Tennessee Valley market and its addition to the Order 11 marketing area, in conjunction with the pooling standards adopted in this decision, will add regulatory stability for the plants with sales in this area. There are no plants in this seven-county area other than the Southern Belle and Flav-O-Rich plants and none outside of this area that would become regulated as a result of the addition of this territory to the Tennessee Valley marketing area.

A conforming change should be made in § 1011.52(a)(3) to include the counties of Jackson, Owsley, and Rockcastle with the other Kentucky counties now included in the minus 32-cent location adjustment zone. Although there are no plants located in these three counties, should a plant be built there the appropriate location adjustment should be minus 32 cents, the same location adjustment that is applicable in the neighboring counties of Laurel, Pulaski, Clay, and Breathitt.

*2. Where To Regulate a Distributing Plant That Meets the Pooling Standards of More Than One Order*

The pooling standards of the Tennessee Valley and Carolina orders should be modified to fully regulate a distributing plant that is located within their respective marketing areas and that meets the pooling standards of §§ 1011.7(a) or 1005.7(a), respectively, even if the plant meets the pooling standards of another order and has more route disposition in such other order's marketing area.

These amendments will allow a distributing plant at Kingsport, Tennessee, that is located within the Tennessee Valley marketing area and that meets all of the pooling standards of the Tennessee Valley order to be regulated under that order rather than under the Carolina order, despite the plant's having greater sales in the Carolina marketing area. Similarly, they will allow a distributing plant located at Somerset, Kentucky—which, as recommended under Issue No. 1, would be part of the Order 11 marketing area—to be regulated under Order 11 even if the plant should develop greater sales in the marketing area of Order 46 or some other order's marketing area. Finally, the amendments will permit a plant located at Greenville, South Carolina (in the Order 5 marketing area), to be regulated under Order 5 even if the plant has more sales in the Southeast marketing area (Order 7).

These amendments and the proposals which prompted them stem from various pricing problems under these orders that have come about for a variety of reasons, including the fact that the marketing areas may not have grown as fast as handlers' distribution areas. The pricing problems identified on the record of this proceeding relate to Land-O-Sun Dairies, Inc., at Kingsport, Tennessee; Southern Belle Dairy Company at Somerset, Kentucky; and Superbrand Dairy Products, Inc., at Greenville, South Carolina.

Land-O-Sun Dairies, Inc., operates a plant at Kingsport, Tennessee, which is in the Tennessee Valley marketing area. Because of this plant's greater route disposition in the Carolina marketing area, it has been regulated under that order. During the past three years (January 1992–November 1994), the blend price at Kingsport under Order 5 has averaged 14 cents below the blend price at that location under Order 11. In some months, the difference has been as high as 32 cents. Although the Class I price at Kingsport is identical under both of these orders, the Tennessee Valley order's higher Class I utilization—e.g., 82.03 percent for Order 11 compared to 77.96 percent for Order 5 during the first 10 months of 1994—has led to a higher blend price under that order at Kingsport during nearly every month for the past three years.

A spokesman for Land-O-Sun testified that the Kingsport plant handles approximately 12 million pounds of milk per month and that about one-third of its Class I sales are distributed on routes within the Tennessee Valley marketing area and the remaining two-thirds within the Carolina marketing area.

The witness testified that Land-O-Sun purchases its raw milk supply from 140 dairy farmers located in northeast Tennessee and southwest Virginia within 100 miles of the Kingsport plant. He noted that this area is also the supply area for other Order 11 pool plants. As a result, he said, any blend price difference to producers in this common supply area leads to market instability. Because the Order 11 blend price is higher than the Order 5 blend price, he stated, Land-O-Sun is forced to pay over-order prices to retain its producers. He indicated that Land-O-Sun could not consistently pay these higher prices and remain a viable business entity.

Southern Belle Dairy at Somerset, Kentucky, has been regulated under Order 11 since 1989. In recent years, the plant has had nearly equal sales in the Order 46 and Order 11 marketing areas. If regulation of the plant had shifted to Order 46, the applicable Class I differential price would be 19 cents lower than under Order 11 (i.e., $2.26 compared to $2.45), but the blend price difference would be even more substantial. For example, in the past 35 months (January 1992–November 1994), the Order 46 blend price averaged 30 cents below the Order 11 blend price at Somerset. In some months during this period, the difference in blend prices was as much as 67 cents.

At the hearing, a Southern Belle spokesman testified that the handler sought the marketing stability that would be provided by regulating the plant under Order 11 based upon its location within the Order 11 marketing area. The spokesman stated that Southern Belle would experience procurement problems if it could only pay its producers the Order 46 blend price in competition with Order 11 handlers—such as the Flav-O-Rich plant at London, Kentucky, 37 miles east of Somerset—which also procure milk from the same supply area. He also cited the marketing instability that would result from the plant shifting back and forth between the two orders, particularly in view of the differing base and excess payment plans to producers in each of these orders.

Superbrand Dairy Products at Greenville, South Carolina, has been regulated under the Georgia order since May 1992 despite the fact that it is located within the marketing area of the Carolina order and meets the pooling standards of that order.

A spokesman for Mid-America Dairymen, Inc. (Mid-Am), which has a full supply contract with the Superbrand plant, testified that the Carolina order should be amended to

provide the same type of pooling standard that has been proposed for the Tennessee Valley order and that was incorporated in the Department's recommended [and final] decisions for the new Southeast order.[1] Inclusion of this provision in each of these orders will provide regulatory compatibility throughout the Southeast, he said.

The witness stated that the Mid-Am proposal would return the Superbrand plant to its former status as a pool plant under Order 5. In terms of its sales and procurement pattern, the plant is more closely associated with the Carolina market, he added.

The Mid-Am spokesman testified that the proposed change in pooling standards is a departure from the traditional method of determining where a distributing plant should be regulated when it meets the pooling standards of more than one order. The traditional method, he explained, regulated a plant wherever it had the most sales. He said that the principle behind that practice was to insure that all handlers having sales in an order area were subject to the same regulatory provisions as their competition. However, he added, with the advent of large processing plants with sales distribution over wide geographic areas, the traditional method of pooling distributing plants has become obsolete.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

For the most part, Federal milk orders have traditionally regulated plants according to where they had the most sales. The reasoning behind that policy has been to ensure that all handlers having sales in a Federal order marketing area were subject to the same minimum prices (adjusted for plant location) and other regulatory provisions as their competition. When these provisions were first incorporated in orders, markets were primarily local in nature. At any given location, it was common for Class I prices to differ among orders, and it was common for each order to have a unique set of provisions.

Most of the provisions in Federal milk orders today are standardized. For example, all orders have uniform classification and allocation provisions. Similarly, most Federal order Class I prices are properly aligned. As noted above, for example, the Class I price at Kingsport, Tennessee, is the same whether Land-O-Sun's plant is regulated under Order 5 or Order 11; the Southern Belle plant at Somerset, Kentucky, would be subject to a higher Class I price under Order 11 than would apply at the plant under Order 46; and the Superbrand plant at Greenville would be subject to the same Class I price whether it was regulated under Order 5 or Order 7.

Consequently, it must be concluded that the competitive equity that was, and continues to be, sought by having competing handlers subject to the same rules and Class I prices can be achieved in these marketing areas by pooling distributing plants under the orders applicable to the marketing areas in which the plants are located. Specifically, the pooling standards of the Tennessee Valley and Carolina orders should be amended to fully regulate all distributing plants that meet the orders' pooling standards and that are located within their respective marketing areas.

Under the provisions adopted here for the Carolina and Tennessee Valley orders, a plant that qualifies as a pool distributing plant and which is located within the marketing area will be regulated under the order applicable to that marketing area even if it meets the pooling standards of another order and has greater sales in such other order's marketing area. The nearby Southeast order, Louisville-Lexington-Evansville order, and Upper Florida order contain provisions (§§ 1007.7(g)(4), 1046.7(e)(3), and 1006.7(d)(3), respectively) that conform to the proposed provisions by yielding regulation of such plants to the other order.

Orders 5 and 11 also should be modified to recognize another order's primacy to regulate a plant that meets such other order's pooling standards and that is within the other order's marketing area. This is accomplished in §§ 1005.7(e)(3) and 1011.7(e)(3).

A clarifying change should also be made to §§ 1005.7(e)(5) and 1011.7(e)(5). At present, these paragraphs, which are designated as §§ 1005.7(d)(4) and 1011.7(d)(4), state that ''the term pool plant shall not apply to a plant qualified pursuant to paragraph (b) of this section which also meets the pooling requirements for the month under another Federal order.'' A problem could arise with this language because during certain months of the year a supply plant may qualify as a pool plant by shipping less than 50 percent of its receipts to distributing plants. For example, if a supply plant shipped 40 percent of its receipts to pool distributing plants under Order 5 and 40 percent of its receipts to distributing plants under Order 11, both orders, pursuant to the language quoted above, would yield regulation of the plant to the other order, leaving the plant in a state of regulatory limbo. To prevent this unlikely event from occurring, the paragraph should be modified to read: ''The term pool plant shall not apply to a plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order.''

*3. Supply Plant Pooling Standards Under the Tennessee Valley Order*

The supply plant pooling provisions for the Tennessee Valley order should be amended to provide automatic pooling status for a supply plant which met the order's shipping standards during the preceding months of July through February.

Armour Food Ingredients Company (Armour) proposed the change in supply plant pooling standards. A spokesman for Armour testified that the company operates a supply plant at Springfield, Kentucky, that has been a pool plant under Order 11 since August 1992. He said that the facility is a ''dual Grade A/Grade B plant.'' The Grade A part of the plant is used to assemble Grade A milk from producers' farms for transshipment to pool distributing plants, while the Grade B facility is used to process surplus milk into Class III products, he explained.

The witness testified that Order 11 now requires Armour to ship milk to distributing plants every month of the year. However, much less milk is needed from Armour during the spring than during the other months of the year, he said. Consequently, he concluded, Armour and its distributing plant customers are incurring receiving and hauling costs for no other purpose than to satisfy the order's shipping requirements.

The witness introduced an exhibit which showed that from August 1992 through October 1994 Armour shipped a monthly average of 71 percent of its receipts to pool distributing plants. The exhibit also showed that when shipments of surplus milk from these same pool distributing plants to Armour were subtracted from the receipts from Armour, the distributing plants, on average, kept 34 percent of the milk that was sent to them.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The provision proposed by Armour is included in many Federal milk orders

[1] Official notice is taken of the final decision for the Southeast order issued on May 3, 1995 (60 FR 25014).

because of the seasonal variation in milk production. This variation is also evident in the Tennessee Valley market. In 1993, the average daily production per producer in this market was 2,220 pounds. However, this daily average reached a low of 1,941 pounds during the month of July and peaked at 2,481 pounds during May. As a group, the months of March through June had a daily average of 2,375 pounds, compared to 2,149 pounds during the months of July through February.

There is no merit in requiring supply plants to receive, reload, and ship milk to distributing plants if the milk is not needed or if closer milk is available directly from producers' farms. In addition to the statistics suggesting that supply plant shipments during the months of March through June are unnecessary, the lack of any contradictory testimony from Order 11 distributing plant operators must be interpreted as concurrence with the view that supply plant shipments are simply not needed during the months of March through June. In view of this evidence, the proposal should be adopted.

Section 1011.7(b)(3) of the Tennessee Valley order, as proposed to be amended here, also should be modified to clarify what would happen if a shipping requirement were instituted during the months of March through June pursuant to § 1011.7(b)(4). First, it should be understood that a new supply plant or one that did not meet the order's shipping requirements during the months of July through February would be subject to the 40 percent supply plant shipping requirement now in the order.

If the market is short of milk during the ''free-ride'' months of March through June and the market administrator determines that additional milk is needed from pool supply plants pursuant to § 1011.7(b)(4), any increase in shipping percentage would be added to the percentage that is then applicable to the plant. For instance, if the market administrator determines that a 10-percentage point increase in shipments is needed, a plant that would have had to ship 40 percent of its receipts would be required to ship 50 percent. However, a plant in ''free-ride'' status, which normally would not have had to make any shipments, would have to ship 10 percent. The market administrator's ability to require additional milk from supply plants, even during the free-ride period of March through June, will help to ensure that the market has adequate supplies of milk for fluid use during all months of the year.

At the present time, §§ 1005.7(b) and 1011.7(b) of the Carolina and Tennessee Valley orders, respectively, authorize the Director of the Dairy Division to adjust supply plant shipping standards to obtain needed shipments of milk or to prevent uneconomic shipments. This provision was not an issue at the hearing. However, in conjunction with the other changes in pooling provisions that were adopted, the recommended decision stated that authority to adjust supply plant shipping standards should be given to the market administrator of Orders 5 and 11. Although interested parties were invited to comment on this, as on other recommendations, no comments were received in opposition to this suggestion.

With all of the marketing information immediately available to him or her, the market administrator is in an ideal position to sense the changing needs of the market and to obtain industry views concerning the desirability of adjusting supply plant shipping requirements. As a result, the market administrator will be able to attend to the need for such temporary revisions in a timely fashion and will be able to better serve the changing needs of handlers and producers under the Carolina and Tennessee Valley orders.

A similar conforming change also should be made in § 1011.13(e)(3) of the Tennessee Valley order for the same reasons. This change will allow the market administrator to increase or decrease, by 10 percentage points, the diversion limitations applicable to a proprietary bulk tank handler.

*4. Distributing Plant Pooling Standards Under the Carolina Order*

Proposals to amend the Order 5 in-area route disposition requirement for pool distributing plants should not be adopted.

At the present time, a distributing plant must dispose of at least 60 percent of its fluid milk product receipts in Class I during the months of August through November, January, and February and at least 40 percent in each of the other months to qualify as a pool plant under Order 5. In addition, at least 15 percent of the plant's route disposition must be in the marketing area.

Milkco, Inc., testified in support of its proposal to change the in-area route disposition standard of Order 5 from 15 percent to 10 percent. At the hearing, Milkco modified its proposal to the lesser of 1500 pounds daily or 10 percent of a plant's fluid milk receipts sold as Class I.

A witness representing Milkco, Carolina Dairies, Hunter Farms, Inc., Dairy Fresh, Inc., and Pine State Creamery testified that the original proposal had been modified to include language similar to that contained in the recommended decision of the proposed Southeast Federal order.

The witness testified that the reason for proposing a change in the in-area route disposition requirement was that partially regulated handlers were constantly increasing their Class I distribution into the Order 5 marketing area. He estimated that the average distribution for 1994 was between 25 million and 35 million pounds. He claimed that this distribution is attributed to sales from partially regulated plants located in Virginia.

The witness explained that the Virginia State Milk Commission prices Class I sales made outside the State of Virginia at the Federal order Class II price. He said that this creates a problem of accountability for those Class I sales moving from Virginia to another state. He claimed that the possibility exists that, in some instances, not all of those sales may be accounted for and paid for at the appropriate price.

The witness stated that the proposed amendment would provide uniformity between Order 5 and surrounding orders. He also claimed that the proposed change would not be burdensome to handlers located in Virginia if these handlers are already paying prices equivalent to, or greater than, the Order 5 Class I price.

The general manager for Carolina Virginia Milk Producers Association (CVMPA) also testified in support of the revised proposal. He stated that the proposal would provide uniformity between Order 5 and neighboring orders and that it would eliminate potential inequities between Order 5 handlers and handlers regulated by the Virginia Milk Commission.

The CVMPA representative asserted that the proposal would regulate some partially regulated plants that may be subject to a lower price for milk used in fluid milk products than fully regulated plants under Order 5. He explained that handlers regulated under Order 5 must pay at least the minimum Federal order class prices for their milk. He claimed that plants located in Virginia and regulated by the Virginia Milk Commission have a competitive advantage on raw milk costs compared to handlers fully regulated under Order 5. The witness indicated that the Class I price established and regulated by the Virginia Milk Commission has historically been higher than the Order 5 price but that the Commission

requires that only the Class II price be paid for sales out of the State.

The CVMPA witness testified that sales from partially regulated handlers located in Virginia into the Carolina marketing area have a significant impact on the market. Since January 1992, he pointed out, sales from these plants have ranged from one to three million pounds of Class I sales or between .84 and 2.26 percent of total route disposition in Order 5. He said that while these Class I sales from Virginia partially regulated plants are confined to a small portion of the marketing area, they have had a disruptive effect on the market in eastern North Carolina.

The CVMPA representative testified that Federal orders contiguous to the Carolina marketing area have more restrictive pool plant requirements than the Carolina order. He noted that the Tennessee Valley order's in-area route disposition requirement was 10 percent and that the recommended Southeast order would fully regulate handlers if a plant distributed either 10 percent of its total fluid milk receipts or at least 1500 pounds of Class I sales per day in the marketing area. Such requirements are appropriate for orders with relatively high Class I utilization, he said.

Maryland & Virginia Milk Producers Cooperative Association, Inc. (MVMPCA), proposed a change to the Order 5 in-area route disposition requirement that would have exactly the opposite effect of Milkco's proposal. The MVMPCA proposal would base the in-area requirement on 15 percent of ''dairy farmer receipts'' rather than 15 percent of ''total route disposition.'' Because dairy farmer receipts would be larger than total route disposition, the proposal would have the effect of making it more difficult to qualify for full regulation under Order 5.

A spokesman for MVMPCA testified that the proposed change would amend the Order 5 provision to conform more closely with the provisions of the Middle Atlantic order (Order 4). He said that these definitions should be more closely aligned to allow distributing plants in the Commonwealth of Virginia, which are partially regulated under both Orders 4 and 5, to be subject to the same in-area route distribution standard under either Federal order.

Without alignment of these provisions, he said, there could be results which are neither intended nor orderly. For instance, he stated, a plant could have more route sales in Order 4 but become fully regulated under Order 5.

The witness stated that there are currently three dairies partially regulated in both Orders 4 and 5: Richfood at Richmond, Virginia; Land-O-Sun Dairies, Inc., at Portsmouth, Virginia; and Marva Maid Dairy at Newport News, Virginia. He said that these Virginia plants are the only partially regulated distributing plants subject to Order 5 other than the several plants which distribute long-shelf-life fluid milk products in a broad geographic area over most of the United States. Consequently, he concluded, the MVMPCA proposal would not have a substantial impact upon any other plants.

A witness representing Richfood Dairy, Inc. (Richfood), Richmond, Virginia, testified in opposition to Milkco's proposal to reduce the Order 5 in-area route disposition requirement and in support of Richfood's proposal to increase the requirement from 15 percent to 20 percent.

The witness stated that Richfood has about 83 percent of its fluid milk product sales in that part of Virginia that is outside the Middle Atlantic (Order 4) marketing area. The plant has approximately 12 percent of its sales in the Carolina marketing area, 4 percent in the Order 4 marketing area, and the remaining 1 or 2 percent in the Ohio Valley marketing area. Richfood's sales into the Carolina marketing area account for about 1 percent of the market's total in-area sales, according to the witness.

The Richfood witness stated that Richfood primarily has fluid milk sales in the eastern Virginia market with some in the western Virginia market. During October 1994, the witness noted, the eastern and western markets' Class I prices were $16.29 and $16.02, respectively. He said that these Virginia prices, based on the way in which Federal order Class I prices are set, would represent October Class I differentials of $4.56 for the eastern market and $4.29 for the western market. Federal order Class I differentials of this magnitude, he emphasized, are not even found in Miami, the highest priced location under the Federal order system. These facts, he claimed, show that purchasers of raw milk in Virginia do not have an unfair competitive advantage over handlers regulated under a Federal order. He concluded that a plant with 10 percent of its sales in the Carolina marketing area and 80 percent in Virginia should not be forced to be fully regulated under Order 5.

The administrator of the Virginia State Milk Commission (the Commission) testified in opposition to Milkco's original proposal. The administrator stated that pooling Virginia plants that have less than 15 percent of their total sales in a Federal order marketing area would be disruptive to the Commission's ability to price and pool milk in the Virginia marketing areas. He argued that there are less intrusive ways to accomplish class price integrity for pooling producer milk.

The witness stated that the Commission was willing to assist the Department to ensure proper reporting and pricing within Federal milk marketing areas to alleviate the concerns of those who have doubts that Virginia's out-of-area prices are being enforced. The witness explained that the Commission has the ability to report sales by Virginia plants into Federal orders in a timely and accurate manner, and is willing to provide such information to the appropriate Federal order market administrator to help enforce proper pricing.

Neither Milkco's proposal, which would make it easier to fully regulate an out-of-area plant, nor MVMPCA's or Richfood's proposal, which would make it harder to fully regulate an out-of-area plant, should be adopted.

Proponents of Milkco's proposal argued that the amount of sales into the Carolina marketing area from partially regulated plants located in Virginia is constantly increasing due to the presence of these plants. Record evidence does not support this argument. For instance, route disposition in Order 5 by partially regulated plants during the months of July through October 1994 was lower than for the same period of 1993. In addition, statistics show that in-area route disposition into Order 5 from partially regulated plants located in Virginia have been at a relatively constant level over the past two years. For example, in 1993 and 1994, the average share of total Order 5 Class I route disposition from these plants was 2.05 and 1.95 percent, respectively.

No evidence presented at the hearing supported the arguments advanced by Milkco and CVMPA concerning the alleged competitive advantage that partially regulated plants in Virginia have in the Carolina marketing area. The record is devoid of any data to support this claim.

With respect to proponents' arguments that changes in Order 5 would bring this order into conformance with the Middle Atlantic order or the Southeast order, marketing conditions in the Carolina order do not warrant any change to the in-area route disposition requirement for this reason. Moreover, it is not clear why differences in the in-area route disposition requirements of these orders would matter in most circumstances. The only area where this

issue seems to be particularly acute is in Virginia. Even in Virginia, however, there is an insufficient basis to conclude that any competitive advantage exists that would warrant undermining of the Virginia State Milk Commission regulation.

The in-area route disposition requirement is a locally tailored standard that indicates when a plant is sufficiently associated with a market to warrant full regulation under the order regulating that marketing area. Whether the standard should be 10 percent or 15 percent depends upon particular circumstances in that area and the demonstrated need for one standard or the other. Based on the testimony and data in this hearing record, the present 15 percent in-area route disposition requirement under Order 5 should remain unchanged.

MVMPCA submitted comments in support of the findings and conclusions of the recommended decision regarding the Order 5 in-area route disposition requirement.

*5. Location Adjustments Under the Carolina Order*

The location adjustment under the Carolina order for a location within the Middle Atlantic Federal order marketing area should be determined by subtracting the Order 4 Class I price at that location from the base zone Class I price specified in Order 5.

At the present time, the Order 5 location adjustment for a plant located in the State of Maryland is based upon the shortest hard-surfaced highway distance, as determined by the market administrator, that such plant is from Greensboro, North Carolina. Once that distance is determined, it is broken down into 10-mile increments (except for the last increment, which may be smaller than 10 miles), which are then multiplied by 2.5 cents to determine the location adjustment. Thus, for example, the location adjustment for a plant that is located 295 miles from Greensboro would be 75 cents (i.e., $30 \times 2.5 = .75$).

Maryland and Virginia Milk Producers Cooperative Association proposed a change in the location adjustment applicable to its butter/powder plant at Laurel, Maryland. Initially, the cooperative proposed treating the Laurel plant as if it were within the State of Virginia; this would result in a zero location adjustment at Laurel. However, at the hearing a spokesman for the cooperative stated that it would support an alternative proposal that would subtract the Order 4 Class I differential price at Laurel (i.e., $3.03) from the Order 5 Class I price at Greensboro (i.e., $3.08), which results in a location adjustment of minus 5 cents. The witness stated that ''our only caveat to this pricing formula is that the Order 5 language should be amended so that the price at Strasburg, Virginia, is established on the same basis as the price at Laurel, Maryland.''

The cooperative's spokesman testified that MVMPCA supplies the Kroger Westover Dairy Order 5 pool distributing plant at Lynchburg, Virginia, on a year-round basis. In addition, he said that since 1992 the cooperative has supplied supplemental milk to nine other Order 5 distributing plants on a seasonal basis.

The witness said that MVMPCA has served as a seasonal balancing agent in supplying Order 5 plants. He introduced an exhibit showing that MVMPCA's monthly sales to Order 5 plants reach a peak during the short production months of July through October.

The witness stated that when producers' milk is not needed by Order 5 plants, it is diverted to MVMPCA's butter-powder plant at Laurel, which serves as a major balancing plant for the Middle Atlantic region. The witness also noted that there is another balancing facility for Order 5 surplus milk—the Valley Milk butter/powder plant located at Strasburg, Virginia—which is approximately 80 miles west of Laurel and outside of any Federal order marketing area. He said that Order 5 now prices milk in an inequitable manner by providing a base zone uniform price for milk that is diverted to Strasburg, but a minus 75-cent location adjustment for milk that is diverted to Laurel.

There was no opposition to this proposal either at the hearing or in the post-hearing briefs that were filed.

MVMPCA's argument and alternative proposal for pricing milk at Laurel is persuasive and should be adopted. The location adjustment at Laurel clearly should not be minus 75 cents. It should be minus 5 cents, the difference between the Order 5 base zone Class I price and the Order 4 Class I price at Laurel.

The appropriate Federal order Class I price at Laurel, Maryland, is the price established for that location under the Middle Atlantic Federal order, which encompasses Laurel. Thus, if a distributing plant located at Laurel were to become regulated under Order 5, its Class I price would be the same as the price that would apply under Order 4. This would ensure competitive pricing among competing handlers. Determining location adjustments for plants in this manner helps to assure the proper alignment of Class I prices throughout the Federal order system and to minimize procurement problems for plants that are located in one Federal order marketing area but regulated under a different order.

The evidence introduced by MVMPCA shows that its producers supplying the Order 5 market are located as far south as the Virginia/North Carolina border and as far north as Cumberland County, Maryland. The exhibit, for example, shows that MVMPCA has producers in Halifax County, Virginia, just north of the Order 5 base zone. When producer milk from Halifax is delivered to a distributing plant at Lynchburg or to a North Carolina handler in the base zone, the milk is priced at the base zone price. Yet, under present order provisions, if the milk is not needed for fluid use by an Order 5 distributing plant and must be diverted to MVMPCA's butter-powder plant at Laurel, 247 miles away, it receives 75 cents less than the base zone price. Consequently, not only does MVMPCA receive a much lower price for this milk, it also absorbs the hauling cost to get the milk to Laurel.

A location adjustment of minus 5 cents at Laurel will narrow the difference to 5 cents between the Laurel and Strasburg plants. This adjustment should alleviate the inequity that now exists in pricing between the two plants. To further reduce the difference in price by imposing a minus 5-cent location adjustment at Strasburg, as suggested by MVMPCA, would entail changing location adjustments throughout the State of Virginia, which goes beyond the scope of the hearing proposals.

MVMPCA filed comments supporting the Order 5 proposed location adjustment change.

*6. Base-Paying Months Under the Carolina Order*

Maryland & Virginia Milk Producers Cooperative Association, Inc., originally submitted a proposal to delete the month of June from the base-paying period of the Order 5 base and excess payment plan. At the hearing, however, the cooperative modified its proposal to add the month of February as well as delete the month of June. As modified, the base-paying months would be February through May.

The MVMPCA witness stated that the purpose of the base-excess plan is to provide producers with an incentive to level their production on a seasonal basis. He indicated that the plan encourages production during the months when milk is needed for fluid use and discourages production during flush production months. Under current marketing conditions, he contended, June is not a surplus month but a month

when supplemental supplies are frequently needed by Order 5 distributing plants. Likewise, he asserted that February is a month of substantial surplus production and should be added to the base-paying period rather than remain a base neutral month.

During 1992 and 1993, the MVMPCA witness noted, daily average production per Order 5 producer from May to June declined about 8 percent, from 4,259 pounds per day to 3,978, and from 4,424 to 4,076, respectively. However, he indicated that daily average production in Order 5 in February 1993 of 4,684 pounds was the highest production month of the year, and production in February 1992 was the third highest month.

The witness also testified that a collateral consequence of including June as a base-paying month is that when supplemental supplies are needed under Order 5, unnecessary and inefficient movements of milk are required to avoid the penalty of absorbing the excess price for supplies of milk that are required for the market's Class I needs. The witness explained that when supplemental milk is needed during the month of June, MVMPCA avoids the penalty of receiving only the excess price for milk delivered directly from producers' farms by instead delivering plant milk from its Laurel plant. To do this, however, the cooperative must receive the milk at Laurel, reload it onto a tank truck, and ship it to an Order 5 distributing plant. He said that the modified proposal would eliminate unnecessary and inefficient movements of milk for the sole purpose of avoiding the order's excess price.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The modified proposal to change the base-paying period from March through June to February through May should be adopted. The removal of June and the addition of February to the base-paying period will bring the base-paying months into closer conformity with the Class I needs of the market.

For the past three years, the average Class I utilization in January has been 77.8 percent while the June Class I utilization has averaged 79.8 percent for this same time period. By comparison, the average Class I utilization for the months of February through May has been 75.6, 75.7, 73.9, and 75.1 percent, respectively. The record also shows that June is a month in which supplemental supplies of milk are needed to meet the Class I needs of the market.

On the basis of the statistical data and the testimony presented at the hearing, the month of February should be included in the base-paying period and June deleted to change the base-paying period to February through May. These changes should result in a base and excess plan that better serves the needs of the market and that will avoid the unnecessary and inefficient movements of needed supplemental milk described by MVMPCA.

Several conforming changes in order language have been made in response to the addition of February and the removal of June as a base-paying month. In § 1005.32(a), dealing with ''other reports,'' the words ''March through June'' should be changed to ''February through May''. In the introductory text of § 1005.61(a) and in § 1005.61(a)(5), the words ''July through February'' must be changed to ''June through January'', and in § 1005.61(b) the words ''March through June'' must be changed to ''February through May''. In §§ 1005.90, 1005.91, and 1005.93(b) the words ''March through June'' must be changed to ''February through May'', and the words ''February 1'' in § 1005.93(b) and § 1005.94 should be changed to ''January 1'' to maintain the existing relationship between the start of the base-paying period and the time when transfers must be completed without the imposition of conditions concerning the receipt or transfer of additional base. Finally, ''March 1'' should be changed to ''February 1'' in § 1005.93(e).

MVMPCA submitted comments in support of the proposed modifications to the Order 5 base-excess plan.

## Motion for a New Hearing

Purity Dairy and Fleming Dairy, both of Nashville, Tennessee, argued that the remedies proposed at this hearing were not sufficient to address some major problems. They maintain that while the proposed amendments would temporarily correct some problems, in the long run these remedies would only make the problems worse. They urged the Secretary to hold a new hearing to consider a merger of Orders 5, 11, and 46 or the merger of Orders 5 and 11 with the proposed Southeast marketing area.

A major study of Orders 5, 11, and 46 and other marketing areas is currently underway at Cornell University. One of the purposes of this study is to develop recommendations for a merged order in this area.

There have been several major changes in cooperative representation, supply arrangements, and plant ownership in these markets. Milk has been shifting among the markets. The alleged problem in south central Kentucky of misaligned uniform prices causing Purity and Fleming to be at a competitive disadvantage for milk supplies has been corrected by the association of additional milk with Order 11, which has lowered that order's Class I utilization. There is no point in considering a merger of orders in this area until such time as producers and handlers propose such a merger. For all of these reasons, the motion to hold a new hearing is denied.

## Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

## General Findings

The findings and determinations hereinafter set forth supplement those that were made when the aforesaid orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) The tentative marketing agreements and the orders, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreements and the orders, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest;

(c) The tentative marketing agreements and the orders, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, marketing agreements upon which a hearing has been held; and

(d) All milk and milk products handled by handlers, as defined in the tentative marketing agreements and the orders as hereby proposed to be amended, are in the current of interstate commerce or directly burden, obstruct, or affect interstate commerce in milk or its products.

Rulings on Exceptions

No exceptions were received in opposition to the proposed amendments set forth in the recommended decision.

Marketing Agreement and Order

Annexed hereto and made a part hereof are two documents, a Marketing Agreement regulating the handling of milk, and an Order amending the orders regulating the handling of milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville marketing areas, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered that this entire decision and the two documents annexed hereto be published in the Federal Register.

Determination of Producer Approval and Representative Period

August 1995 is hereby determined to be the representative period for the purpose of ascertaining whether the issuance of the orders, as amended and as hereby proposed to be amended, regulating the handling of milk in the aforesaid marketing areas is approved or favored by producers, as defined under the terms of the individual orders (as amended and as hereby proposed to be amended), who during such representative period were engaged in the production of milk for sale within the aforesaid marketing areas.

List of Subjects in 7 CFR Parts 1005, 1011, and 1046

Milk marketing orders.

Dated: December 4, 1995.

Shirley R. Watkins,

*Acting Assistant Secretary, Marketing and Regulatory Programs.*

Order Amending the Orders Regulating the Handling of Milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville Marketing Areas

This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) *Findings.* A public hearing was held upon certain proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure (7 CFR Part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said orders as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the aforesaid marketing areas. The minimum prices specified in the orders as hereby amended are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest;

(3) The said orders as hereby amended regulate the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, marketing agreements upon which a hearing has been held; and

(4) All milk and milk products handled by handlers, as defined in the order as hereby amended, are in the current of interstate commerce or directly burden, obstruct, or affect interstate commerce in milk or its products.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, the handling of milk in each of the specified orders' marketing areas shall be in conformity to and in compliance with the terms and conditions of each of the orders, as amended, and as hereby amended, as follows:

The provisions of the proposed marketing agreements and orders amending each of the specified orders contained in the recommended decision issued by the Administrator, Agricultural Marketing Service, on August 17, 1995, and published in the Federal Register on August 24, 1995 (60 FR 43986), shall be and are the terms and provisions of this order, amending the orders, and are set forth in full herein.

## PART 1005—MILK IN THE CAROLINA MARKETING AREA

1. The authority citation for 7 CFR parts 1005, 1011, and 1046 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. In § 1005.7, the reference ''(d)'' in the introductory text is revised to read ''(e)'', in paragraph (b) the words ''Director of the Dairy Division'' and ''Director'' are revised to read ''market administrator'' wherever they appear, paragraph (d) is redesignated as paragraph (e) and revised, and a new paragraph (d) is added to read as follows:

**§ 1005.7 Pool plant.**

* * * * *

(d) A plant located within the marketing area (other than a producer-handler plant or a governmental agency plant) that meets the qualifications described in paragraph (a) of this section regardless of its quantity of route disposition in any other Federal order marketing area.

(e) The term ''pool plant'' shall not apply to the following plants:

(1) A producer-handler plant;

(2) A governmental agency plant;

(3) A plant with route disposition in this marketing area that is located within the marketing area of another Federal order and that is fully regulated under such order;

(4) A plant qualified pursuant to paragraph (a) of this section which is not located within any Federal order marketing area but which also meets the pooling requirements of another Federal order and from which there is a greater quantity of route disposition, except filled milk, during the month in such other Federal order marketing area than in this marketing area; and

(5) A plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order.

**§ 1005.32 [Amended]**

3. In § 1005.32(a), the words ''March through June'' are revised to read ''February through May'' wherever they appear.

4. In § 1005.53, paragraph (a)(6) is redesignated as paragraph (a)(7) and revised, and a new paragraph (a)(6) is added to read as follows:

**§ 1005.53 Plant location adjustments for handlers.**

(a) * * *

(6) For a plant located within the Middle Atlantic Federal Order Marketing Area (part 1004), the adjustment shall be computed by subtracting the base zone Class I price specified in § 1005.50(a) from the Class I price applicable at such plant under the Middle Atlantic Federal Order; and

(7) For a plant located outside the areas specified in paragraphs (a)(1) through (a)(6) of this section, the adjustment shall be a minus 2.5 cents for each 10 miles or fraction thereof (by the shortest hard-surfaced highway distance as determined by the market administrator) that such plant is from the nearer of the city halls in Greenville, South Carolina, or Charlotte or Greensboro, North Carolina.

**§ 1005.61 [Amended]**

5. In § 1005.61 paragraphs (a) introductory text and (a)(5), the words ''July through February'' are revised to read ''June through January'' and in paragraph (b) introductory text the words ''March through June'' are revised to read ''February through May''.

**§§ 1005.90 and 1005.91 [Amended]**

6. In §§ 1005.90 and 1005.91, the words ''March through June'' are revised to read ''February through May'' wherever they appear.

**§ 1005.93 [Amended]**

7. In § 1005.93 paragraph (b), the words ''March through June'' are revised to read ''February through May'' wherever they appear, the words ''February 1'' are revised to read ''January 1'', and in paragraph (e) the words ''March 1'' are revised to read ''February 1''.

**§ 1005.94 [Amended]**

8. In § 1005.94, the words ''February 1'' are revised to read ''January 1''.

## PART 1011—MILK IN THE TENNESSEE VALLEY MARKETING AREA

9. Section 1011.2 is amended by revising paragraph (b) to read as follows:

**§ 1011.2 Tennessee Valley marketing area**

* * * * *

(b) In Kentucky, the counties of Bell, Breathitt, Clay, Harlan, Jackson, Knott, Knox, Laurel, Leslie, Letcher, McCreary, Owsley, Perry, Pulaski, Rockcastle, and Whitley.

* * * * *

10. In § 1011.7, the reference ''(d)'' in the introductory text is revised to read ''(e)'', paragraph (b) is revised, paragraph (d) is redesignated as paragraph (e) and revised, and a new paragraph (d) is added to read as follows:

**§ 1011.7 Pool plant.**

* * * * *

(b) A plant, other than a plant described in paragraph (a) of this section, from which fluid milk products, except filled milk, are shipped to plants described in paragraph (a) of this section subject to the following additional conditions:

(1) During the months of August through November, January and February, such shipments must equal not less than 60 percent (40 percent during the months of December and March through July) of the total quantity of milk approved by a duly constituted regulatory agency for fluid consumption that is received during the month at such plant from handlers described in § 1011.9 (c) and (d) and from dairy farmers, including milk that is diverted from the plant pursuant to § 1011.13 but excluding milk diverted to the plant;

(2) The operator of a plant described in this paragraph may include milk diverted from the plant to plants described in paragraph (a) of this section for up to one-half of the shipments required pursuant to this paragraph;

(3) A plant which meets the shipping requirements specified in this paragraph during the months of July through February shall be a pool plant during the following months of March through June unless the milk received at the plant does not continue to meet the requirements of a duly constituted regulatory agency, the plant fails to meet a shipping requirement instituted pursuant to paragraph (b)(4) of this section, or a written application is filed by the plant operator with the market administrator on or before the first day of any such month requesting that the plant be designated a nonpool plant for such month and for each subsequent month through June during which it would not otherwise qualify as a pool plant; and

(4) The shipping requirements described in paragraph (b)(1) and (b)(3) of this section may be increased or decreased up to 10 percentage points by the market administrator if he or she finds that revision is necessary to obtain needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for revision either at his or her own initiative or at the request of interested persons. If the investigation shows that a revision may be appropriate, the market administrator shall issue a notice stating that the revision is being considered and invite data, views, and arguments.

* * * * *

(d) A plant located within the marketing area (other than a producer-handler plant or a governmental agency plant) that meets the qualifications described in paragraph (a) of this section regardless of its quantity of route disposition in any other Federal order marketing area.

(e) The term ''pool plant'' shall not apply to the following plants:

(1) A producer-handler plant;

(2) A governmental agency plant;

(3) A plant with route disposition in this marketing area that is located within the marketing area of another Federal order and that is fully regulated under such order;

(4) A plant qualified pursuant to paragraph (a) of this section which is not located within any Federal order marketing area but which also meets the pooling requirements of another Federal order and from which there is a greater quantity of route disposition, except filled milk, during the month in such other Federal order marketing area than in this marketing area; and

(5) A plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order.

**§ 1011.13 [Amended]**

11. In § 1011.13 paragraph (e)(3), the words ''Director of the Dairy Division'' and ''Director'' are revised to read ''market administrator'' wherever they appear.

12. Section 1011.52(a)(3) is revised to read as follows:

**§ 1011.52 Plant location adjustments for handlers.**

(a) * * *

(3) For such milk which is physically received at a plant located within the Kentucky counties of Bell, Breathitt, Clay, Harlan, Jackson, Knott, Knox, Laurel, Leslie, Letcher, McCreary, Owsley, Perry, Pulaski, Rockcastle, and

Whitley, the Class I price shall be decreased by 32 cents; and

* * * * *

## PART 1046—MILK IN THE LOUISVILLE-LEXINGTON-EVANSVILLE MARKETING AREA

### § 1046.2 [Amended]

13. In § 1046.2, in the list of Kentucky counties, the word ''Pulaski'' is removed.

[Note: The following appendix will not be published in the Code of Federal Regulations.]

Appendix—Marketing Agreement Regulating the Handling of Milk in Certain Specified Marketing Areas

The parties hereto, in order to effectuate the declared policy of the Act, and in accordance with the rules of practice and procedure effective thereunder (7 CFR Part 900), desire to enter into this marketing agreement and do hereby agree that the provisions referred to in paragraph I hereof as augmented by the provisions specified in paragraph II hereof, shall be and are the provisions of this marketing agreement as if set out in full herein.

I. The findings and determinations, order relative to handling, and the provisions of §§ _____[1] to _____, all inclusive, of the order regulating the handling of milk in the said marketing areas (7 CFR part _____[2]) which is annexed hereto; and

II. The following provisions:

§ _____[3] Record of milk handled and authorization to correct typographical errors.

(a) Record of milk handled. The undersigned certifies that he/she handled during the month of _____[4], _____ hundredweight of milk covered by this marketing agreement.

(b) Authorization to correct typographical errors. The undersigned hereby authorizes the Director, or Acting Director, Dairy Division, Agricultural Marketing Service, to correct any typographical errors which may have been made in this marketing agreement.

§ _____[3] Effective date. This marketing agreement shall become effective upon the execution of a counterpart hereof by the Secretary in accordance with Section 900.14(a) of the aforesaid rules of practice and procedure.

In Witness Whereof, The contracting handlers, acting under the provisions of the Act, for the purposes and subject to the limitations herein contained and not otherwise, have hereunto set their respective hands and seals.

Signature

By (Name) _____

(Title) _____

(Address) _____

(Seal)

[1] First and last sections of order.

[2] Appropriate Part number.

[3] Next consecutive section number.

[4] Appropriate representative period for the order.

Attest

[FR Doc. 95–30670 Filed 12–15–95; 8:45 am]

BILLING CODE 3410–02–P

## NUCLEAR REGULATORY COMMISSION

## 10 CFR Part 50

## RuleNet Communication Program; Fire Protection Regulations—Correction

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** RuleNet announcement; Correction.

**SUMMARY:** This document corrects a notice of availability appearing in the Federal Register on November 15, 1995 (60 FR 57370), that listed the electronic address for accessing the RuleNet program. This action is necessary to correct a printing error in the RuleNet address.

**FOR FURTHER INFORMATION CONTACT:** Francis Cameron, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1642.

On page 57370, under the **ADDRESSES** heading, in the fifth line, the electronic address that reads ''http:/nssc.llnl.gov/RuleNet'' should read ''http://nssc.llnl.gov/RuleNet.''

Dated at Rockville, Maryland, this 13th day of December, 1995.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

*Chief, Rules Review Section, Rules Review and Directives Branch.*

[FR Doc. 95–30666 Filed 12–15–95; 8:45 am]

BILLING CODE 7590–01–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 95–NM–88–AD]**

## Airworthiness Directives; Lockheed Model L–1011–385 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the supersedure of an existing airworthiness directive (AD), applicable to all Lockheed Model L–1011–385 series airplanes, that currently requires inspections to detect cracking of certain areas of the rear spar caps, web, skin, and certain fastener holes; and repair or modification, if necessary. That AD was prompted by reports of fatigue cracks in the caps of the wing rear spar inboard of inner wing station 346. The actions specified by that AD are intended to prevent rupture of the rear spar, which could result in extensive damage to the wing and fuel spillage. This action would add various improved inspections and follow-on actions, and would require that the initial inspections be accomplished at reduced thresholds.

**DATES:** Comments must be received by February 13, 1996.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–88–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Lockheed Aeronautical Systems Support Company, Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia.

**FOR FURTHER INFORMATION CONTACT:** Thomas Peters, Aerospace Engineer, Flight Test Branch, ACE–116A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia 30337–2748; telephone (404) 305–7367; fax (404) 305–7348.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 95–NM–88–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–88–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On August 26, 1993, the FAA issued AD 93–17–10, amendment 39–8681 (58 FR 54947, October 25, 1993), which is applicable to all Lockheed Model L–1011–385 series airplanes. That AD requires inspections to detect cracking of certain areas of the rear spar caps, web, skin, and certain fastener holes; and repair or modification, if necessary. That action was prompted by reports of fatigue cracks in the caps of the wing rear spar inboard of inner wing station (IWS) 346. The requirements of that AD are intended to prevent rupture of the rear spar, which could result in extensive damage to the wing and fuel spillage.

Since the issuance of that AD, the FAA has received additional reports of fatigue cracking in the subject areas on these airplanes. The airplanes on which the cracking occurred had accumulated fewer landings than the number of landings specified as the inspection thresholds in AD 93–17–10.

Discussion of Relevant Service Information

Subsequent to the finding of this new cracking, the manufacturer issued, and the FAA reviewed and approved, Lockheed L–1011 Service Bulletin 093–57–203, Revision 4, dated March 27, 1995. The revised service bulletin describes procedures for inspections to detect cracking in certain areas of the rear spar caps, web, skin, and certain fastener holes at earlier inspection thresholds than those specified previously. The service bulletin revision describes the following various improved inspection procedures and follow-on actions:

1. Repetitive X-ray (radiographic) inspections to detect cracking of the upper and lower caps of the rear spar and of the associated web and skin areas between IWS 231 and IWS 343. The inspection procedure specified in the revised service bulletin has been changed from that described in Revision 3 to clarify the location for the X-ray tube head for certain exposures.

2. Repetitive eddy current surface scan inspections to detect cracking of the upper spar cap-to-skin and the upper spar cap-to-web attachment areas around the fasteners from IWS 310 to the main landing gear (MLG) trunnion fitting at approximately IWS 343.

3. A bolt hole eddy current inspection to detect cracking in the 1⅛-inch diameter fastener hole located inboard of IWS 343. The service bulletin specifies that this inspection is accomplished at an initial inspection threshold only. (However, the service bulletin also specifies that this inspection must be accomplished on any fastener hole where the fastener is removed for repair or replacement.)

4. For airplanes on which cracking is found during the bolt hole eddy current inspection of the 1⅛-inch diameter fastener hole located inboard of IWS 343, the service bulletin describes procedures for a bolt hole eddy current inspection to detect cracking at the four ⅝-inch fastener locations directly below the 1⅛-inch fastener.

5. For airplanes on which Option iv or v of Lockheed Repair Procedure LCC–7622–368 has not been accomplished, the service bulletin describes procedures for subsequent repetitive ultrasonic inspections to detect cracking in the fastener hole. These inspections are performed in conjunction with eddy current surface scan inspections to detect cracking of the upper horizontal edge of the rear spar web, ½-inch each side of the inboard edge of the MLG trunnion fitting.

6. Repetitive low frequency eddy current ring probe inspections to detect cracking of the upper cap/skin of the rear spar between IWS 310 to IWS 326 and the cap/web fasteners.

Since the issuance of AD 93–17–10, the FAA has also reviewed and approved later revisions of certain service information specified in paragraph (d) of that AD as an alternative method of repairing confirmed findings of cracking, as follows:

1. Lockheed L–1011 Service Bulletin 093–57–196, Revision 6, dated December 6, 1994, and Lockheed L–1011 Service Bulletin Change Notification 093–57–196, R6–CN1, dated August 22, 1995.

2. Lockheed L–1011 Service Bulletin 093–57–184, Revision 7, dated December 6, 1994, and Lockheed L–1011 Service Bulletin Change Notification 093–57–196, R7–CN1, dated August 22, 1995.

These service bulletins describe procedures for modification of the rear spar upper and lower caps between IWS 228 and 346. Among other things, these service bulletin revisions were issued to standardize the rework of fastener holes, add new instructions to refer to drawings to accomplish the modification, clarify miscellaneous information, and to reference certain service information for web damage extending beyond IWS 327.

Discussion of the Proposed Action

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 93–17–10 to continue to require inspections to detect cracking of certain areas of the rear spar caps, web, skin, and certain fastener holes; and repair or modification, if necessary. The proposed AD would add various improved inspections and follow-on actions, and would require that the initial inspections be accomplished at reduced thresholds. The inspections, follow-on actions, and modification would be required to be accomplished in accordance with the service bulletin described previously. The repair would be required to be accomplished in accordance with a method approved by the FAA or in accordance with the Lockheed Model L–1011 Structural Repair Manual.

Operators should note that only the inspection procedures (and follow-on actions) described in Lockheed L–1011 Service Bulletin 093–57–203 would be required by this proposal. In a separate AD action [AD 94–05–01, amendment 39–8839 (59 FR 10275, March 4, 1994)], the FAA previously addressed the portion of that service bulletin that deals with the modification

Cost Impact

There are approximately 236 Model L–1011–385 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 118 airplanes of U.S. registry would be affected by this proposed AD.

The actions that are currently required by AD 93–17–10 take

approximately 21 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact on U.S. operators of the actions currently required is estimated to be $148,680, or $1,260 per airplane.

The new actions that are proposed in this AD action would take approximately 64 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. [This work hour estimate assumes that X-ray inspections are done of both upper and lower caps, and that the ultrasonic inspection indicates cracking in each of five bolt holes (per wing), thus requiring subsequent bolt hole eddy current inspections to confirm crack findings. The estimate includes inspections of both wings.] Based on these figures, the cost impact on U.S. operators of the proposed requirements of this AD is estimated to be $453,120, or $3,840 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

## Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

## List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

## The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8681 (58 FR 54947, October 25, 1993), and by adding a new airworthiness directive (AD), to read as follows:

Lockhead Aeronautical Systems Company: Docket 95–NM–88–AD. Supersedes AD 93–17–10, Amendment 39–8681.

*Applicability:* All Model L–1011–385–1, L–1011–385–1–14, L–1011–385–1–15, and L–1011–385–3 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

Note 2: Paragraphs (a)(1) and (b) of this AD restate the requirement for repetitive inspections and follow-on actions contained in paragraphs (a) and (b) of AD 93–17–10. Therefore, for operators who have previously accomplished at least the initial inspection in accordance with AD 93–17–10, paragraphs (a)(1) and (b) of this AD require that the next scheduled inspection be performed within 2,000 flight cycles after the last inspection performed in accordance with paragraphs (a) and (b) of AD 93–17–10.

To prevent rupture of the rear spar, which could result in extensive damage to the wing and fuel spillage, accomplish the following:

(a) Perform inspections and various follow-on actions to detect cracking in the areas specified in and in accordance with Part II of the Accomplishment Instructions of the Lockheed service documents listed below. After the effective date of this AD, the inspections and follow-on actions shall be performed only at the times specified in and in accordance with Revision 4 of Lockheed L–1011 Service Bulletin 093–57–203. [The inspections and follow-on actions include: repetitive X-ray (radiographic) inspections; repetitive eddy current surface scan inspections; bolt hole eddy current inspections at various locations; repetitive ultrasonic inspections in conjunction with eddy current surface scan inspections (for certain airplanes); and repetitive low frequency eddy current ring probe inspections.]

- Lockheed L–1011 Service Bulletin 093–57–203, Revision 3, dated October 28, 1991; or
- Lockheed L–1011 Service Bulletin Service Bulletin 093–57–203, Revision 3, dated October 28, 1991, as amended by Lockheed L–1011 Service Bulletin Change Notification 093–57–203, R3–CN1, dated June 22, 1992; or
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 4, dated March 27, 1995.

(1) For airplanes on which the inspections required by AD 93–17–10, amendment 39–8681, have been initiated prior to the effective date of this AD: Perform the inspections and follow-on actions at the times specified in Table I of Lockheed L–1011 Service Bulletin Change Notification 093–57–203, R3–CN1, dated June 22, 1992, or within 6 months after November 24, 1993 (the effective date of AD 93–17–10, amendment 39–8681), whichever occurs later.

Note 3: As allowed by the phrase, ''unless accomplished previously,'' if the inspections and follow-on actions required by this paragraph were conducted prior to November 24, 1993, in accordance with Lockheed L–1011 Service Bulletin 093–57–203, Revision 2, dated January 25, 1991, those inspections need not be repeated.

(2) For airplanes on which the inspections required by AD 93–17–10, amendment 39–8681, have not been initiated prior to the effective date of this AD: Perform the inspections and follow-on actions at the times specified in Table I of Lockheed L–1011 Service Bulletin 093–57–203, Revision 4, dated March 27, 1995, or within 6 months after the effective date of this AD, whichever occurs later.

(b) If no cracking is found, perform the repetitive inspections and follow-on actions specified in the Accomplishment Instructions of the Lockheed service documents listed below thereafter at intervals not to exceed 2,000 flight cycles. After the effective date of this AD, the inspections and follow-on actions shall be performed only in accordance with Revision 4 of Lockheed L–1011 Service Bulletin 093–57–203.

- Lockheed L–1011 Service Bulletin 093–57–203, Revision 3, dated October 28, 1991; or
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 3, dated October 28, 1991, as amended by Lockheed L–1011 Service Bulletin Change Notification 093–57–203, R3–CN1, dated June 22, 1992; or
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 4, dated March 27, 1995;

(c) If any finding of cracking is confirmed, prior to further flight, accomplish paragraph (c)(1), (c)(2), or (c)(3) of this AD.

(1) Repair the cracked area in accordance with a method approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Thereafter, perform the repetitive inspections and follow-on actions required by paragraph (b) of this AD. Or

(2) Repair the rear spar upper and lower caps between IWS 228 and 346 in accordance with the Lockheed Model L–1011 Structural Repair Manual. Thereafter, perform the repetitive inspections and follow-on actions required by paragraph (b) of this AD. Or

(3) Modify the rear spar upper and lower caps between IWS 228 and 346 in accordance with the Lockheed service bulletins listed below, as applicable. Accomplishment of the modification constitutes terminating action for the requirements of this AD.

- Lockheed L–1011 Service Bulletin 093–57–184, Revision 7, dated December 6, 1994, as amended by Change Notification 093–57–184, R7–CN1, dated August 22, 1995; or
- Lockheed L–1011 Service Bulletin 093–57–196, Revision 6, dated December 6, 1994, as amended by Change Notification 093–57–196, R6–CN1, dated August 22, 1995; or
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 4, dated March 27, 1995.

Note 4: Accomplishment of the modification specified in paragraph (c)(3) of this AD prior to the effective date of this AD in accordance with the following Lockheed service bulletins, as applicable, is considered to be in compliance with this paragraph:

- Lockheed L–1011 Service Bulletin 093–57–184, Revision 6, dated October 28, 1991;
- Lockheed L–1011 Service Bulletin 093–57–184, Revision 7, dated December 6, 1994;
- Lockheed L–1011 Service Bulletin 093–57–196, Revision 5, dated October 28, 1991;
- Lockheed L–1011 Service Bulletin 093–57–196, Revision 6, dated December 6, 1994;
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 3, dated October 28, 1991; or
- Lockheed L–1011 Service Bulletin 093–57–203, Revision 3, dated October 28, 1991, as amended by Change Notification 093–57–203, R3–CN1, dated June 22, 1992.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 11, 1995.

Darrell M. Pederson,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 95–30646 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–13–U

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## 14 CFR Part 39

**[Docket No. 95–ANE–41]**

## Airworthiness Directives; General Electric Company CF34 Series Turbofan Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the adoption of a new airworthiness directive (AD) that is applicable to General Electric Company (GE) CF34 series turbofan engines. This proposal would reduce the allowable operating cyclic life limit for affected high pressure compressor (HPC) stage 1 rotor disks. This proposal is prompted by an updated stress and life analysis. The actions specified by the proposed AD are intended to prevent HPC stage 1 rotor disk rupture, engine failure, and damage to the aircraft.

**DATES:** Comments must be received by February 16, 1996.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–ANE–41, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Eugene Triozzi, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7148, fax (617) 238–7199.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 95–ANE–41.'' The postcard will be date stamped and returned to the commenter.

### Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–ANE–41, 12 New England Executive Park, Burlington, MA 01803–5299.

### Discussion

The Federal Aviation Administration (FAA) has reviewed and approved an updated stress and life analysis for high pressure compressor (HPC) stage 1 rotor disks installed in General Electric Company (GE) CF34 series turbofan engines. Although the FAA has not received any reports of cracked or failed HPC stage 1 rotor disks, the stress and life analysis was performed using new, improved methodology. This analysis revealed that the published cyclic life limits were higher than updated calculated lives, which could result in the operation of an HPC stage 1 rotor disk beyond its cyclic life. This condition, if not corrected, could result in HPC stage 1 rotor disk rupture, engine failure, and damage to the aircraft.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would reduce the allowable operating cyclic life limit for affected HPC stage 1 rotor disks.

There are approximately 440 engines of the affected design in the worldwide fleet. The FAA estimates that 150 engines installed on aircraft of U.S. registry would be affected by this

proposed AD, that it would take zero additional work hours per engine to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $7,667 per engine, based on the estimated current part cost, prorated downward by a factor equal to the quotient of the difference between the original cyclic life limit (9000 cycles) and the revised cyclic life limit (6000 cycles) divided by the original cyclic life limit. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $1,150,000.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

General Electric Company: Docket No. 95–ANE–41.

*Applicability:* General Electric Company (GE) Models CF34–1A, –3A, and –3A2 turbofan engines, with high pressure compressor (HPC) stage 1 rotor disks, part number 6040T79G01, installed. These engines are installed on but not limited to Canadair Limited Model CL–600–2A12 and CL–600–2B16 aircraft.

Note: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the Federal Aviation Administration (FAA). This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any engine from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent HPC stage 1 rotor disk rupture, engine failure, and damage to the aircraft, accomplish the following:

(a) Remove from service HPC stage 1 rotor disks prior to accumulating 6,000 cycles in service since new, and replace with a serviceable part.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

Issued in Burlington, Massachusetts, on December 8, 1995.

Jay J. Pardee,

*Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 95–30645 Filed 12–15–95; 8:45 am]

**BILLING CODE 4910–13–U**

## 14 CFR Part 39

**[Docket No. 95–NM–128–AD]**

## Airworthiness Directives; Jetstream Model 4101 Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Jetstream Model 4101 airplanes. This proposal would require an inspection to verify the proper position of ''door open'' placards on the inside of the main entrance door, and replacement with new placards appropriately positioned, if necessary. This proposal is prompted by a report that the ''door open'' placards on the inside of the main entrance door, as currently installed, may not be visible to passengers or flightcrew when the door handle is in the open position. The actions specified by the proposed AD are intended to ensure that certain placards on the inside of the main entrance door are clearly visible and perform their intended function in the event of an emergency evacuation.

**DATES:** Comments must be received by January 23, 1996.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–128–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

**FOR FURTHER INFORMATION CONTACT:** William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2148; fax (206) 227–1149.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such

written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 95–NM–128–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–128–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Jetstream Model 4101 airplanes. The CAA advises that the ''door open'' placards on the inside of the main entrance door may not be properly installed (that is, aligned with the door handle when it is in the ''open'' position), as required by section 25.811 (e) of the Federal Aviation Regulations (14 CFR 25.811), ''Emergency exit marking.'' The placards are currently installed at imprecise locations, since the type design data was not explicit in defining the installation locations. Therefore, these placards may not be visible to the passengers or flightcrew during an emergency evacuation, and consequently, do not fulfill the intent of the regulations, which is to ensure that these placards are visible and properly aligned with the door handle when it is in the ''open'' position. This condition, if not corrected, could delay or impede the evacuation of passengers during an emergency.

Jetstream has issued Service Bulletin J41–11–007, dated May 10, 1995, which describes procedures for a one-time visual inspection to verify the proper position of certain placards on the inside of the main entrance door, and removal of the placard and installation of a new placard, if necessary. The CAA classified this service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist on other airplanes of the same type design, the proposed AD would require a one-time visual inspection to verify the proper position of certain placards on the inside of the main entrance door, and removal of the placard and installation of a new placard, if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 25 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would be supplied by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $1,500, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

**39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

Jetstream Aircraft Limited: Docket 95–NM–128–AD.

*Applicability:* Model 4101 airplanes, constructors numbers 41004 through 41046 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition

addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

To ensure that certain placards on the inside of the main entrance door are clearly visible and properly aligned, accomplish the following:

(a) Within 4 months after the effective date of this AD, perform a one-time visual inspection to verify the proper position of the door open placards on the inside of the main entrance door, in accordance with Jetstream Service Bulletin J41–11–007, dated May 10, 1995. If any placard is found to be improperly positioned, prior to further flight, remove the placard and install a new placard in the specified position, in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 11, 1995.

Darrell M. Pederson,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 95–30644 Filed 12–15–95; 8:45 am]

**BILLING CODE 4910–13–U**

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## 14 CFR Part 39

**[Docket No. 95–CE–61–AD]**

## Airworthiness Directives; Brackett Aircraft Company, Inc. Air Filter Assemblies Installed on Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes to supersede AD 95–03–02, which currently requires repetitively inspecting (visually) the air filter frame for a loose or deteriorating gasket on airplanes incorporating certain Brackett air filter assemblies. The proposed action retains the repetitive inspection and possible replacement requirements as contained in AD 95–03–02, and would incorporate additional Brackett air filter assemblies to the applicability of that AD. Additionally, it would provide a terminating action for the repetitive inspection. The Federal Aviation Administration's determination that these additional Brackett air filter assemblies should be inspected and replaced prompted this AD action. The actions specified by the proposed AD are intended to prevent gasket particles from entering the carburetor because of air filter gasket failure, which, if not detected and corrected, could result in partial or complete loss of engine power and loss of control of the airplane.

**DATES:** Comments must be received on or before February 20, 1996.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–61–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Brackett Aircraft Company, Inc., 7045 Flightline Drive, Kingman, Arizona 86401. This information also may be examined at the Rules Docket at the address above.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Bumann, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5265; facsimile (310) 627–5210.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–61–AD.'' The postcard will be date stamped and returned to the commenter.

### Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–61–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

### Discussion

AD 95–03–02 was published in the Federal Register on August 25, 1994 (59 FR 43784) and applies to airplanes that have a certain Brackett air filter neoprene gasket installed in accordance with Supplemental Type Certificate (STC) SA71GL. The action requires repetitively inspecting (visually) the air filter frame for a loose or deteriorated gasket, and replacing any gasket found loose or deteriorated.

The FAA's continuing investigation of these Brackett neoprene gasket air filter's failure and the continuing unsafe condition described in AD 95–03–02 suggests that a superseding action be proposed. The FAA has discovered that additional Brackett air filters with the same neoprene gasket design are installed as original equipment and in accordance with STC SA693CE on certain additional airplanes. These airplanes would also be subject to air filter assembly failure.

After examining the circumstances and reviewing all available information related to the information described above, the FAA has determined that AD action should be taken to prevent gasket particles from entering the carburetor because of air filter gasket failure, which could result in partial or complete loss of engine power.

Since an unsafe condition has been identified that is likely to exist or develop in other Brackett air filter frame assemblies of the same type design, the proposed AD would supersede AD 95–03–02 with a new AD that would require incorporating additional Brackett air filter assemblies to the applicability paragraph of AD 95–03–02,

retain the repetitive inspection at intervals not to exceed 100 hours time-in-service (TIS) with replacement of the air filter if damaged, and mandatory replacement of the air filter assembly at 500 hours TIS, terminating the repetitive inspection requirement contained in AD 95–03–02.

The FAA estimates that 50,000 airplanes in the U.S. registry would be affected by the proposed AD. To accomplish the proposed repetitive inspection and possible replacement of a damaged air filter would take approximately 1 hour per airplane, and that the average labor rate is approximately $60 an hour. To install a new gasket cost approximately $3 per airplane. Based on these figures, the total cost impact of the proposed repetitive inspection and replacement on U.S. operators is estimated to be $63 per airplane. The FAA knows that each owner/operator would have to repetitively inspect four times before the mandatory replacement of the air filter assembly, and based on the assumption that no operator would incorporate the modification prior to the 500 hours TIS, the total cost of four repetitive inspections with possible replacement of the air filter gasket would be $252 per airplane plus the cost of the proposed terminating action. Based on these figures the total cost impact of the proposed AD on U.S. operators is estimated to be $12,600,000.

In comparison, the cost to incorporate the modification is about 1 workhour per airplane at approximately $60 per workhour. The air filter assembly replacement is estimated to be $40 per airplane. The total estimated cost for the proposed modification required at 500 hours TIS would be $100 per airplane and the total cost impact of the modification is estimated to be $5,000,000 thereby reducing the total cost of the proposed AD by $7,600,000 from $12,600,000 to $5,000,000. The FAA has no way to determine how many owners/operators have completed the repetitive inspections and replacements or the terminating action modification and must calculate the cost impact based on the entire U.S. fleet.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40101, 40113, 44701.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by removing Airworthiness Directive (AD) 95–03–02, Amendment 39–9139, and by adding a new AD to read as follows:

Brackett Aircraft Company: Docket No. 95–CE–61–AD; Supersedes AD 95–03–02, Amendment 39–9139.

*Applicability:* Air filter assemblies presented in the following chart that utilize a neoprene gasket installed on, but not limited to the following airplanes, certificated in any category:

Note 1: These air filters could be installed as original equipment or in accordance with Supplemental Type Certificate (STC) SA71GL or STC SA693CE.

| Air filter assembly | Airplanes installed on |
|---|---|
| BA–2010 ..... | Beechcraft Model 77 Airplanes. |
| BA–4106 ..... | Cessna Models 120, 140, 140A, 150, 150A, 150B, 150C, 150D, 150E, 150F, 150G, 150H, 150J, 150K, 150L, 150M, A150M, 152, and A152; American Champion Models Bellanca (Champion) (Aeronca) 7ACA, 7ECA, and 7FC; Aviat, Inc. Models A–1; Luscombe Models 8, 8A, 8B, 8C, 8D, 8E, 8F, and T–8F; Piper Models PA–22, PA–22–135, PA–22–150, PA–22–160, PA–22–108, PA–20–115, PA–20–135, PA–38–112, J–3, J3C–65, J3C–65S, PA–11, PA–11S, J4A, J4A–S, J4E, J5A, J5A–80, PA–12, PA–12S, PA–16, PA–17, PA–18, PA–18A, PA–18S, PA–18–''125'' (Army L–21A), PA–18AS–''125'', PA–18S–''125'', PA18AS–''135'', PA–18S–''135'', PA–18–''135'', PA–18–''150'', PA–18A–''150'' (SN 18–1 through 18–6963), PA–18S–''150'', PA–19, PA–18A (Restricted), PA–18A–''135'' (Restricted), and PA–18A–''150'' (Restricted) (SN 18–1 through 18–18–6963); Taylorcraft Models BC65, BCS–65, BC12–65, BCS12–65, BC12–D, BCS12–D1, BC12D85, BCS12D85, BC12D–4–85, BCS12D–4–85, 19, F19, F21, DC–65, DCO–65, F22, F22A, F22B, and F22C; Univair Models (Alon) A–2, A2–A, (Forney) F–1, F–1A, and (Mooney) M10; Swift Museum Models (Globe) GC–1A and GC–1B; Augustair Model Varga (Morrisey) 2150A; Aeronca Model 65–CA; American Champion 7ECA (with Cont. O–200–A engine) and 7ACA; Reims Aviation (Cessna) F150G, F150H, F150J, F150K, F150L, F150M, FA150K, FA150L, F152, AND FA152; Socata-Groupe Aerospatiale Models Rallye Series MS880B, MS885, and 100S. |
| BA–4106–1 ... | Aviat, Inc. Model (Christian) A–1. |
| BA–4210 ..... | Gulfstream Models AA–1, AA–1A, AA–1B, AA–1C, and AA–5. |
| BA–5110 ..... | Cessna Models 170, 170A, 170B, 172, 172A, 172B, 172C, 172D, 172E, 172F, 172G, 172H, 172I, 172K, 172L, and 172M; Mooney Mite Model M–18C; Reims Aviation Models (Cessna) F172D, F172E, F172F, F172G, F172H, F172K, F172L, and F172M; Socata-Groupe Aerospatiale Models TB9, TB10, Rallye Series MS892A–150, MS892E–150, MS892E–150T, and MS892E–150ST; Panstwowe Zakolady Kotnicze Model PZL–Koliber 150A; Augustair, Inc. Model Varga (Morrisey) 2180. |
| BA–5110A ..... | Cessna Models 172N and 172P; Reims Aviation Models (Cessna) F172N and F172P. |
| BA–6110 ..... | Maule Models M–4, M–4C, M–4S, M–4T, M–4–220, M–4–220C, M–4–220S, M–4–220T, M–4–180C, M–4–180S, M–4–180T, M–5–220C, M–5–235C, M–5–180C, M–5–210TC, M–6–180, M–6–235, M–7–235, MX–7–180, MXT–7–160, MXT–7–180, MX–7–160, MX–7–235, and MX–8–235; Mooney Models M20, M20A, M20B, M20C, M20D, and M20G. |
| BA–8910 ..... | Dynac Models (Aero Commander) 100 and 100A. |

| Air filter assembly | Airplanes installed on |
|---|---|
| AAF–117 ..... | Cessna Models 120, 140, 140A, 150, 150A, 150B, 150C, 150D, 150E, 150F, 150G, 150H, 150J, 150K, 150L, 150M, A150M, 152, and A152; American Champion Models Bellanca (Champion) (Aeronca) 7ACA, 7ECA, and 7FC; Aviat, Inc. Models A–1; Luscombe Models 8, 8A, 8B, 8C, 8D, 8E, 8F, and T–8F; Piper Models PA–22, PA–22–135, PA–22–150, PA–22–160, PA–22–108, PA–20–115, PA–20–135, PA–38–112, J–3, J3C–65, J3C–65S, PA–11, PA–11S, J4A, J4A–S, J4E, J5A, J5A–80, PA–12, PA–12S, PA–16, PA–17, PA–18, PA–18A, PA–185, PA–18–''125'' (Army L–21A), PA–18AS–''125'', PA–185–''125'', PA–18AS–''135'', PA–18S–''135'', PA–18–''135'', PA–18–''150'', PA–18A–''150'' (SN 18–1 through 18–6963), PA–18S–''150'', PA–19, PA–18A (Restricted), PA–18A–''135'' (Restricted), and PA–18A-''150'' (Restricted) (SN 18–1 through 18–18–6963); Taylorcraft Models BC65, BCS–65, BC12–65, BCS12–65, BC12–D, BCS12–D1, BC12D85, BCS12D85, BC12D–4–85, BCS12D–4–85, 19, F19, F21, DC–65, DCO–65, F22, F22A, F22B, and F22C; Univair Models (Alon) A–2, A2–A, (Forney) F–1, F–1A, and (Mooney) M10; Swift Museum Models (Globe) GC1A and GC–1B; Augustair Model Varga (Morrisey) 2150A; Aeronca Model 65–CA; American Champion 7ECA (with Cont. O–200–A engine) and 7ACA; Reims Aviation (Cessna) F150G, F150H, F150J, F150K, F150L, F150M, FA150K, FA150L, F152, AND FA152; Socata-Groupe Aerospatiale Models Rallye Series MS880B, MS885, and 100S, F22B, and F22C; Univair Models (Alon) A–2, A2–A, (Forney) F–1, F–1A, and (Mooney) M10; Swift Museum Models (Globe) GC–1A and GC–1B; Augustair Model Varga (Morrisey) 2150A; Aeronca Model 65–CA; American Champion 7ECA (with Cont. O–200–A engine) and 7ACA; Reims Aviation (Cessna) F150G, F150H, F150J, F150K, F150L, F150M, FA150K, FA150L, F152, AND FA152; Socata-Groupe Aerospatiale Models Rallye Series MS880B, MS885, and 100S. |
| AAF–118 ..... | Cessna Models 170, 170A, 170B, 172, 172A, 172B, 172C, 172D, 172E, 172F, 172G, 172H, 172I, 172K, 172L, and 172M; Mooney Mite Model M–18C; Reims Aviation Models (Cessna) F172D, F172E, F172F, F172G, F172H, F172K, F172L, and F172M; Socata-Groupe Aerospatiale Models TB9, TB10, Rallye Series MS892A–150, MS892E–150, MS892E–150T, and MS892E–150ST; Panstwowe Zakolady Kotnicze Model PZL–Koliber 150A; Augustair, Inc. Model Varga (Morrisey) 2180. |

Note 2: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required within the next 100 hours time-in-service (TIS) after the effective date of this AD, or within the next 100 hours (TIS) after the last inspection accomplished in accordance with AD 95–03–02, whichever occurs first, and thereafter as indicated in the body of this AD, unless already accomplished in accordance with paragraph (c) of this AD.

To prevent gasket particles from entering the carburetor because of air filter gasket failure, which could result in partial or complete loss of engine power, accomplish the following:

(a) Inspect (visually) the inside and outside of the air filter frame for gasket looseness, movement, or deterioration in accordance with Brackett Document I–194, dated March 16, 1994. Continue this repetitive inspection at intervals not to exceed 100 hours TIS, until accomplishment of the terminating action required in paragraph (c) of this AD.

(b) If the gasket is found to be damaged, prior to further flight, replace the air filter assembly with one having a retaining lip in accordance with the Brackett INSTALLATION INSTRUCTION SHEET corresponding to the new air filter assembly part number that is applicable to the owner/operator's particular model of airplane:

| Air filter assembly | Replace with assembly | Instruction sheet |
|---|---|---|
| BA–2010 ..... | BA–2010 Revision A ..... | BA–2004, dated 6/6/95. |
| BA–4106 ..... | BA–4106 Revision D ..... | BA–4105, dated 6/15/95. |
| BA–4106–1 ..... | BA–4106–1 Revision A ..... | RM–1, dated 7/6/95. |
| BA–4210 ..... | BA–4210 Revision B ..... | BA–4205, dated 6/14/95. |
| BA–5110 ..... | BA–5110 Revision H ..... | BA–5105, dated 5/8/95. |
| BA–5110A ..... | BA–5110A Revision D ..... | BA–5111, dated 5/8/95. |
| BA–6110 ..... | BA–6110 Revision C ..... | BA–6105, dated 6/5/95. |
| BA–8910 ..... | BA–8910 Revision B ..... | BA–8910–3, dated 6/6/95. |
| AAF–117 ..... | BA–4106 Revision D ..... | BA–4105, dated 6/15/95. |
| AAF–118 ..... | BA–5110 Revision H ..... | BA–5105, dated 5/8/95. |

(c) Within the next 500 hours TIS after the effective date of this AD, replace the air filter assembly as a terminating action to this AD in accordance with the Brackett INSTALLATION INSTRUCTION SHEET corresponding to the new air filter assembly part number that is applicable to the owner/operator's particular model of airplane as specified in paragraph (b) of this AD.

(d) The replacement in paragraphs (b) and (c) are considered terminating action for the repetitive inspection required by this AD.

(e) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Los Angeles Aircraft Certification Office, FAA, 3960 Paramount Boulevard, Lakewood, California 90712. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(g) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Brackett Aircraft Company, Inc., 7045 Flightline Drive, Kingman, Arizona 86401; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(h) This amendment supersedes AD 95–03–02, Amendment 39–9139.

Issued in Kansas City, Missouri, on December 11, 1995.

Henry A. Armstrong,

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 95–30675 Filed 12–15–95; 8:45 am]

**BILLING CODE 4910–13–U**

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## 14 CFR Part 71

**[Airspace Docket No. 95–ANE–60]**

## Proposed Amendment to Class D and Class E Airspace; New England Region

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend the Class D airspace areas at Beverly, MA (BVY); Bedford, MA (BED); Danbury, CT (DXR); Norwood, MA (OWD); Lebanon, NH (LEB); and Nashua, NH (ASH); and to amend the associated Class E airspace areas at Beverly (BVY), Lebanon (LEB), and Nashua (ASH). The FAA has determined after a review of the elevation of the surrounding terrain in the vicinity of these airports that the lateral limits of the Class D areas at these airports may be reduced and the appropriate changes made to the Class E airspace areas.

**DATES:** Comments must be received on or before January 17, 1996.

**ADDRESSES:** Send comments on the proposal in triplicate to: Manager, System Management Branch, ANE–530, Federal Aviation Administration, Docket No. 95–ANE–60, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7530; fax (617) 238–7596.

The official docket file may be examined in the Office of the Assistant Chief Counsel, New England Region, ANE–7, Room 401, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7050; fax (617) 238–7055.

An informal docket may also be examined during normal business hours in the Air Traffic Division, Room 408, by contacting the Manager, System Management Branch at the first address listed above.

**FOR FURTHER INFORMATION CONTACT:** Raymond Duda, System Management Branch, ANE–533, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7533; fax (617) 238–7596.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed first under **ADDRESSES** above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–ANE–60.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

### Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

### The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to reduce the lateral limits of the Class D airspace areas at Beverly, MA (BVY); Bedford, MA (BED); Danbury, CT (DXR); Norwood, MA (OWD); Lebanon, NH (LEB); and Nashua, NH (ASH); and, as a consequence to those changes, to make the necessary changes to the associated Class E airspace areas at Beverly (BVY), Lebanon (LEB), and Nashua (ASH). This action is the result of an extensive review of the elevation of the surrounding terrain at airports in the New England region with Class D airspace areas. That review came in response to concerns expressed by operators and other interested parties over recent changes to the lateral limits of Class D airspace areas in the New England Region. By using more detailed topographical charts and more precise calculations, the FAA has determined that reductions in the lateral limits of the Class D airspace areas at BVY, BED, DXR, OWD, LEB, and ASH are appropriate and will not affect aviation safety. As a result of the reductions to the Class D airspace areas at BVY, LEB, and ASH, the FAA must also make minor adjustments to the associated Class E areas at those airports. Class D airspace designations, and Class E airspace designations for airspace areas extending upward from the surface of the earth defined as extensions to Class D airspace areas, are published in paragraphs 5000 and 6004, respectively, of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document would be published subsequently in this Order.

The FAA has determined that these proposed regulations only involve an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, these proposed regulations—(1) are not ''significant regulatory actions'' under Executive Order 12866; (2) are not ''significant rules'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) do not warrant preparation of a Regulatory Evaluation as these routine matters will only affect air traffic procedures and air navigation, it is certified that these proposed rules will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

## PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 5000 Class D Airspace*

* * * * *

MANE MA D Beverly, MA [Revised]

Beverly municipal Airport, MA
(Lat. 42°35′03″ N, long. 70°55′01″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.1-mile radius of Beverly Municipal Airport, excluding that airspace within the Boston, MA, Class B airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE MA D Bedford MA [Revised]

Bedford, Lawrence G. Hanscom Field, MA
(Lat. 42°28′12″ N, long. 71°17′20″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.7-mile radius of Lawrence G. Hanscom Field, excluding that airspace within the Boston, MA, Class B airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE CT D Danbury, CT [Revised]

Danbury Municipal Airport, CT
(Lat. 41°22′17″ N, long. 73°28′56″ W)
Carmel VORTAC
(Lat. 41°16′48″ N, long. 73°34′53″ W)

That airspace extending upward from the surface to and including 3,000 feet MSL within a 6-mile radius of Danbury Municipal Airport, and within 1.2 miles on each side of the Carmel VORTAC 039° radial, extending from the 6-mile radius to the Carmel VORTAC. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE MA D Norwood, MA [Revised]

Norwood Memorial Airport, MA
(Lat. 42°11′27″ N, long. 71°10′23″ W)

That airspace extending upward from the surface to and including 2,600 MSL within a 4.5-mile radius of the Norwood Memorial Airport, excluding that airspace within the Boston, MA, Class B airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice of Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE NH D Lebanon, NH [Revised]

Lebanon Municipal Airport, NH
(Lat. 43°37′35″ N, long. 72°18′15″ W)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.8-mile radius of Lebanon Municipal Airport, and within 1.8 miles each side of the extended centerline of Runway 36, extending from the 4.8-mile radius to 6 miles north of the end of Runway 36. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE NH D Nashua, NH [Revised]

Nashua Boire Field, NH
(Lat. 42°46′54″ N, long. 71°30′53″ W)
Sports Center Airport, Pepperell
(Lat. 42°41′45″ N, long. 71°33′03″ W)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 5-mile radius of Boire Field; excluding that airspace within a 2-mile radius of Sports Center Airport, Pepperell, and that airspace within the Manchester Airport, NH, Class C airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

## Subpart E—Class E Airspace

* * * * *

*Paragraph 6004 Class E airspace areas extending from the surface of the earth defined as extensions to Class D airspace areas.*

* * * * *

ANE MA E4 Beverly MA [Revised]

Beverly Municipal Airport, MA
(Lat. 42°35′03″ N, long. 70°55′01″ W)

That airspace extending upward from the surface within 3.2 miles on each side of the Topsfield NDB 317° bearing extending from a 4.1-mile radius of Beverly Municipal Airport to 7 miles northwest of the Topsfield NDB. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE NH E4 Lebanon, NH [Revised]

Lebanon Municipal Airport, NH
(Lat. 43°3735″ N, long. 72°18′15″ W)
BURGR OM
(Lat. 43°43′57″ N, long. 72°20′00″ W)
Hanover NDB
(Lat. 43°42′08″ N, long. 72°10′39″ W)

That airspace extending upward from the surface within 3.3 miles each side of the BURGR OM 352° bearing from a 4.8-mile radius of Lebanon Municipal Airport to 8 miles north of the BURGR OM, and within 2.4 miles each side of the Hanover NDB 051° bearing extending from the 4.8-mile radius to 7 miles northeast of the Hanover NBD. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

ANE NE E4 Nashua, NH [Revised]

Nashua, Boire Field, NH
(Lat. 42°46′54″ N, long. 71°30′53″ W)
CHERN NDB
(Lat. 42°49′54″ N, long. 71°30′53″ W)
Manchester VORTAC
(Lat. 42°52′06″ N, long. 71°22′10″ W)

That airspace extending upward from the surface within 2.6 miles on each side of the CHERN NDB 303° bearing extending from a 5-mile radius of Boire Field to 7 miles northwest of the CHERN NDB, and that airspace extending upward from the surface within 1.1 miles on each side of the Manchester VORTAC 231° radial extending from the 5-mile radius to 8.4 miles northeast of Boire Field. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective dates and times will threafter be continuously published in the Airport/Facility Directory.

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Issued in Burlington, MA, on December 7, 1995.

John J. Boyce,

*Acting Manager, Air Traffic Division, New England Region.*

[FR Doc. 95–30689 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–13–M

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## 14 CFR Part 71

**[Airspace Docket No. 95–AWP–28]**

## Proposed Establishment of Class E Airspace; Willcox, AZ

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to establish a Class E airspace area at Wilcox, AZ. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 21 and RWY 3 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Cochise County Airport, Willcox, AZ.

**DATES:** Comments must be received on or before January 19, 1996.

**ADDRESSES:** Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, System Management Branch, AWP–530, Docket No. 95–AWP–28, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California, 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, System Management Branch, Air Traffic Division at the above address.

**FOR FURTHER INFORMATION CONTACT:** Scott Speer, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6533.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 95–AWP–28.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish a Class E airspace area at Willcox, AZ. The development of GPS SIAPs at Cochise County Airport has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS RWY 21 and RWY 3 SIAP at Cochise County Airport, Willcox, AZ. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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 10034; 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 proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

AWP AZ E5 Willcox, AZ [New]

Cochise County Airport, AZ
(Lat. 32°14′39″ N, long. 109°53′38″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Cochise County Airport.

* * * * *

Issued in Los Angeles, California, on December 1, 1995.

Harvey R. Riebel,

*Acting Manager, Air Traffic Division, Western-Pacific Region.*

[FR Doc. 95–30690 Filed 12–15–95; 8:45 am]

**BILLING CODE 4910–13–M**

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## 14 CFR Part 71

**[Airspace Docket No. 95–AWP–43]**

## Proposed Amendment of Class E Airspace; Vacaville, CA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend the Class E airspace area at Vacaville, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 20 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Nut Tree Airport, Vacaville, CA.

**DATES:** Comments must be received on or before January 24, 1996.

**ADDRESSES:** Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, System Management Branch, AWP–530, Docket No. 95–AWP–43, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California, 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, System Management Branch, Air Traffic Division at the above address.

**FOR FURTHER INFORMATION CONTACT:** Scott Speer, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6533.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 95–AWP–43.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Vacaville, CA. The development of a GPS SIAP at Nut Tree Airport has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS RWY 20 SIAP at Nut Tree Airport, Vacaville, CA. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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 10034; 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 proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

AWP AZ E5 Vacaville, CA [Revised]

Nut Tree Airport, CA
(Lat. 38°22′37″ N, long. 121°57′45″ W)
Sacramento VORTAC
(Lat. 38°26′38″ N, long. 121°33′02″ W)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Nut Tree Airport and within 2.5 miles radius of the Nut Tree Airport and within 2.2 miles each side of the Sacramento VORTAC 259° radial, extending from the 5-mile radius to 11.3 miles west of the VORTAC and 2.5 miles each side of the 034° bearing from the Nut Tree Airport, extending from the 2.6 mile radius to 10.5 miles northwest of the airport.

* * * * *

Issued in Los Angeles, California, on December 1, 1995.

James H. Snow,

*Acting Manager, Air Traffic Division, Western-Pacific Region.*

[FR Doc. 95–30691 Filed 12–15–95; 8:45 am]

**BILLING CODE 4910–13–M**

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## 14 CFR Part 71

**[Airspace Docket No. 95–AEA–06]**

## Proposed Establishment of Class E Airspace; Stevensville, MD

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule would establish Class E Airspace at Stevensville, MD. A standard instrument approach procedure (SIAP), based on the Global Positioning System (GPS), has been developed for Runway (RWY) 11 at Bay Bridge Airport, Stevensville, MD. The intended effect of

this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations to the airport. The area would be depicted on aeronautical charts for pilot reference.

**DATES:** Comments must be received on or before February 29, 1996.

**ADDRESSES:** Send comments on the proposed rule in triplicate to: Manager, System Management Branch, AEA–530, Docket No. 95–AEA–06 F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the System Management Branch, AEA–530, F.A.A. Eastern Region, Federal Building, #111, John F. Kennedy International Airport, Jamaica, New York 11430.

**FOR FURTHER INFORMATION CONTACT:** Mr. Francis T. Jordan, Jr., Airspace Specialist, System Management Branch, AEA–530, F.A.A. Eastern Region, Federal Building, #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553–4521.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 95–AEA–06.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Fitzgerald Federal Building # 111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at Stevensville, MD. A GPS RWY 11 SIAP has been developed for Bay Bridge Airport. Additional controlled airspace extending upward from 700 feet above the surface (AGL) is needed to accommodate this SIAP and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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 would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, is proposed to be amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

AEA VA E5 Stevensville, MD

Bay Bridge Airport, MD
(Lat. 38°58′35″ N, long. 76°19′ 47″W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Bay Bridge Airport.

* * * * *

Issued in Jamaica, New York, on November 30, 1995.

John S. Walker,

*Manager, Air Traffic Division.*

[FR Doc. 95–30693 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–13–M

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## 14 CFR Part 71

**[Airspace Docket No. 95–AWP–39]**

## Proposed Amendment of Class E Airspace; Columbia, CA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend the Class E airspace area at Columbia, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 35 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight (IFR) operations at Columbia Airport, Columbia, CA.

**DATES:** Comments must be received on or before January 19, 1996.

**ADDRESSES:** Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, System Management Branch, AWP–530, Docket No. 95–AWP–39, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California, 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, System Management Branch, Air Traffic Division at the above address.

**FOR FURTHER INFORMATION CONTACT:** Scott Speer, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6533.

**SUPPLEMENTARY INFORMATION:**

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 95–AWP–39.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A. which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Columbia, CA. The development of a GPS SIAP at Columbia Airport has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS RWY 35 SIAP at Columbia Airport, Columbia, CA. Class E airspace designations for areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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 10034; 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 proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

AWP AZ E5 Columbia, CA [Revised]

Columbia Airport, CA
(Lat. 38°01′50″ N, long. 120°24′53″ W )
Columbia NDB
(Lat. 38°01′52″ N, long. 120°24′46″ W)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Columbia Airport and within 2.6 miles radius of each side of the 211° bearing from the Columbia NDB extending from the 5-mile radius to 10.4 miles south of the NDB and within 2 miles east of the 189° bearing from the Columbia NDB extending from the 5-mile radius to 7.8 miles south of the NDB.

* * * * *

Issued in Los Angeles, California, on December 1, 1995.

James H. Snow,

*Acting Manager, Air Traffic Division, Western-Pacific Region.*

[FR Doc. 95–30694 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–13–M

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## SECURITIES AND EXCHANGE COMMISSION

## 17 CFR Chapter II

**Release Nos. 33–7246, 34–36572, 35–26428, 39–2337, IC–21591, IA–1540; File No. S7–33–95**

## List of Rules To Be Reviewed Pursuant to the Regulatory Flexibility Act

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Publication of list of rules scheduled for review.

**SUMMARY:** The Securities and Exchange Commission is today publishing a list of rules to be reviewed pursuant to Section

610 of the Regulatory Flexibility Act. The list is published to provide the public with notice that these rules are scheduled for review by the agency and to invite public comment on them.

**DATES:** Public comments are due by January 31, 1996.

**ADDRESSES:** Persons wishing to submit written comments should file three copies with Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Room 6184, Stop 6–9, Washington, D.C. 20549. All submissions should refer to File No. S7–33–95, and will be available for public inspection and copying at the Commission's Public Reference Room, Room 1026, at the same address.

**FOR FURTHER INFORMATION CONTACT:** Anne H. Sullivan, Office of the General Counsel, Securities and Exchange Commission 202–942–0954.

**SUPPLEMENTARY INFORMATION:** The Regulatory Flexibility Act (''RFA'') (Pub. L. 96–354, 94 Stat. 1165 (September 19, 1980) requires that each agency review every ten years each of its rules that has a significant economic impact upon a substantial number of small entities. The purpose of the review is ''to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of such small entities'' (5 USC 610(a)).

The RFA stipulates the following specific considerations that must be addressed in the review of each rule: (1) the continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule (5 USC 610(c)).

Pursuant to the RFA, the rules and forms listed below are scheduled for review by staff of the Commission during the next twelve months. The rules are grouped according to which Division or Office of the Commission has responsibility for, and will review, each rule:

Rules and Forms To Be Reviewed by the Division of Corporation Finance

*Title:* Form S–4 (for registration of securities issued in business combination transactions).
*Citation:* 17 CFR 239.25.
*Authority:* 15 U.S.C. 77a *et seq.*

*Title:* Form F–4 (for registration of securities of foreign private issuers issued in certain business combinations).
*Citation:* 17 CFR 239.34.
*Authority:* 15 U.S.C. 77a *et seq.*

*Title:* General rules and regulations pursuant to Section 9(a) of the African Development Bank Act.
*Citation:* 17 CFR Part 288.
*Authority:* 15 U.S.C. 77a *et seq.*; 22 U.S.C. 290i–9a.

*Title:* Regulation 14A; Regulation 14C.
*Citation:* 17 CFR 240.14a–1 through 240.14a–104 (Regulation 14A); 17 CFR 240.14c–1 through 240.14c–101 (Regulation 14C).
*Authority:* 15 U.S.C. 78a *et seq.*

Rules and Forms To Be Reviewed by the Division of Investment Management

*Title:* Rule 2a19–1 (investment company limited partners not deemed affiliated persons).
*Citation:* 17 CFR 270.2a19–1.
*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Rule 10b–1 (definition of regular broker or dealer)
*Citation:* 17 CFR 270.10b–1.
*Authority:* 15 USC 80a–37(a).

*Title:* Rule 22e–2 (pricing of redemption requests in accordance with Rule 22c–1).
*Citation:* 17 CFR 270.22e–2.
*Authority:* 15 USC 80a–6(c), 80a–22(e), and 80a–37(a).

*Title:* Rule 20a–1 (solicitations of proxies, consents and authorizations).
*Citation:* 17 CFR 270.20a–1.
*Authority:* 15 USC 80a–20(a).

*Title:* Rule 30a–1 (annual reports).
*Citation:* 17 CFR 270.30a–1.
*Authority:* 15 USC 80a–29.

*Title:* Rule 30b1–1 (semi-annual report).
*Citation:* 17 CFR 270.30b1–1.
*Authority:* 15 USC 80a–29.

*Title:* Rule 30b1–2 (semi-annual report for totally-owned registered management investment company subsidiary of registered management investment company).
*Citation:* 17 CFR 270.30b1–2.
*Authority:* 15 USC 80a–29.

*Title:* Rule 30f–1 (applicability of Section 16 of the Exchange Act to Section 30(f)).
*Citation:* 17 CFR 270.30f–1,
*Authority:* 15 USC 78p.

*Title:* Rule 34b–1 (sales literature deemed to be misleading).
*Citation:* 17 CFR 270.34b–1.
*Authority:* 15 USC 77j, 77*l*, 78j(b), and 80a–33(b).

*Title:* Form N–2 (registration statement of closed-end management investment companies).
*Citation:* 17 CFR 274.11a–1.
*Authority:* 15 USC 77f, 77g, 77h, 77j, 77s, 80a–8, 80a–24, 80a–29, and 80a–37.

*Title:* Form N–14 (for the registration of securities issued in business combination transactions).
*Citation:* 17 CFR 239.23.
*Authority:* 15 USC 77f, 77g, 77h, 77j, 77s, 80a–8, 80a–24, 80a–29, and 80a–37.

*Title:* Rule 203(b)(3)–1 (definition of ''client'' of an investment adviser for certain purposes relating to limited partnership).
*Citation:* 17 CFR 275.203(b)(3)–1.
*Authority:* 15 USC 80b–6A.

*Title:* Rule 205–3 (exemption from the compensation prohibition of Section 205(1) for registered investment advisers).
*Citation:* 17 CFR 275.203(b)(3)–1.
*Authority:* 15 USC 80b–6A.

*Title:* Rule 6c–3 (exemptions for certain registered variable life insurance separate accounts).
*Citation:* 17 CFR 270.6c–3.
*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Rule 6c–6 (exemption for certain registered separate accounts and other persons).
*Citation:* 17 CFR 270.6c–6.
*Authority:* 15 USC 80a–6(c), 80a–11(a), and 80a–37(a).

*Title:* Rule 6c–7 (exemptions from certain provisions of Sections 22(e) and 27 for registered separate accounts offering variable annuity contracts to participants in the Texas Optional Retirement Program).
*Citation:* 17 CFR 270.6c–7.
*Authority:* 15 USC 80a–6(c); 80a–37(a).

*Title:* Rule 6c–8 (exemptions for registered separate accounts to impose a deferred sales load and to deduct certain administration charges)
*Citation:* 17 CFR 270.6c–8.
*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Rule 6e–3(T) (temporary exemptions for flexible premium variable life insurance separate accounts).
*Citation:* 17 CFR 270.6e–3(T).
*Authority:* 15 USC 80a–6(e) and 80a–37(a).

*Title:* Rule 11a–2 (offers of exchange by certain registered separate accounts or others the terms of which do not require prior Commission approval).
*Citation:* 17 CFR 270.11a–2.
*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Rule 22d–2 (exemption from section 22(d) for certain registered separate accounts).
*Citation:* 17 CFR 270.22d–2.

*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Rule 26a–1 (payment of administrative fees to the depositor or principal underwriter of a unit investment trust; exemptive relief for separate accounts).
*Citation:* 17 CFR 270.26a–1.
*Authority:* 15 USC 80a–6(c), 80a–26(a), and 80a–37(a).

*Title:* Rule 26a–2 (exemptions from certain provisions of sections 26 and 27 for registered separate accounts and others regarding custodianship of and deduction of certain fees and charges from the assets of such accounts).
*Citation:* 17 CFR 270.26a–2.
*Authority:* 15 USC 80a–6(c) and 80a–37(a).

*Title:* Form N–3 (registration statement of separate accounts organized as management investment companies).
*Citation:* 17 CFR 274.11b.
*Authority:* 15 USC 77g, 77j, 77s, 80a–8, 80a–29, and 80a–37.

*Title:* Form N–4 (registration statement of separate accounts organized as unit investment trusts).
*Citation:* 17 CFR 274.11c.
*Authority:* 15 USC 77g, 77j, 77s, 80a-8, 80a-29, and 80a-37.

*Title:* Rule 7 (companies deemed not to be electric gas utility companies).
*Citation:* 17 CFR 250.7.
*Authority:* 15 U.S.C. 79b.

*Title:* Rule 14 (exemption of acquisitions of securities of power supply companies from section 9(a)(2) of the Act).
*Citation:* 17 CFR 250.14.
*Authority:* l5 U.S.C. 79i(a)(2).

*Title:* Rule 15 (exemption of holding company and subsidiary companies under section 3(a)(2) of the Act).
*Citation:* 17 CFR 250.15.
*Authority:* 15 U.S.C. 79c(a)(2).

*Title:* Rule 16 (exemption of non-utility subsidiaries and affiliates).
*Citation:* 17 CFR 250.16.
*Authority:* 15 U.S.C. 79b(a)(8) and 79b(a)(11).

*Title:* Rule 20 (prescribed forms and amendments).
*Citation:* 17 CFR 250.20.
*Authority:* 15 U.S.C. 79f.

*Title:* Rule 21 (filing of documents).
*Citation:* 17 CFR 250.21.
*Authority:* 15 U.S.C. 77a *et. seq.*, 78a *et. seq.*, and 77aaa *et.seq.*

*Title:* Rule 22 (applications and declarations).
*Citation:* 17 CFR 250.22.
*Authority:* 15 U.S.C. 77s, 78m, 78o, 78w, 79o, 77eee, 77ggg, 77nnn, 77sss, 80a–37, 80a–38, 79c and 79t, 80b–3, 80b–4, and 80b–11.

*Title:* Rule 41 (exemption of public utility subsidiaries with respect to limited subsidiaries with respect to limited acquisition of utility assets).
*Citation:* 17 CFR 250.41.
*Authority:* 15 U.S.C. 78m.

*Title:* Rule 52 (exemption of issue and sale of certain securities).
*Citation:* 17 CFR 250.52.
*Authority:* 15 U.S.C. 79f and 79h.

*Title:* Rule 53 (certain registered holding company financings in connection with the acquisition of one or more exempt wholesale generators).
*Citation:* 17 CFR 250.53.
*Authority:* 15 U.S.C. 79z–5a.

*Title:* Rule 54 (effect of exempt wholesale generators on other transactions).
*Citation:* 17 CFR 250.54.
*Authority:* 15 U.S.C. 79c, 79f(b), and 79-i(c)(3).

*Title:* Notices and reports to be filed under Section 33.
*Citation:* 17 CFR 250.57.
*Authority:* 15 U.S.C. 79z–5b.

*Title:* Rule 63 (Approval of reorganization fees.
*Citation:* 17 CFR 250.63.
*Authority:* 11 U.S.C. 608.

*Title:* Rule 64 (scope of applications for approval of reorganization plans).
*Citation:* 17 CFR 250.64.
*Authority:* 15 U.S.C. 79k.

*Title:* Rule 72—Filing of statements pursuant to Section 17(a).
*Citation:* 17 CFR 250.72.
*Authority:* 15 U.S.C. 79q.

Rules To Be Reviewed by the Division of Market Regulation

*Title:* Exemption of certain direct participation program securities from Sections 7(c) and 11(d)(1).
*Citation:* 17 CFR 240.3a12–9.
*Authority:* 15 U.S.C. 78c(a)(12), 78g, 78k and 78w.

*Title:* Options disclosure document.
*Citation:* 17 CFR 240.9b–1.
*Authority:* 15 U.S.C. 77b, 77g, 77j, 77s(a), 78i, 78(o) and 78w(a).

*Title:* Exemptions from Section 12(g).
*Citation:* 17 CFR 240.12g–1.
*Authority:* 15 U.S.C. 78l, 78m, 78o and 78w.

*Title:* Tender offers by issuers.
*Citation:* 17 CFR 240.13e–4; 17 CFR 240.14e-1.
*Authority:* 15 U.S.C. 78c(b), 78i(a)(6), 78j(b), 78m(e), 78n(e), 78w(a) and 80a–23(c).

*Title:* Annual reporting requirements for registered transfer agents.
*Citation:* 17 CFR 240.17Ac2–2.
*Authority:* 15 U.S.C. 78q, 78q–1 and 78w(a).

*Title:* Depository shipment control list transfer instructions; Definition of item.
*Citation:* 17 CFR 240.17Ad–1.
*Authority:* 15 U.S.C. 78b, 781, 78q–1 and 78w.

*Title:* Written inquiries and requests.
*Citation:* 17 CFR 240.17Ad–5.
*Authority:* 15 U.S.C. 78c, 78q–1 and 78w.

Rule To Be Reviewed by the Office of the Chief Accountant

*Title:* Article 4 of Regulation S–X (Rules of General Application).
*Citation:* 17 CFR 210.4.
*Authority:* 15 U.S.C. 77f, 77g, 77s(a), 77aa(25) to (26), 78l, 78m, 78o(d), 78w(a), 79e(b), 79n, 79t(a), 80a–8, and 80a–29.

The Commission invites public comment on both the list and the rules to be reviewed.

Dated: December 12, 1995.

By the Commission.

Margaret H. McFarland,

*Deputy Secretary.*

[FR Doc. 95–30659 Filed 12–15–95; 8:45 am]

BILLING CODE 8010–01–P

## DEPARTMENT OF THE INTERIOR

## Office of Surface Mining Reclamation and Enforcement

## 30 CFR Part 950

**[SPATS No. WY–022]**

## Wyoming Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** OSM is announcing receipt of a proposed amendment to the Wyoming regulatory program (hereinafter, the ''Wyoming program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of the addition and revision of statutes and rules pertaining to shrub density stocking requirements and wildlife habitat. The amendment is intended to revise the Wyoming program to be consistent with SMCRA and the corresponding Federal regulations.

**DATES:** Written comments must be received by 4:00 p.m., m.s.t., January 17, 1996. If requested, a public hearing on the proposed amendment will be held on January 12, 1996. Requests to present oral testimony at the hearing must be

received by 4:00 p.m., m.s.t., January 2, 1996.

**ADDRESSES:** Written comments should be mailed or hand delivered to Guy V. Padgett at the address listed below.

Copies of the Wyoming program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Casper Field Office.

Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Room 2128, 100 East ''B'' Street, Casper, Wyoming 82601–1918

Dennis Hemmer, Director, Department of Environmental Quality, Herschler Building—4th Floor West, 125 West 25th Street, Cheyenne, Wyoming 82002, Telephone: (307) 777–7938

**FOR FURTHER INFORMATION CONTACT:** Guy V. Padgett, Telephone: (307) 261–5824.

**SUPPLEMENTARY INFORMATION:**

## I. Background on the Wyoming Program

On November 26, 1980, the Secretary of the Interior conditionally approved the Wyoming program. General background information on the Wyoming program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Wyoming program can be found in the November 26, 1980, Federal Register (45 FR 78637). Subsequent actions concerning Wyoming's program and program amendments can be found at 30 CFR 950.12, 950.15, 950.16, and 950.20.

## II. Proposed Amendment

By letter dated November 29, 1995, Wyoming submitted a proposed amendment to is program (administrative record No. WY–031–1) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). Wyoming submitted the proposed amendment in response to the required program amendments at 30 CFR 950.16(q) and (bb) through (gg). The provisions of the Wyoming Environmental Quality Act that Wyoming proposes to revise are: Wyoming Statue (W.S.) 35–11–103, definitions, and W.S. 35–11–402, establishment of reclamation standards. The provisions of the coal rules and regulations of the Department of Environmental Quality, Land Quality Division, that Wyoming proposes to revise are: chapter I, section 2, definitions; chapter II, section 2, permit application requirements for surface coal mining operations; chapter IV, section 2, general environmental protection performance standards for surface coal mining operations; chapter X, section 4, coal exploration and reclamation performance standards; chapter XI, section 5, self-bonding; chapter XIII, section 3, notice and opportunity for public hearing on surface coal mining permit revisions; chapter XVII, section 1, definitions for designation of areas unsuitable for surface coal mining; and appendix A, vegetation sampling methods and reclamation success standards for surface coal mining operations.

Specifically, Wyoming proposes to delete the definitions for ''Agricultural lands,'' ''Critical habitat,'' and ''Important habitat'' or ''crucial habitat'' at W.S. 35–11–103(e) (xxviii), (xxix), and (xxx).

Wyoming proposes to revise W.S. 35–11–402(b) to indicate that this statutory provision addresses, to the extent required by Federal law or regulations, State wildlife agencies' approval, rather than consultation and approval, of reclamation standards for fish and wildlife habitat. It proposes to further revise W.S. 35–11–402(b) to require that the Wyoming Game and Fish Department shall consider ''fish and wildlife habitat'' to be that defined at W.S. 35–11–103(e)(xxvi) and not to include grazing land as defined in W.S. 35–11–103(e) (xxvii) ''unless the grazingland has been designated as critical habitat by the United States Fish and Wildlife Service'' or ''crucial habitat by the Wyoming Game and Fish Department prior to submittal of the initial permit application or any subsequent amendments to the permit application.'' Wyoming proposes to revise W.S. 35–11–402(c) to require that native shrubs shall be reestablished on grazing land and that no shrub species shall be required to be more than one-half of the shrubs in the postmining standard.

Wyoming also proposes several revisions to its rules and regulations. In chapter I, Wyoming proposes to revise the definition for ''Critical habitat'' at section 2(v) to be ''those areas essential to the survival and recovery of species listed by the Secretary of the Interior or Commerce as threatened or endangered; (50 CFR Parts 17 and 226).'' It proposes to add a definition for ''Crucial habitat'' at section 2(w) to be ''those areas, designated as such by the Wyoming Game and Fish Department, which determine a population's ability to maintain and reproduce itself at a certain level over a long term.'' It proposes to add a definition for ''Eligible land'' at section 2(ac) to be

> All land to be affected by a mining operation after the shrub standard set forth at Chapter IV, Section 2.(d)(x)(E) is approved by the Office of Surface Mining. Cropland, pastureland, or treated grazingland approved by the Administrator which is to be affected by a mining operation after the shrub standard set forth at chapter IV, section 2.(d)(x)(E) is approved by the Office of Surface Mining is not 'eligible land'.

Wyoming proposes to revise the definition for ''Important habitat'' at recodified section 2(ax) to be

> That habitat which, in limited availability, supports or encourages a maximum diversity of wildlife species or fulfills one or more living requirements of a wildlife species. Examples of important habitat include, but are not limited to, wetlands, riparian areas, rimrocks, areas offering special shelter or protection, reproduction and nursery areas, and wintering areas.

It proposes to revise section 2(bc)(iii) to indicate that ''Grazingland includes rangelands and forest lands where the indigenous native vegetation is actively managed for grazing, browsing, and occasionally hay production, and occasional use by wildlife.'' Wyoming proposes to revise section 2(bc)(viii) to indicate that ''Fish and wildlife habitat means land dedicated wholly or partially to the production, protection or management of species of fish or wildlife.'' It proposes to add at section 2(bc)(xi) a provision to indicate that

> ''Treated grazingland'' means grazingland which has been altered to reduce or eliminate shrubs provided such treatment was applied at least five years prior to submission of the state program permit application. However, grazingland altered more than five years prior to submission of the state program permit application on which full shrubs have reestablished to a density of at least one per nine square meters does not qualify as treated grazingland.

Wyoming proposes to recodify the definitions in chapter 1, section 2, to reflect the additions of new terms as discussed above.

In chapter II, Wyoming proposes to revise section 2(a)(vi)(G)(II) to require that, if crucial habitat, in addition to critical or important habitat, disruption is likely, the Wyoming Game and Fish Department shall be contacted to determine the types and numbers of wildlife likely to be disturbed or displaced. It also proposes to revise section 2(b)(iv)(C), regarding revegetation plans, to require that (1) the Wyoming Game and Fish Department shall be consulted, and its approval received, for minimum stocking and planting arrangements of trees and shrubs, including species composition

and ground cover for crucial and critical habitat, (2) the Wyoming Game and Fish Department shall be consulted for minimum stocking and planting arrangements of trees and shrubs, including species composition and vegetative ground cover for important habitat, and (3) the Wyoming Department of Agriculture shall be consulted on cropland and erosion control techniques.

In chapter IV, Wyoming proposes to revise section 2(d)(x)(E) to include a requirement that the postmining density, composition, and distribution of shrubs shall be based upon site-specific evaluation of premining vegetation and wildlife use. It proposes to revise section 2(d)(x)(E)(I) to require that (1) except where a lesser density is justified from premining condition in accordance with appendix A, at least 20 percent of the eligible land shall be restored to shrub patches supporting an average density of one shrub per square meter, (2) patches shall be no less than .05 acres each and shall be arranged in a mosaic that will optimize habitat interspersion and edge effect, (3) criteria and procedures for establishing the standard are specified in appendix A, and (4) this standard shall apply upon approval by OSM to all lands affected thereafter. It also proposes to revise section 2(d)(x)(E)(II) to require that approved shrub species and seeding techniques shall be applied to all remaining grazingland. Finally, it proposes to revise section 2(d)(x)(E)(III) to require that (1) for areas containing designated critical or crucial habitat, the Wyoming Game and Fish Department shall be consulted about, and its approval received for, minimum stocking and planting arrangements of shrubs, including species composition, and (2) for areas determined to be important habitat, the Wyoming Game and Fish Department shall be consulted for recommended minimum stocking and planting arrangements of shrubs, including species composition, that may exceed the programmatic standard discussed above.

In chapter X, Wyoming proposes to revise section 4(e) to require that coal exploration operations that will substantially disturb the natural land surface shall not disturb critical or crucial habitats and that they shall consult the Wyoming Game and Fish Department prior to disturbing important habitat.

In chapter XI, Wyoming proposes to revise section 5(a) to require that the Administrator of the Division of Land Quality shall require the substitution of a corporate surety for a self-bond if the financial information submitted or requested under section 4(a)(ii), rather than section 3(a)(ii), indicates that the operator no longer qualifies under the self-bonding program.

In Chapter XIII, Wyoming proposes to revise section 3(a) to require that (1) the operator's newspaper notice of application for permit revision shall include the information required by W.S. 35–11–406(j) and the permit number and date approved, and (2) the operator shall mail a copy of the application mine plan map to the Wyoming Oil and Gas Commission in accordance with W.S. 35–11–406(j).

In chapter XVII, Wyoming proposes to revise its rules concerning designation of areas unsuitable for surface coal mining at section 1(a) to define ''Fragile lands'' to include crucial habitats for fish or wildlife.

In appendix A, Wyoming proposes to revise section II.C.3, suggested sampling procedures for ''shrub habitat characteristics,'' to indicate that (1) the postmining density composition and distribution of shrubs shall be based upon site-specific evaluation of the premining vegetation and wildlife use, (2) except where a lesser density is justified from premining conditions, at least 20 percent of the eligible land shall be restored to shrub patches supporting an average density of one shrub per square meter, (3) the baseline vegetation ''shall,'' instead of ''should,'' include premining shrub distribution data, (4) shrub density and cover data ''shall,'' instead of ''should,'' be components of the shrub distribution information, (5) when shrub density data are estimated, they ''shall,'' instead of ''should,'' be gathered from each community, but not from control areas, reference areas, or extended reference areas, (6) ''shrubs'' ''shall,'' instead of ''should,'' be divided into woody species (full shrubs) and suffrutescent species (subshrubs) for sampling purposes, (7) shrub density counts shall be performed within a 50 square meter area using a plot shape appropriate to the community, (8) data ''shall,'' instead of ''should,'' be recorded by species, (9) data ''shall,'' instead of ''should,'' be reported as number per square meter and per acre, (10) all shrub density data collected after the effective date specified in chapter IV, section 2(d)(x)(E) of the rules and regulations shall be subject to the sample adequacy tests specified in appendix A, section IV, although all shrub density data collected on land affected prior to the effective date shall not be subject to sample adequacy tests unless that shrub density data is being used to fulfill the 20 percent shrub density standard, and (11) when sampling, which is not subject to sample adequacy, is conducted, the number of shrub density sample points should correspond to the number of cover samples in each community type.

In appendix A, Wyoming proposes to revise table 1 to include parameter values to be used for 50 square meter shrub density plots in assessing sample adequacy, (2) to revise table 2, minimum and maximum sample sizes for various sampling methods, to delete the belt transect sampling method, and (3) to revise table 2 to require, for 50 square meter shrub density plots, a minimum of 15 samples and to indicate that, if sample adequacy cannot be achieved after sampling 50 shrub density plots, the operator shall contact the Land Quality Division for guidance.

In appendix A, Wyoming proposes to revise section IV.D to require that, with respect to maximum and minimum sampling sizes, shrub density be estimated using a 50 square meter plot.

In appendix A, Wyoming proposes to revise section VII.F, restoration of shrubs, subshrubs, and trees, to require that (1) the postmining density, composition, and distribution of shrubs shall be based upon site-specific evaluation of the premining vegetation and wildlife use and (2) except where a lesser density is justified from premining conditions, at least 20 percent of the eligible land shall be restored to shrub patches supporting an average density of one shrub per square meter. In this section, Wyoming also proposes to delete various shrub density criteria.

In Appendix A, Wyoming proposes to add in section VIII.E various and numerous standards and criteria for the evaluation of shrub density.

Lastly, in appendix A, Wyoming proposes to revise the glossary at appendix VII to define ''dominant'' as the species with the greatest density relative to all other species sampled and ''primary shrub species'' as

> All full shrub species which comprise at least 10 percent of the relative density of full shrubs. However, if an operator selects option IV, the community-specific full shrub and approved subshrub density standard, then 'primary shrub species' means all full shrub and approved subshrub species which comprise at least 10 percent of the relative density of full shrubs. It is further provided under option IV that in order to be considered as a ''primary shrub species,'' fringed sagewort must comprise at least 20 percent of the relative shrub and approved subshrub species composition.

## III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable

program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become a part of the Wyoming program.

*1. Written Comments*

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under ''DATES'' or at locations other than the Casper Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

*2. Public Hearing*

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., m.s.t., January 2, 1996. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

*3. Public Meeting*

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings will be open to the public and, if possible, notices of meeting will be posted at the locations listed under **ADDRESSES.** A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

*1. Executive Order 12866*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

*2. Executive Order 12778*

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

*3. National Environmental Policy Act*

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

*4. Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

*5. Regulatory Flexibility Act*

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining

Dated: December 7, 1995.

Russell F. Price,

*Acting Regional Director, Western Regional Coordinating Center.*

[FR Doc. 95–30649 Filed 12–15–95; 8:45 am]

BILLING CODE 4310–05–M

## POSTAL RATE COMMISSION

**[Docket No. RM95–4; Order No. 1094]**

## 39 CFR Part 3001

## Rules of Practice and Procedure

**AGENCY:** Postal Rate Commission.

**ACTION:** Proposed rulemaking; extension of time.

**SUMMARY:** The Commission is extending the time for the filing of comments on draft rules of practice and procedure published at 60 FR 54981–89.

**DATES:** Comments on the draft rules of practice and procedure must be submitted on or before January 8, 1996.

**ADDRESSES:** Comments and correspondence should be sent to Margaret P. Crenshaw, Secretary of the Commission, 1333 H Street, N.W., Suite 300, Washington, D.C. 20268–0001 (telephone 202/789–6840).

**FOR FURTHER INFORMATION CONTACT:** Stephen L. Sharfman, Legal Advisor, Postal Rate Commission, 1333 H Street, N.W., Suite 300, Washington, D.C. 20268–0001 (telephone 202/789–6820).

**SUPPLEMENTARY INFORMATION:** On October 27, 1995, Order No. 1084, a Notice of Proposed Rulemaking, was published at 60 FR 54981–89. This Notice presented draft rules that were founded on rules initially proposed by the United States Postal Service in a Petition filed April 13, 1995. However, the Commission's draft rules incorporated views expressed and suggestions made in comments filed by twenty-one participants. The deadline established for comments on the Commission's draft rules was December 26, 1995. Notice is hereby given that the deadline for filing comments on the draft rules is extended to January 8, 1996.

The Commission is concerned that the initial deadline for filing comments, December 26, 1995, falls at an inconvenient time, in the midst of the holiday season. As a courtesy to those planning to file comments on the draft rules and in the interest of obtaining comments based on a thorough review of the draft rules, the Commission has conferred this extension. It is Ordered:

1. Comments addressing the draft rules published at 60 FR 54981–89 are now due on January 8, 1996.

2. The Secretary shall publish this Notice and Order in the Federal Register.

Issued by the Commission on December 12, 1995.

Margaret P. Crenshaw,

*Secretary.*

[FR Doc. 95–30640 Filed 12–15–95; 8:45 am]

BILLING CODE 7710–FW–P

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 95–141; RM–8642]**

## Radio Broadcasting Services; Frederiksted, VI and Culebra and Carolina, PR

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; dismissal.

**SUMMARY:** The Commission dismisses the petition for rule making filed by Jose J. Arzuaga, proposing the allotment of Channel 298B1 at Frederiksted, Virgin Islands, as its third local FM transmission service (RM–8642). *See* 60 FR 46563, September 7, 1995. We also dismiss petitioner's counterproposal to allotment Channel 293B in lieu of Channel 298B1 at Frederiksted, Virgin Islands, and to allot Channel 298B1 at Culebra, Puerto Rico. The petitioner has abandoned his interest in a Class B1 allotment at Frederiksted, Virgin Islands, and there are no other timely expressions of interest for the channel. In addition, petitioner's counterproposal is not consistent with the Commission's technical requirements. With this action, this proceeding is terminated.

**FOR FURTHER INFORMATION CONTACT:** Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Report and Order,* MM Docket No. 95–141, adopted November 30, 1995, and released December 11, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 95–30615 Filed 12–15–95; 8:45 am]

BILLING CODE 6712–01–F

## 47 CFR Parts 73 and 76

**[MM Docket No. 95–176; FCC 95–484]**

## In the Matter of Closed Captioning and Video Description of Video Programming

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of inquiry.

**SUMMARY:** This Notice of Inquiry solicits comment on the current availability, cost, and uses of closed captioning and video description of television video programming. This information will provide the Commission a record on these important services, which benefit individuals with disabilities. It will also enable the Commission to assess what further actions may be appropriate to promote these services.

**DATES:** Interested parties may file comments on or before January 29, 1996, and reply comments on or before February 14, 1996.

**ADDRESSES:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Charles Logan, (202) 776–1653.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Inquiry in MM Docket No. 95–176, FCC 95–484, adopted December 1, 1995 and released on December 4, 1995. The complete text of this Notice is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and also may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, N.W., Suite 140, Washington, DC 20037, (202) 857–3800.

Synopsis of Notice of Inquiry

1. The Notice seeks information on the current availability, cost, and uses of closed captioning and video description, and also asks comment on what further Commission actions may be appropriate to promote these services. It also seeks comment on the appropriate means of promoting their wider use in programming delivered by television broadcasters, cable operators, and other video programming providers.

I. Background

2. Captioning is similar to subtitles in that it displays the audio portion of a television signal as printed words on the television screen. To assist viewers who are hearing disabled, captions also identify speakers, sound effects, music, and laughter. Video description provides audio descriptions of a program's key visual elements that are inserted during the natural pauses in the program's dialogue.

3. Both the Senate and the House of Representatives have passed bills (H.R. 1555 and S. 652), which, if enacted, would require the Commission to adopt regulations to ensure that video programming is accessible to persons with hearing disabilities through the provision of closed captioning, including requiring ''video programming providers or owners'' to maximize the accessibility of previously published or exhibited programs by adding closed captioning. Both bills would allow the Commission to exempt programs from these requirements in certain circumstances, including circumstances where the closed captioning would impose an unreasonable financial burden. The House bill would require the Commission to conduct an inquiry into the current extent of closed captioning as well as other issues. In addition, both bills would require the Commission to study the use of video description. The House bill further provides that the Commission may adopt regulation it deems necessary to promote the accessibility of video programming to persons with visual impairments.

II. The Public Interest Benefits of Closed Captioning and Video Description

4. The Notice asks parties to elaborate on the importance and nature of the public interest benefits of closed captioning and video description. It asks parties to submit information regarding the number of individuals with hearing and vision disabilities in this country who can benefit from these innovations, including the basis for such estimates.

Are the number of persons with hearing and vision disabilities expected to grow in the coming years, particularly due to the aging of the population? What proportion of the persons with such disabilities require closed captioning or video description to enjoy television programming, and what proportion currently utilize these technologies? In addition, the Commission requests comment on the number of children with hearing and vision disabilities that can benefit from either closed captioning or video description, and the nature of these benefits. The Notice also seeks comments on other public interest benefits of closed captioning and video description, such as teaching literacy skills to children and illiterate adults.

III. Availability of Closed Captioning and Video Description

5. The Notice asks commenters to provide data regarding the current availability of closed captioning of television video programming. Has the amount of closed captioning been increasing in recent years, or has it reached a plateau? The Commission is particularly interested in data on availability and any discernible trends regarding the following categories: (1) *Program Source.* What is the current availability of closed captioning according to the source of the programming—broadcast network, basic cable and premium cable networks, syndicated programming, locally-produced programming, local and nationally produced public television programming? (2) *Other Delivery Systems.* To what extent is programming carried on wireless cable, satellite master antenna systems, direct-to-home satellite services (including direct broadcast satellite), and local exchange carriers/video dialtone services closed captioned? (3) *Program Type.* To what extent are each of the following types of programs closed captioned (on the media within the scope of FCC jurisdiction): entertainment programs, local and national news, documentaries, public affairs programming, children's educational programming, other types of children's programming, sports, movies, cable public access programming, and live vs. pre-recorded programming? (4) *Previously Published Programming.* The Commission solicits comment on the extent of closed captioning of previously published or exhibited programs, such as reruns and movies, that will be shown to television audiences again. (5) *Market Size and Other Factors.* The Commission also requests comment on the degree to which closed captioning varies by the size of the video programming provider or producer, by market size, and by whether an entity is affiliated with a broadcast network or multiple cable system operator.

6. The Commission also seeks comment on the current availability of video description, including its availability within each of the categories described in its discussion of the availability of closed captioning. It also requests comment on the estimated number of U.S. households that have stereo television receivers, a VCR, or television adaptor capable of receiving video descriptions via the Second Audio Program channel.

7. The Commission asks parties to comment on the impact that implementation of Advanced Television (''ATV''), and the use of digital technology, may have on the provision of closed captioning and video description on video programming carried by broadcasters and other program providers.

IV. The Cost of Closed Captioning and Video Description

8. The Notice requests information on the current costs of providing closed captioning and video description of new as well as previously published or exhibited television programming. What is the cost of the computer hardware and software, as well encoding and other equipment, necessary for these services? What are the current rates for closed captioning and video description services for both prerecorded and live, ''real-time'' programming? Are these rates uniform throughout the country? Do the rates vary by program type, the type of delivery system, or other factors? What is the overall cost of providing closed captioning or video description of different types of programs?

9. The Commission also requests comment on the adequacy of the supply of closed captioning and video description services. In addition, it seeks comment on the governmental and nongovernmental funding sources for these services.

V. Market Incentives for Closed Captioning and Video Description

10. The Notice solicits comment on the role free-market forces have played and can play in promoting the provision of closed captioning of video programming. For example, are advertisers actively seeking to market to individuals with hearing impairments, which could in turn encourage closed captioning of television programming? How does the audience size of a particular program influence the likelihood that the program will be closed captioned? Are there presently a sufficient number of decoder-equipped television receivers in the market to provide the hoped-for incentive for the television industry to provide closed captioning? The Commission also requests comment on the role market-based incentives can play in fostering video description.

VI. Inquiry Regarding Mandatory Captioning and Video Description Requirements

11. As noted, there is legislation pending in Congress that generally would require closed captioning of video programming and which would require the Commission to examine the means of promoting video description. Before these mandatory requirements become law, the legislation must pass both Houses of Congress and be signed by the President. Alternatively, the Commission could assess the possibility of adopting regulatory requirements in this area under it existing statutory authority. The Commission is not presently proposing such action, but it requests comment on the general form any mandatory closed captioning or video description requirements should take if they are deemed necessary. It particularly seeks comment on the following matters: (1) The application of mandatory requirements (i.e., which entities (e.g., program producers, video programming distributors) should be subject to any mandatory requirements); (2) Exemptions to any mandatory requirements due to financial burden or other factors; (3) Technical and quality standards; (4) The appropriate timetables for implementing any closed captioning or video description requirements that may be imposed; (5) Strategies to improve competition and innovation in the provision of these services.

12. The pending Senate and House bills, if enacted, would provide express statutory authority for imposing mandatory closed captioning requirements. The House bill would also permit the Commission to adopt regulations to promote the accessibility of video programming to persons with visual disabilities after conducting an inquiry into video description. However, the Commission seeks comment on the scope of its authority under current law to adopt regulations imposing either closed captioning or video description requirements on broadcast television licensees, cable operators, wireless cable systems, SMATV operators, direct-to-home satellite services, and local exchange carrier/video dialtone systems, as well as on producers/owners and other distributors of such programming.

Commenters should address with specificity the basis for their views concerning the Commission's authority, and also address any other legal constraints that they believe may apply in this area.

*Administrative Matters*

13. Pursuant to applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's Rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on or before January 29, 1996, and reply comments on or before February 14, 1996. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, parties must file an original and four copies of all comments, reply comments and supporting comments. If parties want each Commissioner to receive a personal copy of their comments, an original plus nine copies must be filed. Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center (Room 239) of the Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554.

14. There are no *ex parte* or disclosure requirements applicable to this proceeding pursuant to 47 CFR § 1.1204(a)(4).

List of Subjects

*47 CFR Part 73*

Television broadcasting.

*47 CFR Part 76*

Cable television.

Federal Communications Commission.

William F. Caton,

*Acting Secretary.*

[FR Doc. 95–30549 Filed 12–15–95; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF DEFENSE

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATOIN

## 48 CFR Parts 8, 10, 15, 31, 32, 42, 45, 52 and 53

**[FAR Case 90–017, 90–054, 91–039, 91–057, 91–093, 91–111, 91–114, 91–117, 92–033, & 92–044]**

## Federal Acquisition Regulation; Withdrawal of Proposed Rules

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Proposed rule withdrawals.

**SUMMARY:** The Department of Defense, General Services Administration, and National Aeronautics and Space Administration have decided to withdraw ten proposed rules without further action. The actual text of the Federal Acquisition Regulation is unaffected by this document.

**FOR FURTHER INFORMATION CONTACT:** Ms. Beverly Fayson, FAR Secretariat, Room 4037, GS Building, Washington, DC 20405 (202) 501–4755.

**SUPPLEMENTARY INFORMATION:**

Background

On July 21, 1995, the Councils agreed to withdraw the following five proposed rules because the Director of Defense Procurement is conducting an initiative to rewrite FAR Part 45, Government Property, to make the Government property regulations easier to understand and less burdensome for both Government and industry. The issues addressed by these rules will be considered under the Part 45 Rewrite initiative.

*FAR Case 91–057, Disposal of Hazardous Government Property*

Published at 59 FR 14464, March 28, 1994, to provide guidance relating to the identification and appropriate disposition of hazardous Government property. [RIN 9000–AF62]

*FAR Case 91–093, Special Tooling Under Fixed-Price Contracts*

Published at 59 FR 14462, March 28, 1994, to amend the Government's policy on managing and controlling special tooling for which the Government has the right to title. [RIN 9000–AF66]

*FAR Case 91–111, Commercially Available Government-Furnished Material*

Published at 59 FR 46557, September 2, 1994, to require contractors to provide all material for performing Government contracts, except when Government-furnished material is necessary to achieve significant economy, standardization, or expedited production, or when it is otherwise in the Government's interest. [RIN 9000–AF95]

*FAR Case 91–114, Use of Government Facilities on a No-Charge Basis*

Published at 59 FR 45657, September 2, 1994, to include two clauses to provide controls on the use of Government property by identifying the items of property furnished under a contract or used on a no-charge basis, and by describing the obligation of both parties with regard to the property. [RIN 9000–AF96]

*FAR Case 91–117, Use and Charges Clause*

Published at 60 FR 22442, May 5, 1995, to clarify current language pertaining to rental payments for Government-owned real property and equipment. [RIN 9000–AG23]

The councils agreed to withdraw the following two proposed rules because the Department of Defense decided to retain the guidance in the Defense Federal Acquisition Regulation supplement.

*FAR Case 91–39, Voluntary Refunds*

Published at 56 FR 40716, August 15, 1991, to establish guidance on solicitation and acceptable of voluntary refunds from contractors. [RIN 9000–AE11]

*FAR Case 90–54, Defective Pricing*

Published at 55 FR 50534, December 6, 1990, to revise policies affecting defective pricing reductions. [RIN 9000–AE23]

The councils also agreed to withdraw the following three proposed rules because the issues addressed in these rules have been superseded by other regulations including regulations implementing the Federal Acquisition Streamlining Act of 1994.

*FAR Case 90–017, Exemptions from Cost or Pricing Data*

Published at 55 FR 36774, September 6, 1990, to minimize administrative impediments in the procedures for claiming and granting exemptions from the requirements for submission of certified cost or pricing data, and the

policies regarding price negotiations. [RIN 9000–AD89]

*FAR Case 92–033, Price Competition Exemption*

Published at 59 FR 114458, March 28, 1994, to address unnecessarily requiring the submission of cost or pricing data and to clarify when adequate price competition exists. [RIN 9000–AF81]

*FAR Case 92–044, Reconditioned Material*

Published at 59 FR 46019, September 6, 1994, to combine two clause as an acquisition streamlining measure. [RIN 9000–AG08]

List of Subjects in 48 CFR Parts 8, 10, 15, 31, 32, 42, 45, 52, and 53

Government procurement.

Dated: September 12, 1995.

Edward C. Loeb,

*Acting Director, Office of Federal Acquisition Policy.*

[FR Doc. 95–30651 Filed 12–15–95; 8:45 am]

**BILLING CODE 6820–EP–M**

# Notices

Federal Register
Vol. 60, No. 242
Monday, December 18, 1995

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Natural Resources Conservation Service

### Boulder River Watershed, Montana

**AGENCY:** Natural Resources conservation Service, USDA.

**ACTION:** Notice of intent to deauthorize Federal funding.

**SUMMARY:** Pursuant to the Watershed Protection and Flood Prevention Act, Public Law 83–566, and the Natural Resources Conservation Service Guidelines (7 CFR 622), the Natural Resources Conservation Service gives notice of the intent to deauthorize Federal funding for the Boulder River Watershed project in Jefferson County, Montana.

**FOR FURTHER INFORMATION CONTACT:** Richard J. Gooby, State Conservationist, Natural Resource Conservation Service, 10 East Babcock Street Room 442, Bozeman, Montana 59715, telephone: 406–587–6813.

Boulder River Watershed, Montana

Notice of Intent to Deauthorize Federal Funding

**SUPPLEMENTARY INFORMATION:** A determination has been made by Richard J. Gooby that the proposed works of improvement for the Boulder River Watershed project will not be installed. The sponsoring local organizations have concurred in this determination and agree that Federal funding should be deauthorized for the project. Information regarding this determination may be obtained from Richard J. Gooby, State Conservationist, at the above address and telephone number.

No administrative action on implementation of the proposed deauthorization will be taken until 60 days after the date of this publication in the Federal Register.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of management and Budget Circular A–95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable.)

Dated: December 6, 1995.

Christine Peterson,

*Acting State Conservationist.*

[FR Doc. 95–30658 Filed 12–15–95; 8:45 am]

BILLING CODE 3410–16–M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### National Weather Service Modernization and Associated Restructuring

**ACTION:** Notice.

**SUMMARY:** On October 27, 1995, the Secretary of Commerce released a report to Congress entitled, *Secretary's Report to Congress on Adequacy of NEXRAD Coverage and Degradation of Weather Services under the National Weather Service Modernization for 32 Areas of Concern.* This report was prepared by a Departmental team with expertise in radar meteorology, operational weather services, employee relations, and strategic planning. The Secretary's report applied the criteria developed in the National Research Council's (NRC) study, *Toward a New National Weather Service—Assessment of NEXRAD Coverage and Associated Weather Services,* which was delivered to the Secretary in June, 1995. The Modernization Transition Committee (MTC), a Federal advisory committee established by the Weather Service Modernization Act (WSMA), 15 U.S.C. 313 note, P.L. 102–567, was consulted on the Secretary's Report on October 30, 1995.

The Secretary's report assessed the adequacy of Doppler weather surveillance radar (WSR–88D), also known as NEXRAD, coverage and degradation of weather services under the National Weather Service (NWS) modernization plan for 32 geographical areas of concern and identified mitigation actions for areas where degradation was indicated. Late last year, comments from the public were solicited to identify community concerns about possible degradation of weather services under the NWS modernization plan (published November 4, 1994, 59 FR 55254). Over 67,000 public comments were received from 32 different geographical areas. These 32 areas were then established as areas of concern to receive in depth analysis based on the NRC's assessment criteria (published February 23, 1995, 60 FR 10066).

**FOR FURTHER INFORMATION CONTACT:** Julie Scanlon at 301–713–1413 or Nick Scheller at 301–713–0454.

**SUPPLEMENTARY INFORMATION:** *Mitigation Recommendations:* The mitigation recommendations contained in the report and the Secretary's transmittal letter are:

*Additional WSR–88Ds and/or WFO*—The Secretary's team recommends the acquisition and siting of three additional WSR–88Ds and one Weather Forecast Office (WFO) to provide coverage for:

''(1) Northern Indiana and Northwest Ohio. The Team recommends that the National Weather Service install a WSR–88D, along with a fully staffed WFO, to provide forecast and warning services to the citizens of northern Indiana and northwestern Ohio. The Team finds that this combined area experiences a high frequency of especially severe weather, and that the present NEXRAD configuration will not provide the low level surveillance necessary for detecting reflectivity and velocity signatures associated with tornado formation and other severe weather phenomena. It is the opinion of the Team that the frequency of severe weather, areal extent of radar coverage degradation, increased work load associated with a large spotter network, argues for the establishment of a full-service WFO. In addition, the Team recommends that the NWS re-examine the distribution of county warning responsibility throughout northern Indiana and northwestern Ohio following placement of the WSR–88D. The Team further recommends that the Fort Wayne Weather Service Office and WSR–74C remain in service until the new WSR–88D and WFO are operational.

(2) Northern Alabama and Southeast Tennessee. The Team recommends the addition of a WSR–88D optimized for coverage of severe weather phenomena (particularly mini-supercells and

macrobursts) in the northern Alabama, southeastern Tennessee, and northwestern Georgia region. The climatology of severe weather for this area is such that there are a significant number of tornadoes whose genesis is observable only from low level radar information. The recommended WSR–88D may be operated as a remote radar due to the accessibility of locations in the region, and reliability of commercial communications. The NWS should re-evaluate the county warning area distribution for future WFOs Nashville, TN, Birmingham, AL, Atlanta, GA, and Morristown, TN in order to determine which WFOs are best positioned to provide primary warning responsibilities for counties assumed from the Chattanooga and Huntsville areas. The Team further recommends that the Chattanooga and Huntsville WSR–74C's remain in service until the NWS commissions the new WSR–88D and achieves confirmation of services with users.

(3) Northwest Arkansas/Eastern Oklahoma. The Team recommends that an additional WSR–88D be installed to the southwest of Fort Smith and operated with dedicated communications to both WFO Tulsa and WFO Little Rock. The Fort Smith area experiences a very high frequency of severe thunderstorms and flash floods. The southern portion of the Fort Smith county warning area, comprising the counties of Le Flore, Scott and Polk, is beyond the range of reliable detection of the low, mid and upper altitude radar features used to identify the severe thunderstorms and weak to moderate tornadoes associated with squall lines and intersecting outflow boundaries. Many of the storms move into the area from the southwest of these counties—an area also too far from surrounding WSR–88Ds for reliable severe weather identification. The Team further recommends that the Fort Smith WSR–74C remain in service until the NWS commissions the new WSR–88 and achieves confirmation of services with users.''

*Continuation of Office Operations*—The Secretary's team recommends the continuation of office operations at the following sites:

(1) Caribou, Maine. The Team recommends continued operations at Caribou, Maine, until the NWS can: (a) Validate reliable communications and maintenance for the Hodgdon WSR–88D site; and (b) certify that other distance- and time-sensitive service considerations have been reconciled, including maintenance of equipment and the coordination of northern Maine emergency management requirements and community outreach. If solutions to remote radar (and other equipment) communications and maintenance reliability concerns cannot be found, and if adequate community coordination and outreach cannot be assured, the Team recommends that a nearby WFO be established. The office should incorporate, at a minimum, adequate staffing for maintaining and operating the radar for severe weather observations and the dissemination of warnings, and for coordinating outreach activities with northern Maine communities.

(2) Key West, Florida. The Team recommends continued operations at Key West, Florida, until the NWS can validate reliable communications and maintenance between the Key West WSR–88D site and WFO Miami. If solutions to remote radar communications and maintenance reliability concerns cannot be found, the Team recommends a continued NWS presence at Key West, with, at a minimum, adequate staffing for maintaining and operating the radar for severe weather observations and the dissemination of warnings.''

*Continuation of Radar Operations*—The Secretary's team recommends continued radar operations at the following sites, in addition to those listed above:

''(1) Erie, Pennsylvania. As a result of the degraded radar coverage for certain lake-effect snow events, the Team recommends the continued operation of WSO Erie's WRS–74C pending the results of ''The Lake Effect Snow Study.'' This assessment should compare the adequacy of existing WSR–88D information, and other data sources (the composite system) with the local warning radar to determine capabilities for lake effect snow identification. The Team recommends that the NWS remote the WSR–74C data to WFO Cleveland in order to facilitate the schedule spindown of WSO Erie.

(2) South Bend, Indiana. As a result of the degraded radar coverage for certain lake-effect snow events, the Team recommends continued radar operations at WSO South Bend pending the results of the lake effect snow study. This assessment should compare the adequacy of existing WSR–88D information, and other data sources (the composite system) with the local warning radar to determine capabilities for lake effect snow identification.''

*Continuation of Office and Radar Operations*—The Secretary decided to continue office and radar operations in the Williston, North Dakota, area. The following was extracted from the Secretary's transmittal letter:

''However, I remain concerned about the team's finding of significant degradation of radar coverage at the lower levels for the Williston, North Dakota, area. In this location, the team concluded that weather services should not be degraded, although their assessment included the finding that low-altitude radar coverage would be degraded over portions of all eight counties of the county warning area for certain weather phenomena. The geographic area which would experience some level of degradation of radar information is far more extensive than for any of the other areas examined. Therefore, I have decided that the NWS will maintain the operations of the Williston Weather Service Office and its associated radar for a period of two years before implementing the team's recommendation to proceed with planned radar decommissioning and weather office closure. During this time, the NWS will conduct an operational evaluation to assess whether mid- and upper-altitude NEXRAD data and information from composite system sources provide adequate information to detect, and warn for, all weather phenomena of concern. The team concurs with my decision.''

*Funding for Mitigation Recommendations:* There are no resources (dollars or work force positions) in the current NWS budget for additional radars or offices beyond those already identified in the strategic plan for NWS modernization. Additional radars and offices identified in the Secretary's report will require additional funding authority and appropriations. Recommended mitigation actions, identified in the Secretary's report, will be reflected in the normal budget process beginning in fiscal year 1997.

*Release of Remaining Areas of Concern:* Actions to close, consolidate, relocate, or automate any field office or decommission any NWS radar in an area of concern were prohibited until the Secretary had reported to Congress that he believed that such actions would not result in a degradation of service and a 30-day grace period had elapsed. The Secretary's report was submitted to Congress on October 27, 1995, and the 30-day grace period elapsed on November 27, 1995. Thus the prohibition on actions to close, consolidate, relocate, or automate any field office or decommission any NWS radar in an area of concern is removed for the following areas of concern where the Secretary's report found no degradation of service:

WSO Asheville, NC
WSO Astoria, OR
WSO Athens, GA
WSO Baton Rouge, LA
WSO Cape Hatteras, NC
WSO Charlotte, NC
WSO Colorado Springs, CO
WSO Del Rio, TX
WSO Elkins, WV
WSO Evansville, IN
WSO Grand Island, NE
WSO Greensboro, NC
WSO Harrisburg, PA
WSO International Falls, MN
WSO Kalispell, MT
WSO Lexington, KY
WSO Montgomery, AL
WSO Redding, CA
WSO Toledo, OH
WSO Wichita Falls, TX
WSO Wilmington, DE
WSO Hondo, TX
Central Oregon/Central Washington

The Secretary is still required to satisfy the requirement of sec. 706(b) of the WSMA to certify no degradation of service when she/he restructures a filed office. If the field office is located in an area of concern, the Secretary is required to provide all public comments relating to that area of concern to the Modernization Transition Committee during the certification process.

*Obtaining Copies of the Secretary's Report:* The Secretary's report consists of two volumes. Volume 1 provides the overall report and includes the methodology used by the Secretary's team and a summary of assessment results for each of the 32 areas of concern. Volume 2 consists of an individual package of information for each of the 32 areas of concern. Each package includes all the detailed information considered by the team in making its assessment of potential degradation of service. The report has been submitted to the U.S. Government Printing Office for printing. Copies should be available in February 1996. Distribution of Volume 1 is planned throughout NWS and to Congress and people who submitted the public comments that established the areas of concern. Volume 2 will be available by request only. If you would like a copy of Volume 1 and/or Volume 2 mailed to you, please specify which area(s) of concern you want and send your name and address to: National Weather Service, 1325 East-West Highway, Silver Spring, MD 20910–3283, Attn: Wx21–Patricia Daenecke.

In the interim, copies of the report are available to the public at centrally located libraries in each of the 32 areas of concern. A list of these libraries is attached to this notice.

Dated: December 7, 1995.

Louis J. Boezi,

*Deputy Assistant Administrator for Modernization.*

List of Libraries

Pack Memorial Library, 67 Haywood Street, Asheville, NC 28801
Astoria Public Library, 459 Tenth Street, Astoria, OR 97103
Athens/Clark County Library, 2025 Baxter Street, Athens, GA 30606
East Baton Rouge Parish, Main Library, 7711 Goodwood Boulevard, Baton Rouge, LA 70806
Dare County Library Hatteras Branch, Hatteras Community Center, P.O. Box 309, Hatteras, NC 27943
Caribou Public Library, 30 High Street, Caribou, ME 04736
Deschutes County Library, 507 NW Wall Street, Bend, OR 97701
Yakima Valley Regional Library, 102 North 3rd Street, Yakima, WA 98901
The Public Library of Charlotte and Mecklenburg County, 310 North Tryon Street, Charlotte, NC 28202
Chattanooga/Hamilton County Bicentennial Library, 1001 Broad Street, Chattanooga, TN 37402
Pikes Peak Library District, 5550 North Union Boulevard, Colorado Springs, CO 80901
Val Verde County Public Library, 300 Spring Street, Del Rio, TX 78840
Elkins-Randolph Public Library, 416 Davis Avenue, Elkins, WV 26241
Erie County Library, 27 South Park Row, Erie, PA 16501–1102
Evansville-Vanderburgh County Public Library, 22 Southeast Fifth Street, Evansville, IN 47708–1604
Fort Smith Public Library, 61 South 8th Street, Fort Smith, AR 72901
Allen County Public Library, P.O. Box 2270, Fort Wayne, IN 46801
Edith Abbott Memorial Library, 211 North Washington, Grand Island, NE 68801–5855
Greensboro Public Library, 201 North Greene Street, P.O. Box 3178, Greensboro, NC 27402
Dauphin County Library System, 101 Walnut Street, Harrisburg, PA 17101, 717–234–4961
Hondo Public Library, 1011 19th Street, Hondo, TX 78861
Huntsville/Madison County Public Library, 915 Monroe Street, Huntsville, AL 35801
International Falls Public Library, 750 Fourth Street, International Falls, MN 56649
Flathead County Library, 247 1st Avenue East, Kalispell, MT 59901
Monroe County Library, 700 Fleming Street, Key West, FL 33040–6897
Lexington Public Library, 140 East Main, Lexington, KY 40507–1376
Montgomery City/County Library, 245 High Street, Montgomery, AL 36104
Shasta County Public Library, 1855 Shasta Street, Redding, CA 96001
Saint Joseph County Public Library, 304 South Main, South Bend, IN 46601–2125
Toledo-Lucas County Public Library, 325 North Michigan Street, Toledo, Ohio 43624
Wichita Falls Public Library, 1300 Lamar, Wichita Falls, TX 76301
Williston Community Library, 1302 Davidson Drive, Williston, ND 58801
Wilmington Institute Library, 10th and Market Street, Wilmington, DE 19801

FR Doc. 95–30627 Filed 12–15–95; 8:45 am]

BILLING CODE 3510–12–M

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### New Export Visa Stamp for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in Singapore

December 13, 1995.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs providing for the use of a new export visa stamp.

**EFFECTIVE DATE:** January 1, 1996.

**FOR FURTHER INFORMATION CONTACT:** Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212.

**SUPPLEMENTARY INFORMATION:**

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Beginning on January 1, 1996, the Government of the Republic of Singapore will begin issuing a new export visa stamp for shipments of textile products, produced or manufactured in Singapore and exported from Singapore on and after January 1, 1996. There will be a one-month grace period from December 1, 1995 through December 31, 1995, during which goods exported from Singapore may be accompanied by either the old or the new export visa stamp. Goods exported from Singapore on or after January 1, 1996 must be accompanied by the new export visa stamp.

A facsimile of the new visa stamp is on file at the U.S. Department of Commerce, Office of Textiles and Apparel, 14th and Constitution Avenue, NW., room 3104, Washington, DC.

See 47 FR 6683, published on February 16, 1982; 47 FR 53446, published on November 26, 1982; and

51 FR 43454, published on December 12, 1986.

Troy H. Cribb,

*Chairman, Committee for the Implementation of Textile Agreements.*

Committee for the Implementation of Textile Agreements

December 13, 1995.

Commissioner of Customs,
*Department of the Treasury, Washington, DC 20229.*

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on February 10, 1982, as amended, by the Chairman, Committee for the Implementation of Textile Agreements. That directive establishes export visa requirements for certain cotton, wool and man-made fiber textile products, produced or manufactured in Singapore.

Effective on January 1, 1996, you are directed to amend further the directive dated February 10, 1982 to provide for the use of a new export visa stamp issued by the Government of the Republic of Singapore to accompany shipments of textile products, produced or manufactured in Singapore and exported from Singapore on and after January 1, 1996.

Goods exported from Singapore during the period December 1, 1995 through December 31, 1995 may be accompanied by either the old or the new export visa stamp. Goods exported from Singapore on or after January 1, 1996 must be accompanied be the new export visa stamp.

A facsimile of the visa stamp is enclosed with this letter.

Shipments entered or withdrawn from warehouse according to this directive which are not accompanied by the appropriate export visa stamp shall be denied entry and a new visa must be obtained.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 95–30713 Filed 12–13–95; 4:24 pm]

**BILLING CODE 3510–DR–F**

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**ACTION:** Notice of proposed information collection requests.

**SUMMARY:** The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before February 16, 1996.

**ADDRESSES:** Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronic mailed to the internet address #FIRB@ed.gov, or should be faxed to 202–708–9346.

**FOR FURTHER INFORMATION CONTACT:** Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Department of Education (ED) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Group, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 11, 1995.

Gloria Parker,

*Director, Information Resources Group.*

*Office of Educational Research and Improvement*

*Type of Review:* New

*Title:* Baccalaureate and Beyond Longitudinal Study: Second Follow-up (B&B: 93/97)

*Frequency:* On occasion

*Affected Public:* Individuals or households

*Reporting Burden and Recordkeeping:*
Responses: 11,500
Burden Hours: 7,935

*Abstract:* This study will collect and report data about student who completed a bachelor's degree in 1992–93. Specifically, this follow-up will collect data concerning post-baccalaureate degree attendance, persistence, and completion; transition into and experience after early entry into the work force; and career path of those who entered teaching at the elementary/secondary level.

*Office of Special Education and Rehabilitative Services*

*Type of Review:* Extension

*Title:* Programs Authorized by the Rehabilitation act Amendments of 1992

*Frequency:* Annually

*Affected Public:* Not-for-profit institutions; State, Local or Tribal Government

*Reporting Burden and Recordkeeping:*
Responses: 1000
Burden Hours: 40,000

*Abstract:* Discretionary Grant application package for the use of program authorized by the Rehabilitation Act Amendments of 1992.

*Office of Postsecondary Education*

*Type of Review:* Revision

*Title:* Confirmation Report for the Patricia Robert Harris Fellowship Program—Fellowship Rep.

*Frequency:* Annually

*Affected Public:* Not for Profit institutions

*Reporting Burden and Recordkeeping:*
Responses: 1
Burden Hours: 1100

*Abstract:* Institutions of Higher Education that have received PRH grants are required to demonstrate their compliance with statutory requirements for distribution to fellowships information collected will be used by institutions of higher education to document the eligibility characteristics of students who are

scheduled to receive fellowships under the program and the amount of each student stipend.

*Office of Postsecondary Education*
*Type of Review:* Revision
*Title:* Confirmation Report for the Patricia Robert Harris Fellowship Program—Fellowship Rep.
*Frequency:* Annually
*Affected Public:* Not for Profit institutions
*Reporting Burden and Recordkeeping:* Responses: 1
Burden Hours: 1100
*Abstract:* Institutions of Higher Education that have received PRH grants are required to demonstrate their compliance with statutory requirements for distribution to fellowships information collected will be used by institutions of higher education to document the eligibility characteristics of students who are scheduled to receive fellowships under the program and the amount of each student stipend.

[FR Doc. 95–30686 Filed 12–15–95; 8:45 am]

BILLING CODE 4000–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP96–69–000]**

### CNG Transmission Corporation; Notice of Application

December 12, 1995.

Take notice that on November 14, 1995, CNG Transmission Corporation (CNGT), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP96–69–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon a portion of a storage service provided to Long Island Lighting Company (LILCO) under Part 157 of the Commission's regulations and instead provide additional storage service under Part 284 blanket authorization, all as more fully set forth in the application on file with the Commission and open to public inspection.[1]

CNGT proposes to abandon 101,342 Dt of the Storage Capacity that has been allocated to LILCO under an October 1, 1993, Part 157 Service Agreement, and provided under CNGT's Rate Schedule GSS, in order that 101,342 Dt of additional Storage Capacity may be provided under CNGT's Part 284 blanket authorization.

CNGT states that the Commission originally authorized CNGT to provide this storage capacity to Texas Eastern Transmission Corporation on behalf of LILCO, for a three-year term, as part of the storage services that were approved in Docket No. CP83–386 (25 FERC ¶ 61,355 (1983)). CNGT further states that the term of this certificated storage service was subsequently extended by Commission order in Docket No. CP84–306 (29 FERC ¶61,032 (1984)). CNGT also states that these Part 157 entitlements were transferred to LILCO as part of CNGT's Order No. 636 restructuring proceeding, in Docket No. RS92–14–005, *et al.* (64 FERC ¶61,303 (1993)).

CNGT additionally states that the proposed partial abandonment of this service is consistent with the Stipulation and Agreement filed June 28, 1995, in CNGT Docket No. RP94–96–012, *et al.,* particularly the settlement mitigation for Phase II Billing Determinants more fully described in Appendix ''D'' of CNGT's filing, and will result in an increase in LILCO's GSS Billing Determinants from 34,137 Dt/d to 35,814 Dt/d, which will be offset by a decrease in LILCO's FTNN Billing Determinants from 27,689 Dt/d to 26,012 Dt/d.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 2, 1996, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for CNGT to appear or be represented at the hearing.

Lois D. Cashell,
*Secretary.*

[FR Doc. 95–30620 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

[1] CNGT filed corrected pages 1, 3 and 4 of the application on December 1, 1995.

**[Docket No. ER96–25–000]**

### Coral Power, L.L.C.; Notice of Issuance of Order

December 12, 1995.

On October 3, 1995, as amended October 31, 1995, Coral Power, L.L.C. (Coral Power) submitted for filing a rate schedule under which Coral Power will engage in wholesale electric power and energy transactions as a marketer. Coral Power also requested waiver of various Commission regulations. In particular, Coral Power requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Coral Power.

On December 6, 1995, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Coral Power should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Coral Power is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued

approval of Coral Power's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is January 5, 1996.

Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426.

Lois D. Cashell,

*Secretary.*

[FR Doc. 95–30621 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

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**[Docket No. CP96–94–000]**

## East Tennessee Natural Gas Company; Notice of Request Under Blanket Authorization

December 12, 1995.

Take notice that on December 4, 1995, East Tennessee Natural Gas Company (East Tennessee), Post Office Box 2511, Houston, Texas 77252, filed a request with the Commission in Docket No. CP96–94–000 pursuant to Sections 157.205, 157.212 and 157.216(b) of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to establish a bi-directional point and to abandon certain facilities, authorized in blanket certificate issued in CP82–412–000, all as more fully set forth in the request on file with the Commission and open to public inspection.

At the request of Citizens Gas Utility (Citizens), East Tennessee proposes to modify an existing receipt meter station on its system to establish a bi-directional point for both receipts from and deliveries to Citizens to accommodate a gas storage facility operated by Citizens. To accomplish this, East Tennessee proposes to convert their existing station (#75–9123 ''Citizens Gas'') by abandoning the receipt meter and removing it. East Tennessee would then install the requested bi-directional meter (#75–9012 ''Morgan County No. 1'') by installing two 4-inch meter tubes in parallel to the existing tube. East Tennessee states that they would continue to own, operate, and maintain the existing side valve measurement. The meter station would be located on the existing site provided by Citizens adjacent to the right-of-way.

Any person or the Commission's staff may, within 45 days after the Commission has issued this notice, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the allowed time, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA.

Lois D. Cashell,

*Secretary.*

[FR Doc. 95–30619 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

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**[Docket No. ER96–127–000]**

## Nordic Electric, L.L.C.; Notice of Issuance of Order

December 12, 1995.

On October 20, 1995, as amended November 1, 1995, Nordic Electric, L.L.C. (Nordic) submitted for filing a rate schedule under which Nordic will engage in wholesale electric power and energy transactions as a marketer. Nordic also requested waiver of various Commission regulations. In particular, Nordic requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Nordic.

On December 1, 1995, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Nordic should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Nordic is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Nordic's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is January 2, 1996.

Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426.

Lois D. Cashell,

*Secretary.*

[FR Doc. 95–30622 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

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**[Docket No. ER96–1–000]**

## Powertec International, L.L.P.; Notice of Issuance of Order

December 12, 1995.

On October 2, 1995, as amended October 23, 1995, Powertac International, L.L.P. (Powertec) submitted for filing a rate schedule under which Powertec will engage in wholesale electric power and energy transactions as a marketer. Powertec also requested waiver of various Commission regulations. In particular, Powertec requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Powertec.

On December 1, 1995, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Powertec should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Powertec is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither

public nor private interests will be adversely affected by continued approval of Powertec's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is January 2, 1996.

Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

*Secretary.*

[FR Doc. 95–30623 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

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**[Docket No. ER96–105–000]**

## U.S. Power & Light, Inc.; Notice of Issuance of Order

December 12, 1995.

On October 17, 1995, U.S. Power & Light, Inc. (U.S. Power & Light) submitted for filing a rate schedule under which U.S. Power & Light will engage in wholesale electric power and energy transactions as a marketer. U.S. Power & Light also requested waiver of various Commission regulations. In particular, U.S. Power & Light requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by U.S. Power & Light.

On December 6, 1995, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by U.S. Power & Light should file a motion of intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, U.S. Power & Light is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of U.S. Power and Light's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is January 5, 1996.

Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426.

Lois D. Cashell,

*Secretary.*

[FR Doc. 95–30624 Filed 12–15–95; 8:45 am]

BILLING CODE 6717–01–M

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# ENVIRONMENTAL PROTECTION AGENCY

**[FRL–5346–8]**

## Public Meeting of the Sanitary Sewer Overflows Dialogue

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Environmental Protection Agency (EPA) is convening a public meeting of the Sanitary Sewer Overflows (SSOs) Dialogue. The meeting will be held on January 11 and 12, 1996. The purposes of the meeting are to discuss: (1) The draft SSO framework; (2) permit and compliance priorities; and (3) the overall SSO strategy flowchart. The meeting is open to the public without need for advance registration.

**DATES:** The SSO meeting will be held on January 11 and 12, 1996. On January 11, the meeting will run from 8:30 am to 5:00 pm EST. On January 12, the meeting will run from about 8:30 am until completion.

**ADDRESSES:** The SSO meeting will be held at the Crystal Gateway Marriott Hotel, 1700 Jefferson Davis Highway, Arlington, Virginia. The telephone numbers for the hotel are: 1–800–228–9290, or (703) 920–3230.

**FOR FURTHER INFORMATION CONTACT:** Lam Lim of EPA's Office of Wastewater Management, at (202) 260–7371.

Dated: December 8, 1995.

Michael B. Cook,

*Director, Office of Wastewater Management, Designated Federal Official.*

[FR Doc. 95–30557 Filed 12–15–95; 8:45 am]

BILLING CODE 6560–50–P

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# FEDERAL COMMUNICATIONS COMMISSION

## Notice of Public Information Collections Being Reviewed by FCC for Extension Under Delegated Authority 5 CFR 1320 Authority, Comments Requested

December 11, 1995.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commissions burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. The FCC is reviewing the following information collection requirements for possible 3-year extension under delegated authority 5 CFR 1320, authority delegated to the Commission by the Office of Management and Budget (OMB).

**DATES:** Written comments should be submitted on or before February 16, 1996. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all comments to Dorothy Conway, Federal Communications, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to dconway@fcc.gov.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collections contact Dorothy Conway at 202–418–0217 or via internet at dconway@fcc.gov.

**SUPPLEMENTARY INFORMATION:**

*OMB Approval Number:* 3060–0171.

*Title:* 73.1125 Station main studio location.

*Form No.:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents:*135.

*Estimated Time Per Response:*30 minutes.

*Total Annual Burden:*68 hours.

*Needs and Uses:*Section 73.1125 requires AM, FM or TV licensees to locate their main studio at any point within the station's principal community countours. If the station relocates its main studio from one point to another within the principal community contour or from a point outside the principal community contour to one within it, the licensee is required to notify the FCC. The data is used by FCC staff to assure that the station main studio is located within the principal community contour and serves to notify use of a change in the mailing address.

*OMB Approval Number:*3060–0160.

*Title:*73.158 Directional Antenna Monitoring Points.

*Form No.:*N/A.

*Type of Review:*Business or other for-profit.

*Number of Respondents:*80.

*Estimated Time Per Response:*4 hours.

*Total Annual Burden:*320 hours.

*Needs and Uses:*Section 73.158 requires a licensee of an AM station using a directional antenna system to file an informal application to modify their station license to specify a new location for the field monitoring point when circumstances occur which make the present location no longer accessible or unsuitable. Section 73.158 also requires the licensee to file a request for a corrected station license when the descriptive routing to reach any of the monitoring points as shown on the station license is no longer correct due to road or building construction or other changes. These filings provide up-to-date directions for use by the Complaints and Investigations Bureau's inspectors in accurately locating the monitoring points and obtaining field strength measurements relevant to the Commission's enforcement program aimed at keeping electromagnetic interference to a minumum.

*OMB Approval Number:*3060–0321.

*Title:*73.68 Sampling Systems for Antenna Monitoring.

*Form No.:*N/A.

*Type of Review:*Extension of a currently approved collection.

*Respondents:*Business or other for-profit.

*Number of Respondents:*100.

*Estimated Time Per Response:*2 hours.

*Total Annual Burden:*200 hours.

*Needs and Uses:*Section 73.68(b) requires that licensees of existing AM broadcast stations with antenna monitor sampling systems, meeting the performance standards specified in the rules, may file informal requests for approval of their sampling systems. Section 73.68(d) requires that a request for modification of the station license be submitted to the FCC when the antenna sampling system is modified or components of the sampling system are replaced. The informal request for approval of sampling systems is used by FCC staff to maintain complete technical information regarding licesees to insure that the sampling system is in full compliance with the Commission's Rules and will not cause interference to other facilities, thus reducing the service provided to the public. The request for modification of station license is used to issue a new station license.

*OMB Approval Number:*3060–0387.

*Title:*Field Disturbance Sensors, Authorization and On-Site Verification (Section 15.201(d)).

*Form No.:*N/A.

*Type of Review:*Extension of existing collection.

*Respondents:*Businesses or other for-profit; Small businesses or organizations.

*Number of Respondents:*200.

*Estimated Time Per Response:*18 hours.

*Total Annual Burden:*3,600 hours.

*Needs and Uses:* To monitor non-licensed field disturbance sensors operating in the low VHF television bands, equipment testing is required at each installation. Data is retained by the holder of the equipment authorization issued by the Commission, and made available only at the request of the Commission.

Federal Communications Commission.

William F. Caton,

*Acting Secretary.*

[FR Docs. 95–30653 Filed 12–15–95; 8:45 am]

BILLING CODE 6712–01–F

## FEDERAL MARITIME COMMISSION

### Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. App. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, D.C. 20573.

Amerford FMS, Inc., 441 N. Oak Street, Inglewood, CA 90302, Officers: Michael O Elze, President, Samuel Young, Treasurer

Mark Fromm, 882 Fair Acres Avenue, Westfield, NJ 07090, Sole Proprietor

All American Worldwide, Inc., 211 West Comstock, Dallas, TX 75208, Officers: Judson H. Good, President, Robert A. Nero, Vice President

Pacific Multi-Modal, Inc., 840 W. 12th Street, Long Beach, CA 90813, Officers: Abraham R. Walker, CEO, Karen L. Walker, President

Pactrans Marine Inc., 9520 La Cienega Blvd., Inglewood, CA 90301, Officers: Jesse Domingo, Director, C.T. Tsui, Vice President

Interpacific Airmarine, Inc., 555 Redondo Beach Blvd. #160, Gardena, CA 90248, Officer: Jae H. Chang, President

Robinson Expediters, Inc., 9675 NW 13th Street, Miami, FL 33172, Officers: Jorge Robinson, President, Ebba Robinson, Vice President

Distribution Support Management, Inc., 75 Northcrest, Newman, GA 30265, Officers: Arthur G. Neil, Jr., President, Joan H. Neil, Secretary

JRM International Forwarding, Inc., 1743 Christie Drive, Marietta, GA 30066, Officers: Rose-Marie Miller, President, James Ivey Miller, Secretary

Ace Forwarding, Inc., 510 Plaza Drive, Suite #2760, Atlanta, GA 30349, Officers: Kim McGurgan, President, Frank Petillon, Director

Dated: December 12, 1995.

By the Federal Maritime Commission.

Joseph C. Polking,

*Secretary.*

[FR Doc. 95–30618 Filed 12–15–95; 8:45 am]

BILLING CODE 6730–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Program Announcement 13655.911]**

### Grants to Indian Tribal Organizations for Supportive and Nutritional Services for Older Indians

**AGENCY:** Administrtion on Aging (AoA), OS.

**ACTION:** Extension of deadline to apply for funds under the Older Americans Act, Title VI, Grants for Native Americans, Part A—Indian Program.

**SUMMARY:** Due to the recent shut down of many components of the Federal government, including the AoA, the Administration is extending the date for which the Title VI grant applications for the grant period April 1, 1996–March 31, 1999 are due.

**DATES:** All applications must be received or postmarked on or before December 20, 1995.

**FOR FURTHER INFORMATION CONTACT:** Your local AoA Regional Administration as listed in the original Federal Register announcement dated September 6, 1995 on pages 46283–46287.

Fernando M. Torres-Gil,

*Assistant Secretary for Aging.*

[FR Doc. 95–30667 Filed 12–15–95; 8:45 am]

**BILLING CODE 4130–01–M**

## Administration for Children and Families

### Child Welfare Waiver Demonstrations Pursuant to Section 1130 of the Social Security Act (the Act); Titles IV–E and IV–B of the Act; Public Law 103–432

**AGENCY:** Administration on Children, Youth and Families (ACYF), ACF, DHHS.

**ACTION:** Public notice.

**SUMMARY:** This notice amends the Public Notice published in the Federal Register on September 7, 1995 (60 FR 46616), by extending the December 31, 1995 due date for accepting new child welfare waiver demonstration proposals for any Second Round of proposals. A new Federal Register announcement will be published in January, 1996, to provide a new deadline for submission of additional child welfare waiver demonstration proposals if it is determined that additional proposals will be considered.

**FOR FURTHER INFORMATION CONTACT;** Michael W. Ambrose at (202) 205–8618.

**SUPPLEMENTARY INFORMATION:** On September 7, 1995, the Administration on Children, Youth and Families published a Public Notice in the Federal Register that summarized the child welfare waiver demonstration proposals submitted to date and established December 31, 1994 as a due date for the submission of proposals for Round Two. This amendment cancels the December 31, 1995 due date. Any new Federal Register announcement providing a new deadline for child welfare waiver demonstration proposals will be published in January, 1996.

(Catalog of Federal Domestic Assistance Program Numbers 93.645, Child Services-State Grants; 93.658, Foster Care Maintenance; 93.659, Adoption Assistance)

Dated: December 11, 1995.

Olivia A. Golden,

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 95–30650 Filed 12–15–95; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF THE INTERIOR

## Bureau of Indian Affairs

### Indian Gaming; Lummi Nation, WA

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of approved Tribal/State Compact.

**SUMMARY:** Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal/State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Tribal-State Compact for Class III Gaming between the Lummi Nation and the State of Washington, which was executed on September 21, 1995.

**DATES:** December 18, 1995.

**FOR FURTHER INFORMATION CONTACT:** George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, D.C. 20240, (202) 219–4068.

Dated: November 13, 1995.

Ada E. Deer,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 95–30339 Filed 12–15–95; 8:45 am]

**BILLING CODE 4310–02–P**

### Indian Gaming

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of approved Second Amendment to Tribal-State Compact.

**SUMMARY:** Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Second Amendment to the Winnebago Tribe of Nebraska and the State of Iowa Gaming Compact between the Winnebago Tribe of Nebraska and the State of Iowa, which was executed on September 12, 1995.

**EFFECTIVE DATES:** December 18, 1995.

**FOR FURTHER INFORMATION CONTACT:** George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, D.C. 20240, (202) 219–4068.

Dated: November 13, 1995.

Ada E. Deer,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 95–30655 Filed 12–15–95; 8:45 am]

**BILLING CODE 4310–02–P**

## Geological Survey

### Federal Geographic Data Committee (FGDC); Application Notice Establishing the Closing Date for Transmittal of Applications Under the FGDC National Spatial Data Infrastructure (NSDI) Competitive Cooperative Agreements Program for Fiscal Year (FY) 1996

**AGENCY:** U.S. Geological Survey. Interior.

**ACTION:** Notice inviting applications for competitive cooperative agreement awards for fiscal year 1996.

**SUMMARY:** The purpose of the FGDC National Spatial Data Infrastructure (NSDI) Competitive Cooperative Agreements Program is to facilitate and foster partnerships and alliances within and among various public and private entities to assist in building the NSDI. The NSDI consists of policies, standards, agreements, and partnerships among a variety of sectors and disciplines that will promote more cost-effective production, ready availability, and greater use of high quality geospatial data. The NSDI Competitive Cooperative Agreements Program is intended to encourage resource-sharing projects, between and among the public and private sector through the use of technology, networking, and enhanced interagency coordination efforts. Proposals must involve two or more organizations and participants are expected to cost share in the project. Activities initiated under this program will promote development and maintenance of and access to data sets that are needed for national, regional, state, and local analyses. Authority for this program is contained in the Department of the Interior and Related Agencies Appropriations Act of 1996.

Applications may be submitted by State and local government agencies, educational institutions, private firms, private foundations, and Federally acknowledged or state-recognized Native American tribes or groups.

**DATES:** The program announcement and application forms are expected to be available on or about January 15, 1996. Applications must be received on or before March 29, 1996.

**ADDRESSES:** Copies of Program Announcement 08187 may be obtained by writing to Kathleen Craig, U.S. Geological Survey, Office of Procurement and Contracts, Mail Stop 205A, 12201 Sunrise Valley Drive, Reston, Virginia 22092. (703) 648–7357.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Snyder, FGDC, U.S. Geological Survey, 590 National Center, 12201 Sunrise Valley Drive, Reston, Virginia 22092; telephone number (703) 648–5514; facsimile (703) 648–5755. Internet ''gdc@usgs.gov''.

**SUPPLEMENTARY INFORMATION:** Under this FY 1996 program announcement, proposals are to be directed towards four components of the NSDI. The first component deals with creation of a distributed clearinghouse for finding and accessing geospatial data. Efforts considered applicable include the creation (inventory, evaluate, catalog data, and establish Internet access) and management of a node within the National Geospatial Data Clearinghouse that provides users with a means for finding, accessing, and sharing geospatial data; establish, develop, or expand programs or projects, through development of training programs, information guides and other explanatory materials, that increase the contributions of local, regional, or national data sets to the National Geospatial Data Clearinghouse; and, design, develop, or implement tools to assist in the inventory, evaluation, documentation, cataloging, serving, maintenance, and sharing of geospatial data or metadata.

The second component involves development and promulgation of the use of FGDC-endorsed standards in data collection, documentation, transfer, and search and query. Applicable efforts include conducting programs to increase user comprehension and adoption of the FGDC Content Standards for Digital Geospatial Metadata and the Spatial Data Transfer Standard; developing software tools or techniques to aid the collection, comparison, evaluation, and maintenance of metadata; and stimulating the development of applicable geospatial data standards in partnership with the FGDC Subcommittees and Working Groups.

The third component focuses on the initial implementation of creating a geospatial data framework that provides a base on which to collect, register, or integrate information accurately. Applicable efforts include conducting feasibility projects for implementing technical and institutional aspects of the framework; and, expanding programs or projects to incorporate data content, technical, operational, and business characteristics of the framework.

The fourth component addresses developing and implementing educational outreach programs to increase awareness and understanding of the major NSDI components among members of the broader community. Applicable efforts involve providing programs and services to educate and train constituents on the purpose, benefits, and application of NSDI initiatives, networks, and standards.

Dated: December 11, 1995.

William Gossman,

*Acting Chief, Office of Program Support.*

[FR Doc. 95–30630 Filed 12–15–95; 8:45 am]

BILLING CODE 4310–31–M

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## National Park Service

### General Management Plan; Lava Beds National Monument; Notice of Availability of Draft Environmental Impact Statement

**SUMMARY:** Pursuant to Section 102 (2) (C) of the National Environmental Policy Act of 1969 (Pub. L. 91–190 as amended), the National Park Service, Department of the Interior, has prepared a Draft Environmental Impact Statement (DEIS) assessing the potential impacts of the proposed Draft General Management Plan (DGMP) for Lava Beds National Monument, Modoc and Siskiyou Counties, California. Once approved, the DGMP/EIS will guide the management of the monument over the next fifteen (15) years.

This DGMP/EIS presents a proposal and two alternatives for the management, use, and development of Lava Beds National Monument. The proposed alternative, Alternative B: Minimum Requirements, provides for staffing, facilities, and boundary changes to provide for long-term resource protection, and facilities and programs sufficient to provide for essential visitor services. Physical features of the plan include boundary additions at Petroglyph Point, improvements at that area to reduce damage to the petroglyphs from wind erosion and vandalism, a small-scale research facility to facilitate the recruitment of volunteers for cost-effective research and resource-management projects, a visitor contact station at the north end of the monument, improvements at the existing visitor center, and minor increases in administrative support facilities.

Alternative A: No Action, would continue the current situation at Lava Beds. Lands at Petroglyph Point would not be acquired, resources would not be adequately protected, and no additional steps would be taken to accommodate visitor interest and use. Resource quality and visitor use experience quality would decline.

Alternative C: Enhanced Visitor Experience, would be similar to Alternative B in terms of resource management and protection, but would provide a broader range of visitor service. Increased interpretive and law enforcement staffing would allow a wider range of interpretive programs and faster response to emergency situations. A visitor center at the north end of the monument and a new and larger visitor facility at the Indian Well area would increase the range of exhibits and visitor services. Additional administrative facilities would be needed to support the greater staffing.

The environmental consequences of the proposed action and the alternatives are fully documented, and mitigation provided as appropriate to minimize impacts. No significant impacts are anticipated as a result of implementing the proposed action.

**SUPPLEMENTARY INFORMATION:** Written comments on the DGMP/EIS should be directed to the Superintendent, Lava Beds National Monument, P.O. Box 867, Tulelake, California 96134. Comments on the DGMP/EIS must be received by March 1, 1996.

A public meeting will be held January 10 at the home economics building at the Tulelake-Butte Valley Fairgrounds from 7:00–10:00 p.m. National Park Service personnel will be available to explain the planning alternatives, answer questions, and receive public comments.

Inquiries on the DGMP/EIS and requests for copies of the DGMP/EIS should be directed to Lava Beds National Monument, address as above, or by telephone at (916) 667–2282. Copies of the DGMP/EIS will be available for public inspection at the Monument and at area libraries.

Dated: December 6, 1995.

Stephen Crabtree,

*Field Director, Pacific West Area.*

[FR Doc. 95–30613 Filed 12–15–95; 8:45 am]

BILLING CODE 4310–70–P

## Office of Surface Mining Reclamation and Enforcement

### Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related form may be obtained by contacting the Bureau clearance officer at the phone number listed below. Comments and suggestions on the requirements should be made directly to the Bureau's clearance officer and to the Office of Management and Budget, Paperwork Reduction Project 1029–0083, Washington, DC 20503, telephone 202–395–7340.

*Title:* Application for Blaster Certification in Federal Program States and on Indian Lands, 30 CFR 955.

*Abstract:* This information is being collected to ensure that the qualification of applicants for blaster certification is adequate. This information will be used to determine the eligibility of the applicant. The affected public will be blasters who want to be certified by the Office of Surface Mining Reclamation and Enforcement.

*Bureau Form Number:* OSM–74.

*Frequency:* Every three years.

*Description of Respondents:* Individuals seeking certification as Blasters.

*Estimated Completion Time:* 50 minutes.

*Annual Responses:* 35.

*Annual Burden Hours:* 30.

*Bureau Clearance Officer:* John A. Trelease (202) 208–2617.

Dated: October 25, 1995.

Gene E. Krueger,

*Acting Chief, Office of Technology Development and Transfer.*

[FR Doc. 95–30648 Filed 12–15–95; 8:45 am]

BILLING CODE 4310–05–M

## INTERSTATE COMMERCE COMMISSION

**[Docket NO. AB–6 (Sub-No. 368X)]**

### Burlington Northern Railroad Company—Abandonment Exemption—in Clatsop County, OR

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notice of exemption.

**SUMMARY:** The Commission, pursuant to 49 U.S.C. 10505, exempts from the prior approval requirements of 49 U.S.C. 10903–04 the abandonment by Burlington Northern Railroad Company of 5.04 miles of railroad in Clatsop County, OR, subject to standard labor protective conditions, an environmental condition, and a trail use condition.

**DATES:** Provided no formal expression of intent to file a financial assistance offer has been received, this exemption will be effective on January 17, 1996. Formal expressions of intent to file financial assistance offers [1] under 49 CFR 1152.27(c)(2) and requests for a notice of interim trail use/rail banking must be filed by December 28, 1995. Petitions to stay must be filed by January 2, 1996. Requests for a public use condition must be filed by January 8, 1996. Petitions to reopen must be filed by January 12, 1996.

**ADDRESSES:** Send pleadings referring to Docket No. AB–6 (Sub-No. 368X) to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission,[2] 1201 Constitution Avenue, N.W., Washington, DC 20423; and (2) Petitioner's representative: Sarah J. Whitley, 3800 Continental Plaza, 777 Main Street, Fort Worth, TX 76102–5384.

**FOR FURTHER INFORMATION CONTACT:** Joseph H. Dettmar, (202) 927–5660. [TDD for the hearing impaired: (202) 927–5721.]

**SUPPLEMENTARY INFORMATION:** Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write to, call, or pick up in person from: DC NEWS & DATA, INC., Interstate Commerce Commission Building, 1201 Constitution Avenue, N.W., Washington, DC 20423. Telephone: (202) 289–4357. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: December 5, 1995.

By the Commission, Chairman Morgan, Vice Chairman Owen, and Commissioner Simmons.

Vernon A. Williams,

*Secretary.*

[FR Doc. 95–30656 Filed 12–15–95; 8:45 am]

BILLING CODE 7035–01–P

[1] See *Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

[2] Legislation to sunset the Commission on December 31, 1995, and transfer remaining functions is now under consideration in Congress. Until further notice, parties submitting pleadings should continue to use the current name and address.

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Consent Decree Pursuant to the Comphrensive Environmental Response, Compensation and Liability Act

Notice is hereby given that a proposed consent decree in *United States* v. *American Color & Chemical Corporation et al.*, Civil Action No. 4: CV–92–1352, was lodged on November 30, 1995 in the United States District Court for the Middle District of Pennsylvania. The consent decree settles an action brought under the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9606 et seq., against American Color & Chemical Corporation (''AC&C'') and Beazer East, Inc. (''Beazer'') for reimbursement of response costs incurred in connection with clean-up of the Drake Chemical Superfund Site located in Lock Haven, Pennsylvania.

Under the proposed settlement, AC&C and Beazer agree to finance and perform the groundwater cleanup for Drake Site. In addition, the settling defendants will reimburse the United States and the Commonwealth of Pennsylvania for past costs in the amounts of $3.6 million and $400,000, respectively. Additionally, the settling defendants will co-ordinate the Drake Site groundwater cleanup with a corrective action ongoing at the neighboring AC&C facility pursuant to the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6901 et seq.

In consideration of settling defendants' groundwater remediation and their reimbursement of $4 million in past costs incurred by the United States and the Commonwealth, AC&C and Beazer will receive a covenant not to sue under Sections 106 and 107(a) of CERCLA for the Drake Site and for CERCLA Section 107 costs associated with RCRA management at the AC&C facility. With respect to future liability for the remedial action to be performed, the covenant not to sue for Section 106 of CERCLA becomes effective upon certification of completion of the remedial action by EPA. In addition, the covenants not to sue are conditioned upon the complete and satisfactory performance by each settling defendant of its obligations under the Consent Decree.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and

Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *American Color & Chemical Corporation et al.,* DOJ Ref. # 90–11–2–7A.

The proposed consent decree may be examined at the Office of the United States Attorney, Middle District of Pennsylvania, 1162 Federal Building, 228 Walnut Street Harrisburg, PA 17108; the Region III Office of the Environmental Protection Agency, 841 Chestnut Building, Philadelphia, Pennsylvania, 19107; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy of the body of the proposed decree, please refer to the referenced case and enclose a check in the amount of $52.75 (25 cents per page reproduction costs), for each copy. The check should be made payable to the Consent Decree Library.

Joel M. Gross,

*Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 95–30629 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response Compensation and Liability Act (''CERCLA'')

Notice is hereby given that a proposed consent decree in *United States* v. *Casings, et al.,* Civil Action No. 92–0284 (NPM), was lodged on November 27, 1995, with the United States District Court for the Northern District of New York. The Consent Decree requires defendants to pay to the United States $120,000 within thirty days of entry of the Consent Decree to reimburse Environmental Protection Agency response costs incurred at the Catskill Tire Fire Superfund Site. Total Site costs incurred by EPA were approximately $375,000.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Casings, et al.,* DOJ Ref. #90–11–3–872.

The proposed consent decree may be examined at the office of the United States Attorney for the Northern District of New York, 100 South Clinton Street, Syracuse, New York 13261; the Region II Office of the Environmental Protection Agency, 290 Broadway, New York, New York, 10007–1866 (contact Assistant Regional Counsel Beverly Kolenberg); and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy please refer to the referenced case and enclose a check in the amount of $5.00 (25 cents per page reproduction costs) for the Consent Decree, payable to the Consent Decree Library.

Joel Gross,

*Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 95–30633 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Section 122(d)(2) of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9622(d)(2), and Departmental policy, 28 CFR 50.7, notice is hereby given that on November 28, 1995, a proposed consent decree in *United States* v. *County of Milwaukee, Wisconsin,* Civil Action No. 95–C–1210, was lodged with the United States District Court of the Eastern District of Wisconsin. This consent decree represents a settlement of claims brought against Milwaukee County under CERCLA Sections 106 and 107, 42 U.S.C. 9606 and 9607, for the recovery of costs incurred and to be incurred by the United States in responding to the release and threatened release of hazardous substances at and from the Moss-American Superfund Site in Milwaukee, Wisconsin.

Under the proposed settlement, Milwaukee County will be required to: (1) Relinquish a potential takings claim; (2) withdraw a motion to intervene that is pending before the Court; (3) withdraw its opposition to entry of a proposed consent decree between the United States and Kerr-McGee Chemical Co. (''Kerr-McGee'') that was lodged in 1991 (''Remedial Action Decree''), under which Kerr-McGee would be obligated to perform the final remedial action for the Site, at a cost of $26 million, and pay $1 million of the United States' past costs of $1.8 million (as of January 31, 1991); and (4) grant the United States and its assigns irrevocable access to the Moss-American Superfund Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *County of Milwaukee, Wisconsin,* D.J. Ref. 90–11–2–590A.

The proposed Consent Decree may be examined at: (1) The Mill Road Library, 6431 N. 76th St., Milwaukee, Wisconsin; (2) U.S. Environmental Protection Agency, Region 5, 77 W. Jackson Blvd, Chicago, Illinois 60604 (contact Mr. Russell D. Hart (312–886–4844)); and (3) the U.S. Department of Justice's Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20010, (202) 624–0892. A copy of the consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20010. In requesting a copy, please enclose a check in the amount of $8.25 (consent decree only) or $46.75 (consent decree and appendices) (25 cents per page reproduction cost) payable to the Consent Decree Library.

Joel M. Gross,

*Chief, Environment Enforcement Section, Environmental and Natural Resources Division.*

FR Doc. 95–30631 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy, 28 C.F.R. § 50.7, notice is hereby given that on September 29, 1995, a proposed Consent Decree in *United States of America* v. *The Port of Seattle, et al.,* Civil Action No. C95–1495–Z, was lodged with the United States District Court for the Western District of Washington.

The Complaint in this action was brought pursuant to Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9607, to require the defendants to implement EPA's selected cleanup for the Site, and to recover costs incurred by the United States in response to releases of hazardous

substances at the Harbor Island Superfund Site in Seattle, Washington.

The proposed Consent Decree that is the subject of this Notice requires the defendants to complete the cleanup selected by EPA for the Soil and Groundwater Operable Units of the Site. The United States estimates that the cleanup expense will be approximately $40 million. The Consent Decree also requires the defendants to reimburse the United States for all costs it shall incur in overseeing the completion of the cleanup.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environmental and Natural Resources Division, Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, D.C. 20044. Comments should refer to *United States of America* v. *the Port of Seattle, et al.*, Civil Action No. C95–1495–Z, DOJ Ref. No. 90–11–2–970A.

The proposed Consent Decree may be examined at the Office of Regional Counsel, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington (206) 553–1504; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library. In requesting a copy please refer to the referenced case and enclose a check in the amount of $18.00 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Joel Gross,

*Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 95–30632 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Notice of Lodging of Stipulation of Settlement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on November 24, 1995, a proposed Stipulation of Settlement in *In re St. Johnsbury Trucking Company, Inc.*, Civil Action No. 93–43136, was lodged with the United States Bankruptcy Court for the Southern District of New York. The proposed Stipulation of Settlement concerns the response to the existence of hazardous substances at the Pine Street Canal Site located in Burlington, Vermont pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, as amended.

Under the terms of the Stipulation of Settlement, the United States Environmental Protection Agency will be reimbursed $35,000 for administrative expenses incurred in connection with property formerly owned by St. Johnsbury. St. Johnsbury also agrees to an allowed unsecured claim in the amount of $3,000,000 for costs incurred and to be incurred by the United States in connection with response actions at the Site and in the amount of $150,000 for natural resource damages for resources under the trusteeship of the Department of Interior.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Stipulation of Settlement. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Ben Franklin Station, Washington, D.C. 20044, and should refer to In re St. Johnsbury Trucking Company, Inc., D.J. Ref. 90–11–2–978.

The proposed Stipulation may be examined at the Region 1 Office of the Environmental Protection Agency, One Congress Street, Boston, Massachusetts. Copies of the Consent Decree may be examined at the Environmental Enforcement Section Document Center, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Document Center. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $4.25 (25 cents per page reproduction cost) made payable to Consent Decree Library.

Joel M. Gross,

*Acting Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 95–30628 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Antitrust Division

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—Commercenet Consortium

Notice is hereby given that, on August 17, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), CommerceNet Consortium, (the ''Consortium'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing certain changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the identities of the additional members at the sponsor level are: Justsystem, Inc., Menlo Park, CA; Defense Logistics Agency, U.S. Government, Alexandria, VA; and NASA, Federal Government, Moffett Field, CA.

The following organizations have joined the Consortium as associate members: Concurrent Technologies Corporation, Oakland, CA; DigiCash, New York, NY; Hamilton Hallmark, Culver City, CA; Online Computer Market, Southboro, MA; Hummingbird Software Corporation, Incline Village, NV; Golf Web, Saratoga, CA; The Document Center, Belmont, CA; Media Circus, New York, NY; InterCom-University of Virginia, Computer Science Department, Charlottesville, VA; Sholink Corporation, Mt. View, CA; and Tradewinds Technologies Incorporated, Winston-Salem, NC.

The following organizations have joined as international associate members: Justsystem Corporation, Tokushima, JAPAN; British Telecommunications, London, UNITED KINGDOM; Toshiba Corporation, Tokyo, JAPAN; and Kokusai Denshin Denwa Company, Ltd., Tokyo, JAPAN.

No other changes have been made in either the membership or planned activities of the Consortium. Membership remains open, and the Consortium intends to file additional written notifications disclosing all changes in membership.

On June 13, 1994, the Consortium filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Rederal Register pursuant to Section 6(b) of the Act on August 31, 1994 (59 FR 45012).

The last notification was filed with the Department on June 9, 1995. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on December 5, 1995 (60 FR 62259).

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

FR Doc. 95–30636 Filed 12–15–95; 8:45 am]

**BILLING CODE 4410–01–M**

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—Diode Laser Welding Consortium

Notice is hereby given that, on November 1, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), parties to a joint venture collectively referred to as the ''Diode Laser Welding Consortium'' filed notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the joint venture and (2) the nature and objectives of the joint venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are: SDL, Inc., San Jose, CA; Teledyne Brown Engineering, Huntsville, AL; and Utilase Systems, Detroit, MI. The objective of the joint venture is the development of a fiber-coupled direct diode laser system for the cutting and welding of steel and aluminum parts in the automotive industry.

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

[FR Doc. 95–30635 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–01–M

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—HDP User Group International, Inc.

Notice is hereby given that, on October 30, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), HDP User Group International, Inc., an Arizona non-profit corporation, filed notification simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Amkor Electronics, Chandler, AZ; MCC, Austin, TX; Motorola, Schaumberg, IL; and Texas Instruments, Villeneuve, FRANCE have become members of HDP User Group International, Inc. Combitech, Jonkoping, SWEDEN; Digital Equipment Corporation, Maynard, MA; and ESEC, Phoenix, AZ are no longer members.

No other changes have been in either the membership or the planned activity of the joint venture.

On September 14, 1994, the HDP User Group filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(a) of the Act of March 23, 1995 (60 FR 15306–07). The last notification was filed on February 27, 1995. A notice was published in the Federal Register on May 11, 1995 (60 FR 25251).

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

[FR Doc. 95–30638 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–01–M

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—Southwest Research Institute

Correction

In notice document 95–15787 appearing on page 33432 in the issue of Wednesday, June 28, 1995, in the first column, in the third paragraph, in the eleventh (11th) line, ''65 FR 15307'' should read ''60 FR 15307''.

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

[FR Doc. 95–30634 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–01–M

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—Wilfred Baker Engineering, Inc. Petroleum/Chemical Processing Joint Agreement

Notice is hereby given that, on June 22, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), Wilfred Baker Engineering, Inc., has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing a change in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Hoechst Celanese Chemical Group, Dallas, TX has joined the joint venture. No other changes have been made in either the membership or planned activities of the venture.

On March 14, 1995, Wilfred Baker Engineering, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on May 11, 1995 (60 FR 25252).

Constance K. Robinson,

*Director of Operations Antitrust Division.*

[FR Doc. 95–30639 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–01–M

## Notice Pursuant to the National Cooperative Research and Production Act of 1993—X Consortium, Inc.

Notice is hereby given that, on September 1, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), X Consortium, Inc. (the ''Corporation'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the new member of the Corporation is: Georgia Institute of Technology, Atlanta, GA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and the Corporation intends to file written notifications disclosing all changes in membership.

On September 15, 1993, the Corporation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on November 10, 1993 (58 FR 59737). The last notification was filed with the Department on June 6, 1995. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on June 29, 1995 (60 FR 33849).

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

[FR Doc. 95–30637 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–01–M

## Drug Enforcement Administration

**[Docket No. 94–32]**

## Richard M. Koenig, M.D., Revocation of Registration

On March 2, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Richard M. Koenig, M.D., (Respondent) of Riverhead, New York, notifying him of an opportunity to

show cause as to why DEA should not revoke his DEA Certificate of Registration, AK6455237, under 21 U.S.C. 824(a), and deny any pending applications for renewal of such registration as a practitioner under 21 U.S.C. 823(f), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that the Respondent had been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a), as evidenced by, but not limited to the following:

(a) Between March 1986 and January 1990, (the Respondent) submitted false or fraudulent medical services claims to the New York State Medical Assistance Program, commonly known as Medicaid, and as a result of such submissions (he) obtained approximately $150,000.00 in funds to which (he) was not entitled.

(b) On or about April 19, 1991, (the Respondent) was convicted in the County of Rockland, State of New York, of twenty counts of offering a false instrument for filing, in violation of New York Penal Code, Section 175.35. On or about June 28, 1991, (the Respondent) was sentenced to five years probation with the conditions that, *inter alia*, (he) serve six months in jail and pay a $25,000.00 fine.

(c) Effective on or about March 5, 1992, the Office of the Inspector General, United States Department of Health and Human Services, excluded (the Respondent) from participating in the Medicare program and any State health care program for a period of five years.

On April 11, 1994, the Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Arlington, Virginia, on October 4, 1994, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On February 2, 1995, Judge Bittner issued her Opinion and Recommended Ruling, recommending that the Respondent's DEA registration be revoked and that any pending applications be denied. Neither party filed exceptions to her decision, and on March 6, 1995, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and the filings of the parties, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, and his adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that the Respondent is a Board-certified psychiatrist in private practice in Riverhead, New York, and is also a part-time consultant for North Fork Counseling, a mental health clinic in Mattituck, New York. On June 28, 1991, the Respondent was sentenced in a New York state court to six months imprisonment, fines totalling $25,000, and probation for five years as a result of a jury verdict of guilty to 20 counts of offering a false instrument for filing. Specifically, the Respondent was convicted of filing, with the intent to defraud the State of New York, written instruments containing false statements and false information that he had provided services to certain Medicaid recipients, and that he had not been paid for such services, when in fact he was paid a salary to render such services. On January 24, 1994, the Respondent was discharged from probation.

On February 13, 1992, the Director of the U.S. Department of Health and Human Services Health Care Administrative Sanctions Office of Investigations advised the Respondent that, pursuant to 42 U.S.C. 1320a–7(a), he was mandatorily excluded from Medicare and state health care programs because of his conviction for a criminal offense related to the delivery of an item or service under the Medicaid Program. The letter also advised the Respondent that the exclusion would be in effect for five years. The Respondent did not appeal this revocation.

Pursuant to a Notice of Hearing and Statement of Charges dated December 9, 1992, a hearing was held before a Hearing Committee of the New York State Board For Professional Medical Conduct (Medical Board) on January 20, 1993. By order dated February 5, 1993, the Medical Board found that the Respondent had knowingly submitted invoices to Medicaid representing that he had provided certain services that, in fact, he had not rendered as represented on the invoice. The Medical Board suspended the Respondent's medical license for four months and ordered him to perform one hundred hours of community service.

At the hearing before Judge Bittner, the Respondent testified that the conviction he received concerning ''false instruments'' or Medicaid billings, resulted from ''errors in judgment on (his) part,'' based upon his performing a service on one day and billing for that service as if it had been performed on another day. He also stated that ''I can't tell you how much I regret them,'' but that ''(i)t was an error in thinking. It was a reflection that people would understand and it's not a system that understands and that was at the worst, pathological naivete on my part.'' He further testified that he needed a DEA registration in order to prescribe benzodiazapines as tranquilizers, and Dexedrine and Cylert for attention deficit disorder. Benzodiazepines and Cylert (trade name for pemoline) are Schedule IV controlled substances, and Dexedrine (trade name for dextroamphetamine), is a Schedule II controlled substance. The Respondent further testified that without a DEA registration, he would feel obliged to leave North Fork because of his inability to render appropriate treatment.

Karen Malcolmsen, Ph.D., the Clinical Director of Family Service League, North Fork Counseling (North Fork), testified that North Fork is the only licensed mental health clinic within a forty-mile radius and is located in a very rural community. Further, North Fork provides counseling and psychiatric services primarily to the poor and working poor in the local community, many of whom are migrant farm workers who cannot afford to pay substantial sums for mental health care.

Dr. Malcolmsen testified that she had known the Respondent for six years, for he had performed his community service at North Fork, plus an additional hundred hours of service, and she had supervised him, worked with him on the treatment team, and referred clients to him when they needed medication or if therapists sought a second opinion. Dr. Malcolmsen stated that the Respondent is still a consulting psychiatrist for North Fork, that he is paid a ''very small salary'' by the clinic based on his working seven hours per week, when in fact he actually provided ten to thirteen hours per week of services to the clinic. Dr. Malcolmsen opined that the Respondent's work was excellent, that clients always reported positively about him, and that she found him very caring and honest. Dr. Malcolmsen also testified that the Respondent had told her about the charges against him before the indictment was handed down, that he had told her that he had never intentionally done anything illegal but had made some errors, and that several times in meetings with her he had expressed remorse for his actions and had taken responsibility for them. Finally, Dr. Malcolmsen testified that the Respondent had never abused his authority to handle controlled

substances. She explained that if the Respondent's DEA registration were revoked or suspended, the clinic would not be able to function in emergency situations because the Respondent would be unable to prescribe the appropriate controlled medications needed by the patients. However, since the Respondent's exclusion from Medicare or Medicaid, North Forks has the services of another psychiatrist who works three hours a week and sees the Medicare patients.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for such registration, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or a pending application for registration denied. See Henry J. Schwarz, Jr., M.D. Docket No. 88–42, 54 FR 16,422 (1989). In addition, 21 U.S.C. 824(a)(5) specifies that a DEA registration may be revoked or suspended if the registrant ''has been excluded * * * from participation in a program pursuant to (42 U.S.C. 1320a–7(a)).'' Here, the record demonstrates that the Respondent has been so excluded. Although the Respondent attempted to contest elements of this exclusion in these proceedings, the Deputy Administrator agrees with Judge Bittner's findings that:

> The letter advising Respondent of his exclusion from Medicare and state health programs specified that his exclusion was mandated by 1320a–7(a), and Respondent did not appeal that ruling. He is therefore precluded from attacking that finding collaterally in this proceeding. In light of the above, I conclude that Respondent was excluded from programs pursuant to 1320a–7(a) and that the exclusion constitutes grounds to revoke Respondent's DEA registration pursuant to 42 U.S.C. 824(a)(5).

Next, as to the public interest issue, factors one and five are relevant in determining whether the Respondent's continued registration would be inconsistent with the public interest. Specifically, as to factor one, ''(t)he recommendation of the appropriate state licensing board,'' the Medical Board, after conducting a hearing and reviewing the evidence submitted, found that the Respondent had knowingly submitted false invoices for payment by the State. Accordingly, the Medical Board sanctioned the Respondent by suspending his medical license and ordering him to perform community service.

Further, as to factor five, ''(s)uch other conduct which may threaten the public health or safety,'' the Respondent's conduct of submitting false invoices placed into question his trustworthiness and credibility. Also, Judge Bittner found that the Respondent's testimony before her lacked credibility: ''I note at the outset that I did not find Respondent to be a credible witness. He seemed more interested in tailoring his testimony to his defenses than in accurately portraying relevant events.'' Such lack of credibility in 1994 causes concern as to the Respondent's future conduct if entrusted with protecting the public interest in administering controlled substances. The Respondent argued that since his conviction did not involve controlled substances, the Government had not shown that his continued registration would be inconsistent with the public interest. However, the Deputy Administrator agrees with Judge Bittner who wrote ''(i)t is well established that misconduct involving controlled substances is not a *sine qua non* for revocation of a DEA registration * * *.'' See also Gilbert L. Franklin, D.D.S., 57 FR 3441 (1992).

Yet the Respondent has submitted evidence concerning his rehabilitation. Specifically, Dr. Malcolmsen testified extensively about the Respondent's excellent, honest and caring work, often voluntarily provided to the patients at North Fork, and about the Respondent's statements of remorse for his actions. Dr. Malcolmsen also testified that she believed the Respondent had taken responsibility for his past misconduct, and that she had never observed the Respondent abuse his authority to handle controlled substances. She further explained that if the Respondent's DEA registration was revoked, the clinic would suffer a loss of services because the Respondent would be unable to prescribe controlled substances needed by many of North Fork's patients.

The Respondent also testified about his remorse for his misconduct and his need for his DEA Certificate of Registration. However, Judge Bittner, directly observing the Respondent's testimony, noted that ''(a)lthough counsel for Respondent asserts that Respondent has expressed remorse for his conduct, * * * Respondent's only testimony to that effect in this proceeding was his comment that 'I'm extremely remorseful about it and I've said that.' However, the thrust of his testimony in this proceeding appeared to be that having to go through 'another trial' was unfair and tiring. In these circumstances, I conclude that his purported expressions of remorse are less than reliable.''

Given Judge Bittner's doubts as to the Respondent's credibility and sincerity, and the egregious nature of his conduct in intentionally filing false documents with the State, the Deputy Administrator finds that the public interest is best served by revoking the Respondent's DEA Certificate of Registration and denying and pending registration application at the present time. See *Sokoloff* v. *Saxbe*, 501 F.2d 571, 576 (2 Cir. 1974) (stating that ''permanent revocation'' of a DEA Certificate of Registration may be ''unduly harsh''). Like Judge Bittner, after reviewing the record in total, the Deputy Administrator questions whether the Respondent is currently willing or able to meet the responsibilities inherent in a DEA registration.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AK6455237, issued to Richard M. Koenig, M.D., be, and it hereby is, revoked, and any pending application submitted by the Respondent is denied. This order is effective January 18, 1996.

Dated: December 11, 1995.

Stephen H. Green,

*Deputy Administrator.*

[FR Doc. 95–30654 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF LABOR

### Employment and Training Administration

**[NAFTA—00303; Lucas, Iowa, NAFTA—00303A; Mt. Ayr, Iowa, NAFTA—00303B; Osceola, Iowa, and NAFTA—00303C]**

### Iowa Assemblies, Inc., Murray, Iowa; Amended Certification Regarding Eligibility To Apply for NAFTA Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), the Department of Labor issued a Notice of Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on January 12, 1995, applicable to all workers at Iowa Assemblies, Inc. in Lucas, Mt. Ayr and Osceola, Iowa.

At the request of the State Agency on behalf of the company, the Department reviewed the subject certification. The company reports worker separations will occur at the subject firm's manufacturing facilities in Mt. Ayr, Osceola, and Murray, Iowa. The workers produce among other products, automotive wiring harnesses and wiring assembly. The Department's review of the certification for workers of the subject firm found that workers in Mt. Ayr and Osceola, Iowa are currently covered under the certification. When the certification was issued, the Mt. Ayr and Osceola locations of the subject firm were not separately assigned a suffix number. The intent of the Department's certification is to include all workers of Iowa Assemblies, Inc. adversely affected by increased imports of wiring harnesses and assembly from Mexico or Canada. Therefore, the Department is amending the certification for workers of the subject firm to separately identify the Mt. Ayr and Osceola, Iowa locations, and provide for the worker separations in Murray, Iowa.

The amended notice applicable to NAFTA–00303 is hereby issued as follows:

''All workers of Iowa Assemblies, Inc., Lucas (NAFTA–303), Mt. Ayr (NAFTA–303A), Osceola (NAFTA–303B), and Murray (NAFTA–0303C) Iowa engaged in employment related to the production of wiring harnesses and assembly who became totally or partially separated from employment on or after December 8, 1993 are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.''

Signed at Washington, DC., this 5th day of December 1995.

Russell T. Kile,

*Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.*

[FR Doc. 95–30652 Filed 12–15–95; 8:45 am]

BILLING CODE 4510–30–M

## LIBRARY OF CONGRESS

### Copyright Office

**[Docket No. 95–8]**

### Copyright, Cable Compulsory License

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Notice of policy decision.

**SUMMARY:** The Copyright Office of the Library of Congress is announcing a policy decision with respect to the examination and reporting of local broadcast signals in light of the amendment to section 111 of the Copyright Act made by the Satellite Home Viewer Act of 1994. For examining cable statements of account, the Office will use the same ADI list used by the Federal Communications Commission for its must-carry/retransmission consent election, and will treat a broadcast signal as local for copyright purposes only within that station's ADI.

**FOR FURTHER INFORMATION CONTACT:** Marilyn J. Kretsinger, Acting General Counsel, or William Roberts, Senior Attorney for Compulsory Licenses. Telephone (202) 707–8380. Telefax (202) 707–8366.

**SUPPLEMENTARY INFORMATION:**

I. Background

On October 18, 1994, the President of the United States signed into law the Satellite Home Viewer Act of 1994. Public Law No. 103–369. In addition to extending and amending the compulsory license for satellite carriers in 17 U.S.C. 119, the Home Viewer Act expanded the cable compulsory license definition of the ''local service area of a primary transmitter'' in 17 U.S.C. 111 to include a broadcast station's ''television market as defined in section 76.55(e) of title 47, Code of Federal Regulations (as in effect on September 18, 1993), or any modifications to such television market made, on or after September 18, 1993, pursuant to section 76.55(e) or 76.59 of title 47 of the Code of Federal Regulations'' (parenthetical in original). The amendment was made effective beginning with the second accounting period of 1994.

The definition of the ''local service area of a primary transmitter'' in 17 U.S.C. 111(f) determines whether a broadcast station is local or distant to a cable system and consequently when it must submit a royalty fee for retransmission of that signal. Cable systems pay royalties for carriage of distant signals and may retransmit local broadcast signals to their subscribers without incurring copyright liability.[1] Prior to the passage of the Home Viewer Act, the local service area definition provided that a broadcast station was local in the area that it could ''insist upon its signal being retransmitted by a cable system pursuant to the rules, regulations and authorizations of the Federal Communications Commission in effect on April 15, 1976* * *'' 17 U.S.C. 111(f) (1976). This was a reference to the Commission's must-carry rules in effect in 1976, and the Copyright Act fixed these rules for all future copyright determinations. Although these must-carry rules were ultimately declared unconstitutional, *see Quincy Cable T.V., Inc.* v. *FCC,* 768 F.2d 1434 (D.C. Cir. 1985), *cert. denied,* 476 U.S. 1169 (1986) and *Century Communications* v. *FCC,* 835 F.2d 292 (D.C. Cir. 1987), *cert. denied,* 486 U.S. 1032 (1988), they remain in effect for purposes of 17 U.S.C. 111. *See Quincy,* 768 F.2d at 1454 n. 42. However, because of the passage of time and changes in telecommunications law and policy, the 1976 must-carry rules no longer reflect the realities of the current marketplace. Congress, therefore, amended the local service area definition in the Home Viewer Act to provide an additional means of determining the local/distant copyright status of broadcast stations.

The Home Viewer Act amendment provides that, in addition to the area encompassed by the 1976 must-carry rules, a broadcast station is local for copyright purposes in the area that comprises that station's television market as defined in § 76.55(e) of the FCC's rules, and any subsequent modifications made by the FCC to that market. In many circumstances, a station's television market under § 76.55(e) creates a larger local service area than under the 1976 must-carry rules. Cable systems may use either the television market or the 1976 must-carry

[1] There is one exception to this rule: a cable system which retransmits only local broadcast signals must nonetheless submit a minimum royalty fee under 17 U.S.C. 111. However, if the system carries one or more distant signals, royalties are only paid for those distant signals, and the local signals carried are copyright-free. As a practical matter, there are very few cable systems which only carry local broadcast signals and no distant signals.

rules, or both, in determining the local service area of each broadcast station they retransmit to their subscribers.

Section 76.55(e) of the FCC's rules defines a television market for purposes of the Commission's new must-carry rules adopted to implement the Cable Television Consumer Protection and Competition Act of 1992. Public Law 102–385. The section provides in its entirety:

(e) Television market. For purposes of the must-carry rules:

(1) A local commercial broadcast television station's market shall be defined as its Area of Dominant Influence (ADI) as determined by Arbitron and published in its *Television ADI Market Guide* or any successor publication, as noted below, except that for areas outside the contiguous 48 states the area of dominant influence may be defined using Nielsen's Designated Market Area (DMA), where applicable, and that Puerto Rico, the U.S. Virgin Islands and Guam will each be considered one ADI;

(2) A cable system's television market(s) shall be the one or more ADIs in which the communities it serves are located;

(3) In addition, the county in which a station's community of license is located will be considered within its market.

Note: For the 1993 must-carry/retransmission consent election, the ADI assignments specified in the 1991–1992 *Television ADI Market Guide,* available from the Arbitron Ratings Co., 312 Marshall Ave., Laurel MD, will apply. ADI assignments will be updated at three year intervals. For the 1996 election period, the 1994–1995 ADI list will be used; the applicable list for the 1999 election will be the 1997–1998 list, etc.

47 CFR 76.55(e) (1993). The Home Viewer Act fixes 47 CFR 76.55(e) as of September 18, 1993, but expressly includes any subsequent modifications to television markets made under § 76.55(e) or § 76.59 of the Commission's rules. Modifications were recognized by the Home Viewer Act because, at the time of its passage, the Arbitron Company had discontinued its publication of the Television ADI Market Guide and had filed for bankruptcy.

Subsequent to the enactment of the Home Viewer Act, the Copyright Office amended its cable and satellite carrier compulsory license rules and discussed the changes brought about by the Act. 59 FR 67635 (December 30, 1994). The new definition of the ''local service area of a primary transmitter'' did not require amendment of the rules; however, the Office described the change in the definition:

The other change to the cable compulsory license made by the 1994 Home Viewer Act is the broadening of the section 111(f) definition of the ''local service area of a primary transmitter.'' The definition is used to determine when a broadcast station is local or distant to a cable operator, which in turn determines whether the operator must pay a royalty fee for that station. Effective July 1, 1994, the local service area of a broadcast station for copyright purposes also includes the area in which the station is entitled to insist upon carriage of its signal by a cable system (i.e. its must-carry zone), in accordance with the rules of the Federal Communications Commission in effect on September 18, 1993, and any subsequent modification of those rules.

*Id.* To date, this is all the Office has said regarding the change made to the local service area definition by the Home Viewer Act.

## II. Policy Issues

Amendment of the definition of the ''local service area of a primary transmitter'' has led to questions in the administration of the cable compulsory license. Two of these questions must be resolved in order for the Copyright Office to administer the cable compulsory license. The first question involves the Copyright Office's use of ADI in its examination of cable statements of account. As discussed above, the amendment to the local service area definition was made effective beginning with the second accounting period of 1994, and cable systems are now using broadcast stations' ADI for determining the local/distant status of the signals. The question has arisen, however, as to the appropriate ADI information to consider in calculating the local service area of a broadcast signal. The Note to 47 CFR 76.55(e) states that the FCC is using the 1991–1992 Television ADI Market Guide for the 1993 must-carry/retransmission consent election, and that ADI assignments will be updated at three year intervals.[2] Should cable systems use the 1991–1992 Television ADI Market Guide for the 1994/2 accounting period and the 1995 accounting year, or should they apply the current ADI list to the corresponding accounting period—i.e. the 1994 list to the 1994 accounting year and the 1995 list to the 1995 accounting year, where such information is available?

The second question involves the determination of a broadcast station's ''television market'' for a cable system that serves a community or communities in more than one county where those counties are assigned to different ADIs. Is the broadcast station local for copyright purposes only in those counties assigned to its ADI, or are there circumstances where the station may be reported as local outside of its ADI?

## III. Policy Decision

As part of its responsibility to administer the cable compulsory license, the Copyright Office is resolving both the issues raised in this Notice. With respect to which ADI (or subsequent) list to use in examining statements of account, the Office will use only the list designated by the Commission for the must-carry/retransmission consent election. For determinations of the local/distant status of a broadcast station, the Office is clarifying the circumstances under which a station may be reported as local for copyright purposes.

### *A. The ADI list*

The amended local service area definition expressly adopts Arbitron's ADI list in effect on September 18, 1993, plus any subsequent modifications made to that list pursuant to § 76.55(e) or § 76.59 of the FCC's rules. Section 76.55(e) provides that the ADI list in effect on September 18, 1993, is the list appearing in the 1991–1992 Television ADI Market Guide. 47 CFR 76.55(e)(Note). It is further provided that 1991–1992 Television ADI Market Guide list will remain in effect until the time of the 1996 must-carry/retransmission consent, when the 1994–1995 ADI list will be used. While it is presumed that the ADI list applicable for 1996 will account for the termination of publication of the Television ADI Market Guide, § 76.55(e) makes it clear that the Commission will only revise the ADI list at three-year intervals. Because of the Home Viewer Act's direct reference to 47 CFR 76.55(e), the Copyright Office believes that it is consistent with legislative intent to use only the ADI (or replacement) list used by the Commission for the must-carry/retransmission consent election. Thus, for the 1994/2 accounting period, and both accounting periods for 1995, the Copyright Office will use the 1991–1992 Television ADI Market Guide in determining the local/distant status of broadcast signals. Cable operators should use only this list for these accounting periods; in examining Statements of Account, the Copyright Office will not recognize the ADI of a broadcast station derived from any source other than the 1991–1992 Television ADI Market Guide. For the

[2] The Note further states that the 1994–1995 ADI list will be used for the 1996 election, the 1997–1998 list for the 1999 election, etc. Arbitron, however, discontinued the *Market Guide* after publication of the 1993–1994 edition. New criteria, presumably Nielsen's Designated Market Area, must be adopted before the 1996 must-carry/retransmission consent election, and the Commission has stated that it will address the issue before October 1, 1996. *See Opinion & Order in MM Docket No. 92–259* at 10 n. 45 (November 4, 1994).

1996, 1997 and 1998 accounting years, cable operators should use the list adopted by the Commission for the 1996 must-carry/retransmission consent election, and, for subsequent years, the list adopted by the Commission for each must-carry/retransmission consent election period. If the Commission should make modifications to television markets in accordance with §§ 76.55(e) and/or 76.59, or should generate a television market list for the must-carry/retransmission consent election other than at three-year intervals, those modifications should be applied to their corresponding compulsory license accounting periods in determining the local service area of a broadcast station.

*B. Local/Distant Status*

In the December 30, 1994, adjustment of our regulations to account for the statutory changes made by the Home Viewer Act, we described the Act's amendment to the local service area definition in 17 U.S.C. 111(f) as ''includ[ing] the area in which the station is entitled to insist upon carriage of its signal by a cable system (i.e. its must-carry zone), in accordance with the rules of the Federal Communications Commission in effect on September 18, 1993, and any subsequent modification of those rules.'' 59 FR 67635 (December 30, 1994). We believe we need to clarify this statement as it relates to cable systems that serve communities in more than one county assigned to different ADIs.

Cable carriage by one system across one or more ADIs does not appear to be an uncommon occurrence. Each county in the United States is allocated to a market based on which home-market stations receive a preponderance of total viewing. Because many larger cable systems typically serve several counties, a ''straddle'' situation can occur where a cable system carries a broadcast signal assigned to one market in communities within counties assigned to other markets. This situation is further complicated when such carriage is pursuant to the FCC's new must-carry rules. How should cable systems straddling different markets report carriage of broadcast signals in those markets for compulsory license purposes?

The Home Viewer Act amendment to the 17 U.S.C. 111(f) local service area definition makes it clear that a broadcast station's television market is its ADI. The Home Viewer Act defines ''television market'' by reference to § 76.55(e) of the FCC's rules, which provides that a broadcast station's television market is ''its Area of Dominant Influence (ADI) as determined by Arbitron and published in its *Television ADI Market Guide* * * *'' 47 CFR 76.55(e)(1). A broadcast station's ADI is also the area in which it is entitled to assert mandatory carriage rights on cable systems located in that ADI. *See Broadcast Signal Carriage Issues,* 8 FCC Rcd 2965, 2976–2977 (1993). Thus, the Office acknowledged in its December 30, 1994, Federal Register notice the correspondence between a broadcast station's must-carry area and its ADI; however, it did not describe what application, if any, this would have to cable systems straddling more than one ADI.

After reviewing the provisions of the Cable Television Consumer Protection and Competition Act of 1992 (''1992 Cable Act''), Public Law No. 102–385, and the FCC's implementing rules, it is apparent that there are circumstances, e.g., the ''straddle'' situation, where the must-carry zone of a broadcast station exceeds its ADI. The FCC stated in its *Report & Order* implementing the 1992 Cable Act's must-carry requirements that in circumstances where a cable system serves a community or communities in more than one county and those counties are assigned to different ADIs, ''all broadcast stations in both ADIs will be considered 'local' for must-carry purposes.'' 8 FCC Rcd at 2976.

We do not believe that the application of the must-carry rules adopted pursuant to the 1992 Cable Act have any direct bearing in determining the size of the local service area of a broadcast station for copyright purposes. The copyright local service area is a broadcast station's television market as defined in 47 CFR 76.55(e), which means that it is the station's ADI, plus any modifications made to the ADI by the Commission under § 76.55 or § 76.59 of its rules.[3] The Office should not have stated in the December 30, 1994, Federal Register notice that the local service area was equal to the station's must-carry zone, since such zone can, in certain circumstances, be considered to extend beyond a station's ADI. Thus, in the ''straddle'' situation, a cable system may only report carriage of a broadcast station as local under 17 U.S.C. 111 in those communities assigned to the station's ADI, even though the system may have must-carry obligations to deliver the signal to communities located in other ADIs.

We believe that this interpretation is consistent with Congress' intent in amending the local service area definition. The legislative history to the Home Viewer Act does not indicate any intention to equate the copyright local service area with the must-carry obligation, and to do so would do violence to 17 U.S.C. 111(d)(1)(B) by substantially reducing the occurrence of partially local/partially distant signals. Furthermore, Congress expressly recognized in the 1992 Cable Act that broadcast stations could be considered distant signals for copyright purposes in communities where they enjoyed must-carry rights. 1992 Cable Act, section 614(h)(1)(b)(ii). Nothing in the Home Viewer Act indicates an intention to change this result.

Dated: December 4, 1995.

Marybeth Peters,

*Register of Copyrights.*

Approved by:

James H. Billington,

*The Librarian of Congress.*

[FR Doc. 95–30458 Filed 12–15–95; 8:45 am]

**BILLING CODE 1410–31–P**

[3] We acknowledge that changes made to a station's ADI under 47 CFR 76.55(e) or 76.59 will undoubtably be for reasons related to the must-carry rules; however, it is only changes made to a station's ADI under these two rules that matter for copyright purposes.

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–36568; Filed No. SR–CBOE–95–62]**

## Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposed Rule Change Regarding Book-Entry Settlement of Securities Transactions and Depository Eligibility Requirements

December 8, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 19, 1995, the Chicago Board Options Exchange, Incorporated (''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by CBOE. On October 26, 1995, CBOE filed an amendment to the proposed rule change.[2] The Commission is publishing this notice to solicit comments on the

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] CBOE amended its proposal to correct a typographical error in the filing. Letter from Michael L. Meyer, Schiff, Hardin & Waite, to Mark Steffensen, Division of Market Regulation (''Division''), Commission (October 26, 1995).

proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to adopt new Rules 30.136 and 30.137 in order to conform its rules to those of other self-regulatory organizations regarding book-entry settlement of transactions in depository eligible securities and regarding the establishment of depository eligibility requirements for issuers that apply to list securities on CBOE.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[3]

The purpose of the proposed rule change is to encourage book-entry settlement of securities transactions by adding two new rules to Chapter XXX of the CBOE rules.[4] Both of the proposed new rules are substantially the same as rules previously adopted by six other national securities exchanges and the National Association of Securities Dealers (''NASD'') in response to recommendations of the Group of Thirty, U.S. Working Committee (''U.S. Working Committee''), Clearance and Settlement Project (''Project''), regarding book-entry settlement of securities transactions.[5] In connection with the Project, several years ago the U.S. Working Committee recommended that settlements and other movements of corporate and municipal securities for transactions among financial intermediaries (brokers, dealers, and banks) and between financial intermediaries and their institutional clients be effected only by book-entry movements within a depository. Thereafter, six national securities exchanges and the NASD adopted uniform rules in conformity with the U.S. Working Committee's recommendation.[6]

Because CBOE did not then provide a market in depository-eligible securities, it did not adopt the uniform rule. It now is proposing the adoption of Rule 30.136, which would implement such a book-entry settlement requirement for securities listed on CBOE. The addition of Rule 30.136 will conform the rules of CBOE to those of other U.S. self-regulatory organizations, which rules are designed to ensure that the vast majority of securities transactions effected in the U.S. markets will be settled by book-entry.

Subject to certain exceptions set forth in the text of the rule and described below, Rule 30.136 will require the use of the facilities of a registered securities depository for the book-entry settlement of all transactions in depository eligible securities between a member firm and a financial intermediary or a member of a national securities exchange or a registered securities association. The rule also will apply to transactions in depository eligible securities between member firms and their clients if settlement is to be effected on a delivery-versus-payment (''DVP'') or receipt-versus-payment (''RVP'') basis. As is the case under comparable rules adopted by other self-regulatory organizations, Rule 30.136 will not apply to or affect the manner in which member firms settle transactions with traditional retail customers,[7] the settlement of transactions in securities that are not depository eligible,[8] or transactions in which settlement occurs outside the U.S. Rule 30.136 also will not apply to transactions where the securities to be delivered in settlement of a transaction are not on deposit at a securities depository and (1) the transaction is for same-day settlement and the deliverer cannot by reasonable efforts deposit the securities prior to a depository's cut-off time for same-day crediting of deposited securities or (2) the deliverer cannot by reasonable efforts deposit the securities prior to a cut-off date time established for that issue of securities by the depository. The latter exception is intended to address corporate reorganizations and other extraordinary activities.

The second rule being proposed by CBOE, Rule 30.137, also reflects a response to a directive from the Group of Thirty to address the need to raise clearing and settlement standards. The rule is substantially identical to a uniform depository eligibility rule that was developed through the coordinated effort of six national securities exchanges and the NASD and that has been incorporated into the rules of those self-regulatory organizations.[9]

Rule 30.137 will require that before a domestic issuer's issue of securities is listed that the issuer represent to CBOE that the CUSIP number identifying the issue has been included in the file of eligible issues maintained by a registered securities depository. This requirement will not apply to a security if the terms of such security cannot be reasonably modified to meet the criteria for depository eligibility at all registered securities depositories. In addition, the rule will not apply to American Depository Receipts for securities of a foreign issuer.

Rule 30.137 also sets forth additional requirements that must be met before a security will be deemed to be ''depository eligible'' within the meaning of the rule. The rule specifies different requirements for depository

[3] The Commission has modified the text of the summaries provided by CBOE.

[4] The rules in Chapter XXX govern the listing and trading of debt and equity securities, warrants, UIT interests, and such other securities as may be determined by CBOE's Board of Directors. Chapter XXX does not apply to the trading of option contracts.

[5] The Group of Thirty is an independent, nonpartisan, nonprofit organization established in 1978. In its March 1989 report, the Group of Thirty made nine recommendations for harmonizing clearance and settlement practices worldwide. The U.S. Working Committee, comprised of representatives from brokerage firms, banks, other financial intermediaries, and major industry organizations was formed to study the existing U.S. clearance and settlement system and to recommend reforms consistent with the Group of Thirty recommendations. After reviewing the nine Group of Thirty recommendations, the U.S. Working Committee concluded that at that time the U.S. substantially complied with all but two of those recommendations, T+3 settlement and same-day funds settlement. In order to achieve T+3 settlement, the U.S. Working Committee recommended requiring book-entry settlement between financial intermediaries and between financial intermediaries and their institutional clients and depository eligibility for all new issuances. U.S. Working Committee, Implementing the Group of Thirty Recommendations in the United States (November 1990). The U.S. Working Committee's recommendations were supported strongly by the report of the Bachmann Task Force. Bachmann Task Force on Clearance and Settlement Reform in U.S. Securities Markets, Report Submitted to the Chairman of the Securities and Exchange Commission (May 1992).

[6] Securities Exchange Act Release No. 32455 (June 11, 1993), 58 FR 33679 (order approving proposed rule change of the American Stock Exchange (''Amex''), Boston Stock Exchange (''BSE''), Midwest Stock Exchange (now the Chicago Stock Exchange) (''CHX''), New York Stock Exchange (''NYSE''), Pacific Stock Exchange (''PSE''), Philadelphia Stock Exchange (''PHLX''), and NASD regarding the book-entry settlement of securities transactions).

[7] Because retail customers do not settle their trades on a DVP/RVP basis, the rule will not alter their current method of settlement.

[8] Under proposed Rule 30.136(d), depository eligible securities means securities that (i) are part of an issue (as identified by a single CUSIP number) of securities that is eligible for deposit at a securities depository and (ii) with respect to a particular transaction are eligible for book-entry transfer at the depository at the time of settlement of the transaction.

[9] Securities Exchange Act Release No. 35798 (June 1, 1995), 60 FR 30909 (order approving proposed rule change of Amex, BSE, CHX, NYSE, PSE, PHLX, and NASD regarding uniform depository eligibility rules).

eligibility depending upon whether a new issue is distributed by an underwriting syndicate before or after the date a securities depository system is available for monitoring repurchases of the distributed shares by syndicate members (*i.e.*, a ''flipping tracking system'').

Currently, a flipping tracking system is being developed that will include a securities depository service that (i) can be activated upon the request of the managing underwriter for a period of time that the managing underwriter specifies, (ii) in certain circumstances will require the delivering participant to provide to the depository information sufficient to identify the seller of such shares as a precondition to the processing of book-entry delivery instructions for distributed shares, and (iii) will report to the managing underwriter the identify of any other syndicate member or selling group member whose customer(s) sold distributed shares (but will not report to the managing underwriter the identity of such customer[s]) and in certain circumstances will report to such syndicate member or selling group member the identity of such customer(s). Prior to the availability of a flipping tracking system, the managing underwriter may delay the date a security is deemed ''depository eligible'' for up to three months after trading has commenced in the security. After the availability of a flipping tracking system, a new issue must be depository eligible before commencement of trading on CBOE.

The proposed rule change is consistent with Section 6(b)(5) of the Act in that by reducing the number of transactions in depository eligible securities for which settlement is effected by the delivery of physical securities, by requiring that transactions between member firms and transactions between member firms and clients that settle on a DVP or RVP basis generally occur in a book-entry environment, and by requiring securities listed in CBOE be depository eligible, the efficiency of the U.S. clearance and settlement system will be enhanced and the potential for systemic risk will be reduced. Furthermore, the proposal is designed to foster cooperation and coordination with persons engaged in regulatory, clearing, settling, and facilitating transactions in securities and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

*(B) Self-Regulatory Organization's Statement on Burden on Competition*

The CBOE does not believe that the proposed rule change will impose any burden on competition.

*(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others*

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which CBOE consents, the Commission will:

(a) By order approve such proposed rule change or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of CBOE. All submissions should refer to File No. SR–CBOE–95–62 and should be submitted by January 8, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

[10] 17 CFR 200.30–3(a)(12) (1994).

Margaret H. McFarland,

*Deputy Secretary.*

[FR Doc. 95–30661 Filed 12–15–95; 8:45 am]

**BILLING CODE 8010–01–M**

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**[Release No. 34–36573; File No. 600–27]**

## Self-Regulatory Organizations; Clearing Corporation for Options and Securities; Order Approving Application for Exemption From Registration as a Clearing Agency

December 12, 1995.

On December 14, 1992, the Clearing Corporation for Options and Securities (''CCOS'')[1] filed with the Securities and Exchange Commission (''Commission'') an application for exemption from registration as a clearing agency pursuant to Section 17A of the Securities Exchange Act of 1934 (''Act'')[2] and rule 17Ab2–1 thereunder.[3] Notice of CCOS's application was published in the Federal Register on June 23, 1993.[4] Fourteen comment letters were received in response to the notice of filing of the CCOS application.[5] On October 7, 1993, CCOS filed an amendment to its application[6] setting forth its intention to register Chicago Board Brokerage, Inc. (''CBB'') as a U.S. government securities broker pursuant to Section 15C of the Act[7] and to proceed with CBB's membership with the National Association of Securities Dealers (''NASD'') as required by that section.[8] Notice of the amendment was published in the Federal Register on April 22, 1994, to solicit comments.[9] One hundred eleven comment letters were received in response to the notice of filing of the amendment.[10] This Order grants CCOS's application for

[1] CCOS is a wholly-owned subsidiary of the Board of Trade Clearing Corporation (''BOTCC'') which provides clearing services for futures and commodities transactions executed on the Board of Trade of the City of Chicago (''CBOT'').

[2] 15 U.S.C. § 78q–1 (1988).

[3] 17 CFR 240.17Ab2–1 (1994).

[4] Securities Exchange Act Release No. 32481 (June 16, 1993), 58 FR 34105 [File No. 600–27] (notice of filing of application for exemption from registration as a clearing agency) (''CCOS Release'').

[5] A complete list of comment letters for File No. 600–27 is available for review in the Commission's Public Reference Room.

[6] Letter from Dennis Dutterer, Executive Vice President and General Counsel, BOTCC, to Jonathan Katz, Secretary, Commission (October 6, 1993). Letter from Fred Grede, Vice President, Board of Trade of the City of Chicago (''CBOT''), to Brandon Becker, Director, Division of Market Regulation (''Division''), Commission (October 6, 1993).

[7] 15 U.S.C. § 78o-5 (1988).

[8] 15 U.S.C. § 78o-5(e)(1) (1988).

[9] Securities Exchange Act Release No. 33911 (April 15, 1994) 59 FR 19263 [File No. 600–27] (notice of filing of amendment to application for exemption from registration as a clearing agency).

[10] *Supra* note 5.

exemption from registration as a clearing agency subject to certain limitations and conditions as set forth below.

I. Description

*A. Trade Clearance and Settlement*

1. Overview

CCOS will provide clearance and settlement facilities for trades executed by CBB and its customers in the CBB trading system.[11] As described in the amendment,[12] CBB's business will be limited to acting as an intermediary for U.S. government securities transactions paired through its computer system.[13]

The CBB trading system is designed to offer CBOT members an opportunity to execute a customized package of transactions related to Treasury futures contracts traded on the CBOT.[14] The system will permit the trading of government securities, independently and in conjunction with CBOT futures on government securities (''basis trades''),[15] and repurchase and reverse repurchase agreement contracts in government securities (''dollar rolls'').[16] Using the CBB trading system, therefore, CBOT traders in government securities will be able to buy and sell the government securities underlying CBOT futures contracts and using dollar rolls will be able to execute trades that help inventory management. CBB will execute transactions for system participants as broker. All trades will be effected through the CBB's electronic network. The settlement date for outright purchase and sale transactions will be the next business day except for when-issued (''WI'') securities which will settle on the day of issuance by the U.S. Treasury.

Under the terms of the proposal, any CCOS participant or any customer of a CCOS participant that is also a CBOT member or member firm (hereinafter collectively referred to as a CBOT member) will be able to obtain a CBB trading terminal.[17] Each CCOS participant will be required to enter into an agreement with CBB setting forth the terms and conditions of access to and use of CBB's terminals. Using a CBB terminal, a terminal operator will be able to view the terminal displays to see the prices and quantities of current bids and offers, which are displayed on an anonymous basis, and to review its trading activity.

CBB is developing several methods for market participants to access the CBB trading system. CBB will: (1) provide CBOT work station terminals which will access the CBB trading system and include other market information and trading systems available through the CBOT;[18] (2) provide an interface between CBB's central computer and a CBOT member's internal computer network; and (3) provide access through an interface with quotation vendors.[19]

The system will permit users to execute basis trades as a single transaction where the price will reflect the spread in basis points between the futures contract and the underlying government securities. The government securities will be priced at a certain number of basis points above or below the futures contract.[20]

The system also will provide users with the ability to execute dollar roll transactions. Dollar roll transactions are designed to facilitate the financing of government securities through the lending of government securities in exchange for cash and to facilitate the lending of funds in exchange for government securities.[21] Dollar rolls will result in the creation of two simultaneous government trades.

CBB will have a morning trading session for dollar rolls from the opening of trading at 8:00 a.m. to 11:00 a.m. and an afternoon session for dollar rolls from 3:15 p.m. to 5:00 p.m.[22] For dollar rolls executed during the morning session, the first leg will be for same day (''T'') settlement, and the second leg will be for next day (''T+1'') settlement. For dollar rolls executed during the afternoon session, the first leg will settle on T+1, and the second leg will settle on the following business day (''T+2'').

CBB will match member trades and will submit the matched trades to CCOS on a real time basis so that trade data executed through CBB immediately flows to CCOS.[23] CCOS will perform the

[11] CBB is a wholly-owned subsidiary of the CBOT and has requested no-action relief from the Commission staff with respect to the operation of the automated trading system for government securities. Letter from Mark D. Young, Kirkland and Ellis, Counsel for CBB, to Richard R. Lindsey, Division Director, Commission (December 11, 1995). The staff issued a no-action letter to CBB granting the relief requested and the Commission is issuing this order based on its belief that CBB is in compliance with the terms and conditions of the no-action letter. Letter from Richard R. Lindsey, Division Director, Commission, to Mark D. Young, Kirkland and Ellis, Counsel for CBB (December 12, 1995).

[12] *Supra* note 6.

[13] The government securities listed for purchase or sale through the CBB system will consist of U.S. Treasury bills, notes, and bonds in their various maturities which are deliverable under financial futures contracts traded on the CBOT.

[14] Only CBOT individual members, employees of individual members, and employees of CBOT member firms will be permitted to operate terminals. Each terminal will be uniquely identified in its communication with the central site, and each terminal operator will be assigned an identification number. CBB will maintain complete, time-sequenced electronic audit trails on all orders entered on, and all transactions executed through, the CBB trading system. The recorded activity will indicate, for a given order or transaction, the identity of the terminal operator entering, changing, or cancelling orders, the time such entry or change was effected, and the date, time, volume, security, and price of each transaction executed through the trading system.

[15] A basis trade is a trade in which the participants agree to simultaneously buy or sell government securities against the offsetting equivalent CBOT treasury futures contract. The basis represents the price differential between a government security and the futures delivery price.

[16] In a dollar roll transaction, the seller of the contract delivers notes or bonds to the buyer in exchange for cash. Settlement occurs the same day. At the time of execution, the seller and buyer also agree to reverse the transaction at a price that includes a financing interest amount with settlement occurring the next day.

[17] The Board of Directors of CCOS may permit other clearing agencies registered with the Commission or that are exempted from registration by the Commission access to some or all of the services offered by CCOS according to terms and conditions prescribed by the Board of Directors. Clearing agencies that are granted access to CCOS's services pursuant to CCOS Rule 309 will not be considered participants of CCOS under the rules except as determined by the Board of Directors. Letter from John C. Hiatt, President and Chief Executive Officer, BOTCC, to Jonathan Kallman, Associate Director, Commission (September 13, 1994).

[18] The CBB trading system is based on a modification of the CBOT's Project A trading system. Project A, available to CBOT members, is an electronic order entry facility developed to allow trading over a local area network (for example, within the CBOT building) of CBOT's futures contracts, options on futures contracts, and other financial products. The Project A system is designed to facilitate trading by active order matching or through the posting of bids/offers on an electronic bulletin board.

[19] Quotation vendors will offer CBB trading screens and order entry capability through their terminals which are served by national telecommunications networks. CBB will contract on a nonexclusive basis with one or more quotation vendors, each having interactive capabilities, to carry the CBB system for use by CBOT members.

[20] The futures leg of the basis trade will take the last reported trade price from the CBOT trading floor as the futures transaction price. The transaction ticket for the government securities leg of basis trades will include the commission charges and accrued interest. Settlement for the government securities leg will occur on the next business day in the same manner as outright government securities trades.

[21] The CBB terminals will list the dollar roll spreads through bid and offer financing rates reflecting the annualized interest rates paid or received on the transactions. The transaction amount or value price on the trade date will reflect the settlement value of the first leg of the dollar roll. The settlement value is the amount of funds required to make or take delivery of the security. The transaction amount for the second leg of the dollar roll will reflect the fact that the holder of the overnight bond will not earn the coupon interest during the term of the transaction.

[22] Unless otherwise noted, all times stated are Eastern Standard Time.

[23] CBB will create, operate, and maintain the computer system that enables orders to be entered and executed. CBB has developed trade matching

Continued

clearance and settlement functions for transactions executed through CBB, including: delivery versus payment processing, position consolidation, and original and variation margin calculation and processing as discussed below.

2. CCOS & BOTCC Cross-Margining Agreement

CCOS and BOTCC will establish a cross-margining arrangement whereby all CCOS members, all of which are BOTCC members or CBOT members affiliated with a BOTCC member, will hold certain futures and government securities cleared by the respective clearing organizations in special cross-margin accounts.[24] All futures positions will be held at BOTCC, and all government securities will be held at CCOS. Government securities and futures held in the cross-margin accounts at the respective clearing organization will be margined as if held in a single account based upon the net risk of the positions. To facilitate the cross-margining arrangement, CCOS and BOTCC will establish procedures whereby CCOS and BOTCC each will have a security interest in the positions held in the cross-margin accounts to secure all obligations of the clearing members arising in connection with those positions.

*B. System Safeguards*

1. Margin Payment/Collection

CCOS will adopt, as one of its principal safeguards, a practice of collecting original margin and variation margin on participant obligations.[25] In essence, CCOS will use the margin calculation and payment time frames currently used by BOTCC in connection with its clearance of CBOT futures contracts.[26] CCOS will modify BOTCC's margining system to address risks specific to the U.S. government securities market.

CCOS will calculate margin requirements at least twice daily, with one calculation reflecting trading activity occurring from the 8:00 a.m. opening to 1:30 p.m. and with another calculation reflecting trading activity from 1:30 p.m. to 5:00 p.m. CCOS will collect margin deficiencies arising from participants' morning trading activity at 4:00 p.m. on that trade date (''T'') and will collect margin deficiencies arising from participants' afternoon trading activities at 7:40 a.m. on T+1. In the event a clearing member fails to perform its obligations to CCOS, the original margin will be used to cover any financial liabilities which may result from the failed obligation. CCOS will retain the authority to collect additional margin at any time.[27]

In order to margin government securities and futures positions in a parallel fashion, CCOS will convert government securities to futures contract equivalents prior to original margin determination.[28] CCOS will convert government securities positions to futures-equivalents based upon conversion factors established and published by the CBOT for the most similar futures delivery month and the most similar futures contract par amounts (*i.e.*, face values).[29] CCOS will net the futures-equivalent positions of all government securities deliverable with the corresponding futures contracts to produce a net futures-equivalent position.[30] The performance bond for all trades generally will be collected at 7:40 a.m. on T+1.

CCOS will calculate each participant's variation margin pay/collect amount and transmit the data to BOTCC for margin payment or collection. Payment or collection amounts for each participant will include the combined variation effects of the government securities and futures positions in the participant's cross-margined account. Participants will pay or collect midday variation margin in same-day funds by 4:00 p.m. each day, through their settlement banks. BOTCC will pay out 80% of variation gains in excess of original margin deficits[31] and will collect 100% of variation losses.

2. Settlement Values

At 3:00 p.m., CCOS will establish a settlement value for government securities trades executed between 8:00 a.m. and 1:30 p.m. That value will be based on the prices collected at 2:30 p.m. from GovPx, a government securities pricing vendor. CCOS will mark new positions from their transaction value,[32] which will be

software for U.S. Treasury bills, notes, and bonds, including when-issued securities, basis trades, and dollar rolls.

[24] Because all CCOS members are also BOTCC members or CBOT members affiliated with a BOTCC member, all accounts at CCOS are cross-margin accounts.

[25] Original margin represents a performance bond that both buyers and sellers must post when executing trades to assure that their respective contractual obligations will be satisfied. Variation margin is a mark to the market payment collected on a twice daily basis to account for changes in the value of the positions before the delivery process.

[26] BOTCC collects clearing member margin on a portfolio, or net basis, reflecting the overall risk to the clearing corporation associated with the totality of contracts in that clearing member's portfolio. BOTCC uses a portfolio-based simulation model, the Standard Portfolio Analysis (''SPAN'') system, which establishes parameters to collect original margins based on the simulated losses of clearing member portfolios under various scenarios.

[27] BOTCC, as facilities manager, will perform all margin collection/payment functions on behalf of CCOS. CCOS will collect commissions and settlement payments through its agent, the Bank of New York.

[28] In establishing the original margin for government securities it clears, CCOS began with the premise that cross-margined government securities and futures products have essentially the same market and credit risks. Therefore, CCOS will use the original margin rates for futures contracts established by the Board of Governors of BOTCC following recommendations of the BOTCC Risk Management Committee.

The BOTCC Risk Management Committee is comprised of five of the nine Governors of the BOTCC Board of Governors. All nine Governors are owners or officers of BOTCC clearing member firms. The BOTCC Risk Management Committee meets once a month or at the call of the BOTCC Board Chairman or the Risk Management Committee Chairman. The Committee bases its recommendation upon review by BOTCC and CBOT staff of the conditions of the market place, including: statistical analysis of central tendencies, dispersion, and correlations between price changes of different commodities. Additionally, the Committee draws upon the experiences of its members and uses their judgement to predict market conditions in the near future. From this information, the Risk Management Committee will typically set margin rates that cover approximately the 99th percentile of absolute daily price changes over the previous one, three, and six month periods.

[29] The formula for the conversion of government securities is:

Futures-Equivalents=*Government Securities Par Amounts*×*Conversion Factor*÷Futures Par Amount

Since bonds being delivered into futures contract obligations will have greater or lesser value than the futures, the conversion factor is a means of equating bonds with various coupons and maturity dates with the standard bond set by BOTCC. The standard bond, which is equal to the corresponding future, has an 8% coupon and a conversion factor of 1.

For example, assume there are two bonds, Bond X and Bond Y. Bond X is the standard bond having an 8% yield to maturity and conversion factor of 1 (Bond X is equal to the corresponding future). Bond Y is worth 1.5 times Bond X (Bond Y could have greater coupon rates or a longer period to maturity). If the future is trading at 85, then Bond X is worth 85, and Bond Y is worth 1.5 times 85. Therefore, 1.5 is the conversion factor for Bond Y. In order to determine the number of futures that equate with Bond Y, the face amount of Bond Y is multiplied by the conversion factor, producing the futures value amount. The futures value amount is then divided by 100,000 (each futures contract equals $100,000) to give the number of futures contracts equal to the bond.

[30] Futures on government securities act as an index of the many bonds deliverable into them. Treasury bonds (''T-bonds'') having at least fifteen years remaining to maturity are deliverable into the T-bond future. Ten-year Treasury notes (''T-notes'') must have maturities between six and one-half and ten years to be deliverable into the ten-year T-note future. Five-year T-note futures accept Treasury notes with time to maturity between four years, three months and five years, three months. Two-year notes having maturities between one year, nine months and two years are deliverable into the two-year T-note future.

[31] CCOS will withhold distribution of any variation margin gains from participants with original margin requirement deficits.

[32] The transaction value provided by CBB to CCOS will include the accrued interest paid or received on each transaction. For normal deliveries the accrued interest at the time of the transaction and at marking to market are the same amount, but

established at the execution of the trade, to their settlement value,[33] which will reflect gains or losses in the interim period, and CCOS will mark open positions that were previously marked to the prior day's settlement value to the new settlement value.

Trades executed from 1:30 p.m. through the 5:00 p.m. end of the day's trading session will be marked to the 3:00 p.m. settlement value, and the variation margin on the entire position will be calculated at the end of the day. Participants will pay or collect the second variation margin obligation the following morning at 7:40 a.m. CCOS will send delivery instructions for normal settlement of government securities transactions executed on T to the participants' settlement banks at 11:30 a.m. on T+1.[34]

3. Loss Allocation and Liquidity Sources

CCOS will begin operations with an initial capitalization of $2 million. Together with CCOS's earnings, BOTCC will commit to provide CCOS with additional capital as necessary to cover CCOS's continuing costs of operations. Because CCOS will rely on BOTCC for certain liquidity resources and because BOTCC's capital and credit lines are committed to its futures business, BOTCC has agreed to dedicate specific credit and financial resources to CCOS, and CCOS and BOTCC have established a framework for allocating losses arising from cross-margined accounts between the two entities.

With respect to liquidity, CCOS will establish a committed credit facility which will be guaranteed by BOTCC. The credit facility initially will be $5 million and will be increased in increments of $5 million for each $1 billion increase in CCOS's daily average net settlements of government securities transactions over a ninety day period. When the credit facility reaches $30 million as a result of daily average net settlements of government securities reaching $6 billion, CCOS will review the size of the credit facility in consultation with the Division staff.[35]

With respect to loss allocation, under the cross-margining arrangement between CCOS and BOTCC, all government securities positions cleared by CCOS will be maintained in a cross-margin account for which BOTCC and CCOS have agreed to assume joint responsibility in the event that a default or failure to settle occurs and there is a shortfall in that account. BOTCC and CCOS each are guaranteeing up to 50% of the obligations owed to each other with respect to a defaulting participant's cross-margin account after use of the original margin deposits of the participant and proceeds from the liquidation of the participant's positions. Therefore, CCOS will have adequate resources to protect itself and to fulfill its settlement obligations for a loss up to at least $60 million.[36]

II. Comment Letters

Public comment both supported and opposed CCOS's application.[37] More than sixty commenters, including several common members of the Government Securities Clearing Corporation (''GSCC'') and CCOS, supported the proposal. More than forty commenters opposed the proposal, raising three basic arguments as to why the Commission should deny the exemption request.[38] These arguments include the potential fragmentation of clearance and settlement facilities for the U.S. Treasury market the concern that exempting CCOS will mean ineffective and unequal regulation of clearing facilities for those securities, and the concern that approval of CCOS will not promote fair competition among clearing agencies. CCOS filed several responses to the comments.[39]

The Commission received two letters from the Commodity Futures Trading Commission (''CFTC'') regarding CCOS's application.[40] BOTCC, as a futures clearing organization, is subject to regulation by the CFTC under the Commodity Exchange Act (''CEA''); therefore, the Commission carefully considered the comments of the CFTC regarding CCOS's application. In its first letter to the Commission,[41] the CFTC noted that because of its position as the regulator of BOTCC, it would have to consider and address the potential impact of CCOS's activity on the financial integrity of BOTCC and on the futures market for which it clears. Specifically, the CFTC was concerned with BOTCC's role as a guarantor of CCOS's obligations and the impact on BOTCC's financial integrity of any minimum capitalization or other requirements imposed on CCOS by the Commission.[42] The CFTC also stated that any arrangements presenting cross-jurisdictional issues between the CFTC and the Commission would require approval by both agencies. This would include cross-margining programs, the imposition of clearing limits and/or minimum margin requirements, and futures/cash basis trades traded on the CBB and cleared through BOTCC and CCOS. The CFTC urged a cooperative effort between itself and the Commission to avoid duplicative or inconsistent regulation being imposed on the affected entities.

The CFTC's second letter[43] responded to CCOS's amended application in which CBOT set forth its intention to register CBB as a government securities broker and its willingness to enter into certain linkage arrangements with GSCC. The CFTC noted that the proposal to enter into a linkage

for failed deliveries, the seller will have to pay the incremental accrued interest for each day the fail continues. The daily variation margin payments will include this incremental accrued interest.

[33] Settlement values will reflect the settlement price established twice a day and will include accrued interest but will not include commissions and finance charges from dollar rolls.

[34] Participants may transact dollar rolls (with same-day settlement for the first leg) between 8:00 a.m. and 11:00 a.m. on T+1 to offset delivery obligations due to settle on T+1.

[35] As discussed below, $6 billion is the maximum average daily net settlements of transactions in government securities agreed to by CCOS and the Division during the exemptive period. Also as agreed to by CCOS and the Division, CCOS's operations will be limited to a maximum of $24 billion average daily net settlements of dollar rolls.

These limits represent approximately five percent or less of government securities and average daily volumes in dollar rolls. The Commission believes these limits are appropriate at this time in that they are large enough to allow CCOS to commence effective operations yet of a limited nature that allows the Commission to observe the effects of the CCOS clearing and settlement activities on the government securities market.

[36] *I.e.*, $30 million from CCOS's guaranteed credit facilities (repayment of which is guaranteed by BOTCC) plus $30 million from BOTCC under its guarantee of cross-margining losses.

[37] *Supra* note 5.

[38] Commenters raised additional issues in opposition to CCOS's application. These issues included the concern that the introduction of CCOS as another government securities clearing agency would result in an increase in costs for U.S. Treasury brokers and the concern that in the future decisions at GSCC will be made based on the fear of losing potential customers to CCOS rather than based on the best interest of the participants. With regard to the first point, the Commission believes that if in fact any increase in costs results from granting CCOS's exemption application, the benefits to the government securities market, such as innovation arising from competition, will outweigh any such costs. With regard to the second point, while the Commission believes that GSCC will continue in the future to base its decisions on what is in the best interest of its participants and the government securities market and not on any fear of losing current or potential participants, commenters should be comforted by the fact that GSCC is subject to Section 19(b) of the Act which requires SROs to file with the Commission any proposed changes to their procedures, operations, or rules.

[39] The comment letters and CCOS's responses are discussed in detail in the Discussion section of this order.

[40] Letters from Jean A. Webb, Secretary, CFTC, to Jonathan G. Katz, Secretary, Commission (July 23, 1993 and May 31, 1994).

[41] Letter from Jean A. Webb (July 23, 1993), *supra* note 40.

[42] Ultimately, this concern was alleviated by changing the general BOTCC guarantee to a guarantee of a limited committed credit facility. Refer to ''BOTCC Guarantee'' above.

[43] Letter from Jean A. Webb (May 31, 1994), *supra* note 40.

arrangement with GSCC could have positive effects on the government securities market, that the CBB/CCOS amended proposal could increase competition among market participants, that the CBB electronic trading system would provide government securities market participants with easier access to market information, and that the registration of CCOS as a clearing agency might lower the level of risk present in the government securities market. While the CFTC's comments were generally positive, it also reiterated its regulatory interests and the need to review the potential impact of the various arrangements on BOTCC's financial integrity and to assure compliance with the CEA.

The Commission recognizes the validity of the CFTC's concerns and understands the importance of coordinating efforts among all regulators concerned with the government securities market. The Commission will continue to coordinate with these regulatory agencies to safeguard one of the world's largest securities markets.

III. Discussion

*A. Overview*

The Commission is granting CCOS's application for exemption subject to the conditions described below. The Commission believes such action is consistent with the Act including the goals of fostering cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, removing impediments to and perfecting the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, and protecting investors and the public interest.

As noted above, CCOS proposes to provide clearing facilities in support of CBB's and CBOT's proposals. CBB's proposed automated trading system for government securities represents an effort to make government securities more readily available to CBOT members that trade futures on government securities and thereby improves the efficiency of arbitrage between the futures and cash markets and potentially increases liquidity in both of those markets. Traders in these markets often are called upon to accept position or market risks from participants in the market for government securities. The market for U.S. Treasury bonds, bills, and notes is the deepest, most liquid market in the world. While these securities are traded all over the world, the primary U.S. marketplace involves a core group of dealers, brokers' brokers, banks, and institutional investors that trade extensively among themselves over-the-counter. These market participants often rely on futures markets, such as the CBOT, for their derivative products as a way to transfer to traders on these markets position and market risks related to U.S. government securities. Traders on the futures exchanges, in turn, must be able to buy and sell government securities to help manage their own risk and position exposures efficiently.

Approval of the CCOS application will allow CCOS and its parent, BOTCC, to provide the clearance and settlement services that are necessary to support the CBB and CBOT proposals. This in turn should help foster greater integration of clearing facilities that serve the futures market and the underlying cash markets and should facilitate the development of cross-margin facilities between those markets. BOTCC already has extensive arrangements with its clearing bank network to receive and deliver government securities among its clearing members, and its clearing members maintain government securities at those banks for their proprietary and customer accounts. As described above, CCOS plans to build on those arrangements in providing its services in support of CBB. Exempting CCOS from clearing agency registration should allow CBB to move forward with its proposal and should allow CCOS and BOTCC to obtain greater experience in managing risk exposures before taking on self-regulatory responsibilities that would otherwise accompany clearing agency registration.

Because many of CCOS's likely users are GSCC members and use GSCC's services to clear and settle trades among themselves, a linkage among CCOS, BOTCC, and GSCC to facilitate efficient clearance of trades is essential.[44] To this end, the Boards of Directors of GSCC, BOTCC, and CCOS have been requested to establish a joint user committee to settle the outstanding linkage and cross-margining issues and to report to the GSCC, BOTCC, and CCOS Boards the committee's proposal for linkage and cross-margining within three months of formation of the committee.[45]

The Commission will monitor closely efforts in this regard and expects prompt action to implement linkages and cross-margin systems that are acceptable to the common membership so that appropriate linkages are in place when warranted. If it does not appear after six months that the parties are able to agree to establish appropriate linkage and cross-margining facilities, the Commission will consider whether to mandate the development of linkage and cross-margining facilities. If necessary, the Commission will use its authority under the Act to direct that the responsible parties act in their best interests to establish ''linked or coordinated facilities for clearance and settlement of transactions in securities * * * [and] contracts of sale for future delivery * * *.''[46]

Approval of the application also should help foster innovation in clearance and settlement of government securities. The CCOS proposal will provide central clearing facilities for dollar rolls, which represent a type of repurchase agreement transaction. CCOS's proposal was one of the first formal responses to the recommendations of the 1992 Joint Report on the Government Securities Market,[47] and the Commission believes that the CCOS proposal may well have encouraged others, including GSCC, to develop similar or wider services.

*B. Section 17A of the Act*

1. Grant of Exemption

Section 17A(b)(1) of the Act authorizes the Commission to exempt applicants from some or all of the clearing agency requirements of Section 17A if the Commission finds such exemptions are consistent with the public interest, the protection of investors, and the purposes of Section 17A including the prompt and accurate clearance and settlement of securities transactions and the safeguarding of securities and funds.[48] While the

[44] *Market Reform Act of 1990*, S. Rep. 101–300 at 58–62. President's Working Group on Financial Markets, Interim Report, Appendix D (May 1988).

[45] Letter from Richard R. Lindsey, Division Director, Commission, to John G. Macfarlane III, Chairman of the Board, GSCC, and David Johnson, Chairman of the Board, BOTCC (December 12, 1995). The Commission believes it is appropriate for CCOS to begin limited operations prior to the implementation of such arrangements because these arrangements, while important to coordinating GSCC's and CCOS's systems, are not necessary for CCOS to commence operations.

[46] 15 U.S.C. §§ 78q–1 (a)(2)(A)(ii) and (d)(1) (1988).

[47] *Joint Report on the Government Securities Market*, issued by the Department of Treasury, the Securities and Exchange Commission and the Board of Governors of the Federal Reserve System (January 1992) at 31 (recommending that an efficient processing system for government securities repo activity be developed).

[48] For legislative history concerning Section 17A of the Act, *see, e.g.*, Report of Senate Comm. on Housing and Urban Affairs, Securities Acts Amendments of 1975: Report to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess., 4 (1975); Conference Comm. Report to Accompany S. 249, Joint Explanatory Statement of Comm. of Conference, H.R. Rep. No. 229, 94th Cong., 1st Sess., 102 (1975).

Commission has never exercised its authority to exempt an applicant entirely from the requirements of Section 17A, it has granted newly registered clearing agencies narrowly drawn, temporary exemptions from specific statutory requirements imposed by Section 17A in a manner that achieves those statutory goals.[49]

The market break in October 1987 and the markets' decline in October 1989 demonstrated the central role of clearing agencies in U.S. securities markets in reducing risk, improving efficiency, and fostering investor confidence in the markets.[50] In light of the foregoing, the Commission believes it is appropriate for applicants requesting exemption from clearing agency registration to meet standards substantially similar to those required of registrants in order to assure that the fundamental goals of Section 17A (*i.e.*, safe and sound clearance and settlement) will be achieved.

Because the Commission believes that CBB and CCOS will promote innovation in the trading and clearing of government securities and will further the integration of the futures and government securities markets, it is approving CCOS's application for exemption in order that CCOS may begin limited operations without meeting the entire panoply of clearing agency registration requirements.[51] Although, as described below, CCOS is being held to substantially the same standards as other registered clearing agencies, certain areas of CCOS's operation require further development before CCOS can be considered for registration under Section 17A of the Act. The Commission believes that granting CCOS an exemption from registration subject to the regulatory requirements and Commission oversight on CCOS during the exemptive period should allow CCOS to further develop its system for clearing and settling government securities in a safe and sound manner before its seeks full registration as a clearing agency. In granting CCOS an exemption from clearing agency registration, the Commission believes that such an exemption is consistent with the requirements of Section 17A and that the framework of the exemption is such that the Commission retains adequate regulatory power and oversight to ensure that CCOS's services do not pose a threat to the stability of the government securities markets.

The Commission is imposing significant limits on CCOS as set forth below.[52] Should CCOS determine that a change in its operations or procedures is necessary, CCOS will be required pursuant to this exemptive order to amend its CA–1 and request that the Commission modify the exemptive order. The Commission's oversight of CCOS, in conjunction with the CFTC's oversight responsibilities of BOTCC, should help nurture the establishment of safety mechanisms, such as cross-margining, that further the goals of competition and integration in the government securities and futures markets. Furthermore, as competition leads to innovation and progress, the Commission believes CCOS's entry into the clearance and settlement of government securities should be a positive step towards the continued development of the world's largest government securities market.

2. Registration Standards

Before granting registration to a clearing agency, Section 17A of the Act requires that the Commission make a number of determinations with respect to the clearing agency's organization, capacity, and rules. Paragraphs (A) through (F) of Section 17A(b)(3) set forth general criteria which a clearing agency must satisfy in order to be registered. Congress reserved to the Commission the task of making specific determinations as to whether an applicant's organization, capacity, and rules satisfy the general criteria. In Securities Exchange Act Release No. 16900, the Division set forth its views and positions concerning satisfaction of the general criteria (''Standards Release'').[53]

These statutory standards are designed to assure the safety and soundness of the clearance and settlement system. As previously stated, the Commission, in granting CCOS's exemption is requiring CCOS to meet in substantial form these same statutory standards and is satisfied that CCOS's operation will not be a threat to the safety or soundness of the national market system. Furthermore, the Commission will continue to monitor CCOS's operations to assure its soundness in the clearance and settlement of government securities.

a. Safeguarding of Securities and Funds

Sections 17A(b)(3) (A) and (F) of the Act require a clearing agency be organized and its rules designed to facilitate the prompt and accurate clearance and settlement of securities transactions for which it is responsible and to safeguard securities and funds in its custody or control or for which it is responsible.[54] The Commission believes that CCOS meets these standards. Among other things, CCOS will maintain appropriate audit and internal controls[55] and will make available

[49] *E.g.*, in the Commission's order approving GSCC's temporary registration as a clearing agency, the Commission temporarily exempted GSCC from compliance with the statutory standards of Sections 17A(b)(3)(B) and 17A(b)(4)(B) of the Act regarding a clearing agency's rules designating classes of participants and the standards used by the clearing agency to determine participation. The Commission also exempted GSCC from Section 17A(b)(3)(C) regarding fair representation of clearing agency participants in the selection of its directors. Securities Exchange Act Release No. 25740 (May 24, 1988), 53 FR 19839.

[50] Gerald Corrigan, President of the Federal Reserve Bank of New York (''FRBNY''), noted: ''[T]he greatest threat to the stability of the financial system as a whole [during the 1987 market break] was the danger of a major default in one of these clearing and settlement systems.'' Luncheon Address: Perspectives on Payment System Risk Reduction by E. Gerald Corrigan, President, FRBNY, *reprinted in The U.S. Payment System: Efficiency, Risk and the Role of the Federal Reserve* 129–30 (1990).

[51] Section 17A, as amended by the Market Reform Act, directs the Commission to use its authority to facilitate the establishment of linked or coordinated facilities for clearance and settlement of transactions in securities, securities options, contracts of sale for future delivery and options thereon, and commodity options. [Market Reform Act of 1990, § 5, amending § 17A(a)(2) of the Securities Exchange Act of 1934, 15 U.S.C. 78q–1 (1990)].

[52] The limits are described in Section III., Part D., Conditions.

[53] Securities Exchange Act Release Nos. 16900 (June 17, 1980), 45 FR 41920 (announcement of standards for the registration of clearing agencies) and 20221 (September 23, 1983), 48 FR 45167 (omnibus order granting full registration as clearing agencies to The Depository Trust Company, Stock Clearing Corporation of Philadelphia, Midwest Securities Trust Company, The Options Clearing Corporation, Midwest Clearing Corporation, Pacific Securities Depository, National Securities Clearing Corporation, and Philadelphia Depository Trust Company).

Refer also to Section 19 of the Act, 15 U.S.C. 78s (1988), and Rule 19b–4, 17 CFR 240.19b–4 (1992), setting forth certain procedural requirements for registration and continuing Commission oversight of clearing agencies and other self-regulatory organizations.

[54] 15 U.S.C. 78q–1(b)(3) (A) and (F) (1988).

In addition to BOTCC's responsibilities as facilities manager, CCOS must assure itself that BOTCC complies with all of the safeguards, as appropriate, set forth in the section of the Standards Release regarding the safeguarding of securities and funds and prompt and accurate clearance and settlement of securities transactions; and that these operations will be subject to examination by CCOS's independent public accountant, the Commission and the appropriate regulatory agency to the same extent as in the case of a clearing agency which carries out its own processing. Standards Release, supra note 53.

[55] Clearing agencies should have an audit committee which selects or makes recommendations to the Board of Directors of the clearing agency regarding the selection of the clearing agency's public accountant. CCOS Rule 213 requires the establishment of an audit committee consisting of at least three nonmanagement directors of CCOS. The committee will, among other things, make recommendations to the Board of Directors regarding the selection of CCOS's independent public accountants.

Continued

reports to participants concerning its internal accounting controls.[56] In addition, CCOS has developed several procedures to safeguard securities and funds; prevent loss or destruction of securities, funds, or data; and to recover from losses that do occur.[57]

i. Organization and Processing Capacity

A clearing agency should be organized in a manner that effectively establishes operational and audit controls while fostering director independence.[58] As in the example set forth in the Standards Release, CCOS meets these standards by keeping its Board of Directors informed of its operations and the impact that new or expanded services or volume increases would have on its processing capacity. CCOS also will keep its Board of Directors informed by reporting on periodic risk assessments of CCOS's operations, automated data processing systems, and facilities and by supervising the establishment, maintenance and updating of safeguards.[59] The Commission is satisfied that CCOS's organizational and processing capacity meets the requirements of the Act, explained in the Standards Release, by providing a necessary flow of information to its Board of Directors which will allow it to oversee management's performance and to assure the operational capability and integrity of CCOS.

ii. Financial Reports

Participants that have made clearing fund contributions or have money or securities in a clearing agency's system should receive timely, audited annual financial statements. CCOS meets the requirements regarding financial reports, and the distribution of financial statements will enable CCOS's Board of Directors and participants to remain apprised of the clearing agency's financial condition and the adequacy and accuracy of its records.[60] By making the financial statements available, CCOS is assisting the Commission and other appropriate regulatory agencies in the discharge of their regulatory responsibilities by facilitating access to important information that is necessary in evaluating the safety and soundness of clearing agencies.

b. Fair Representation

Section 17A(b)(3)(C) of the Act requires that the rules of a clearing agency provide for fair representation of the clearing agency's shareholders or members and participants in the selection of the clearing agency's directors and administration of the clearing agency's affairs. This section contemplates that users of a clearing agency have a significant voice in the direction of the affairs of the clearing agency.

CCOS is a privately owned for profit corporation run for the benefit of its sole shareholder, BOTCC. Therefore, the Board of Directors of CCOS will be selected from members of the Board of Governors of BOTCC, and the officers of CCOS will be elected by the Board of Directors. While CCOS participants will have the opportunity to provide input to the CCOS Board through the CCOS Participant's Advisory Committee, this committee is only advisory in nature and its advice or recommendations is not binding on CCOS.[61]

The Commission believes that neither the method in which CCOS's directors are selected nor the method for participant input meets the requirements of fair representation under Section 17A(b)(3)(C) of the Act but that the request for an exemption is appropriate in this context, as it was in the context of Delta Government Options Corp. CCOS expects that if its clearing volumes grow, it will file with the Commission for full registration as a clearing agency. At that time, the Commission will reevaluate whether CCOS's methods for assuring participants representation in the selection of its Board of Directors and in the administration of its affairs is consistent with the Act. If in its reevaluation the Commission believes that because of changed circumstances an exemption that does not comport with the fair representation requirement is no longer justified, the Commission will modify the conditions or terminate CCOS's clearing agency exemption.[62]

c. Financial Risk Management

Commenters expressed concern about the financial resources available to CCOS in the event of liquidity problems. Because CCOS will rely on BOTCC for certain liquidity resources and because BOTCC's capital and credit lines are committed to its futures business, commenters expressed concern that a shortfall could occur if a member common to BOTCC and CCOS were to fail. In response, BOTCC has agreed to dedicate specific credit and financial resources to CCOS, and CCOS and BOTCC have established a framework for allocating losses between the two entities. As a condition to its exemption, CCOS has agreed to evaluate

CCOS proposes to employ outside independent auditors rather than establish an internal audit department for CCOS. The outside independent auditors will perform those duties typically performed by an internal audit department and will report to the audit committee, and conduct audit reviews as requested by the audit committee, but not less than once per fiscal year. The Commission believes that CCOS's method of establishing an audit committee and its use of outside independent auditors meets the requirements of the Act. Although the Standards Release recommends the use of an internal audit department, the Commission has on previous occasions found the use of outside auditors acceptable and falling within the requirements of the Act. *See* Securities Exchange Act Release No. 27611 (January 12, 1990), 55 FR 1890 (order granting Delta Government Options Corp. temporary registration as a clearing agency).

[56] The Standards Release noted that the objectives of internal accounting control are presumed to be a fundamental aspect of management's responsibilities. CCOS proposes to direct its independent public accountants to prepare an annual report on CCOS's system of internal accounting controls, and present the report to the CCOS Board of Directors. CCOS's proposal to use independent public accountants to produce an annual report on its system of internal accounting controls meets the requirements of the Act with regard to the security and accuracy requirements under Section 17A(b)(3) (A) and (F) because it aids in assessing the safety and integrity of the clearing agency operations and promotes confidence and increased participation in the national clearance and settlement system.

[57] CCOS proposes three levels of safeguards to prevent or minimize interruption of service as a result of hardware, systems software, or applications software failures. The first level addresses procedural practices within CCOS to control migration of changes in application systems to the production environment and the implementation of new systems. The second and third levels address interruptions in service due to equipment and systems software failures at different levels of severity, *i.e.* short and long term interruptions.

[58] *Standards Release, supra* note 53.

[59] For a detailed description of the Commission's policy on self-regulatory organization systems reviews, refer to Securities Exchange Act Release No. 29185 (May 9, 1991), 56 FR 22490 [File No. S7–12–91] (release setting forth the Commission's second automation review policy statement [''ARP II'']).

[60] CCOS Rule 214 states that within 60 days after the end of each of the Corporation's fiscal years, CCOS shall deliver to each participant unconsolidated audited financial statements for the fiscal year then ended covered by a report prepared by CCOS's independent public accountants. CCOS Rule 214 also states that upon request by any participant, CCOS shall deliver unconsolidated, unaudited quarterly financial statements.

[61] As provided in CCOS Rule 501, the Participant's Advisory Committee will be comprised of three to ten participants who may advise CCOS on matters pertaining to the operation of CCOS. The purpose of the Participant's Advisory Committee is to provide representation to participants on matters which are of concern to them. In addition, participants will have prior notice of changes to rules that may affect their rights, obligations, or clearing requirements. CCOS will accept comments from participants with respect to any such changes; however, the Participant's Advisory Committee serves only in an advisory capacity and any advice or recommendation of the Committee is not binding on CCOS.

[62] Because CCOS is being granted full exemption from registration as a clearing agency, a specific exemption is not being issued with regard to fair representation. Rather, the exemption from these requirements is included within the grant of a complete exemption from registration as a clearing agency.

its capital and liquidity resources periodically, and BOTCC has agreed to supplement, in consultation with the Commission and the CFTC, CCOS's liquid resources as necessary to meet prudential standards.

In addition to its financial resources, CCOS has facilities to identify its potential financial exposure from its participants and to collect margin deposits or other collateral adequate to address that exposure. As discussed above, CCOS in conjunction with BOTCC will calculate margin requirements and collect margin deposits from its participants for open positions. CCOS will obtain information from its participants regarding their financial condition and will have the authority to collect additional margin or collateral if it deems it appropriate. CCOS and BOTCC also will cooperate in sharing risk management information, to the extent possible, with securities and futures clearing organizations where CCOS and BOTCC members also are members.

The Commission believes that entering into additional information sharing agreements is an area in which CCOS should explore in order to help ensure the safety and soundness of the clearance and settlement system and to promote financial risk management. The Commission recommends that CCOS become a part of the information sharing system established between all of the commodities clearing houses.[63] In addition, the Commission encourages CCOS to pursue obtaining membership in the Securities Clearing Group (''SCG'').[64] The Commission believes that CCOS's membership in both of these information sharing systems should permit CCOS and other clearing organizations to be more aware of common member risks and to implement effective crisis management procedures if needed.

The Commission believes that CCOS's rules and procedures are adequately designed to protect CCOS and its participants against financial losses associated with its services. CCOS's financial risk management initiatives, including its initial capitalization, its twice daily margin collection,[65] and its committed credit facility, are aimed at preventing financial loss by participants and CCOS.[66] As a result, the Commission believes that CCOS's rules and procedures and the methods by which CCOS proposes to safeguard the financial security of its clearing facilities adequately satisfies the requirements of the Act.

d. Participation standards

Section 17A(b)(3)(B) of the Act enumerates certain categories of persons that a clearing agency's rules must authorize as potentially eligible for access to clearing agency membership and services. Section 17A(b)(4)(B) of the Act contemplates that a registered clearing agency have financial responsibility, operational capability, experience, and competency standards that are used to accept, deny, or condition participation of any participant or any category of participants enumerated in Section 17A(b)(3)(B). The Commission believes that an exempt clearing agency should impose the same standards. In addition, the Act recognizes that a clearing agency may discriminate among persons in the admission to or the use of the clearing agency if such discrimination is based on standards of financial responsibility, operational capability, experience and competence.

CCOS Rule 301 requires each member to maintain personnel and facilities adequate to ensure the expeditious and orderly transaction of business with CCOS or other participants. In addition, CCOS Rule 302 requires participants in CCOS to meet initial and continuing financial and operational standards as determined by the CCOS Board of Directors and administered by CCOS management.[67] Participation in CCOS will be open to members of BOTCC and members of the CBOT that are affiliated with members of BOTCC.[68] The Board of Directors also may approve access by other clearing agencies that are regulated by the Commission or are excepted from regulation by the Commission.[69]

[63] Since 1980, the Chicago Mercantile Exchange (''CME'') and BOTCC have been sharing original margin and pay/collect information. In 1987, an information sharing agreement was executed between all U.S. commodity clearing houses. The Options Clearing Corporation (''OCC'') became a party to this information sharing agreement in 1993. Letter from Dennis Dutterer, Executive Vice President and General Counsel/Secretary, BOTCC, to Margaret R. Blake, Attorney, Division of Market Regulation, Commission (May 5, 1995). Pursuant to the information sharing agreement, each commodity clearing house and the OCC send its margin requirements and daily cash flow information to BOTCC every night. The following morning, BOTCC sends the information back to the clearing houses so they can compare the margin account excesses, deficits, and cash flows.

[64] The SCG was established in 1989 as a result of developments surrounding the October 1987 Market Break and subsequent studies on the causes of the Market Break. The stated purpose of the SCG is to increase cooperation and coordination among securities clearing entities and to facilitate the sharing of certain clearance and settlement information regarding surveillance and member risk monitoring. While SCG membership is limited to registered clearing agencies, the Commission encourages SCG to review its membership standards and consider whether certain clearing agencies with conditional registration exemptions should be eligible for membership.

[65] *Supra* note 28. The Commission believes that the method by which CCOS converts government securities to futures equivalents in its margin calculations is a prudent risk management measure.

[66] As discussed above, CCOS will begin operations with an initial capitalization of $2 million and BOTCC's commitment to provide additional capital as necessary to cover CCOS's continuing costs of operations. CCOS will calculate margin requirements at least twice daily and will collect margin deficiencies from participants on T and on T+1 while retaining the authority to collect additional margin at any time. CCOS will establish a committed credit facility guaranteed by BOTCC. The credit facility initially will be $5 million and will be increased in increments of $5 million for each $1 billion increase in CCOS's daily average net settlements over a 90 day period.

[67] CCOS will monitor each participant's financial condition as measured by its financial stability, the level and quality of its earnings, and other generally accepted measures of liquidity, capital adequacy, and profitability.

[68] BOTCC's by-laws require BOTCC members to be CBOT members, approved by the CBOT board of directors for BOTCC membership. In addition, the BOTCC board of directors sets, from time to time, BOTCC membership requirements, including, but not limited to, financial and operational requirements, continuing compliance with CBOT and BOTCC rules, financial and other reporting, and such other factors as the BOTCC board may consider necessary or appropriate in assessing an applicant's suitability for participation in BOTCC. BOTCC also has the authority to require additional capital on a discretionary basis and parental guarantees on member proprietary positions. *See, e.g.,* BOTCC By-Law 401.

BOTCC's minimum financial requirements for BOTCC corporate futures commission merchants (''FCM'') include the greater of a specified amount of capital or a percentage of funds required to be segregated and secured pursuant to the Commodities Exchange Act, 7 U.S.C. §§ 1, *et seq.* (1988), combined with non-customer margin requirements for proprietary trading. Once admitted, a clearing member may operate below the initial minimum, but must maintain a specific minimum amount of capital with no formal action taken (Level I). When the clearing member's initial minimum falls below the Level I minimum, but remains above the Level II minimum, the clearing member is subject to detailed financial analysis with a written report provided to senior management recommending no action or a change in status to Level III. At Level III the clearing member must maintain a minimum amount of capital and is immediately subject to 125% of normal margin requirements and provision of pro forma weekly capital computations for one month. If the capital ratios do not meet Level I standards by the next month, the clearing member will be moved to Level IV status. The Risk Management Committee is notified when the firm is subject to Level III requirements. When the clearing member falls below the Level III minimum they will be immediately subject to 150% of normal margin requirements. A formal report will be prepared for the Risk Management Committee outlining the problem with a recommendation for appropriate action which may include a further increase in margin requirements, restrictions on business activities or suspension or termination of clearing privileges. Letter from Dennis A. Dutterer, General Counsel, BOTCC, to Margaret R. Blake, Attorney, Division of Market Regulation, Commission (May 1, 1995).

[69] Clearing agencies that are granted access to CCOS's services are not considered participants of CCOS for the purposes of CCOS's Rules except to the extent determined by the Board of Directors.

Continued

The Commission believes that temporarily exempting CCOS from Sections 17A(b)(3)(B) and 17A(b)(4)(B) of the Act is appropriate. CCOS rules do not meet the requirements of Section 17A(b)(3)(B) of the Act with regard to participants because CCOS rules do not provide for membership by all of the enumerated categories of persons. In addition, CCOS rules do not specify applicant and member financial standards as contemplated in Section 17A(b)(4)(B) of the Act.[70] Financial and operational membership standards depend on factors that CCOS will develop based on the scope of CCOS's operations. CCOS's Board of Directors will review these factors from time to time and establish membership standards based on its findings. Presently, however, the participant standards have not been determined as required by the Act, and an exemption from participation requirements is appropriate.

*C. Comments and the Commission's Responses*

1. Fragmentation of the Clearance and Settlement of Government Securities

Some commenters believe that approval of CCOS's exemption application will result in fragmentation of the clearance and settlement of government securities and will preclude one account settlement. These commenters believe allowing CCOS to settle government securities trades in a manner not effectively integrated with the existing registered clearing corporation process would be deleterious to the systemic risk management currently provided by GSCC by causing lowered overall netting capability, incomplete management of the risk exposure presented by individual firms, and impairment of crisis management. The commenters argue that government securities transactions will operate in the safest and most efficient manner if participants have all of their government securities trades netted, margined, and settled through one central facility (''one account settlement'').[71]

Although commenters fear fragmentation in the clearance and settlement of government securities, the clearance and settlement of government securities transactions already is subject to diverse clearing arrangements. While GSCC is the only registered clearing agency providing clearance and settlement services in the government securities market, it is not the sole government securities clearing facility. Banks currently clear and settle substantial amounts of government securities transfers among themselves through the Federal Reserve System's book-entry wire system without any involvement by GSCC. Furthermore, BOTCC provides clearance and settlement services for futures and options on government securities including the physical delivery of government securities to satisfy futures delivery obligations.

Section 17A(a)(2) of the Act directs the Commission, having due regard for the maintenance of fair competition among clearing agencies, to facilitate the establishment of linked or coordinated facilities for clearance and settlement of transactions in securities, securities options, contracts of sale for future delivery and options thereon, and commodity options.[72] Moreover, the requirement in Section 17A(b)(3)(B)(ii) that clearing agencies admit other clearing agencies as participants appears to indicate that Congress, and the Commission which worked with Congress in developing the 1975 Amendments,[73] contemplated a national system for the clearance and settlement of securities transactions in which there could be multiple clearing agencies serving a securities market.

Where more than one clearing agency for a market exists, the Commission believes that the linking of these clearing agencies, such as the envisioned linkage of CCOS, BOTCC, and GSCC, promotes competition and innovation while still allowing for one-account settlement. The Commission believes that one-account settlement can be achieved in a multiple-clearing agency environment through the use of interclearing agency links and interfaces.[74]

The approach to one-account processing for the clearance and settlement of government securities transactions advocated by GSCC, where one clearing agency compares, nets, and settles all trades in government securities, is not the approach taken by the Commission when establishing the National System for clearance and settlement. The Commission believes that rather than mandate centralized clearance and settlement in the government securities market, it should encourage the coordination of any competing systems through economically efficient linkages that ultimately will foster both competition and investor confidence. For these reasons, the Commission, as a part of its granting CCOS an exemption from clearing agency registration, is urging CCOS, BOTCC, and GSCC to develop settlement interface and cross-margining programs.[75]

2. Illusory Regulatory Oversight

As stated above, BOTCC will be the sole shareholder and will act as the facilities manager for the CCOS operations. Because of the relationship between CCOS and BOTCC, some commenters expressed concern that the Commission would be unable to oversee appropriately the operations of CCOS. Furthermore, these commenters stated that the Commission's regulatory authority over CCOS would be illusory because CCOS would be controlled and operated by BOTCC. These commenters stated that CCOS is merely a shell for BOTCC and that approval of CCOS's application will allow BOTCC to provide clearance and settlement services for government securities. Finally, several commenters noted their concern with and objection to CCOS performing the services of a registered clearing agency without the federal oversight imposed upon all other registered clearing agencies. These commenters argued that for the safety and soundness of the national clearance and settlement system, CCOS should be subject to the same standards and requirements as all other registered clearing agencies.

Under the proposal, CCOS will share office space and staff with BOTCC, and BOTCC will perform all margin calculations and collection and payment

Following Commission approval of its application and upon receipt of a bona fide request for access, CCOS will prepare and submit to the Commission for review, rules providing broader access to CCOS services for persons other than those currently envisioned by the CCOS Rules, consistent with the requirements of Section 17A of the Act.

[70] CCOS Rule 302 and Rule 309 anticipate the determination of participant financial standards by the Board of Directors. At this time, however, the standards remain undefined.

[71] One-account settlement enables a market participant to settle all of its trades through one clearing agency regardless of the location of the other parties to the trades and regardless of the markets in which the trades were executed.

[72] *Standards Release, supra* note 53.

[73] Securities Acts Amendments of 1975, Pub. L. No. 94–29 § 17A(a), 89 Stat. 97.

[74] In the Commission release addressing conditions for the National Securities Clearing Corporation's (''NSCC'') approval as a clearing agency, the Commission stated that ''even though a broker-dealer would be able to achieve one account processing through any one of the clearing corporation components of the National System, a broker-dealer would be able to use more than one clearing corporation if the broker-dealer chose to do so.'' Later in that same release the Commission stated, ''The development and expansion of interfaces during the past year, particularly the establishment of regional interfaces for the processing of over-the-counter transactions, has made one-account processing almost universally available.'' Securities Exchange Act Release No. 12954 (November 3, 1976), 41 FR 49722.

[75] *Supra* note 45.

functions for CCOS. Sharing office space and staff among clearing agencies and contracting out certain clearing agency functions is not unusual.[76]

The standards established for registration of a clearing agency that hires a facility manager to perform data or other processing functions requires the clearing agency to maintain appropriate procedures to insure the prompt and accurate clearance and settlement of securities transactions.[77] The clearing agency also should assure itself that the facilities manager complies with all of the appropriate safeguards set forth in the Standards Release. The Standards Release also requires any such clearing agency to assure itself that its facility manager will cooperate fully with clearing agency auditors, Commission examiners, independent public accountants, and any other appropriate regulatory agency to the same extent as a clearing agency which conducts its own processing functions.

The Commission's experience with facilities management arrangements is that the Commission can carry out its clearing agency oversight responsibilities through its jurisdiction over the clearing agencies. Facilities managers cannot, for example, unilaterally make systems changes that would alter the rules of the clearing agency or the rights and obligations of clearing agency participants without having those changes filed by the clearing agency with the Commission.[78] To the extent that the Commission needs access to a facilities manager's premises or personnel, the Commission expects and has found clearing agencies and their facilities managers to be cooperative with Commission staff.[79]

Regarding commenters' concerns about the need for uniform federal oversight, in granting its application for exemption the Commission is requiring CCOS to meet basically the same standards as those registered clearing agencies must meet, and believes that CCOS has set forth a plan to enable it to meet those standards.[80] CCOS recognizes that it must comply with the regulatory standards governing the operations of clearing agencies in a manner consistent with its operational structure and with the specific services it will offer. CCOS has represented that it intends to comply fully with all relevant regulatory requirements applicable to other clearing agencies.[81]

3. Fair Competition

Some commenters believe that the approval of CCOS's application will not promote fair competition among clearing agencies as contemplated by Section 17A of the Act because CCOS will have exclusive access to cross-margining with BOTCC with respect to government securities. The Commission recognizes that to promote competition among clearing agencies, the benefits of CCOS's operations (*e.g.*, greater access to the government securities market by persons other than primary dealers, the development of improved systems capabilities and new services, and perhaps lower prices to participants) must not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes'' of the federal securities laws.[82]

Since approval of the first cross-margining program in 1988,[83] the Commission repeatedly has found that cross-margining programs are consistent with clearing agency responsibilities under Section 17A of the Act. As the Commission has previously noted, cross-margining programs, among other things, tend to enhance clearing member and systemic liquidity both in times of normal trading and in times of stress.[84] Under routine trading, clearing members that participate in cross-margining programs have lower margin requirements which help clearing members manage their cash flows by increasing available cash to be used for other purposes. In times of market stress and high volatility, lower margin requirements could prove crucial in maintaining the liquidity of clearing members and thus could enhance liquidity in the market as a whole. By enhancing market liquidity, cross-margining arrangements remove impediments to and help perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.[85]

Because CCOS and BOTCC have proposed a cross-margining plan between themselves, the Commission has encouraged CCOS, BOTCC, and GSCC to create and implement a cross-margin arrangement so that fair competition in the clearing of government securities will exist. The Commission believes that competition among clearing agencies should not be based on margin levels but should be based on technology, services, or product types offered by the competing clearing agencies. Therefore, the Commission views the implementation of a cross-margining arrangement among CCOS, BOTCC, and GSCC as vital to the satisfaction of the statutory goals of Section 17A of the Act. Towards this end, CCOS, BOTCC, and GSCC have entered into negotiations regarding cross-margining and linkage agreements. However, because such an agreement has not yet been finalized, the Commission believes it is appropriate to allow CCOS to begin operations with certain limits in place prior to the implementation of cross-margining and linkage agreements.[86]

*D. Conditions*

This Order exempts CCOS from registration as a clearing agency under Section 17A of the Act subject to certain conditions which the Commission believes are appropriate for an entity operating under an exemptive framework. As explained in detail below, these conditions include:

[76] In 1988, GSCC began operations with a facilities management agreement with NSCC whereby NSCC provides GSCC with the necessary administrative and technical services. GSCC continues to share staff and office space with its affiliates, NSCC and International Securities Clearing Corporation. In fact, NSCC and GSCC do not operate their own clearance and settlement systems; instead, they contract that function out to the Securities Industry Automation Corporation.

[77] *Standards Release, supra* note 53.

[78] As discussed below, because CCOS will operate under an exemption from registration as a clearing agency, it will not file rule changes under the Section 19(b) process. Rather, CCOS will have to file amendments to its Form CA–1 exemption application and request modification of its exemptive order to change its rules or procedures.

[79] The Commission generally has not required that facilities management contracts specifically grant the Commission unlimited access to a facilities manager's premises. If in the future the Commission perceives a need for express authority for such access, it will revisit the issue at that time.

[80] *Id.*

[81] Letters from John C. Hiatt, President and Chief Executive Officer, BOTCC, to Jonathan G. Katz, Secretary, Commission (May 23 and June 22, 1994).

[82] 15 U.S.C. 78q–1(b)(3)(I) (1988).

[83] Securities Exchange Act Release No. 26153 (October 3, 1988), 53 FR 39567 (approving nonproprietary cross-margining program between OCC and ICC).

[84] *E.g.*, Securities Exchange Act Release Nos. 30413 (February 26, 1992), 57 FR 7830 (order approving OCC/Kansas City Board of Trade Clearing Corporation cross-margining program for proprietary positions); 29991 (November 26, 1991), 56 FR 61458 (order approving expansion of OCC/CME cross-margining program to include positions held for market professionals); 29888 (October 31, 1991), 56 FR 56680 (order approving OCC/BOTCC cross-margining program for proprietary positions); 27296 (September 26, 1989), 54 FR 41195 (order approving OCC/CME cross-margining program for proprietary positions).

[85] Shortly after the 1987 market break, then Treasury Secretary Nicholas F. Brady referred to the clearance and settlement system as the weakest link in the nation's financial system and noted that improvements to the clearance and settlement system, such as those provided by cross-margining arrangements, would ''help ensure that a securities market failure does not become a credit market failure.'' *The Market Reform Act of 1989: Joint Hearings on S. 648 before the Subcomm. on Securities and the Senate Comm. on Banking, Housing and Urban Affairs*, 101st Cong., 1st Sess. 225 (Oct. 26, 1989) (statement of Nicholas F. Brady, Secretary of the Treasury).

[86] *Supra* note 45.

1. Establishment of acceptable linkage and cross-margining agreements between CCOS, BOTCC, and GSCC;

2. The Commission's access to CCOS and related BOTCC facilities and records in order to inspect CCOS's operations and to insure CCOS's compliance with the federal securities laws and this Order;

3. The requirement that all proposed material changes to CCOS's rules, operations, and systems be submitted as proposed amendments to its Form CA–1;

4. The requirement that CCOS notify the Commission of participant defaults;

5. The establishment of sound automation review programs including system change notification procedures and system outage notification procedures; and

6. Until the establishment of acceptable linkage and cross-margining agreements between CCOS, BOTCC, and GSCC, the requirement that CCOS limit its activity to no more than $3 billion net daily settlement for government securities and $12 billion for dollar rolls.

1. Linkage and Cross-Margining

Throughout this Order, the Commission has emphasized the importance of linkage and cross-margining agreements between CCOS, BOTCC, and GSCC. While the Commission recognizes that such agreements will entail substantial negotiations among the parties, the Commission also recognizes the importance of allowing CCOS to begin operations without further delay.[87] Therefore, the Commission is approving CCOS's application for exemption and will allow CCOS to commence operating with a volume cap of $3 billion net daily settlement for government securities and $12 billion for dollar rolls.[88] During CCOS's initial period of operation, the Commission anticipates that CCOS, BOTCC, and GSCC will finalize linkage and cross-margining agreements pursuant to the Commission's recommendations at which time CCOS will be permitted to proceed to its exemptive limits of $6 billion and $24 billion.[89] Either upon CCOS's request or by its own initiative, the Commission may review whether the current volume limitations should be modified or removed. Such review may be conducted even if the linkage and cross-margining agreements among CCOS, BOTCC, and GSCC have not been finalized.

2. Inspection

As noted above, pursuant to this Order the Commission has the authority to inspect at any time the operations of CCOS in order to insure its compliance with its obligations to safeguard securities and funds and to provide prompt and accurate clearance and settlement of securities transactions. As facilities manager for CCOS, BOTCC's facilities and operations as they pertain to CCOS are also subject to inspection by the Commission in order that the Commission may assure itself that BOTCC's operations with regard to CCOS are in compliance with the safety and soundness requirements set forth in the Act. The Commission expects to coordinate any inspections of BOTCC with the CFTC.

3. Rule Changes

Under Section 19(b)(1) of the Act,[90] a registered clearing agency as a self-regulatory organization must file proposed rule changes with the Commission for approval. The Commission uses the rule filing process as a method to monitor and regulate the operations of clearing agencies. Because CCOS is not a registered clearing agency, amendments to its rules need not be made through use of the Section 19(b) process. As a condition to this Order, however, should CCOS desire to amend its rules, it must submit proposed amendments to its Form CA–1 for Commission review.[91] The Commission believes that this method of notifying the Commission of proposed changes at CCOS will allow the Commission to conduct a thorough examination of each proposed change and its potential effects on CCOS and the clearance and settlement of government securities. Submission by CCOS of a proposed amendment to its Form CA–1 each time it proposes to make a change in its rules, operations, or systems is an appropriate method by which the Commission can exercise its regulatory responsibilities with regard to CCOS.

4. Notice of Defaults

CCOS will be required to notify the Commission of any defaults by participants so that the Commission can monitor the situation and determine if all appropriate methods of recovery are being utilized. Failure by a participant or user could create or exacerbate systemic risks. Prompt notification should help facilitate cooperation and coordination among regulators and market participants.

5. Automation Review

CCOS also will be required to establish a sound automation review program based upon the Commission's second automation review policy statement (''ARP II'').[92] The automation review program should include appropriate planning processes (i.e., contingency planning and security assessment), independent reviews by CCOS of its systems, notification to the Commission of significant systems changes, and procedures for timely notification of significant system outages. The Commission believes the automation review program is essential for the safety and soundness of CCOS's operations and the national market system because it will require, among other things, CCOS to evaluate regularly its processes related to the capacity and vulnerabilities of its automated systems.

6. Limits on Activity

The Commission believes that until acceptable linkage and cross-margining plans are in place, CCOS's clearing activity should be limited to one half of the maximum daily net settlement amounts agreed to by CCOS and the Division. These limit amounts are no more than $3 billion in net daily settlement for government securities, and $12 billion for dollar rolls. Once the linkage and cross-margining plans are in place, CCOS's activity may proceed to the full amounts agreed to in this Order.

The Commission reserves the right to modify by order the terms, scope, or conditions of CCOS's exemption from registration as a clearing agency, including such terms, scope, or condition that the Commission may issue in the future regarding amendments to CCOS's Form CA–1, if the Commission determines that such modification is appropriate for the

[87] As noted, a joint user committee established by the Boards of Directors of GSCC, BOTCC, and CCOS will provide to the respective Boards within three months of formation of the committee a report of its analysis and proposed resolutions to the outstanding linkage and cross-margining issues. The Commission expects prompt action with regard to the establishment of linkage and cross-margining facilities, and if necessary, the Commission will use its authority under the Act to direct that such facilities be established. *Supra* notes 45–46 and accompanying text.

[88] These amounts are half of the maximum daily net settlement amounts agreed to by CCOS and the Division, as discussed in note 35. The Commission believes these limits are large enough to allow CCOS to begin effective operations while it works with GSCC to develop linkage and cross-margining facilities to advance efficient clearance and settlement.

[89] These are the maximum average daily net settlements agreed to by CCOS and the Division during the exemptive period. In addition, limits on CCOS's clearing capacity must be considered in light of the limits to be placed on CBB as a government securities broker. CCOS will be limited to clearing $6 billion in net daily cash securities and $24 billion in dollar rolls on an average basis over a ninety-day period. *Supra* note 35.

[90] 15 U.S.C. § 78s(b)(1) (1988).

[91] CCOS will be required to amend its CA–1 application for any proposed changes to its stated policies, practices, or interpretations as that phrase is defined in Rule 19b-4 (17 CFR 240.19b-4).

[92] Securities Exchange Act Release Nos. 27445 (November 16, 1989) [54 FR 48704] (''ARP I''), and 29185 (May 9, 1991) [56 FR 22489], (''ARP II'').

protection of investors or in the public interest. Furthermore, the Commission reserves the right to suspend or revoke this exemption or to censure or impose limitations upon the activities, functions, and operations of CCOS if the Commission finds that CCOS has violated or is unable to comply with any of the provisions set forth in this Order or in its own rules or that CCOS has failed without reasonable justification to enforce compliance with any provision of its own rules by one of its participants.

IV. Conclusion

The Commission finds that CCOS's application for exemption from registration as a clearing agency meets the standards and requirements deemed appropriate for such an exemption including those standards set forth under Section 17A of the Act.

It is therefore ordered, pursuant to Section 19(a)(1) of the Act, that the application for exemption from registration as a clearing agency filed by the Clearing Corporation for Options and Securities (File No. 600–27) be, and hereby is, approved subject to the conditions listed in this Order.

By the Commission.

Margaret H. McFarland,

*Deputy Secretary.*

[FR Doc. 95–30660 Filed 12–15–95; 8:45 am]

BILLING CODE 8010–01–P

## SMALL BUSINESS ADMINISTRATION

### Data Collection Available for Public Comments and Recommendations

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new, and/or currently approved information collection.

**DATES:** Comments should be submitted on or before February 16, 1996.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline White, Management Analyst, Small Business Administration, 409 3rd Street, S. W., Suite 5000, Washington, D. C. 20416. Phone Number: 202–205–6629. Copies of these collections can also be obtained.

**SUPPLEMENTARY INFORMATION:**

Title: Office of Women's Business Ownership Year End Follow Up Survey

Type of Request: New Information Collection

Description of Respondents: Women-owned businesses

Annual Responses: 2,750

Annual Burden: 825

Comments: Send all comments regarding this information collection to Harriet Fredman, Small Business Administration, Women's Business Ownership, 409 3rd Street, S. W., Suite 6200, Washington, D. C. 20416. Phone No. 202–205–6673. Send comments regarding whether this information collection is necessary for the proper performance of the function of the agency, accuracy of burden estimate, in addition to ways to minimize this estimate, and ways to enhance the quality.

Dated: December 13, 1995.

Jacqueline White,

*Acting Chief, Administrative Information Branch.*

[FR Doc. 95–30679 Filed 12–15–95; 8:45 am]

BILLING CODE 8025–01–P

### Data Collection Available for Public Comments and Recommendations

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new, and/or currently approved information collection.

**DATES:** Comments should be submitted on or before February 16, 1996.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline White, Management Analyst, Small Business Administration, 409 3rd Street, SW., Suite 5000, Washington, DC 20416. Phone Number: 202–205–6629. Copies of these collections can also be obtained.

**SUPPLEMENTARY INFORMATION:**

*Title:* Prime Contracts Program Quarterly Report.

*Type of Request:* Extension of a currently approved information collection.

*Description of Respondents:* Procurement Center Representatives.

*Annual Responses:* 1,340.

*Annual Burden:* 670.

*Comments:* Send all comments regarding this information collection to Susan Monge, Small Business Administration, Office of Government Contracting, 409 3rd Street, SW., Washington, DC 20416. Phone No.: 202–205–6471.

Send comments regarding whether this information collection is necessary for the proper performance of the function of the agency, accuracy of burden estimate, in addition to ways to minimize this estimate, and ways to enhance the quality.

Jacqueline White,

*Acting Chief, Administrative Information Branch.*

[FR Doc. 95–30680 Filed 12–15–95; 8:45 am]

BILLING CODE 8025–01–P

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

**[CGD 95–084]**

### Review of Icebreaking Program for the East Coast of the United States

**AGENCY:** Coast Guard, DOT.

**ACTION:** Request for comments.

**SUMMARY:** The Coast Guard is reviewing its domestic icebreaking mission along the east coast of the United States from Maine to Virginia. Consistent with the President's effort to reinvest government, this review is necessary to assess the effectiveness of the present program, the impacts resulting from changes in the Coast Guard's icebreaking fleet, and the needs of the future. The Coast Guard is requesting comments and data to assist in this review.

**DATES:** Comments must be received on or before February 16, 1996.

**ADDRESSES:** Written comments may be mailed to the Chief, Ice Operations Division, U.S. Coast Guard Headquarters, 2100 Second Street S.W., Washington, DC 20593–0001, or may be delivered to room 1202A at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1450.

**FOR FURTHER INFORMATION CONTACT:** LCDR Robert Garrett, Icebreaker Facilities Branch, Ice Operations Division, Office of Navigation Safety and Waterway Services between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Telephone (202) 267–1460, telefax (202) 267–4425.

**SUPPLEMENTARY INFORMATION:**

Request for Comments

The Coast Guard encourages interested persons to participate in this review by submitting written views and data on icebreaking operations on the east coast of the United States. Persons submitting comments should include their names and addresses, identify this docket (CGD 95–084), identify the aspect of icebreaking operations on

which comments are submitted, and state the expected impacts on current icebreaking operations and the reasons for those impacts. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

Background

Under Executive Order No. 7521 of December 21, 1936, the Coast Guard has assisted as practicable in keeping the channels and harbors along the northeast and mid-Atlantic coast of the United States open to shipping during the winter and in preventing flooding from ice jams. In doing so, the Coast Guard has attempted to meet the reasonable demands of commerce and to support other agencies in their icebreaking efforts.

To accomplish this mission, the Coast Guard maintains a fleet of icebreaking tugs, ice-capable buoy tenders, and ice-reinforced boats. This fleet has undergone substantial changes since the 1960's. Replacement cutters and boats generally have been larger and more capable of meeting the changing requirements of their primary mission areas. However, they are fewer in number and may not have all of the icebreaking capabilities of the vessels they replaced. For example, the physical size of the larger cutters and boats may restrict their ability to operate in the upper reaches of rivers where ice jams typically form.

On occasion, private interests have operated or hired commercial tugs for icebreaking services. [Coast Guard policy prohibits if from competing with commercial icebreaking concerns.] However, commercial concerns apparently have not been able to meet worst-year ice conditions.

The Review

Consistent with the President's effort to reinvent government, the Coast Guard is now reviewing its East Coast icebreaking program to assess its effectiveness, to identify the impacts resulting from changes in the Coast Guard's icebreaking fleet, and to determine the program's needs for the future. The Coast Guard is particularly interested in receiving comments and data on the following subjects:

1. The Coast Guard's present ability to satisfy the reasonable demands of commerce for icebreaking along the East Coast.

2. The continuing need for the Coast Guard to maintain icebreaking capabilities along the East Coast.

3. The impact and alternatives available should the Coast Guard no longer provide icebreaking services along the East Coast.

4. Private industry's ability to provide icebreaking services.

5. The need, if any, to replace the Coast Guard's 65 foot icebreaking tugs and the capabilities required of the replacement vessels to minimize costs while maintaining necessary support.

This list of subjects is not intended to suggest that the Coast Guard's role or level of service should or will change. It is intended to assist the Coast Guard in evaluating the costs and benefits of its present icebreaking program and its needs for the future.

Dated: December 12, 1995.

J. A. Creech,

*Captain, U.S. Coast Guard, Acting Chief, Office of Navigation Safety and Waterway Services.*

[FR Doc. 95–30678 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–14–M

## National Highway Traffic Safety Administration

## Announcing the Thirteenth Meeting of the Motor Vehicle Safety Research Advisory Committee

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Meeting announcement.

**SUMMARY:** This notice announces the thirteenth meeting of the Motor Vehicle Safety Research Advisory Committee (MVSRAC). The Committee was established in accordance with the provisions of the Federal Advisory Committee Act to obtain independent advice on motor vehicle safety research. Discussions at this meeting will include NHTSA's research programs, including critical injury control issues facing the agency.

**DATE AND TIME:** The meeting is scheduled to begin at 9:00 a.m., on Wednesday, January 17, 1996, and conclude at 1:00 p.m., on Thursday, January 18, 1996.

**ADDRESSES:** The meeting will be held in Rooms 6244–48 of the U.S. Department of Transportation Building, which is located at 400 Seventh Street, S.W., Washington, DC.

**SUPPLEMENTARY INFORMATION:** In May 1987, the Motor Vehicle Safety Research Advisory Committee was established. The purpose of the Committee is to provide an independent source of ideas for motor vehicle safety research. The MVSRAC will provide information, advice and recommendations to NHTSA on matters relating to motor vehicle safety research, and provide a forum for the development, consideration and communication of motor vehicle safety research, as set forth in the MVSRAC Charter.

The meeting is open to the public, but attendance may be limited due to space availability. Participation by the public will be determined by the Committee Chairperson.

A public reference file (Number 88–01) has been established to contain the products of the Committee and will be open to the public during the hours of 9:30 a.m. to 4:00 p.m. at the National Highway Traffic Safety Administration's Technical Reference Division in Room 5108 at 400 Seventh Street, S.W., Washington, DC 20590, telephone: (202) 366–2768.

**FOR FURTHER INFORMATION CONTACT:** Ms. Barbara Coleman, Office of Research and Development, 400 Seventh Street, S.W., Room 6206, Washington, DC 20590, telephone: (202) 366–1537.

Issued on: December 13, 1995.

William A. Boehly,

*Chairperson, Motor Vehicle Safety Research Advisory Committee.*

[FR Doc. 95–30687 Filed 12–15–95; 8:45 am]

BILLING CODE 4910–59–P

## Research and Development Programs Meeting

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of meeting cancellation.

**SUMMARY:** This notice announces the cancellation of a public meeting at which NHTSA was scheduled to describe and discuss specific research and development projects. Further, the notice requests comments regarding a proposed schedule change from quarterly meetings to biannual meetings.

**BACKGROUND:** The National Highway Traffic Safety Administration holds quarterly public meetings devoted primarily to detailed presentations of specific research and development projects. Three meetings each year are held in Detroit, Michigan, and a fourth meeting is held in Washington, DC, in conjunction with the National Highway Traffic Safety Administration's quarterly meetings on safety performance standards and safety assurance programs.

**MEETING CANCELLATION:** The National Highway Traffic Safety Administration's public meeting devoted primarily to presentations of specific research and development projects as announced in the Federal Register (Vol. 60, No. 212, page 55752) for December 19, 1995, has

been canceled. The meeting on safety performance standards and safety assurance programs, scheduled for December 20, 1995, and announced in the same Federal Register notice has not been canceled and will be held as scheduled.

**ADDRESSES:** Requests for further information and comments may be directed to the Office of the Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, Room 6206, 400 Seventh St., SW, Washington, DC 20590. The telefax number is 202–366–5930.

**SUPPLEMENTARY INFORMATION:** NHTSA provides detailed presentations about its research and development programs in a series of public meetings. The series started in April 1993. The purpose is to make available more complete and timely information regarding the agency's research and development programs. The twelfth meeting in the series will be held on March 12, 1996, in Detroit, Michigan. Thereafter, the meetings on the agency's research and development programs only will be held biannually, with the meeting sites alternating between Washington, DC, and Detroit, Michigan, scheduled to be held in conjunction with the agency's quarterly meetings on safety performance standards and safety assurance programs. No other changes to the format for the research and development programs meetings are planned. Each meeting will be announced in the Federal Register along with a request for suggested presentation topics and deadlines for submission of topics and questions. Before the meeting, the agenda for the meeting listing the research and development topics to be presented will be published in the Federal Register.

NHTSA requests comments from interested parties on the proposed schedule change from quarterly to biannual meetings. Comments should be submitted by 4:15 p.m. on January 17, 1996, to the Office of the Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, Room 6206, 400 Seventh St., SW, Washington, DC 20590. The telefax number is 202–366–5930.

**FOR FURTHER INFORMATION CONTACT:** Rita Gibbons, Staff Assistant, Office of Research and Development, 400 Seventh Street, SW, Washington, DC 20590. Telephone: 202–366–4862. Fax number: 202–366–5930.

Issued: December 12, 1995.

William A. Boehly,

*Associate Administrator for Research and Development.*

[FR Doc. 95–30688 Filed 12–13–95; 4:25 pm]

**BILLING CODE 4910–59–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Cost-of-Living Adjustments and Headstone or Marker Allowance Rate

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** As required by law, the Department of Veterans Affairs (VA) is hereby giving notice of cost-of-living adjustments (COLAs) in certain benefit rates and income limitation. These COLAs affect the pension and parents' dependency and indemnity compensation (DIC) programs. These adjustments are based on the rise in the Consumer Price Index (CPI) during the one-year period ending September 30, 1995. VA is also giving notice of the maximum amount of reimbursement that may be paid for headstones or markers purchased in lieu of Government-furnished headstones or markers in Fiscal Year 1996, which began on October 1, 1995.

**DATES:** These COLAs are effective December 1, 1995. The headstone or marker allowance rate is effective October 1, 1995.

**FOR FURTHER INFORMATION CONTACT:** Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service (211B), Veterans Benefit Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7210.

**SUPPLEMENTARY INFORMATION:** Under 38 U.S.C. 2306(d), VA may provide reimbursement for the cost of non-Government headstones or markers at a rate equal to the actual cost or the average actual cost of Government-furnished headstones or markers during the fiscal year preceding the fiscal year in which the non-Government headstone or marker was purchased, whichever is less.

Section 8041 of Public Law 101–508 amended 38 U.S.C. 2306(d) to eliminate the payment of the monetary allowance in lieu of VA-provided headstone or marker for deaths occurring on or after November 1, 1990. However, in a precedent opinion (O.G.C. Prec. 17–90), VA's General Counsel held at that there is no limitation period applicable to claims for benefits under the provisions of 38 U.S.C. 2306(d).

The average actual cost of Government-furnished headstones or markers during any fiscal year is determined by dividing the sum of VA costs during that fiscal year for procurement, transportation, Office of Memorial Programs and miscellaneous administration, inspection and support staff by the total number of headstones and markers procured by VA during that fiscal year and rounding to the nearest whole dollar amount.

The average actual cost of Government-furnished headstones or markers for Fiscal Year 1995 under the above computation method was $101. Therefore, effective October 1, 1995, the maximum rate of reimbursement for non-Government headstones or markers purchased during Fiscal Year 1996 is $101.

Cost-of-Living Adjustments

Under the provisions of 38 U.S.C. 5312 and section 306 of Public Law 95–588, VA is required to increase the benefit rates and income limitations in the pension and parents' DIC programs by the same percentage, and effective the same date, as increases in the benefit amounts payable under title II of the Social Security Act. The increased rates and income limitations are also required to be published in the Federal Register.

The Social Security Administration has announced that there will be a 2.6 percent cost-of-living increase in social security benefits effective December 1, 1995. Therefore, applying the same percentage, the following increased rates and income limitations for the VA pension and parents' DIC programs will be effective December 1, 1995:

TABLE 1.—IMPROVED PENSION

[Maximum annual rates]

(1) Veterans permanently and totally disabled (38 U.S.C. 1521):
- Veteran with no dependents, $8,246
- Veteran with one dependent, $10,801
- For each additional dependent, $1,404

(2) Veterans in need of aid and attendance (38 U.S.C. 1521):
- Veteran with no dependents, $13,190
- Veteran with one dependent, $15,744
- For each additional dependent, $1,404

(3) Veterans who are house bound (38 U.S.C. 1521):
- Veteran with no dependents, $10,080
- Veteran with one dependent, $12,634
- For each additional dependent, $1,404

(4) Two veterans married to one another, combined rates (38 U.S.C. 1521):
- Neither veteran in need of aid and attendance or housebound, $10,801
- Either veteran in need of aid and attendance, $15,744
- Both veteran in need of aid and attendance, $20,686
- Either veteran housebound, $12,634

TABLE 1.—IMPROVED PENSION—Continued

[Maximum annual rates]

Both veterans housebound, $14,469
One veteran housebound and one veteran in need of aid and attendance, $17,575
For each dependent child, $1,404

(5) Surviving spouse alone and with a child or children of the deceased veteran in custody of the surviving spouse (38 U.S.C. 1541):
Surviving spouse alone, $5,527
Surviving spouse and one child in his or her custody, $7,240
For each additional child in his or her custody, $1,404

(6) Surviving spouses in need of aid and attendance (38 U.S.C. 1541):
Surviving spouse alone, $8,839
Surviving spouse and one child in his or her custody, $10,548
For each additional child in his or her custody, $1,404

(7) surviving spouses who are housebound (38 U.S.C. 1541):
Surviving spouse alone, $6,758
Surviving spouse and one child in his or her custody, $8,466
For each additional child in his or her custody, $1,404

(8) Surviving child alone (38 U.S.C. 1542), $1,404

*Reduction for income.* The rate payable is the applicable maximum rate minus the countable annual income of the eligible person. (38 U.S.C. 1521, 1541 and 1542).

*Mexican border period and World War I veterans.* The applicable maximum annual rate payable to a Mexican border period or World War I veteran under this table shall be increased by $1,867. (38 U.S.C. 1521(g))

*Parents' DIC*

DIC shall be paid monthly to parents of a deceased veteran in the following amounts (38 U.S.C. 1315):

TABLE 2

[*One parent.* If there is only one parent, the monthly rate of DIC paid to such parent shall be $391 reduced on the basis of the parent's annual income according to the following formula:]

| For each $1 of annual income | | |
|---|---|---|
| The $391 monthly rate shall be reduced by | Which is more than | But not more than |
| $0.00 | $0 | $800 |
| .08 | 800 | 9,381 |

No DIC is payable under this table if annual income exceeds $9,381.

*One parent who has remarried.* If there is only one parent and the parent has remarried and is living with the parent's spouse, DIC shall be paid under Table 2 or under Table 4, whichever shall result in the greater being paid to the veteran's parent. In the case of remarriage, the total combined annual income of the parent and the parent's spouse shall be counted in determing the monthly rate of DIC.

*Two parents not living together.* The rates in Table 3 apply to (1) two parents who are not living together, or (2) an unmarried parent when both parents are living and the other parent has remarried. The monthly rate of DIC paid to each such parent shall be $281 reduced on the basis of each parent's annual income, according to the following formula:

TABLE 3

| For each $1 of annual income | | |
|---|---|---|
| The $281 monthly rate shall be reduced by | Which is more than | But not more than |
| $0.00 | $0 | $800 |
| .06 | 800 | 900 |
| 0.7 | 900 | 1,100 |
| .08 | 1,100 | 9,381 |

No DIC is payable under this table if annual income exceeds $9,381.

*Two parents living together or remarried parents living with spouses.* The rates in Table 4 apply to each parent living with another parent; and each remarried parent, when both parents are alive. The monthly rate of DIC paid to such parents will be $264 reduced on the basis of the combined annual income of the two parents living together or the remarried parent or parents and spouse or spouses, as computed under the following formula:

TABLE 4

| For each $1 of annual income | | |
|---|---|---|
| The $264 monthly rate shall be reduced by | Which is more than | But not more than |
| $.00 | $0 | $1,000 |
| .03 | 1,000 | 1,500 |
| .04 | 1,500 | 1,900 |
| .05 | 1,900 | 2,400 |
| .06 | 2,400 | 2,900 |
| .07 | 2,900 | 3,200 |
| .08 | 3,200 | 12,611 |

No DIC is payable under this table if annual income exceeds $12,611.

The rates in this table are also applicable in the case of one surviving parent who has remarried, computed on the basis of the combined income of the parent and spouse, if this would be a greater benefit than that specified in Table 2 for one parent.

*Aid and attendance.* The monthly rate of DIC payable to a parent under Table 2 through 4 shall be increased by $209 if such parent is (1) a patient in a nursing home, or (2) helpless or blind, or so nearly helpless or blind as to need or require the regular aid and attendance of another person.

*Minimum rate.* The monthly rate of DIC payable to any parent under Tables 2 through 4 shall not be less than $5.

TABLE 5.—SECTION 306 PENSION INCOME LIMITATIONS

(1) Veteran or surviving spouse with no dependents, $9,381 (Pub. L. 95–588, section 306(a)).
(2) Veteran with no dependents in need of aid and attendance, $9,881 (38 U.S.C. 1521(d) as in effect on December 31, 1978).
(3) Veteran or surviving spouse with one or more dependents, $12,611 (Pub. L. 95–588, section 306(a)).
(4) Veteran with one or more dependents in need of aid and attendance, $13,111 (38 U.S.C. 1521(d) as in effect on December 31, 1978).
(5) Child (no entitled veteran or surviving spouse), $7,668 (Pub. L. 95–588, section 306(a)).
(6) Spouse income exclusion (38 CFR 3.262), $2,992 (Pub. L. 95–588, section 306(a)(2)(B)).

TABLE 6.—OLD-LAW PENSION INCOME LIMITATIONS

(1) Veteran or surviving spouse without dependents or an entitled child, $8,211 (Pub. L. 95–588, section 306(b)).
(2) Veteran or surviving spouse with one or more dependents, $11,840 (Pub. L. 95–588, section 306(b)).

Dated: December 8, 1995.

Jesse Brown,

*Secretary of Veterans Affairs.*

[FR Doc. 95–30643 Filed 12–15–95; 8:45 am]

BILLING CODE 8320–01–M

## Poverty Threshold

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Department of Veterans Affairs (VA) is hereby giving notice of the weighted average poverty threshold in 1994 for one person (unrelated individual) as established by the Bureau of the Census.

**DATES:** The 1994 poverty threshold is for consideration effective October 5, 1995,

the date on which it was established by the Bureau of the Census.

**FOR FURTHER INFORMATION CONTACT:** Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7210.

**SUPPLEMENTARY INFORMATION:** VA published a final regulation amendment 38 CFR 4.16(a) in the Federal Register on August 3, 1990, pages 31579–80. The amendment provided that marginal employment generally shall be deemed to exist when a veteran's earned annual income does not exceed the amount established by the Bureau of the Census as the poverty threshold for one person. VA noted that the weighted average poverty threshold in 1988 for one person (unrelated individual) as established by the Bureau of Census was $6.024 and stated we would publish subsequent poverty threshold figures as notices in Federal Register.

The Bureau of the Census recently published the weighted average poverty thresholds for 1994. The threshold for one person (unrelated individual) is $7,547.

Dated: December 8, 1995.

Jesse Brown,

*Secretary of Veterans Affairs.*

[FR Doc. 95–30642 Filed 12–15–95; 8:45 am]

BILLING CODE 8320–01–M

# Sunshine Act Meetings

Federal Register
Vol. 60, No. 242
Monday, December 18, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

## BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

**TIME AND DATE:** 10 a.m., Thursday, December 21, 1995.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

*Summary Agenda:* Because of their routine nature, no discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed amendments to Regulation K (International Banking Operations) concerning general consent authority (proposed earlier for public comment; Docket No. R–0896).
2. Publication for comment of proposed amendments to Regulation K (International Banking Operations) concerning interstate banking operations of foreign banking organizations.
3. Any items carried forward from a previously announced meeting.

*Discussion Agenda:* PLEASE NOTE THAT NO DISCUSSION ITEMS ARE SCHEDULED FOR THIS MEETING.

Note: If an item is moved from the Summary Agenda to the Discussion Agenda, discussion of the item will be recorded. Cassettes will then be available for listening in the Board's Freedom of Information Office, and copies can be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: December 14, 1995.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 95–30817 Filed 12–14–95; 3:09 pm]

BILLING CODE 6210–01–P

## BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

**TIME AND DATE:** Approximately 10:15 a.m., Thursday, December 21, 1995, following a recess at the conclusion of the open meeting.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 2lst Streets, NW., Washington, DC 20551.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: December 14, 1995.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 95–30818 Filed 12–14–95; 3:09 pm]

BILLING CODE 6210–01–P

# Corrections

Federal Register
Vol. 60, No. 242
Monday, December 18, 1995

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Parts 611, 675, 676, and 677

**[Docket No. 95112820–5280–01; I.D. 111495A]**

### Groundfish Fishery of the Bering Sea and Aleutian Islands; Limited Access; Foreign Fishing; Proposed 1996 Initial Harvest Specifications

*Correction*

In proposed rule document 95–29722 beginning on page 62373 in the issue of Wednesday, December 6, 1995, make the following corrections:

1. On page 62378, in Table 3, in the first column, the second and third entries should be combined to read ''Hook-and-line/Pot-gear''.

2. On page 62380, in Table 5, in the fourth column, ''725'' should appear opposite ''Pacific cod Hook-and-line''; and ''175'' should appear opposite ''Other nontrawl:''.

3. On page 62381, in the third column, the Date above the signature should read ''December 1, 1995''.

BILLING CODE 1505–01–D

## SOCIAL SECURITY ADMINISTRATION

### 20 CFR Part 404

**[Regulation No. 4]**

**RIN 0960-AE21**

### When You Are A Full-Time Elementary or Secondary Student

*Correction*

In proposed rule document 95–29534 beginning on page 62783 in the issue of Thursday, December 7, 1995, make the follwing correction:

**§ 404.369 [Removed]**

On page 62786, in the second column, the heading above amendatory instruction 7 should read as set forth above.

BILLING CODE 1505–01–D

federal register

Monday
December 18, 1995

# Part II

# Department of Health and Human Services

## Food and Drug Administration

## 21 CFR Parts 123 and 1240

## Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 123 and 1240**

**[Docket No. 93N–0195]**

**RIN 0910–AA10**

# Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is adopting final regulations to ensure the safe and sanitary processing of fish and fishery products (hereinafter referred to as seafood), including imported seafood. The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control that can be used by processors to ensure the safety of their products to consumers. FDA is issuing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

**DATES:** Effective December 18, 1997. Submit written comments on the information collection requirements by February 16, 1996.

**ADDRESSES:** Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Philip C. Spiller, Center for Food Safety and Applied Nutrition (HFS–401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

For further information concerning the guidance entitled ''Fish and Fishery Products Hazards and Controls Guide,'' contact: Donald W. Kraemer (address above).

**SUPPLEMENTARY INFORMATION:** The contents of this preamble are listed in the following outline:

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## I. Background

### *A. The Proposal*

In the Federal Register of January 28, 1994 (59 FR 4142), FDA published a proposed rule to establish requirements relating to the processing and importing of seafood for commercial distribution in the United States. The requirements involved the application of HACCP principles by processors and importers to ensure food safety to the maximum extent practicable. HACCP is a system by which food processors evaluate the kinds of hazards that could affect their products, institute controls to keep these hazards from occurring or to significantly minimize their occurrence, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

In addition to publishing the proposed rule, FDA published in the Federal Register of April 7, 1994 (59 FR 16655), a notice of availability of draft guidelines, primarily directed toward processors, on how to develop HACCP controls for specific types of processing operations. The notice of availability requested comments on the draft. Among other things, these draft guidelines, which were titled the ''Fish and Fishery Products Hazards and Controls Guide'' (the Guide), inventoried known likely food safety hazards associated with many species of seafood and many processing methods and made recommendations on ways to control those hazards. Comments received by FDA on the draft Guide are under review. The agency intends to publish the first edition of the Guide before the effective date of these regulations.

FDA established on the proposed rule a comment period of 90 days, to end on April 28, 1994. The agency also asked for comment on the draft guidelines by the same date. During that comment period, FDA held public meetings in nine cities to help ensure that the public was aware of the proposal, to answer questions about its contents, and to encourage participation in the rulemaking process through the submission of comments. In addition, at these meetings, FDA staff explained to the public how to use the draft guidelines to develop HACCP controls in specific processing operations.

The agency received several written requests for an extension of the comment period. After considering these requests, FDA published a notice in the Federal Register on April 7, 1994 (59 FR 16578), announcing a 30-day extension of the comment period to May 31, 1994, for both the proposed rule and the draft guidelines.

### *B. Factual Basis for the Proposal—Summary*

In the preamble to the proposed rule, FDA stated five principal reasons for this initiative: (1) To create a more effective and efficient system for ensuring the safety of seafood than currently exists; (2) to enhance consumer confidence; (3) to take advantage of the developmental work on the application of HACCP-type preventive controls for seafood that had already been undertaken by industry, academia, some States, and the Federal government; (4) to respond to requests by seafood industry representatives that the Federal government institute a mandatory, HACCP-type inspection system for their products; and (5) to provide U.S. seafood with continued access to world markets, where HACCP-type controls are increasingly becoming the norm.

The preamble to the proposal cited the conclusion of a 1991 study on seafood safety by the National Academy of Sciences' (NAS) Institute of Medicine that, while most seafoods on the market are unlikely to cause illness to the consumer, there are significant areas of risk and illnesses that do occur. The study concluded that improvements in the current system of regulatory control are needed and repeatedly recommended the application of HACCP controls where warranted.

Ensuring the safety of seafood presents special challenges to both the industry and the regulator. Seafood consists of hundreds of edible species from around the world. Depending upon species and habitat, seafood can be subject to a wide range of hazards before harvest, including bacteria and viruses, toxic chemicals, natural toxins, and parasites. The harvesting of previously underutilized species—a practice that is increasing because of the depletion of traditionally harvested species—can be expected to create new source and process hazards that must be identified and controlled.

Unlike beef and poultry, seafood is still predominately a wild-caught flesh food that frequently must be harvested under difficult conditions and at varying distances from processing, transport, and retail facilities. It is also subject to significant recreational harvest, some of which finds its way into commercial channels. As fish farming (aquaculture) increases, new problems emerge as a result of habitat, husbandry, and drug use.

An additional complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, or from as many countries, as seafood. Over 55 percent of seafood consumed in this country is imported from approximately 135 countries. Several of these countries have advanced regulatory structures for seafood safety, but many others are developing nations that lack infrastructures capable of supporting national programs for seafood regulations comparable to those in more developed nations.

To ensure safety, it is of utmost importance that those who handle and process seafood commercially understand the hazards associated with this type of food, know which hazards are associated with the types of products with which they are involved, and keep these hazards from occurring through a routine system of preventive controls. For the most part, however, seafood processors and importers are not required, through licensure or examination, to demonstrate an understanding of seafood hazards as a prerequisite to being able to do business. In fact, there is evidence that such an understanding does not exist in a significant portion of the industry. A survey conducted by FDA from 1992 to 1993 of manufacturers of ready-to-eat seafood products revealed that, in significant measure, firms have not been employing the types of preventive processing controls necessary to ensure a safe product by design. FDA and State surveys have also revealed that many

processors of smoked and smoke-flavored fish are operating outside of the parameters that have been demonstrated through scientific research to be necessary to ensure that the hazard from botulism is adequately controlled.

Because of seafood's unique characteristics (e.g., the fact that it is predominantly wild caught and presents a wide range of possible hazards), FDA began to question whether the current Federal regulatory system, which was developed for the general food supply, is best suited for the seafood industry. Seafood processors are subject to periodic, unannounced, mandatory inspection by FDA. These inspections provide the agency with a ''snapshot'' of conditions at a facility at the moment of inspection, but assumptions must be made about conditions before and after that inspection. Concern about the reliability of these assumptions over the intervals between inspections creates questions about the adequacy of the system.

Inspections today verify the industry's knowledge of hazards and controls largely by inference. Whether a company produces products that are adulterated, or whether conditions in its plant are consistent with current good manufacturing practice (CGMP), are measures of how well the company understands what is necessary to produce a safe and wholesome product. This system places a burden on the Government to find a problem and to prove that it exists, rather than on the firm to establish for itself, for the regulator, and for consumers, that it has adequate controls in place to ensure safety.

Given the nature and frequency of the current inspection system for seafood, it has failed to produce a situation in which the public has full confidence in the safety and wholesomeness of these products. There has been a similar failure with respect to imports.

Media and other public attention on seafood safety, and on the adequacy of the current regulatory program for seafood, has been substantial in recent years. Many hearings on the sufficiency and direction of the Federal seafood safety program have been held in both Houses of Congress since the late 1980's, and numerous bills have been considered for the stated purpose of improving seafood safety. This public concern has motivated representatives of the U.S. seafood industry to request that FDA develop a HACCP-based program for these products.

Although not a public health issue, international trade is also a major consideration in determining the advisability and benefits of a new system of seafood regulation. Participation in the international trade in seafood is critical to U.S. consumers and to the U.S. seafood industry. The United States is the world's second largest seafood importing nation and the second largest exporter of fishery products.

The international movement toward harmonization, coupled with the Codex Alimentarious Commission's adoption of HACCP for international use, clearly argue for the adoption of this approach in the United States for seafood. Failure by the United States to adopt a mandatory, HACCP-based system could ultimately undermine its export success, with considerable economic consequences. Such failure also would undermine the United States ability to meet growing international expectations that it enter into mutual recognition-type agreements with trading partners based on HACCP.

## II. The Comments

FDA received over 250 submissions from over 200 commentors on both the proposed regulations and the draft Guide. Individual companies, the majority of which are in the seafood business, submitted slightly over half of the comments. Nearly 40 trade associations submitted comments. As with the companies, the majority of these associations represent seafood interests, but a significant minority have memberships reflecting a range of food products.

Comments were also received from consumer advocacy and similar groups, and coalitions of such groups. All totaled, the views of over 50 organizations were represented in these comments.

Other commenters included State agencies, the Association of Food and Drug Officials (AFDO), the Interstate Shellfish Sanitation Conference (ISSC), several scientific associations and bodies, departments of three universities, foreign governments, and about 25 individuals.

Overall, the comments covered virtually every aspect of the proposal and guidelines. FDA appreciates the effort, interest, and thoughtfulness reflected by these comments.

The following materials address the significant comments that were received on the proposed regulations, both on the specific provisions of the proposal and on related matters. The materials on the provisions of the proposed regulations explain, among other things, why the agency did or did not modify the provisions based on the comments. Any provisions not addressed below were not changed substantively or were not the subject of significant comment.

FDA will respond to those comments that relate solely to the draft Guide when the first edition of that document is completed and made available to the public. The agency intends to address those comments in a notice of availability to be published in the Federal Register.

### *A. Legal Basis*

#### 1. Introduction

About 25 comments addressed the legal basis for these regulations. Nearly half of these comments were either companies that process foods other than seafood or trade associations that represent such companies, some of who indicated that they were motivated to comment, at least in part, by the possible precedent that these regulations could set for HACCP programs beyond seafood. Some of these comments deferred comment on the legal basis for the HACCP regulations for seafood but commented on whether the legal basis that FDA was proposing for seafood would be appropriate for mandatory HACCP programs for other kinds of foods.

FDA is issuing these HACCP regulations for seafood under various sections of the Federal Food, Drug, and Cosmetic Act (the act), including, most significantly, sections 402 (a)(1) and (a)(4) and 701(a) (21 U.S.C. 342 (a)(1) and (a)(4) and 371(a)). Section 402(a)(1) of the act states that a food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health. Section 402(a)(4) of the act states that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972). The question is thus whether the conditions in a plant are such that it is reasonably possible that the food may be rendered injurious to health. The agency believes that, if a seafood processor does not incorporate certain basic controls into its procedures for preparing, packing, and holding food, it is reasonably possible that the food may be rendered injurious to health and, therefore, adulterated under the act. Section 701(a) of the act

authorizes the agency to adopt regulations for the efficient enforcement of the act.

2. General Authority

1. One comment stated that FDA had not met its responsibility to present the shortcomings in the existing law when demonstrating the need for these regulations.

FDA believes that this comment is misguided. The agency's statutory authority is not deficient in this area. FDA does have a responsibility, however, to demonstrate that there is a need for the regulations, and that the regulations are reasonably related to the purposes of the act that they are designed to advance. FDA has fulfilled this responsibility.

As outlined above, the act provides a broad statutory framework for Federal regulation to ensure human food will not be injurious to health and to prevent commerce in adulterated foods. As the record in this proceeding amply demonstrates, there is a range of circumstances and conditions that have raised concerns about how the safety of seafood sold in this country is ensured. Given these concerns and its responsibility under the act, FDA has concluded that it is necessary to require that firms incorporate certain basic measures into how they process seafood. The agency also concludes that failure to incorporate these measures into a firm's processing procedures would mean that the firm would be producing the product under insanitary conditions whereby it may be rendered injurious to health. (See *United States* v. *Nova Scotia Food Products Corp.,* 568 F.2d 240, 247 (2d Cir. 1977).)

2. A few comments took the view that FDA lacked the authority to issue these regulations because Congress had considered legislation relating to seafood safety in recent years but had not enacted it. Much of this legislation contained provisions authorizing the establishment of a mandatory Federal inspection program based on HACCP-type principles. According to the comments, Congress' failure to authorize this program after considering doing so indicated that the contents of FDA's seafood HACCP regulations remain within the domain of Congress and have not been delegated to FDA to implement.

FDA does not agree with this contention. Unquestionably, seafood safety has received considerable attention from Congress in recent years, most notably in the late 1980's through the early 1990's. Many hearings were held on the subject in both the House of Representatives and the Senate during this period, and several bills were introduced in both chambers. The high water mark for this activity occurred at the end of the 101st Congress when differing seafood safety bills passed both chambers. These bills could not be reconciled before the end of the term, however, so nothing was enacted. Legislation introduced in the 102d Congress did not pass either chamber.

The fact that Congress has considered the issue of seafood safety, however, does not preclude FDA from implementing a mandatory seafood HACCP program. The effect of legislation that was never enacted on a Federal agency's initiatives was considered in *National Confectioners Association* v. *Califano,* 569 F.2d 690, 693 n.9 (D.C. Cir. 1978), a case involving a challenge to FDA's statutory authority to issue good manufacturing practice regulations for candy making. The court rejected an argument that the existence of legislation that was not enacted that would have given FDA express authority to require some of the things that the agency included in its regulations indicated that Congress intended to exclude such authority from the act as it was then written. Instead, as will be discussed below, in upholding the validity of the regulations, the court looked at whether the statutory scheme as a whole justified the promulgation of the regulations.

It is true that a deliberate refusal by Congress to authorize a specific program would at least be one factor to be weighed in determining the validity of a regulation. See *Toilet Goods Association* v. *Gardner,* 387 U.S. 158 (1967). The expiration of the 101st Congress before competing seafood bills could be reconciled did not, however, amount to a refusal on the part of Congress to authorize a mandatory HACCP program, including HACCP-based inspections for seafood. Thus, FDA concludes that there is no merit to the comments' assertion.

3. Insanitary Conditions

3. Several comments, most of whom were trade associations or companies involved in the processing of products other than seafood, questioned whether section 402(a)(4) of the act was an appropriate authority upon which to base a mandatory HACCP program. Most of the concern hinged on whether a failure to have a HACCP plan, or to keep HACCP records, could really be considered an ''insanitary'' condition under section 402(a)(4) of the act. Some questioned whether safety issues relating to chemical or physical hazards, or to pesticides, unapproved additives, and drug residues, as included in the proposed regulations, could be deemed to have been the result of insanitary conditions. Two comments expressed the view that section 402(a)(4) of the act does not concern food safety generally but only safety problems caused by insanitary conditions.

The relevant case law supports a broad reading of ''insanitary.'' In *Nova Scotia, supra,* 568 F.2d at 247, the court read ''insanitary'' to cover a wide set of circumstances necessary to ensure that food was not produced under conditions that may render it injurious to health. Specifically, the court concluded that FDA's regulations mandating time-temperature-salinity requirements for smoked fish products were within the agency's statutory authority under section 402(a)(4) of the act. The court rejected the argument that ''insanitary'' limited coverage under section 402(a)(4) of the act only to bacterial hazards that could enter the raw fish from equipment in the processing environment and not to proper processing to kill bacteria that entered the processing facility in the raw fish itself.

Acceptance of a restrictive reading of section 402(a)(4) of the act, the court in *Nova Scotia* noted, would probably invalidate several existing FDA regulations, including those relating to the thermal processing of low-acid canned foods in part 113 (21 CFR part 113). When dealing with the public health, the court concluded, the statute should not be read too restrictively but consistent with the act's overall purpose to protect the public health. (See also *United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969); *United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943).)

4. Notwithstanding these cases, one comment cited the case of *United States* v. *General Foods Corp,* 446 F. Supp 740 (1978), *aff'd* 591 F.2d 1332 (2d Cir. 1978), for the proposition that a failure to have a HACCP plan could not alone be a violation of section 402(a)(4) of the act because it would not constitute insanitation.

FDA does not agree that the *General Foods* case stands for this proposition. Rather, the court in *General Foods* explicitly recognized that ''[b]ecause the purpose of 402(a)(4) is to prevent contamination, or nip it in the bud, actual contamination of the finished product need not be shown.'' *Id.* at 752. Significantly, the court appeared to be impressed with the preventive controls that were in place in the defendant's plant and took these into consideration in deciding that the agency had failed to prove that section 402(a)(4) of the act had been violated. However, the court did not deal at all with the limits on

FDA's authority to do rulemaking under sections 402(a)(4) and 701(a) of the act to establish standards for such preventive controls.

Thus, it is not inconsistent with *General Foods* for FDA to adopt HACCP regulations that are designed to define the minimum steps that a seafood processor must take to ensure that the food that it produces is not prepared under conditions that may render it injurious to health. Clearly, given the risks inherent in many seafood operations, if a processor does not identify the critical control points in its process, and does not monitor what goes on at those points, there is a reasonable possibility that the food that it produces will be injurious to health.

A primary objective of the seafood HACCP regulations is to establish a system of preventive controls for human food safety. The HACCP plan is a fundamental step in the development of these controls. It is the step in which the manufacturer analyzes its process, identifies the points at which problems may occur, and establishes the parameters that must be met if those problems are to be avoided. Thus, failure to have a HACCP plan would, in fact, constitute an ''insanitary condition'' as this term must be understood in light of the relevant case law.

Section 402(a)(4) was added to the act to ensure ''the observance of those precautions which consciousness of the obligation imposed upon producers of perishable food products should require in the preparation of food for consumption by human beings.'' Hearings before the Senate Committee on Commerce, S. 2800, 73d Cong., 2d Sess., Mar. 1934, as cited in *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc., supra,* 339 F. Supp. 140–141. Clearly, HACCP reflects the emerging, internationally recognized understanding of the precautions necessary to produce safe food. These regulations embrace HACCP and provide processors with directions for establishing HACCP systems and operating them as a matter of routine custom and habit that will ensure the safety of the food that they produce. Thus, FDA finds that operation under an effective HACCP system is necessary to meet a processor's obligation under section 402(a)(4) of the act.

4. Records

In *Confectioners,* the court upheld FDA's authority to issue regulations under section 402(a)(4) of the act that included recordkeeping requirements. The recordkeeping provisions of the regulations were challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but the records were deficient. Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the act.

Citing *Toilet Goods,* the court rejected this argument and held that the primary consideration was whether the statutory scheme as a whole, not just section 402(a)(4) of the act, justified the agency's regulations. The court pointed out that this consideration involved an inquiry into practicalities as well as statutory purpose, i.e., enforcement problems encountered by FDA and the need for various forms of supervision in order to accomplish the goals of the act.

5. Two comments expressed the view that the holding in *Confectioners* should be limited to the specific facts in that case. One comment stated that the case only upheld FDA's authority to impose recordkeeping requirements on firms to facilitate recalls of potentially dangerous products. The other comment noted that the case only granted FDA access to shipping records. The comment pointed out that FDA already has access to such records from carriers under section 703 of the act.

While it is true that the records that FDA was requiring, and to which the agency claimed access under the regulations involved in *Confectioners,* were source coding and distribution records in order to facilitate recalls, the court's ruling involved broad principles relating to the validity of the regulations generally and was not limited to recalls or shipping records. The court stated that in light of the statutory scheme as a whole, ''we find no basis for the Association's distinction between the FDA's role in preventing and remedying commerce in adulterated foods. The agency believes that the Act imposes on the FDA an equal duty to perform each role.'' *Id.* at 694. This statement simply is not consistent with the narrow reading suggested by the comment. Rather, it fully supports FDA's authority to adopt regulations to prevent the introduction of adulterated foods into interstate commerce. Clearly, compliance with FDA's seafood HACCP regulations will help to achieve that end.

It is also true, as one comment pointed out, that section 703 of the act expressly grants FDA access to shipping records and not to the kinds of processing records required in these regulations. FDA cannot agree, however, that *Confectioners* stands for the proposition that FDA should have access only to food manufacturers' shipping records because those are the only kinds of records to which FDA has access under section 703 of the act. The court concluded that the narrow scope of section 703 of the act is not a limitation on the right of the agency to require recordkeeping and have access to records that are outside the scope of section 703 of the act, so long as the recordkeeping requirement is limited, clearly assists the efficient enforcement of the act, and the burden of recordkeeping is not unreasonably onerous (569 F.2d at 693 n.9).

The recordkeeping required under these regulations passes the *Confectioners* test. First, the recordkeeping requirements are limited. The HACCP recordkeeping and record access requirements in the final rule are tied specifically to the critical control points (CCP's) in the manufacturing process. In other words, the recordkeeping requirements are limited to those points in the process at which control is essential if assurance that the resultant product will not be injurious to health is to be achieved.

Second, the recordkeeping assists in the efficient enforcement of the act. The recordkeeping requirements, by focusing on the CCP's, ensure that the processor and the agency focus on those aspects of processing that most jeopardize food safety. Unlike the current inspection system, recordkeeping in a HACCP-type system documents that preventive controls are being followed and enables the regulator to verify this fact. Such a system, therefore, assists in effective and efficient enforcement of the act.

Finally, the HACCP-recordkeeping burden is not unduly onerous. It is limited to those aspects of processing that are critical to food safety. Documentation that control is being maintained over these aspects of processing need only be a minor additional step in most instances. The documentation required in the final rule is narrowly tailored to ensure that only essential information needs to be recorded.

6. Several comments questioned whether FDA may have access to HACCP records and plans on the grounds that the act does not explicitly authorize such access. Some of these comments pointed to the lack of authorization in section 704 of the act (21 U.S.C. 74), the provision that authorizes the inspection of food processors and other types of establishments. The comments pointed out that section 704 of the act authorizes agency access to certain records relating to prescription drugs and medical devices during the course of those inspections but not to records relating to

foods. One comment felt that the specific grant of records access for drugs and devices in section 704 of the act precluded expansion of access to records not specifically mentioned in the act. Other comments felt that FDA was barred from access simply because the act does not expressly grant it.

FDA does not agree, as the agency's authority under sections 402 and 701(a) of the act to issue these regulations provides ample authority for records access. The line of cases cited above stands for the proposition that a lack of explicit delegated authority does not invalidate agency regulations so long as the regulations are consistent with the act's overriding purpose. In *Confectioners,* the court upheld FDA's authority to adopt recordkeeping requirements in the absence of an explicit delegation of authority. In that case, moreover, the court found no evidence that Congress intended to immunize food processors from limited recordkeeping (569 F.2d at 695). Similarly, the court in *Nova Scotia* concluded, in the absence of such evidence, that there was no impediment to a broad reading of the statute based on the general purpose of the Congress in protecting public health (568 F.2d at 248).

FDA has concluded, therefore, that these regulations are consistent with section 704 of the act and with the act as a whole. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied. The case law supports FDA's authority to require such recordkeeping and to have access to such records.

Other countries, including Canada, the European Union (EU) Norway, Australia, and New Zealand, which have already implemented HACCP-type systems, have deemed it necessary to the success of their systems to provide for recordkeeping and record access along the lines of this regulation (for either their entire seafood industries or seafood export industries). Thus, it is widely accepted that recordkeeping and inspectional access are essential components of a HACCP-type seafood system. In addition, in order to maintain other countries' faith in the safety standards of U.S. seafood exports, FDA needs similar access to records showing HACCP implementation.

7. One comment expressed the view that the copying of records by FDA, as authorized by these regulations, is beyond the scope of section 704 of the act.

FDA points out that it is not acting under section 704 of the act. To effectuate the broad purposes of the act, there may be some circumstances in which access to the records would be meaningless without the opportunity to copy them. While the agency does not anticipate that copying will be necessary in most instances, perhaps the most readily predictable circumstance in which copying would be necessary is when an investigator needs assistance from relevant experts in headquarters to evaluate the record. Without copying, it would be necessary for the agency to rely solely on the notations and report of the investigator.

This reliance may not be adequate in many circumstances. For example, there may be a deviation from a critical limit (CL) that poses no health risks. Without the ability to show a copy of the records to someone within the agency with the necessary expertise in the area, an investigator would have to cite the company for a violation. If, however, an agency expert determined that the deviation posed no safety risks, the agency could use its enforcement discretion not to pursue a violation.

8. One comment expressed the view that the act does not support a mandatory HACCP program that includes access to records for the entire seafood industry. According to the comment, the act permits FDA access to records only under extreme conditions where there is a potential for injury, but, the comment noted, hazards are only associated with a small percentage of fish.

FDA cannot agree. While it is true that those seafood-related illnesses that are reported to public health authorities tend to be associated with a limited number of species, potential hazards are much broader. As indicated above, the 1991 NAS report on seafood safety provides an extensive inventory of hazards.

For the benefit of the commentor it is worth noting that if a processor is involved with species and processes for which there are no food safety hazards that are reasonably likely to occur, a HACCP plan will not be necessary under these regulations. As will be discussed later in this preamble, the agency anticipates a post-implementation dialog with firms on whether they have hazards that must be controlled in accordance with these regulations and, if so, how many.

9. One comment expressed the view that the authority to inspect ordinary food records has not been asserted before. This statement was made in support of the contention that there is no statutory basis for FDA access to ordinary food records.

The legal basis for FDA's access to records has already been fully addressed in this preamble. It is important to note that the agency is not claiming a right of access to food records coextensive with that for drugs and devices under section 704 of the act. Rather, FDA is asserting a right to access to records that is narrowly tailored to advance the purposes of the sections of the act that it is implementing here, i.e., records relating to the CCP's in a firm's process.

While the agency is not sure what the comment meant by ''ordinary'' food records, it is worth pointing out that the position in this regulation on agency access to records is a longstanding interpretation for regulations of this type. Agency access to processing and production records has been required since the early 1970's in FDA's regulations for thermally processed low-acid foods packaged in hermetically sealed containers (part 113) and for acidified foods part 114 (21 CFR 114). As discussed in the new section, these regulations were issued primarily under the authority of both sections 402(a)(4) and 404 of the act (21 U.S.C. 344), neither of which specifically mention access to records.

5. Relevance of Section 404 of the Act

10. Several comments expressed the view that FDA should base HACCP regulations on section 404 of the act rather than on section 402(a)(4) of the act. Some of these comments were referring to these seafood HACCP regulations, while others were primarily concerned with any HACCP regulations that FDA might issue for other foods. Other comments expressed the view that FDA's existing low-acid canned food regulations should serve as a model for new HACCP programs. Because some of the low-acid canned food regulations have been issued under section 404 of the act, all of these comments may have been making the same general point.

Most of those that advocated use of section 404 of the act as the legal basis expressed concerns about the appropriateness of relying on section 402(a)(4) of the act and the narrow grants of access to records in the act, especially in section 704 of the act, and concluded that the act only grants the agency access to records under extreme situations. One comment urged that FDA issue the seafood HACCP regulations under the authority of section 404 of the act in order to enhance the agency's ability to achieve compliance through the permit system.

Section 404 of the act is entitled ''Emergency Permit Control.'' It authorizes FDA to establish a permit system for processors of food that may be injurious to health when two conditions are met: (1) Contamination is with microorganisms, and (2) the injurious nature of the product cannot be adequately determined after the product enters interstate commerce. Section 404 of the act authorizes FDA to inspect firms that operate under this permit system but does not mention records or FDA access to records.

As indicated previously, FDA has issued regulations under this authority. Regulations at part 108 (21 CFR part 108) subpart A establish the permit system generally. Regulations at part 108 subpart B establish that acidified foods and thermally processed low-acid foods in hermetically sealed containers (i.e., low-acid canned foods, or ''LACF'') meet the criteria in section 404 of the act and are therefore subject to the permit system. Subpart B requires processors of these foods to register with FDA and to submit detailed information to FDA on their manufacturing processes.

As an adjunct to these regulations, FDA has also issued the regulations, referred to previously, at part 113 and part 114 for these products. These latter regulations require the maintenance of day-to-day processing records that are retained by the processor and are in addition to the processing information that must be sent to FDA. FDA investigators have access to, and may copy, these records (§§ 108.25(g) and 108.35(h)).

While the permit system may have some compliance advantages, as pointed out by one comment, there are other considerations in this case that are more important. The permit system is, as the title of section 404 of the act declares, an ''emergency'' system. Because it is an extreme remedy for extreme situations, FDA has used section 404 of the act relatively sparingly.

In the case of seafood, although FDA strongly believes that a HACCP system will correct deficiencies in the current system and provide significant further assurance of safety, the agency cannot conclude that seafood is in an overall state of emergency from a public health standpoint. This conclusion is consistent with the position taken by the NAS. The NAS' Institute of Medicine, in its 1991 report entitled ''Seafood Safety,'' devoted hundreds of pages to areas of risk and made numerous recommendations about control measures, including the application of HACCP where appropriate. However, the NAS also concluded that most seafood in the U.S. marketplace is unlikely to cause illness.

FDA believes that, for seafood at least, HACCP should be the norm rather than an exceptional remedy for an extreme situation. A functioning HACCP system reflects an understanding of the wide range of hazards to which seafood may always be subject and provides for a systematic application of the preventive controls necessary to minimize the occurrence of those hazards. It is the most effective and efficient way known of ensuring food safety as a matter of design. In this regard, FDA has concluded that, for seafood, the efficient enforcement of the act should not have to depend on a finding of an emergency under section 404 of the act.

It is also worth noting that section 404 of the act would limit the application of HACCP to hazards by reason of contamination from microorganisms. FDA is not aware of any HACCP expert or authoritative body, including the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), which advocates limiting HACCP to these hazards only. A full discussion of hazards to which seafood HACCP should apply appears later in this preamble.

FDA does not agree that section 404 of the act is the only basis for these seafood HACCP regulations, or that it would be a more appropriate basis. It is not clear, moreover, how section 404 of the act can be cited as supporting the proposition that the agency only has access to records in extreme situations. As indicated earlier, section 404 of the act contains no express grant of access to records. Again, FDA has concluded from the case law that, under appropriate circumstances, the agency has access to specific types of records on foods and food processing for specific purposes, where such access is not expressly provided for in the act, but the agency cannot conclude that this right is limited to extreme situations. Some of the comments provided examples of extreme situations to which HACCP regulations should be limited from their standpoint. These examples raise important issues that will be addressed elsewhere in this preamble.

11. Two comments expressed the view that the LACF regulations should serve as a model for the types of records that would be accessible under HACCP regulations.

FDA did in fact use the LACF regulations as a model in that regard. The HACCP plan required here is similar to the scheduled processes that processors must submit in the LACF regulations. Likewise, there is little difference between the HACCP-monitoring records required here and the day-to-day processing records that are required in LACF regulations.

*B. HACCP Pro and Con*

1. Overview

Nearly half of the comments included specific statements of support or opposition for the concept of a mandatory HACCP program to ensure the safety of seafood. The supporters outnumbered the opponents by over 10 to 1.

Nearly all of those who supported the approach also had technical comments on various provisions in the proposal. Some conditioned their support on the availability of additional enforcement authorities or resources for FDA. These aspects of their comments will be responded to elsewhere in this preamble. A small number of these comments supported the concept of a mandatory HACCP program for seafood but opposed the proposal as drafted.

The supporters of the concept included most of the seafood trade associations that commented, businesses, consumer advocacy organizations, Federal and State agencies, professional societies, academics, and a member of Congress. The reasons for this support included: Enhancement of consumer confidence, the superiority of HACCP-type preventive controls over traditional CGMP-type controls and end-product sampling, the view that HACCP is the most efficient and effective way to ensure safety, and the view that a mandatory HACCP system reflects an appropriate assigning of primary responsibility to industry for producing safe food. Other reasons included a leveling of the competitive playing field, both domestically and internationally; the need for prompt adoption of a mandatory HACCP program by FDA to enable the seafood industry to maintain its market position in Europe and elsewhere throughout the world; greater productivity; and increased industry control over processing.

One large seafood trade association stated:

> [The association] strongly supports the adoption of a comprehensive regulatory program by the FDA which is designed for fish and seafood using HACCP principles. HACCP systems have been applied successfully by individual firms in our industry, and they have been shown to be a very cost-effective way of controlling safety hazards. Of equal importance, the adoption of a HACCP-based regulatory program should lead to more effective and efficient use of FDA resources, and less disruption of the processing and importing of seafood for consumers.

A small number of comments expressed opposition to the mandatory HACCP approach for seafood, however. One State comment expressed the view that HACCP would not have any significant effect on reducing illnesses from molluscan shellfish. Another comment stated that, overall, seafood-related illness data do not justify mandatory HACCP for seafood. (Several other comments questioned the need for these regulations in light of the NAS' conclusion that commercial seafood is generally safe. These comments either generally opposed the proposed regulations as drafted, or opposed its application to the comments' segments of the seafood industry, but did not express opposition to mandatory HACCP as a concept.) None of these comments supplied any new seafood-related illness data.

2. The Significance of the Illness Data

The preamble to the proposed regulations described broadly what is known and not known about the extent of seafood-related illness in the United States. Foodborne illnesses tend to be significantly underreported to public health authorities. Consequently, precise data on the numbers and causes of foodborne illness in this country do not exist. FDA does know, however, that illness from seafood does occur, and that a wide variety of hazards have been identified that could cause illness from seafood (see Ref. 7, pp. 1–13). The overwhelming majority of these hazards are amenable to preventive controls. FDA's draft Guide addresses controls for over 20 specific types of safety hazards.

The primary purpose of these regulations is to ensure that preventive controls are systematically applied in seafood processing as a matter of routine custom and usage, and in a way that can be verified by company management as well as by regulatory authorities. Thus, while the reported illness data are highly relevant to whether these regulations should be issued, they are not the sole basis for the regulations.

For molluscan shellfish in particular, FDA agrees with the commenters who believe that the principles of the National Shellfish Sanitation Program (NSSP) should continue to form the basis for the molluscan shellfish safety program in this country. There is no clear alternative to proper water classification and patrol by State authorities as the basis for molluscan shellfish safety. HACCP provides processors with an excellent system for ensuring that these preventive-type controls are adhered to in a systematic way.

It may be argued—and some comments made the point—that the best way to reduce the overall number of illnesses from raw molluscan shellfish is to provide additional resources to the States to enhance their water classification and monitoring abilities. Classifying and patrolling shellfish harvesting waters are important means of preventing molluscan shellfish that have been contaminated from sewage from entering the marketplace. However, additional Federal resources will probably not be available for this purpose in the foreseeable future. It is imperative, therefore, that the system that is in place be made as efficient as possible.

It would be incongruous to exempt from a national system of preventive controls the processors of products identified by the NAS as the source of the greatest numbers of seafood-associated illnesses. FDA strongly believes that HACCP controls will help shellfish processors and regulators alike to better focus on potential safety problems and less on tangential matters than historically has been the case. A full discussion of the application of HACCP to raw molluscan shellfish appears later in this preamble.

3. Exempt Specific Industry Segments?

12. Comments stating that HACCP systems should not be mandated for specific industry segments usually referred to either the crab processing or the catfish industries. These comments generally expressed the view that HACCP requirements for these industries were not necessary.

FDA advises that these regulations are flexible enough so that HACCP-type controls are not required where they are not necessary, i.e., where it is reasonably likely that hazards do not exist. It is the agency's experience, however, that there are reasonably likely hazards associated with crabmeat as a cooked, ready-to-eat product, including the growth of pathogens as a result of time-temperature abuse of the product and the potential for pathogen survival from inadequate pasteurization. There are reasonably likely hazards associated with the processing of catfish (e.g., contamination from agricultural chemicals, improperly used aquaculture drugs, and a variety of hazards resulting from the in-plant processing operations). It is incumbent on processors of these products to know and control such hazards.

The agency recognizes that whether reasonably likely hazards exist involves case-by-case determinations. As will be discussed in the ''HACCP plan'' section of this preamble, processors will be given every opportunity to demonstrate why no hazards exist in their operations.

4. Would Voluntary HACCP Be Superior?

13. Some comments believed that a voluntary approach to HACCP for seafood would be preferable to a mandatory approach. One reason given for this view was that, under a mandatory system, the risk of regulatory action by FDA would compel processors to design HACCP controls that were the minimum necessary to comply with the rule. There would be a significant disincentive for processors to design HACCP plans that have the greatest practical impact on food safety out of fear that occasional failure to meet those higher standards would trigger a regulatory response.

If voluntary HACCP systems were already universal, or nearly so in the seafood industry, and they generally applied safety controls that were beyond the minimum needed for safety, FDA would see little reason to establish a mandatory system. However, HACCP is not the norm, and given the current situation in the seafood industry, FDA finds that making HACCP mandatory is necessary to ensure that safe, wholesome, and unadulterated product is produced. Thus, FDA is adopting part 123 (21 CFR part 123).

The agency acknowledges the possibility that, under a mandatory system, firms will perceive that they are on safer ground with FDA if they establish minimum acceptable controls that are more easily met, rather than more stringent controls that are beyond the minimum necessary to ensure safety and, therefore, are harder to meet. For example, in deciding what CCP's to identify in a HACCP plan, a processor might err on the side of inclusion under a voluntary plan but keep the number of CCP's down to the minimum acceptable to FDA if having a plan is mandatory.

It remains to be seen whether processors will really choose to behave this way under a mandatory system. The choices that processors will make may depend, in part, on FDA policy toward HACCP plans that are beyond the minimum. The logic in favor of the agency initiating regulatory action when a processor fails to meet its own CL but succeeds in meeting a minimum level that would have been an acceptable CL to FDA, would be that the firm is out of control vis a vis its own preventive process. The logic against initiating regulatory action would be that the processor is still in control in terms of meeting minimum necessary safety parameters, and that the product is, in

FDA's opinion, safe to eat. As an additional factor, FDA does not want to discourage firms from establishing preventive controls for themselves that are beyond the minimum necessary to ensure safety.

In evaluating monitoring records, FDA will first determine whether the recorded values are within the processor's critical limits as set out in its HACCP plan. Where values are found that are outside the CL's, the agency will determine the cause and extent of such occurrences, and what corrective action, if any, the processor has taken. Where product that was involved in a CL deviation was distributed without first being subjected to appropriate corrective action, FDA will determine the cause and extent of the control failure.

In determining the appropriate agency regulatory response to CL deviations, FDA will assess the public health risk that the product poses. This assessment will, in part, involve a determination of whether the minimum limit necessary to ensure safety was breached. FDA acknowledges that this level and the processor's CL may not always be the same. The agency is not likely to take action against a product that it finds poses no significant public health risk, regardless of whether it has or has not met the processor's CL.

Nonetheless, processors must establish controls to ensure that appropriate corrective actions are taken when their CL's are breached. Where such controls fail, FDA expects processors to redesign their control mechanisms as necessary. Chronic failure to appropriately respond to CL deviations demonstrates that a processor's HACCP system is inadequate, and that fact could cause FDA to have some regulatory concern.

14. Another comment urged that HACCP for seafood should be voluntary on the grounds that FDA lacks the resources and statutory enforcement authorities to operate a mandatory system. Other comments expressed the same types of concerns about FDA resources and enforcement authorities without concluding that a voluntary system would be preferable. One comment, from a consumer advocacy organization representing several other organizations, supported the concept of a mandatory HACCP system but expressed reservations about FDA's ability to adequately perform HACCP-based inspections of processors without additional resources. Other commenters expressed the same kinds of concerns. The comment pointed out that because HACCP inspections will take longer than current inspections, the intervals between inspections will increase significantly, creating ''an unenforced industry honor system.'' The commenter, and some others, also advocated additional enforcement authorities.

The success of this program will depend on a number of factors. One of these factors, unquestionably, will be the ability of a regulatory authority, or authorities, to adequately monitor processors' HACCP systems through inspections. If the frequency of inspections is too low, safety may not be ensured, consumer confidence may be eroded, and the accusation that the program is self-regulatory may have merit, even though a HACCP-based inspection allows the investigator to view a firm's critical operations over time, not just at the moment of the inspection.

The use of a HACCP-based system bears on the adequacy of FDA's inspection resources in two important respects. The first is the effect of the use of HACCP-based inspections on inspection frequencies. The time needed to conduct a HACCP-based inspection will undoubtedly vary depending on the number of hazards, complexity of the operation, and other factors. The first round of HACCP inspections will likely take longer—possibly as much as twice as long in high-risk and complex operations—as the CGMP-based inspections FDA presently conducts, but the time-per-inspection is likely to drop significantly thereafter. It remains to be seen whether inspection times will eventually shorten to current times, or whether HACCP-based inspections will always take longer on average. In any event, FDA finds some merit in the comments' basic concerns about inspection frequencies.

Second, as a countervailing matter, a HACCP-based inspection can be a more efficient and effective inspection than a CGMP-based inspection, largely because it can be highly focused on matters that are critical to safety, and because access to key safety monitoring records allows the investigator to evaluate the process over time. Thus, some compensation for increased intervals between inspections will be provided by the fact that the investigator gets not merely a snapshot of the operation of the plant in time but a broad view of how the plant has been operated over the preceding months or even years, as reflected in the plant's records. Thus, FDA concludes that, on balance, the somewhat longer inspection intervals that might occur under a HACCP-based system would be fully compensated for by the broader view provided by a HACCP-based inspection.

In addition, FDA intends to increase the frequency and improve the consistency of processor inspections through HACCP-based work sharing partnerships with the States. One of the agency's goals is for these regulations to serve as a basis for partnerships that involves a pooling of resources.

While FDA acknowledges the comments' concerns about resources, the agency would not agree that the HACCP program should be abandoned because of resource constraints. Quite the contrary, resource constraints make it imperative that FDA seafood inspections be based on the most effective and efficient system devised to date. HACCP is that system. Moreover, the agency believes that there is enough flexibility in a HACCP-based inspection system to permit gradations in implementation (e.g., focusing on the most extreme hazards; selectively reviewing records) to accommodate whatever resource situation exists at any given moment.

With regard to enforcement authorities, as made clear above, the act provides ample authority for the establishment and implementation of a HACCP-based system by FDA. Regardless of whether additional authorities might be desirable, there simply is no reason for FDA not to proceed to establish and implement a HACCP-based system forthwith.

15. Another comment expressed opposition to mandatory HACCP for the seafood industry on the grounds that HACCP diverts the responsibility for ensuring a safe product from the government to the fish processors.

FDA's intent is not to transfer its legitimate responsibilities with regard to food safety to the regulated industry. In point of fact, the industry already has responsibility under the law to produce a safe product. HACCP helps to clarify, however, how responsibility for human food safety is divided between industry and the regulator.

Industry, as stated above, must take primary responsibility for the production of safe food, while the regulator must be responsible for setting standards (including program regulations such as these), verifying that the industry is doing its job, and taking remedial action when it is not. HACCP requires that the industry be aware of the human food safety hazards that are reasonably likely to occur, and that industry operate under a system that is designed to ensure that those hazards are not realized. Thus, HACCP enables the industry to demonstrate that it is meeting its legitimate responsibilities.

5. Other Issues

16. One comment supported the concept of HACCP but expressed the view that the regulation drafting process should be started over by forming a committee consisting of representatives from various segments of the seafood industry, and appropriate government and university personnel. A few other comments expressed the view that FDA had acted too quickly in issuing the proposed regulations and also requested that FDA start over by engaging in discussions with industry, foreign regulatory agencies, academia, and consumers. These latter comments, which were mostly from companies not primarily involved in the processing of seafood, preferred a voluntary approach to HACCP, with mandatory applications only in exceptional situations. FDA did not act too quickly, or without appropriate consultation, in issuing the proposal in this proceeding. As the preamble to the proposed rule documented at some length, the proposal was the culmination of an extensive process by FDA and others, including the seafood industry itself, that led major representatives of that industry to request the issuance of the proposal. Before that, industry trade associations testified repeatedly before Congress in the late 1980's through the early 1990's in support of legislation that would have required a mandatory inspection system for seafood based on HACCP principles.

FDA participated in pilot programs in the past such as the seafood HACCP pilot conducted jointly by FDA and the National Marine Fisheries Service (NMFS) of the Department of Commerce (DOC) in 1990 to 1991. In addition, FDA ran programs with seven other countries. In developing these regulations, the agency also took advantage of information from the Model Seafood Surveillance Project (MSSP). The MSSP was conducted by the DOC at the request of Congress in 1986 to design an inspection system for seafood consistent with HACCP principles. As part of the MSSP project, 49 workshops were conducted involving 1,200 industry, State, and university participants. Canada currently has a HACCP system, and the EU has issued directives that move in that direction. The agency has concluded that sufficient field trials have already taken place to conclude that HACCP is a viable method of hazard control for the seafood industry.

Public input into the development of the HACCP approach contained in these regulations has been substantial. As described earlier in this preamble, FDA engaged in a series of ''town meetings'' in nine cities across the country shortly after the proposal was published in order to answer questions about the proposed regulations and encourage comments. The public response to FDA's proposal contributed substantially to the contents of the final regulations.

C. *Should Some Types of Processors Be Exempt?*

In the preamble to the proposed regulations FDA asked for comment on whether either processors of ''low-risk'' products or small processors, or both, should be exempted from the requirements of the final regulations. The agency asked for information on whether the regulatory burden could be reduced without compromising the public health protection goals of the regulations, and whether there exists a rational way to distinguish ''high risk'' from ''low risk,'' and big processors from little processors, for purposes of HACCP.

1. Exempt Low Risk?

The most obvious way of distinguishing high-risk products from low-risk products would be on the basis of reported, confirmed, seafood-related illnesses. The preamble to the proposed regulations pointed out some problems with this approach. First, the agency pointed out that the underreporting and skewed reporting that occurs with respect to foodborne illness creates significant concern as to whether reported illnesses represent a reliable enough factor to serve as the basis for an exemption to these regulations. Second, FDA stated that it was concerned that there could be a significant potential for harm that could be controlled by HACCP but that would not have shown up in the data that is relied on to establish risk. For example, while there may be no reported cases of botulism associated with some products that have the potential for *Clostridium botulinum* toxin, the severity of the consequences of the hazard warrant preventive controls. Likewise, while there may be no reported cases of domoic acid intoxication associated with shellfish from a particular area, preventive controls are warranted as soon as a such a case is made public. Thus, the preamble asked whether potential for harm might be a reasonable way to distinguish high-risk from low-risk products for purposes of an exemption. FDA was interested in whether comments could provide usable criteria for such an exemption.

About 45 comments addressed the question of whether the regulations should apply to high-risk products only. Roughly two-thirds of these comments preferred a high-risk approach. For the most part, they either did not define ''high risk,'' or defined it as including essentially the top three reported seafood- related illnesses (virus-related from raw molluscan shellfish, scombrotoxin, and ciguatoxin). For the most part, other hazards were assumed to represent a low risk.

17. One comment recommended that the regulations initially cover the hazards reported at the highest levels of to the Centers for Disease Control and Prevention (CDC) because these hazards are at least known to be causing illness, and that the agency should phase in other hazards as appropriate if the foodborne-illness reporting system were to reveal a need to do so.

Few comments were received on whether there could be a basis for distinguishing high risk from low risk other than reported illnesses. Some comments suggested that the agency should consider severity of illness as a criterion. Some of these comments specifically cited smoked and smoke-flavored fish as products that should be covered on this basis because of the devastating effects of botulism. A few comments expressed the view that mandatory HACCP should be limited to hazards that can cause loss of life or irreversible injury.

Several comments objected to a ''low risk'' exemption in any form. Some pointed out that, given the underreporting and skewed reporting that exists, the CDC foodborne-illness reporting system does not provide a suitable basis for making determinations of comparative risk (i.e., high risk versus low risk). These comments expressed concern that linking the requirements of these regulations to illness reporting that has already occurred would have the effect of exempting emerging hazards, at least until they caused reported illness.

Other comments stated that there is no significant advantage to exempting low-risk products because processors of these products will have simpler HACCP plans than those who process products with more potential safety hazards. One comment stated that a high risk-only approach made some sense but, as a practical matter, would negate the added assurance to consumers from HACCP that seafood is safe and processed under some form of regulation. According to this comment, from a large seafood trade association, it is more important that the entire food category be recognized as having been subjected to modern safety assurance

procedures than that the regulations exempt the low risk end of the industry.

FDA has considered these points of view and has concluded that, at least for now, there is no reasonable way to divide seafood products into high risk and low risk for purposes of these regulations. The comments that suggested defining ''high risk'' in terms of the most frequently reported illnesses are correct that the volume of reporting tends to concentrate substantially in the three hazard areas mentioned above. Because illnesses that are confirmed and reported tend to be those that are the most easily traced or diagnosed, however, the relative significance of the high level of reporting in these three areas—as well as the drop-off in reporting in other areas—is not fully known. Moreover, illnesses associated with chronic hazards are virtually unreported because of the difficulties in associating such illnesses to specific food sources.

The comments did not include any new data that would reveal whether the risks associated with the most reported illnesses are actually the highest risks or only the most apparent. No new information was provided to allow FDA to determine whether distinguishing high risk from low risk on the basis of reported illnesses would constitute a rational division for purposes of these regulations. Nor has FDA been supplied with information that would allow it to conclude whether other valid criteria exist.

FDA agrees with the comments that pointed out that the requirements of HACCP are less when risks are low. Moreover, as will be discussed later in this preamble, FDA has revised the final regulations to provide that HACCP plans are not required when there are no reasonably likely safety hazards to control. Thus, HACCP inherently tends to distinguish between high- and low-risk products without the need for explicit exemptions.

FDA also agrees that broad exemptions would put at risk some of the principal objectives of these regulations. Explicit exemptions make the system less flexible and might not cover emerging situations for which preventive controls are necessary to keep illnesses from occurring in the first place. A system that includes such exemptions would likely not provide as much consumer confidence as would a complete HACCP system. In addition, FDA notes that the benefits to the industry in international trade from adopting a HACCP system might be minimized if such exemptions were adopted because the United States' international trading partners are opting for complete systems.

2. Exempt Small Processors?

18. Over 60 comments addressed the question of whether the regulations should exempt small businesses. About five out of six of these comments opposed an exemption.

Those that supported an exemption for small businesses expressed concern about the effect of the general costs of implementation, particularly the costs of training and recordkeeping. One comment observed that many small businesses are economically-strapped, old, family enterprises that support an often fragile local economy. Another comment expressed the view that small businesses should be exempt because they are not involved in international trade. One comment noted that the highest volume producers (i.e., large businesses) are where a mistake affects the most consumers.

One comment recommended that FDA develop exemption procedures to relieve small companies of paperwork and training requirements, especially if they produce low-risk products. A few comments suggested that small businesses, or at least small businesses with good records, be exempt from ''positive'' recordkeeping, i.e., recording the results of each monitoring. Under this kind of exemption, small businesses would only record unusual occurrences and corrective actions.

The majority of comments that argued against exempting small businesses provided a number of reasons. One comment pointed out that as much as half of seafood consumed in the United States is from small firms. Several comments stated that size is not related to risk. Small firms are the major producers of many high-risk products (e.g. cooked, ready-to-eat and raw molluscan shellfish). Thus, according to the comment, the final regulations would represent a futile exercise if small firms were not included. One comment observed that small companies sometimes represent more of a risk potential than large companies due to lack of enough trained quality control personnel. Other comments pointed out that small businesses with simple operations would have simple plans and a minimum of recordkeeping.

One comment pointed to difficulties that FDA would have in administering exemptions to the regulations, particularly in distinguishing between firms that were and were not entitled to an exemption. Another concern expressed by comments was the potential unfairness of exempting some companies while requiring HACCP of others.

One State that has implemented mandatory HACCP for seafood processors observed that HACCP requirements had not proven to be an excessive burden to small businesses in that State.

Some comments that supported including small businesses in the coverage of the HACCP requirement recommended, nonetheless, that FDA should provide assistance to small businesses through guidelines, model plans, and technical and financial assistance. Some comments acknowledged that small firms can work through trade groups on common plans and training.

Other comments felt that dropping small firms from the final regulations would adversely affect consumer confidence. One comment expressed fear that the international standing of FDA's seafood safety program would be in jeopardy if the regulations were to exempt some firms.

FDA does not know how to exempt small business without jeopardizing the public health objectives of the regulations. An exemption for small processors of ''low-risk'' products would run into the difficulties explained above in the discussion of whether these regulations should only apply to ''high-risk'' products. FDA agrees with the comments that, in the seafood industry, the size of the operation often does not coincide with the number or type of hazards that must be controlled in order to ensure a safe product (i.e., small size does not automatically mean minimal hazards). For example, cooked, ready-to-eat seafood processing, a relatively complex manufacturing operation, typically requiring a larger than average number of CCP's, is concentrated in the small business portion of the seafood industry. Additionally, the processing of raw molluscan shellfish, a product identified by NAS as being associated with a disproportionately large percentage of the seafood-borne illnesses, is most commonly performed by small firms. FDA also agrees that, because seafood businesses tend to be small, an exemption for small businesses could make HACCP the exception, rather than the rule, in this industry.

The concerns expressed in the comments about the possible adverse consequences of these regulations on small business, however, should not be taken lightly, and the agency has not done so. FDA has no desire to establish a mandatory regime that cannot be met by otherwise responsible companies,

small or otherwise, that are producing safe food. Indeed, these regulations are based on the premises that: (1) Preventive controls for safety should be within the reach of anyone who is producing seafood for commerce (i.e., preventive controls should not be prohibitively burdensome, either financially or conceptually); and (2) it is in the public interest that everyone who is producing seafood for commerce should practice preventive control for human food safety. The fundamental question that the issue of whether to exempt small business raises is whether these premises are valid.

Having fully considered the comments on this issue, FDA is not persuaded that awareness of likely food safety hazards would cause financial hardship to small businesses, or that having reasonable, practical controls for those hazards will cause undue harm. As will be discussed in the ''Records'' section of this preamble, the costs associated with the recordkeeping requirements of HACCP are really incidental to the cost of monitoring and need not place a significant burden on small businesses. For example, after checking the temperature of a refrigerator, the observer need only take an additional moment to document the result of the observation. The agency cannot emphasize too strongly that, in most instances, only very simple recordkeeping is needed to adequately serve the purposes of the system. The question from the agency's standpoint, therefore, is whether the actual monitoring of critical operations, at reasonable frequencies, would be prohibitively expensive to the small operator. FDA has not been provided with a basis for such a conclusion.

This leaves plan development and training as costs. The guidelines that FDA is making available on plan development should help substantially to keep development costs down. FDA is also aware that trade associations and others are interested in developing model plans that, when used in concert with the guidelines, should further reduce the resources that a firm will need for plan development. The creation of a HACCP plan does require some thought and effort by the processor to ensure that hazards and controls are understood and identified. Nonetheless, the guidelines and model plans will enable small processors to be able to apply the thought and effort necessary to create a HACCP plan with maximum efficiency and minimum cost.

FDA is requiring that all processors either employ at least one trained individual or contract for services from at least one trained individual, as needed. There are unavoidable costs associated with this requirement. It is imperative that these costs be affordable to small business and be no greater than necessary. As discussed at length in the ''Training'' section of this preamble, FDA has been extensively involved with a consortium called the ''Seafood HACCP Alliance'' (the Alliance) consisting of representatives from Federal and State agencies, industry, and academia, to create a uniform, core training program that will meet the requirements of these regulations and will cost very little. The agency is also aware of HACCP training that has been provided for years for members of industry by NMFS and others. As an additional matter, FDA is allowing job experience to serve as a form of training in order to avoid the unnecessary expense to a processor of having to pay for a HACCP course when at least one employee already has knowledge that is equivalent to that provided by the course.

These efforts should alleviate the concerns of those who believe that the training requirement will be too burdensome on small business. The agency will monitor the situation closely once this training gets underway. If costs turn out to be significantly higher than FDA anticipates, the agency will consider some modification to the requirement.

While the agency regrets that grant monies are not available to small businesses from FDA, the effort that the agency is investing in guidelines and training development is a form of subsidy that should keep costs down generally.

*D. Definitions*

1. General

In addition to relying on the definitions contained in the act and those in the umbrella good manufacturing practice regulations at part 110 (21 CFR 110), FDA proposed at § 123.3 (a) through (t) to define 20 terms that are essential to the interpretation of part 123. Approximately 100 comments addressed various aspects of the proposed definitions at § 123.3.

The majority of the comments on definitions were concerned with the meanings that FDA proposed for ''processor'' (§ 123.3(n)) and ''processing'' (§ 123.3(m)). These comments generally asked for clarification about the applicability of the definitions to a given commercial activity, or contended that the definitions should be amended to either include or exclude certain activities. Most of the other comments that addressed the definitions were primarily concerned with the meanings proposed for ''fish,'' fishery product,'' ''critical control point,'' ''cooked ready-to-eat,'' and ''importer.'' As a result of the comments as well as agency decisions to modify other provisions in part 123, FDA has deleted, revised, and added definitions to those proposed at § 123.3.

2. Cooked, Ready-To-Eat Fishery Product

19. The proposed regulations contained a definition for ''cooked, ready-to-eat fishery product'' at § 123.3(b). The term was used at proposed § 123.10(a) and in the appendices to the proposed regulations. The final regulations no longer contain this term, and the appendices are not being codified. For these reasons, FDA has eliminated the definition of ''cooked, ready-to-eat fishery product'' from the final regulations.

Nonetheless, a large number of comments expressed concerns about the definition as it was proposed. In general, the comments urged that certain products be excluded from the definition of ''cooked, ready-to-eat fishery products;'' those that are not fully cooked by the processor or that will be recooked by the consumer, and low-acid canned foods subject to the provisions of part 113.

FDA recognizes the significance of the use of the term. Because the agency has excluded use of the term in these final regulations, it will defer consideration of the comments until drafting of the Guide.

3. Critical Control Point (CCP)

FDA proposed at § 123.3(c) to define a critical control point as ''a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final food.'' The word ''hazard'' in this definition was intended to refer primarily to food safety hazards. It could also have applied to quality and economic hazards, however, because the agency was proposing at § 123.6(c) to encourage processors to apply HACCP to these hazards as well.

20. A significant number of comments urged the agency to modify the definition so that it clearly addresses only food safety. These comments recommended that the word ''hazard'' should be prefaced with either ''food safety'' or ''health,'' or that FDA should codify the definition for ''hazard'' that has been recommended by the NACMCF.

Several of the comments urged FDA to adopt the NACMCF definition for

''critical control point'' so that the agency's regulations would be consistent with nationally and internationally agreed upon HACCP definitions. One objected to the phrases: ''high probability,'' because of its connotation in statistical applications; ''improper control,'' because of a lack of a standard for proper control; and ''cause, allow, or contribute,'' because it could allow the elevation of trivial concerns to critical control point status.

FDA is persuaded by those comments that urged consistency with the NACMCF definition for ''critical control point.'' The agency has, therefore, modified proposed § 123.3(c) (redesignated as § 123.3(b)) to read, ''*Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.'' The modified language is consistent with the agency's decision to limit the HACCP provisions of part 123 to the avoidance of food safety hazards (see the ''HACCP Plan'' section of this preamble for discussion). It is also compatible with modifications described elsewhere in this preamble aimed at greater consistency with the NACMCF recommendations. The wording change will not have any practical impact on the requirements of the regulations because the definition still reflects the agency's intent to require that seafood be processed in a way that eliminates, to the extent possible, the chance that it will be rendered injurious to health by procedures that are under the control of the processor.

The NACMCF definition does not contain the phrases that were objected to by one of the comments as described above. Thus, the concerns raised by this comment have been resolved.

21. A few comments, however, stated that the definition should also apply to the control of all decomposition because it is a major problem associated with seafood.

FDA acknowledges that, because of the highly perishable nature of fish, decomposition is probably the most common problem associated with seafood. The agency further acknowledges the comments that expressed concern that failure to control this problem will continue to adversely affect consumer confidence. The industry especially should heed this concern and consider the application of HACCP principles to decomposition, if necessary, to help maintain the quality of its products.

Nonetheless, decomposition that is not associated with safety is not appropriately a part of these mandatory HACCP regulations but should remain subject to traditional good manufacturing practices controls (see, e.g., § 110.80(b) (21 CFR 110.80(b))). As discussed earlier, these regulations are being issued, in part, under section 402(a)(4) of the act. That section provides that a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. While decomposition in some species can be injurious to health and is therefore within the scope of section 402(a)(4) of the act, most decomposition affects the quality of seafood but not its safety. Decomposition that affects quality but not safety is subject to section 402(a)(3) of the act. Therefore, FDA is not subjecting decomposition that is not safety related to the requirements of these final regulations but will continue to regulate decomposition under traditional CGMP control.

FDA points out that it has defined ''food safety hazard,'' a term that the agency uses in the definition of ''critical control point,'' in § 123.3(f). The agency discusses this definition, which is consistent with the NACMCF recommended definition, later in this section.

4. Critical Limit (CL)

FDA proposed in § 123.3(d) to define a ''critical limit'' as ''the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard.'' In the preamble to the proposed regulations, the agency explained that the proposed definition was intended to be consistent with the concept of the NACMCF recommended definition, which reads, ''a criterion that must be met for each preventive measure associated with a critical control point.'' However, the proposed definition was also intended to be more explanatory than is the NACMCF definition, especially as it relates to the assignment of a minimum or maximum value and in the relationship of these values to a minimization of the risk, rather than to an absolute elimination of risk.

22. Several comments stated that the proposed definition of a ''critical limit'' should be modified to be the definition recommended by the NACMCF. The comments asserted that the NACMCF definition is the internationally accepted standard, and that its use in the regulations would avoid confusion. A few comments argued that FDA's use of the phrase ''minimize the risk'' implies that the CL must be set to attain the lowest possible risk, unlike the ''reduce to an acceptable level'' standard in the NACMCF definition for CCP.

Although FDA agrees that the definitions in these regulations should closely adhere to the NACMCF's recommended definitions, the agency concludes that, in this instance, FDA's wording is more descriptive for regulatory purposes and more useful to processors. However, FDA has been persuaded that the phrase ''minimize the risk'' may be misinterpreted as requiring outcomes that are not realistically achievable by a processor. To provide clarification and consistency with the revised definition of ''critical control point,'' FDA has replaced the phrase ''minimize the risk'' with the phrase ''prevent, eliminate, or reduce to an acceptable level'' in the final regulation (now codified as § 123.3(c)). As noted previously, this language also appears in the NACMCF definition of ''critical control point.'' The new language correctly provides for the making of scientific judgments about appropriate degrees of hazard reduction, based on the nature of the hazard and the availability of controls, and is more consistent than the proposed language with accepted HACCP convention.

23. One comment stated that the word ''identified'' should be deleted from the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. The ''identified hazard'' refers to the hazard identified in the HACCP plan.

24. One comment stated that the phrase ''in the end product'' should be added following the word ''hazard'' in the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. Food safety hazards are, by definition, those that cause ''a food to be unsafe for human consumption.'' This definition implies a consideration of the end product that will be offered for human consumption.

25. One comment objected to the phrase ''the maximum or minimum value'' in the definition, stating that, as in the case of certain food additives, there are situations where both a maximum and a minimum value exist, and a processor is required to maintain the process between these values.

FDA is not persuaded to make any changes to the proposed language in response to this comment. The word ''or,'' which the agency uses in the definition, is inclusive. Thus, properly read, § 123.3(c) states that a CL is the maximum value, the minimum value, or both the maximum and minimum

values within which the parameter must be controlled to protect against the occurrence of a food safety hazard.

For consistency with the definition of ''critical control point,'' FDA has added the phrase ''food safety'' before the word ''hazard'' in the text of § 123.3(c). The language in the final regulation now reads, ''*Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.''

5. Fish

26. FDA proposed to define ''fish'' as ''fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life other than birds or mammals.'' A significant number of comments suggested that FDA should modify this definition to clarify whether it includes species such as sea snails, abalone, frogs, alligators, turtles, other reptiles, amphibians, sea cucumbers, plants, or algae.

FDA agrees that this type of clarification would be helpful and has modified the definition at § 123.3(d) to read:

*Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

The term ''mollusks'' includes abalone, sea snails, and land snails (e.g., escargot and any other terrestrial gastropods, such as the giant African land snail (*Achatina fulica*)). The addition of examples of aquatic animal life and the mention of mollusks are intended to make clear which species are covered by the term ''fish.'' Water-dwelling reptiles and amphibians other than alligators, turtles, and frogs have not been specifically listed because they are not significant commercial food sources in the United States. Finally, FDA notes that, consistent with the proposed definition, aquatic plants (including algae) are excluded. This definition is consistent with the traditional treatment of these products by FDA.

The new language also serves to emphasize that these regulations apply only to those products that are intended for human consumption. This point was explicit in the proposed definition for ''fishery product'' but was inadvertently not mentioned in the proposed definition of ''fish.''

27. Two comments contended that there should be separate definitions for finfish and shellfish, to differentiate between relative levels of safety concerns (e.g., high and low risk).

FDA disagrees with this comment. Such a differentiation would serve no purpose in these regulations. The purpose of these regulations is to set up a unitary system that responds to a particular product based on the risks it presents, not to establish a system that is divided up based on risk presented. The merits of differentiating between products on the basis of risk is addressed in the section of the preamble entitled ''Should Some Types of Processors be Exempt?''

6. Fishery Product

FDA proposed to define ''fishery product'' as ''any edible human food derived in whole or in part from fish, including fish that has been processed in any manner.'' The preamble to the proposed regulations stated that the intent of the definition was to include products that contain seafood as an ingredient as well as those products that are comprised of seafood alone, because hazards derived from seafood are reasonably likely to occur in both types of products.

28. A few comments urged that FDA exclude from the meaning of ''fishery product'' any product that is made in whole or in part from commercially sterilized fishery products subject to the requirements of parts 113 and 114, (i.e., thermally processed low-acid canned foods and acidified foods).

FDA disagrees with this comment. Although such foods are required to be produced in accordance with certain HACCP-type control procedures to reduce the risk of the hazard of *C. botulinum* toxin production, these control measures do not address other potential hazards. For example, part 113 provides no assurance that the raw material used in the canning of tuna will be free from contamination with dangerous levels of histamine. Likewise, products made in part from low-acid canned foods and acidified foods can also present hazards that must be addressed. For example, a salad made in part from canned tuna can be subjected to recontamination with pathogenic microorganisms and time-temperature abuse during preparation.

Although FDA cannot exclude those products made in whole or in part from low acid canned foods or from acidified foods from the definition of a ''fishery product,'' it is worth noting that the agency has exempted processors who are following the requirements of part 113 or part 114 from having to include controls for *C. botulinum* in their HACCP plans. This hazard is already addressed by the requirements in those parts (see § 123.6(e) of these regulations and the ''HACCP Plan'' section of this preamble).

29. One comment suggested that the language of the proposed definition inappropriately excludes fish roe.

FDA points out that the phrase ''any edible human food product derived in whole or in part from fish,'' in the proposal was intended to cover these products. FDA, however, has modified the definition of ''fishery product,'' and it no longer includes this language. Therefore, to make clear that roe are covered, FDA has made explicit in the definition of ''fish'' that the roe of the covered animals are included.

30. A significant number of comments urged that the definition exclude products that contain only a minimal amount of fish. These comments suggested various standards that FDA should apply to exclude such foods from the definition. These included: Products that contain less than 50 percent fish; products that contain less than 10 percent fish; products that contain 2 percent or less of cooked, or 3 percent or less of raw, fish; products in which fish is not a characterizing ingredient; and products that contain any nonfish ingredient unless a hazard analysis identifies a significant hazard associated with the fish ingredient. The comments provided no justification for the percentages suggested.

FDA agrees that foods that contain inconsequential amounts of fish, such as Worcestershire sauce, are not the types of foods that should come under the purview of these regulations. It is doubtful that they pose reasonably likely hazards associated with their fish components. Moreover, these products are neither represented nor perceived as being fish-based foods.

The comments provided FDA with no basis, however, upon which to select a specific minimum content of fish ingredient for the definition of ''fishery product.'' There is no obvious minimum percentage of fish on which to exempt a food that contains only a small amount of fish from the provisions of these regulations.

Instead, the agency accepts the comment that, to meet the definition of a ''fishery product,'' a food should be characterized by the qualities of the fish that it contains. Thus, these regulations will apply to those foods whose basic nature is defined by the fish that they contain. Accordingly FDA has modified the proposed definition (§ 123.3(e)) to read in part, ''*Fishery product* means any edible human food product in

which fish is a characterizing ingredient.'' This revision will serve to ensure that mandatory HACCP requirements do not apply to products that contain inconsequential amounts of fish from a public health standpoint.

31. One comment stated that fish oil that is intended for use in human food should not be subject to the requirements of these regulations until it has been separated, through initial processing, from the oil that will be used for animal feeds and other industrial purposes. FDA does not find that the comment provided sufficient justification to treat this product differently from other human food products processed from fish. The agency acknowledges that the hazards associated with these products may be minimal. If that is the case, the fish oil processor's burden will also be minimal, perhaps limited to training expenses and the performance of a hazard analysis. Moreover, these regulations do not apply to products that are not for human consumption and fish oil processors that are confident that their production will not be used for human consumption need not apply the requirements of these regulations.

7. Food Safety Hazard

32. A number of the comments recommended that FDA define ''safety hazard'' or ''food safety hazard.'' Several of these comments recommended that FDA adopt a definition that is consistent with the NACMCF recommended definition for ''hazard.'' The comments were primarily concerned with the coverage of these regulations. They urged that the regulations be clear that only food safety hazards need be addressed by the HACCP plan and argued that a definition would help to accomplish that.

The NACMCF definition of ''food safety hazard'' reads, ''A biological, chemical, or physical property that may cause a food to be unsafe for consumption.'' While FDA provided no definition of ''food safety hazard'' in the proposed regulations, it did raise the issue of the coverage of the regulations in proposed § 123.6(b) (redesignated as § 123.6(c)), which mandated coverage of food safety hazards only and listed nine types of food safety hazards posed by the various types of fish and fishery products. This list included examples of biological, chemical, and physical hazards. Additionally, the preamble to the proposed regulations discussed at length the significance of a number of these types of hazards.

FDA agrees that the meaning ascribed by the agency to a food safety hazard should be as clear as possible in these regulations. The examples of hazards in the proposed regulations—and codified in these final regulations—are consistent with the NACMCF definition for a food safety hazard. Therefore, for the sake of clarity, FDA has decided to characterize these examples in a definition § 123.3(f), which reads, ''*Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.'' The only difference between this definition and the NACMCF recommendation is the addition of the word ''human.'' FDA has included this word to prevent confusion about the application of these regulations to pet or animal feed.

In keeping with the new definition, and to provide further clarification about the nature of the hazards that are required to be addressed by these regulations, the term ''hazard'' has been changed to ''food safety hazard'' where it appears throughout the codified portion of this document.

8. Harvester

FDA proposed to define ''harvester'' as ''a person who has an identification number issued by a shellfish control authority for commercially taking molluscan shellfish by any means from a growing area.'' After review, the agency has concluded that it was not necessary to limit ''harvesters'' to those persons who have an identification number, primarily because in some jurisdictions, identification numbers may not be issued by a shellfish control authority. Without this limitation, FDA has concluded that there is no need to establish a particular meaning for this term for the purposes of these regulations. Therefore, the agency has removed this definition from the final regulations.

9. Importer

FDA proposed to define ''importer'' as ''a person, or his representative in the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.'' The preamble to the proposed regulations explained that the importer is the owner of the imported goods or the owner's representative in the United States. The preamble further noted that freight forwarders, food brokers, food jobbers, carriers, and steamship representatives would not usually be considered to be the importer of the product for the purposes of these regulations because they are not usually in a position to make decisions that can ensure the safety of the product. However, the preamble did not categorically rule out that these individuals could be the importer because sometimes they may be in a position to make decisions relevant to safety.

33. Several comments stated that FDA should modify the definition of ''importer'' to specifically exclude intermediary agents involved in the importing process, such as freight forwarders, licensed U.S. customs brokers, food brokers, food jobbers, carriers, and steamship representatives. These comments noted that, although imported products may enter the United States under the name of an intermediary, this practice is done for convenience in handling the paperwork at the port of entry. The comments stated that the intermediary has little responsibility for conducting the negotiations with an overseas producer and rarely takes possession of the products. Therefore, the comments stated, the intermediary has limited influence on the safety of the imported goods. Two comments pointed out, for example, that customs brokers that provide their clients with the service of using the broker's customs bond are listed as the ''importer of record'' and may thereby, unintentionally, be regarded as importers under the proposed definition, even though they do not own or control the product being imported.

Conversely, two comments argued that agents, such as food brokers, should be included in the definition of an ''importer'' because they bring product into the United States and sell it. The comments argued that the brokers should, therefore, be held responsible for ensuring that the foreign processor complies with the provisions of these regulations, to avoid an unfair advantage over domestic processors.

FDA concludes, based on the information provided in the comments, that these intermediaries can neither be categorically included or excluded. However, the agency recognizes that the number and type of comments on this issue demonstrate that the language of proposed § 123.3(h) was inadequate to convey the agency's intent, as articulated in the preamble. For this reason, FDA has clarified the definition of ''importer'' in § 123.3(g) to read, in part:

*Importer* means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.

Reference to the owner or consignee of the imported goods parallels the language in section 801 of the act (21 U.S.C. 381).

Because the ownership of imported products can change many times in a relatively short period of time after entry, the party who is the owner or consignee at the time that these products are offered for entry must be identified as the importer. As the person that has the ability to decide whether to offer the product for entry, this person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this fact to FDA.

FDA must be able to verify the existence of the evidence of compliance by the foreign processor. This evidence, according to the provisions of § 123.12, is to be in the possession of the ''importer.'' It must be available in the United States, however, if FDA is to consider the information in deciding whether to admit the products. Thus, where products are offered for entry by a U.S. owner or consignee, that owner or consignee will, for purposes of these regulations, be considered the importer because it will have control of this evidence. Where products are often offered for entry without a U.S. owner or consignee, the U.S. agent of the foreign owner or consignee will be considered the ''importer'' for purposes of these regulations to make clear who will be expected to have this evidence for such products.

FDA recognizes that the U.S. owner or consignee of the product, or the U.S. representative of the foreign owner or consignee, at the time of entry into the United States may also serve other functions. For example, it may also be a food broker for, or warehouser or processor of, the product. It may, in some instances, also be the freight forwarder, customhouse broker, or carrier for the product. These other functions will not matter, however, if the person is the U.S. owner or consignee of the product, or the U.S. representative of the foreign owner or consignee, at the time of entry into the United States. From FDA's experience, while certainly not impossible, it is at least unlikely that this qualification will be met by the customhouse broker, the freight forwarder, the carrier, or the steamship representative.

The agency has attempted to clarify this definition by including a sentence that reads, ''For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.'' Further, FDA does not intend to rely exclusively upon the assignment of the ''Importer of Record'' or the holder of the U.S. Customs Surety Bond in determining the ''importer'' for the purposes of these regulations, as was suggested in the preamble to the proposed regulations. In some instances the ''Importer of Record'' or the holder of the U.S. Customs Surety Bond will not meet the qualifications of an importer that are set out in § 123.3(g).

10. Lot of Molluscan Shellfish

FDA proposed to define a ''lot of molluscan shellfish'' as ''a collection of shellstock or containers of shellstock of no more than 1 day's harvest from a single, defined growing area harvested by one or more harvesters.'' Because of language changes that FDA has made in subpart C of part 123, this term isno longer used in the regulations. Consequently, FDA has decided that there is no need to define this term and has eliminated the definition.

11. Molluscan Shellfish

34. Comments from a number of State agencies, trade associations, seafood processors, and the ISSC objected to the use of the term ''fresh or frozen'' in the proposed definition of ''Molluscan shellfish.'' The comments were concerned because this definition would have the effect of exempting canned and any other heat-processed molluscan shellfish from the source control, recordkeeping, and tagging provisions of proposed subpart C of part 123 and proposed § 1240.60(b).

The comments stated that limiting these provisions to raw products would allow foreign firms to continue to heat-treat or can molluscan shellfish that are harvested from foreign waters that do not meet National Shellfish Sanitation Program (NSSP) standards and to export them to the United States. The comments stated that this situation was not in the best interest of the public health because of the potential for the presence of heat-stable natural toxins, such as paralytic shellfish poison or amnesiac shellfish poison, as well as chemical contaminants. The comments also complained that, because State laws and regulations require that all molluscan shellfish harvested in the United States come from waters approved by a shellfish control authority regardless of whether they are to be consumed raw or cooked,continuing to allow foreign processors who export cooked shellfish to the United States to use molluscan shellfish from unapproved growing waters places the domestic shellfish industry at a competitive disadvantage.

FDA believes that these comments are generally valid but are beyond the scope of this rulemaking. The point of this rulemaking it to determine whether FDA should require that HACCP be followed in the processing of seafood. The question of whether cooked molluscan shellfish that is being offered for import into this country is being harvested in a manner that creates public health concerns and unfair competitive advantages is a separate matter that the agency will address, if necessary, in the future.

Similar issues with respect to the use of the term ''fresh or frozen'' and the term ''raw'' in proposed subpart C of part 123 of these regulations and in proposed part 1240 are discussed in the ''Molluscan Shellfish'' section of this preamble (see comment 144).

12. Potable Water

FDA proposed to define ''potable water'' as ''water which meets the U.S. Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141.'' Because of changes that the agency has made in proposed § 123.10 (redesignated as § 123.11), the term is no longer used in these regulations. Consequently, FDA has eliminated the definition.

Nonetheless, a significant number of comments questioned when it would be necessary for processing water to meet the definition of ''potable water.'' Because it is likely that both terms (i.e., processing water and potable water) will be used in the first edition of the Guide, FDA will consider these comments during the redrafting of the Guide.

13. Preventive Measure

FDA has added a definition for the term ''preventive measure'' at § 123.3(i). Although the term was not used in the proposal, the concept of preventive measures was a fundamental part of the hazard analysis that was implicit in proposed § 123.6(b). ''Preventive measure'' is used in the final regulations in § 123.6(a) in the description of a hazard analysis.

FDA proposed to require that all processors create a HAACP plan. Based on comments received, however, as explained below, FDA has decided to require that processors conduct hazard analyses to determine whether they need to develop a HACCP plan. This decision necessitates that FDA define ''preventive measure.'' In accordance with the recommendations of the NACMCF (see Ref. 34, p. 189), a hazard analysis must identify both the food safety hazards that are reasonably likely to occur and the preventive measures that are available to the processor to control such hazards.

Identifying the preventive measures is necessary in order to determine whether a processing step is a CCP for that hazard. A processing step cannot be a CCP for a hazard if no preventive measure is available at that step to control the hazard. The definition of ''preventive measure'' in these regulations is essentially the same as that recommended by the NACMCF.

14. Process Monitoring Instrument

The term ''process control instrument'' was used in the proposal for consistency with the phrase ''the procedures * * * that will be used to control and monitor each of the critical control points.'' For consistency with the NACMCF principles of HACCP, FDA has modified the language of § 123.6(c)(4) to eliminate the word ''control.'' In order to achieve consistency within these regulations, the agency has concluded that the appropriate term for such instruments is, therefore, a ''process monitoring instrument.''

15. Processing and Processor

Along with the term ''importers,'' the terms ''processor'' and ''processing'' collectively define who is subject to these regulations.

FDA proposed to define ''processing'' as:

[W]ith respect to fish or fishery products, handling, storing, preparing, heading, gutting, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, or holding. Practices such as heading or gutting intended solely to prepare a fish for holding on board a harvest vessel are excluded. This regulation does not cover the operation of a retail establishment.

FDA proposed to define ''processor'' as:

[A]ny person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. Persons engaged in the production of foods that are to be used in market or consumer tests are also included. Persons who only harvest or transport seafood, without otherwise engaging in processing, are not covered by these regulations.

a. *Vessels, carriers, and retail.* As explained in the preamble to the proposed regulations, the definitions of ''processor'' and ''processing'' excluded fishing vessels that essentially only harvest, transportation companies that carry but do not otherwise process fish and fishery products, and retail establishments. FDA invited comment on these exclusions.

In the preamble, FDA acknowledged that food safety hazards can be introduced at these three points in the commercial distribution chain. However, FDA tentatively decided to exclude fishing vessels, carriers, and retailers from the definition of ''processor''—and thus from direct coverage under these regulations—because of practical considerations, such as the fact that the large size of the U.S. fishing fleet and the large numbers of carriers and retailers would overwhelm any rational Federal inspection system, and because the agency believed that the public health goals of the regulations could still be met.

FDA expressed its tentative view that the HACCP regulations would affect fishing vessels and carriers indirectly though the controls that processors impose to meet their obligations under HACCP. As for retail establishments, the preamble explained that, historically, they have been the regulatory responsibility of State and local governments. FDA traditionally has provided support through training, technical assistance, and the development of model codes. Since the issuance of the proposal, FDA has published its retail and institutional ''Food Code,'' with the recommendation that it be adopted by State and local jurisdictions. The Food Code covers handling and receiving practices at retail, and its most recent version includes HACCP elements.

FDA's approach to these issues is based on agency discretion and does not derive from a lack of statutory authority. FDA has broad authority to regulate Food that is shipped in interstate commerce. While carriers are exempt from most direct FDA regulation in accordance with section 703 of the act (21 U.S.C. 373), the food being transported is not exempt. Moreover, FDA has authority under the Public Health Service Act (the PHS Act) (42 U.S.C. 264) to take such measures as it deems necessary to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the States or from one State or possession into any other State or possession.

FDA received a significant volume of comment on the question of coverage by these regulations of fishing vessels, carriers, and retail establishments. The majority of comments strongly favored inclusion of these entities within the scope of the these regulations.

35. The arguments relating to vessels and carriers tended to overlap. Those who favored inclusion noted that hazards—particularly those associated with time-temperature abuse and insanitation—can originate with fishing vessels and carriers. The comments argued that not controlling the conditions under which seafood is harvested and transported would amount to leaving CCP's unregulated. One comment observed that carriers have an incentive to turn off refrigeration units to save gas.

Several comments expressed the view that exclusion of vessels and carriers from the coverage of these regulations unfairly makes processors responsible for these aspects of seafood production. One comment pointed out that vessels, especially those that harvest scombroid toxin-forming species, should be legally responsible for any safety hazards that they cause through improper handling. Some comments asserted that HACCP can be practiced on fishing vessels and by carriers, at least with regard to temperature controls.

One State agency expressed the view that holding processors responsible for the behavior of fishing vessels has, in its experience, not worked, nor has education of fishing vessel owners or voluntary compliance by owners. The comment did not document the basis for these conclusions, however. Some comments argued that, while it would be difficult to include all vessels and carriers, those involved with high-risk products should be included.

Comments in favor of excluding vessels and carriers from these HACCP regulations noted that FDA's rationale for exclusion was prudent given the number, location, and diversity of the U.S. fishing fleet and the complexity of transport arrangements. For carriers, one comment noted that partial loads that are dropped off in different locations would be especially difficult to control. Some comments asserted that direct regulation of these entities was not necessary because processors could establish minimum requirements as a condition of purchase, as part of their HACCP systems. Some comments urged, however, that fishing vessels be subject to HACCP requirements when they deliver directly to an entity that is not subject to these regulations (e.g., a restaurant). One comment argued that receiving firms should require that product be in the same condition that it was in when it left the previous processor.

Some comments questioned the ability of fishing vessels and carriers to comply with HACCP requirements. A number of comments favored alternatives to HACCP, such as guidelines and standard operating procedures (SOP's).

FDA is impressed by the strong support for inclusion, of fishing vessels and carriers in the coverage of these regulations. Some of this support was based on concern over the loss of quality because of poor handling

practices (e.g., the effect of time-temperature abuse on shelf life and spoilage unrelated to safety) rather than on food safety considerations. Nonetheless, members of these two industries should be aware that significant concerns have been expressed with regard to their practices.

For some species and products, the practices of fishing vessels and transporters can have significant public health consequences. These practices can put pressure on a processor who is receiving these products to carefully scrutinize the condition of incoming materials. The practices can also put pressure on a processor to determine whether carriers are suitable to transport their finished products (e.g., that carriers have proper refrigeration).

The agency appreciates the argument that all entities that can affect safety in the distribution chain should accept and share this responsibility. These points notwithstanding, FDA received no comment that provided information about how the agency could operate an inspection program for carriers and harvest vessels with its current resources. For this reason, the agency concludes that such a program is impractical at this time.

When processors accept raw materials for processing, especially from vessels, they assume some responsibility for the condition of the incoming materials, regardless of how others are regulated. This is true under both general commercial law and the laws administered by FDA. Carriers likewise have responsibilities. If a carrier fails to exercise such controls as are necessary, food that it carries may be rendered adulterated and the owner of the product, i.e., the processor, could suffer product loss. Food handlers generally should exercise sufficient control over the products in their custody to ensure that any food safety hazards that are reasonably likely to occur during that period are being addressed.

As an additional matter, FDA agrees with those comments that advocated a step-wise regulatory approach to these entities.

Mandatory HACCP for seafood is a pioneering venture. While the groundwork has been prepared for it through pilot projects and other efforts over the years, there is no substitute for actual experience once it is operating. The agency would prefer, therefore, to construct the system through a series of manageable steps if it needs to do so, rather than to risk overextending itself and the system initially. While these regulations exempt carriers and harvest vessels from direct coverage, experience with the application of a mandatory HACCP program may, at some later date, cause the agency to reconsider its approach.

For fishing vessels, FDA intends, for the time being, to issue good handling practice guidelines. To that end, the agency is studying those issued by the State of Alaska and by the Codex Alimentarius Commission of the Food and Agriculture Organization/World Health Organization, among other such available guidance. FDA will evaluate the effect of these guidelines, in addition to any requirements that States have or may adopt regarding fishing vessel practices, and reassess at a later date whether there is a need for mandatory Federal controls. The agency invites continued correspondence and the sharing of views on this matter.

The comments that recommended that vessels that sell directly to ''non-HACCP'' establishments (e.g., restaurants) should be required to have HACCP plans are advised that the Food Code addresses the subject of source control for retail establishments and recommends the requirement of HACCP plans for retail establishments in some circumstances. This matter relates principally to State and local laws and is addressed below in the discussion of retail establishments.

For carriers, the situation is complicated by the restriction in section 703 of the act that was described previously. As one comment recommended, FDA has had conversations with other Federal agencies on the subject of transportation of food and will continue to do so. In the meantime, FDA strongly recommends that processors review the material in the Guide on how they can exercise control over incoming raw materials as well as over shipments of their own products. One emerging area that the agency is monitoring—and processors should consider also—is the development of inexpensive time-temperature sensors that indicate whether proper temperatures have been maintained over a period of time.

36. The question of the inclusion of retail establishments within the mandatory seafood HACCP system involves some different considerations. Processors have less influence, if any, over how their products are handled at retail than they do over how their products are handled by vessel operators or carriers. Some comments pointed out, for example, that a processor's best efforts could be for naught if the product is subsequently mishandled at retail.

Several comments pointed out that many retail establishments carry out activities that meet the definition of ''processing.'' According to these comments, such establishments should not be exempt from HACCP requirements.

Other comments took the view that these regulations should not apply to retail establishments, primarily for the reasons provided in the preamble to the proposal. Some recommended that retail establishments should not be subject to the regulations so long as the Food Code applies to them. Others suggested that HACCP should apply if the retail establishment buys directly from a fishing vessel or from sport fishermen. Some suggested better consumer education and voluntary HACCP-type programs.

FDA agrees that there are hazards that occur at the retail level that can render meaningless the controls that may have been in place elsewhere in the chain of production and distribution. The NAS has cited retail and food service establishments as sources of seafood-related illnesses (see Ref. 7, p. 27). FDA is convinced—and the comments support—that proper controls at the retail level are imperative to ensuring a safe product.

Nonetheless, FDA's observation in the preamble to the proposed regulations remains valid that retail establishments pose an inspection burden well beyond the capacity of FDA. No comments have provided any basis for the agency to conclude otherwise or would justify the significant shift of resources that would be necessary for FDA to even begin to address the retail sector in a meaningful way. FDA notes that State and local governments provide significant regulation of the retail food sector. FDA has committed the resources that it has available for addressing retail problems, by providing training and technical assistance to State and local governments. Most significantly, FDA has provided guidance in the form of the Food Code, which provides the latest and best scientifically based advice about preventing foodborne illness for adoption by those jurisdictions that have regulatory responsibility for food service, retail, and vending operations.

It is worth noting that the Food Code suggests the use of HACCP controls at retail in some circumstances where comments argued for such controls as part of these regulations. Under the regulatory controls suggested in the Food Code, a retail establishment that purchases a scombroid toxin forming species of fish from a recreational harvester, for example, would need a HACCP plan relating to how it will ensure that fish had been handled so as to avoid time-temperature abuse. Under

the Food Code, fish caught recreationally generally require the approval of a regulatory authority in order to be sold to a retail establishment. The States should be aware that the Food Code is responsive to concerns raised by comments in these respects. FDA urges the States to consider adopting the Food Code for retail and institutional operations.

It is worth noting that the Food Code applies HACCP requirements to retail establishments as an exception for extreme situations, rather than as the rule. There is still much to be learned about the application of HACCP to retail establishments. Also, it may not be wise to single out seafood for the application of HACCP at retail. Retail operations can be complex and involve the handling of many types of foods. Trying to operate a HACCP system solely for seafood could divert attention away from important safety practices for high-risk products other than seafood.

For all these reasons, therefore, the agency concludes that FDA should not mandate HACCP systems for the seafood component of retail establishments at this time. Also, the agency has not been provided with any information on how an FDA inspection program for such establishments would be feasible. Nonetheless, the agency will take all comments on retail establishments under advisement for future consideration as the system evolves.

It is important to note, however, that where a processor engages in mixed operations (i.e., some retail and some wholesale), as in the case of cash-and-carry warehouses noted by one of the comments, the wholesale portion of the operations will be subject to the provisions of these regulations. As a further point of clarification in response to one comment, FDA has traditionally, and will continue to, classify central kitchens that distribute product to retail outlets that are owned by the same firm as a retail operation.

b. *Warehouses.* In the preamble to the proposed regulations FDA stated that the definition of ''processor'' included warehouses. Warehouses store fish and fishery products, one of the operations included in the proposed definition of ''processing.'' A ''processor'' is simply an entity that engages in processing.

There are food safety hazards that can be introduced while storing a product (e.g., in a warehouse). These hazards include, among other things, pathogen growth in cooked, ready-to-eat products and histamine development in scombroid toxin-forming species, as a result of improper storage temperatures. Nonetheless, the warehouse environment usually has few hazards compared to complex processing operations. Consequently, the preamble to the proposed regulations invited comment on whether warehouses should be exempted from the definition of ''processor'' and, by implication, whether ''storing'' should not be included in the definition of ''processing,'' as one way of scaling the regulations back in terms of cost and burden.

37. The comments split about evenly on this subject. Those that gave a reason for including warehouses cited the need to monitor storage temperatures for species that are prone to safety hazards if they are temperature abused. Those that opposed and provided a reason tended to argue that storage alone should not subject an establishment to the requirements of the regulations. A related concern was the view that warehouse operators do not have a thorough knowledge of the products that they handle and only store products that are provided to them by others. This concern was expressed both by those who objected to the inclusion of warehouses and those who simply asked for clarification about the role of warehouses. Others who asked for clarification expressed the view that warehouses could be responsible for conditions during storage.

After consideration of these comments, FDA has decided to retain warehouses (e.g., public storage warehouses, foodservice distribution warehouses, and wholesale grocers) within the definition of ''processor'' and to retain ''storing'' within the definition of ''processing.'' It is important to recognize that section 402(a)(4) of the act covers storage along with other forms of processing. It states that a product is adulterated if it is ''prepared, packed, or held under unsanitary conditions * * * whereby it may have been rendered injurious to health.'' These regulations are being issued for the efficient enforcement of section 402(a)(4) of the act. Moreover, as described above, hazards can be introduced as well as controlled during storage. HACCP is an appropriate system for the control of these hazards.

FDA believes that the burden on warehouses will be minimal given the simplicity of the operation and the fact that, in most cases, a warehouseman's responsibility under HACCP will only extend to conditions within the warehouse that could cause a safety hazard to occur.

For the most part, hazards deriving from the environment (pesticides, etc.) will be controlled during the initial processing of the product (i.e., by the first processor to take possession). As a result, subsequent processors will receive products that are generally free of environmental hazards and thus will not need to establish HACCP controls for them. More often than not, storing will not be the first processing operation. Thus, a warehouse will not usually be responsible for environmental hazards. The same principle holds true for hazards arising during processing operations that occur before storage in a warehouse. Those hazards must be controlled during the prior processing and generally not during storage.

There may be occasions, however, when storage is the first processing operation (e.g., when a warehouse will be the first processor to receive raw material fish from a fisherman or aquacultural producer). Under these circumstances, the warehouse, rather than a distant owner of the product, may be in the best position to obtain information that may be needed about harvest site, fishing practices, and transportation to the dock that would be germane to safety. There should be some arrangement between the warehouse and the owner on this matter to ensure that environmental hazards are properly addressed.

38. One comment objected to the inclusion of storage within the definition of processing on the grounds that FDA should not dictate where CCP's should be.

The agency is not attempting to do so. FDA acknowledges that whether storage is a CCP will depend on the circumstances. For example, refrigerated storage of a scombroid species will likely be designated as a CCP, whereas dry storage of canned fish will not likely be considered as such.

39. Another comment objected to including ''airline warehousing'' within these regulations.

If airlines hold product as part of their usual course of business as carriers, they are exempt from having HACCP plans in accordance with section 703 of the act.

c. *Other processing operations.* 40. A few comments requested clarification on whether waterfront facilities that unload vessels and pack the catch for shipment to buyers are engaging in processing and thus meet the definition of ''processor.''

These firms perform activities such as handling and storing that are included in the definition of processing and fall within the purview of the ''prepared, packed, or held'' clause of section 402(a)(4) of the act. Additionally, these activities warrant coverage under these regulations because of their relationship to reasonably likely hazards. For example, these firms are, by design, usually the first processors to receive

the product from the fisherman or aquacultural producer. As such, they are often in the best position to control environmental hazards, as was previously discussed. They also often store the product, at least for short periods of time. In this capacity, they may be responsible for ensuring that the product is not exposed to time-temperature abuse, a phenomenon that critically affects the safety of some products.

For these reasons, FDA has clarified the definition of ''processing'' at proposed § 123.3(m) (redesignated as § 123.3(k)) to specifically include dockside unloading.

41. One comment took the view that only processors who own the products that they are processing should be subject to these regulations and suggested that the term ''processor-owner'' be substituted for ''processor.'' Several other comments questioned whether custom processors that do not own the product, should be subject to the provisions of these regulations.

The definition of ''processor'' does not hinge on ownership. As indicated earlier, whether a product is adulterated under section 402(a)(4) of the act depends on the condition under which it was ''prepared, packed, or held.'' Ownership is not a relevant factor. Consistent with this principle, these regulations define a processor as simply an entity that engages in processing. ''Processing'' is defined as including a number of activities, such as manufacturing and packing, that are normally performed by a custom packer.

Like warehouses that store products for distant owners, custom packers are often in the best position to exercise HACCP controls for the products that they process. Because of the real-time nature of HACCP (i.e., because monitoring provides immediate feedback as to whether a hazard is being controlled), the processor can most effectively apply HACCP monitoring controls to a food being processed, regardless of whether the processor is the actual owner of the food. FDA recognizes that it will often be beneficial for the custom processor and the owner of the product to fully discuss and agree upon the HACCP controls that will be effected by the custom processor while the product is in its possession.

42. One comment argued that custom packers should be included within the scope of these regulations because these processors often can or smoke recreationally caught products and are often the only commercial entity that can assure the safety of such products. While the definition of ''processing'' clearly covers the kinds of activities performed by custom packers, it is not the intent of these regulations to address arrangements between a recreational fisherman and a custom packer for the processing of fish for the personal use of the fisherman. The regulations only cover custom packing that is performed on behalf of an owner who intends to introduce the fish into interstate commerce. Nonetheless, the agency does not believe that clarification to the regulations is needed on this point.

43. One comment urged that aquacultural producers that also eviscerate the fish before delivery to a processing plant be required to comply with the requirements of these regulations.

FDA agrees with the comment and further states that the process of eviscerating is specifically included in the definition of ''processing.'' Eviscerating is excluded from the definition only when it occurs on a harvest vessel for the purpose of preparing the fish for holding en route to the processor.

44. A few comments objected to FDA including labeling in the definition of ''processing.'' The comments argued that labeling operations are unlikely to introduce hazards to the product. FDA has considered these comments but finds that there is potential during some labeling operations for the development of hazards. For example, improperly controlled labeling operations for scombroid species could result in time-temperature abuse of the product, increasing the risk of histamine contamination. Cooked, ready-to-eat products could similarly be subjected to time-temperature abuse, resulting in the potential for pathogen growth. The inclusion of labeling in the list of processing operations is not intended to imply that this step should always, or even frequently, be considered a CCP. That can only be determined through the conduct of a hazard analysis.

FDA proposed to exempt ''heading or gutting intended solely to prepare a fish for holding on board a harvest vessel'' from the definition of ''processing.'' In drafting the proposed regulations, FDA was concerned that, in the absence of such an exemption, harvest vessels that are presently heading or gutting fish would stop the practice to avoid being subject to the requirements of these regulations. FDA did not want an inadvertent consequence of these regulations to be a reduction in product quality. In addition, FDA tentatively concluded that safety hazards introduced by these operations are generally minimal.

45. One comment noted that FDA should include the practice of freezing fish on harvest vessels in the list of exempted operations.

FDA agrees that freezing is an operation that is routinely used onboard a harvest vessel in order to preserve the quality of the fish until it is landed for further processing (e.g., freezing performed onboard tuna harvesting vessels). For this reason, the agency has revised the definition of ''processing'' to include an exemption for onboard freezing.

46. One comment suggested that FDA also exempt onboard scallop shucking operations.

Unlike shucking other molluscan shellfish, shucking scallops involves eviscerating, a procedure that falls within the exemption in § 123.3(k). Consequently, onboard shucking of scallops does not constitute processing for purposes of these regulations. The agency does not believe that a change in the definition is necessary in this regard.

47. One comment suggested that, with respect to molluscan shellfish, ''processors'' should include shellfish shippers, reshippers, shucker-packers, repackers, and depurators.

The persons that perform all of these types of operations are ''processors'' under § 123.3(k)(1) and subject to the provisions of these regulations. Thus, the agency has concluded that no change in the definition is necessary.

16. Scombroid Toxin-Forming Species

The term ''scombroid toxin-forming species'' appears in § 123.6(c)(1)(vi) of this final rule. While FDA did not propose to define this term in the codified portion of the proposed regulations, it did propose to define it in part 123 appendix B as:

> [T]una, bluefish, mahi mahi, mackerel, sardines, herring, kahawai, anchovies, marlin, and other species, whether or not of the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

Appendix B of part 123 is no longer included in these regulations, as is discussed elsewhere in this preamble. Consequently, FDA is transferring the definition from part 123 appendix B to § 123.3(m) to clarify the meaning of § 123.6(c)(1)(vi).

48. A number of comments objected to the inclusion of herring in the list of scombroid toxin-forming species, arguing that there has been no association between herring and cases of histamine poisoning.

In response to the comments, FDA has modified the definition of scombroid

toxin forming species to make specific reference to only tuna, bluefish, and mahi mahi, since the overwhelming majority of scombroid poisonings are associated with these types of fish. Processors should assess the potential of other species to product histamine. The key to the definition is whether significant levels of histamine may be produced in the flesh of the fish.

17. Shellfish Control Authority

FDA proposed to define ''shellfish control authority'' as ''a Federal or State health authority, or foreign government health authority, legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish processors.''

49. A few comments pointed out that the definition should not require that a shellfish control authority be a State ''health'' authority because in some States the responsibility is vested in other than a health agency, such as a resource management agency.

FDA recognizes that these comments are correct. For this reason, the agency has modified the language in § 123.3(o) to read, in part, ''State agency.'' FDA believes that this term is sufficiently broad to encompass any of the present State arrangements. FDA has made a parallel change with respect to foreign government authorities, in order to accommodate the same kind of variations in regulatory arrangements. These final regulations similarly refer to a ''foreign agency.''

50. One comment, from a State regulatory agency, stated that within the United States, FDA should be the responsible shellfish control authority and should mandate that processors register with FDA, much as it has done with low-acid canned foods and medical devices. The comment further stated that a requirement in Federal regulations that State agencies perform this function may be unconstitutional.

The comment misconstrued the provision. The provision is intended to define the term ''shellfish control authority'' rather than to provide substantive requirements. Furthermore, these regulations at no point mandate that States perform certain functions.

51. Some comments expressed concern that the proposed definition of ''shellfish control authority'' was too narrow in that it did not include any entities that could serve the function of a shellfish control authority for Federal waters. The effect of the proposal, the comments pointed out, would be to close unnecessarily all molluscan shellfish harvesting in Federal waters.

It was never FDA's intent to close Federal waters to molluscan shellfish harvesting. These waters are beyond the jurisdiction of State shellfish control authorities, and no Federal agency classifies them in the same way that States classify their own waters. FDA is seeking a means to classify Federal waters. An agreement with NMFS relating to the classification of Federal waters is one possible solution. For this reason, FDA has modified proposed § 123.3(o) to state that a shellfish control authority may be ''a Federal agency.'' This subject is also discussed in the ''Molluscan Shellfish'' section of this preamble.

52. One comment urged that FDA provide for the possibility of sovereign tribal governments serving as shellfish control authorities.

FDA recognizes that the proposed definition was deficient because it failed to include tribal governments in the list of possible shellfish control authorities. The agency, the State of Washington, and 19 Indian tribes have recently entered into a settlement that will likely result in such an arrangement in the State of Washington (Ref. 202). When such governments meet the necessary criteria, it is the intent of the agency to formally recognize them for purposes of classifying shellfish growing waters and certifying shellfish processing plants for inclusion on the Interstate Certified Shellfish Shippers List. To provide for this situation, FDA has modified the definition of ''shellfish control authority'' to include ''sovereign tribal governments.''

FDA has also recognized that in many cases the functions of ''classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish,'' as listed in the proposed regulations, are not carried out by a single agency. To provide for such a situation, FDA has modified the proposed language at § 123.3(o) to read, ''program that includes activities such as,'' rather than simply ''program that includes.''

18. Smoked and Smoke-Flavored Fishery Products

The terms such as ''smoked fishery products,'' ''smoked fish,'' ''smoked and smoke-flavored fishery products'' were used in the proposed regulations and throughout appendix 1 to the proposal. As a result of decisions discussed elsewhere in this preamble, reference to ''smoked and smoke-flavored fishery products'' has been eliminated in these regulations except in part 123, subpart B.

While no definition of ''smoked and smoke-flavored fishery products'' was included in the definitions section of the proposed regulations, the terms ''smoke-flavored fish'' and ''smoked fish'' were separately defined in appendix 1 to the proposal as: ''*Smoked-flavored fish* means fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke, such as immersing it in a solution of liquid smoke,'' and ''*Smoked fish* means fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.'' FDA solicited comment on the materials in appendix 1. Because the term is used in these final regulations and FDA is concerned that there may be confusion about its application, the agency has determined that a definition of ''smoked and smoke-flavored fishery products'' is needed in the codified portion of these regulations. FDA has included one at § 123.3(s) that is consistent with those proposed in the appendix 1 to the proposal. Section § 123.3(s) reads:

> *Smoked or smoke-flavored fishery products* means the finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

FDA received numerous comments on the regulatory treatment of smoked and smoke-flavored fishery products, but none that would affect this definition.

*E. The HACCP Plan*

Approximately 100 comments addressed one or more of the provisions of proposed § 123.6. This section of the proposed regulations set out who must write and implement a HACCP plan, and what the HACCP plan must include.

1. Preliminary Steps

FDA proposed in § 123.6 to require that all processors of fish and fishery products prepare and implement a HACCP plan that identifies the hazards that are reasonably likely to occur and thus that must be controlled for that product. In the proposal, FDA acknowledged the process recommended by the NACMCF for developing a HACCP plan but did not propose to require that processors follow it. The process recommended by the NACMCF includes: Assembling a HACCP team, describing the food and its distribution, identifying the intended use and consumers of the food, developing a flow diagram, verifying the

flow diagram, and performing a hazard analysis (Ref. 34, pp. 187–188). All but the last of these have been identified by NACMCF as the ''five preliminary steps'' of HACCP.

It was, and still is, the agency's belief that processors would benefit from a process that included these five steps as well as a hazard analysis in order to successfully arrive at an appropriate HACCP plan. Nonetheless, the agency did not propose to require adherence to the ''five preliminary steps,'' or explicitly propose to require that a hazard analysis be performed. So long as the processor had, in the end, a HACCP system that was appropriate for species and process, and was being implemented effectively, the agency tentatively concluded that these regulations did not need to manage the process any further.

53. A number of the comments contended that FDA should require that firms adhere to these procedures in preparing a HACCP plan. Specifically, a few comments argued that the proposed rule significantly diminished the potential effectiveness of HACCP by not requiring that processors engage in the ''five preliminary steps.'' The comments argued that inclusion of the preliminary steps would facilitate international trade and reduce confusion on the part of seafood importers and exporters through consistency with an internationally recognized standard for HACCP.

Several other comments urged that the NACMCF recommendation for the development of a process flow diagram, in particular, by a processor be made mandatory. These comments identified several benefits from such a requirement: To facilitate employee implementation of the plan, to facilitate processor verification activities, to reduce the time needed for regulators to review the manufacturing process, and to enable the regulator to determine whether the processor properly considered the entire manufacturing process. One comment stated that FDA's assumption that flow diagrams are burdensome or unnecessary is contrary to the 1992 NACMCF Report which notes that flow diagrams could be simple representations that accurately depict the steps in a process, rather than detailed, technical drawings.

FDA acknowledges that, for the reasons stated in the comments, many processors will find that the development of a flow diagram is a useful preliminary step to the preparation of a HACCP plan. Other processors may find, however, that, because of the simplicity of their operations, the preparation of a written flow diagram is an unnecessary step. In either case, FDA is convinced that a processor's decision to develop or not to develop a flow diagram will be, and should be, driven by its perception of the benefits of doing so. The comments received on this subject were not sufficiently persuasive for the agency to conclude that a flow diagram should be made mandatory. The comments provided no basis to find that in the absence of a flow diagram, a processor could not properly develop a HACCP plan, or that a plan, so developed, would likely cause the HACCP program to fail.

As some of the comments pointed out, there may be some benefit to the regulator to have access to a flow diagram during an inspection, but this convenience is not a sufficient reason to mandate it. FDA investigators will likely develop their own flow diagrams during their in-plant inspections and compare them with the decisions reached by the processor in the development of the HACCP plan (e.g., the identification of hazards and CCP's). While it may be beneficial for the investigator to be able to compare his or her flow diagram with that of the processor, it is not essential to the conduct of the inspection.

FDA agrees with the comments that stated that the other four elements of the ''five preliminary steps'' are desirable attributes of the HACCP development process. However, the agency has not been persuaded that, in the absence of a regulatory requirement that they be followed, the HACCP program is unlikely to succeed. In order to write an appropriate plan some or all of these steps will likely have to be performed, even without a regulatory requirement to do so. However, if a processor can write a plan without these steps, the goals of the regulations will still have been met. For FDA to require them to be performed and documented in every case would add burden and reduce flexibility unnecessarily. Moreover, FDA is unconvinced that any inhibition to foreign trade is likely to occur if adherence to these steps is not required. FDA believes that foreign trading partners will be satisfied by the presence of a successful HACCP system and will not reject U.S. exports because steps preliminary to HACCP were not documented.

Even without a requirement mandating specific preliminary steps, FDA believes that most processors will follow the spirit, if not the exact letter, of the recommended procedures. These procedures provide the processor with a recognized method of plan development that will help lead to a successful outcome. FDA is primarily interested in that outcome. The NACMCF recommendation for the assembly of a HACCP team, in particular, could be a significant burden for the many small businesses operating in the seafood industry. For these reasons, the final regulations do not mandate any preliminary steps that processors must perform as a prerequisite to conducting a hazard analysis or drafting a HACCP plan.

2. Conducting a Hazard Analysis

54. A number of comments from trade associations and processors objected to the requirement in the proposal that every processor have and implement a written HACCP plan. These comments contended that FDA should revise this provision to require that a processor first conduct a hazard analysis to determine whether any food safety hazards exist that can be controlled through HACCP and then prepare and implement a HACCP plan only when the hazard analysis identifies at least one such food safety hazard. One comment stated that conducting a hazard analysis is the first step in a two-step process, with developing a HACCP plan being the second step. The comments urged consistency with the NACMCF recommendations in this regard.

FDA agrees with the approach suggested by the comments and believes that it is essentially consistent with what the agency proposed. Although FDA did not explicitly propose to require that every processor conduct a hazard analysis, completion of such an analysis by every processor was implicit in the requirement in proposed § 123.6(b)(1) and (b)(2) that processors identify both the hazards that are reasonably likely to occur and the CCP's for each of these hazards.

In response to the comments, FDA has decided to clarify its regulations to make the requirement that a hazard analysis be conducted explicit rather than implicit in order to clarify the steps that are required as part of a HACCP system. Moreover, this change allows the agency to make clear that conducting the analysis may or may not lead to the preparation of a HACCP plan.

Thus, FDA is providing in § 123.6(a) that processors shall conduct a hazard analysis or have one conducted on their behalf. It is the agency's expectation that most seafood processors will, after performing a hazard analysis, find it necessary to control for at least one hazard and, therefore, be obligated to prepare a HACCP plan. However, when no hazard is reasonably likely to occur, there is no reason to prepare a HACCP plan. Therefore, § 123.6(b) states, in

part, ''(b) *The HACCP plan*. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section.''

The agency does not believe that the methodology of conducting hazard analyses is sufficiently standardized at this time to justify mandating what the analysis must include. FDA encourages processors to utilize the NACMCF document as guidance in performing this activity. In addition, the agency recognizes that the best way for it to verify a processor's hazard analysis is indirectly, through its own evaluations of whether a processor ought to have a HACCP plan, and whether a HACCP plan appropriately identifies the food safety hazards and CCP's that are reasonably likely to occur. In other words, it is the end product of the hazard analysis, the HACCP plan and its implementation, that should be judged by the regulator. For this reason, the agency is not requiring that hazard analyses be performed according to a standardized regimen, or that they be documented in writing for FDA review.

Even though FDA is not requiring that the hazard analysis be available to the agency, there may be cases in which it would be to the processor's advantage to have a carefully documented written hazard analysis to show to FDA. Such documentation may prove useful in resolving differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's. Written hazard analyses may also be useful to processors in that they may help provide the rationale for the establishment of critical limits and other plan components. Having the basis for these decisions available may be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

3. Types of Hazards

FDA received a number of comments on the types of hazards that a mandatory HACCP system should control, and that the hazard analysis should examine. The proposed regulations did not distinguish among hazards but proposed to require that HACCP plans identify all food safety hazards that are reasonably likely to occur. The comments that addressed the question of what types of hazards mandatory HACCP should address generally preferred that its focus be on some subset of hazards, rather than on the entire spectrum that could cause seafood to be adulterated. The comments argued that the hazards that were not the focus of the HACCP regime established by the regulations could be covered by more traditional food safety mechanisms. A review of these comments follows.

55. Several comments, from processors and trade associations, stated that the hazard analysis should only be used to identify those food safety hazards that have the potential to cause ''serious adverse health consequences.'' These comments stated that such consequences included those that would trigger a ''Class I'' recall as defined by FDA, particularly those that involve contamination of the food with pathogenic microorganisms. A Class I recall involves a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death and would not be used to respond to situations in which the health consequences are temporary, medically reversible, or remote (21 CFR 7.3(m)(1) and (m)(2)). Other processor comments suggested the use of the phrase ''significant food safety hazard'' to limit the scope of the HACCP regime without proposing a definition for the phrase.

One comment stated that focusing on truly serious hazards is the only way to keep the number of CCP's to a minimum, so that a HACCP plan can realistically be implemented. The comment also stated that having too many CCP's, or CCP's that are not related to serious health risks, would so burden food processing personnel that effective compliance with the HACCP plan would be undermined, and it would be significantly more difficult to control truly critical processes.

Several of these comments argued that hazards should have immediate, as well as serious, health consequences before being required to be identified in a HACCP plan. These and several other processor comments generally expressed the view that hazards that can cause a food to be adulterated under the act, but that do not have the potential to cause acute illness, should not be required to be included in a HACCP plan. For example, two of the comments stated that FDA should not use the HACCP regulations to ensure conformity with food additive regulations, pesticide residue tolerances, or action levels for environmental contaminants. One comment stated that although process controls that are similar to HACCP controls are often used by food manufacturers to monitor these kinds of contaminants, the controls should not be regarded as part of HACCP because they do not address acute health hazards. A few comments suggested that existing regulatory programs are adequate to address these types of hazards.

On the other hand, comments from one trade association and a number of individuals acknowledged that drug residues and pesticide residues should be addressed by HACCP plans; where they are likely to occur at levels over tolerance. Comments from a number of processors of aquaculture-raised finfish acknowledged that drug and pesticide residues are food safety hazards that affect their industry, but these comments questioned the appropriateness of the control mechanisms provided in FDA's draft Guide. Finally, comments from several consumer advocacy groups expressed continued concern for the hazards posed by environmental contaminants.

Having considered these comments, FDA confirms its tentative view, reflected in the proposal, that HACCP should be the norm, rather than the exception, for controlling safety related hazards in the seafood industry. Existing standards for such contaminants as drug residues, pesticides, and industrial contaminants, are established to ensure that their presence in foods does not render the food unsafe. Processors of fish and fishery products are obliged to produce foods that meet these standards.

Processors are obliged to exercise control over all food safety hazards that are reasonably likely to occur. A failure to do so would mean that the food was prepared under insanitary conditions whereby it may have been rendered injurious to health or is otherwise adulterated. The criteria for including a food safety hazard in a processor's HACCP plan should be the degree to which the hazard is likely to develop in that product (e.g., based on the processing technique, the harvest location, the species) and not the nature or immediacy of the illness or injury that it is likely to cause.

FDA views as highly speculative the concerns, expressed by a few comments from the food industry, that inclusion in HACCP of those hazards that generally require chronic exposure to produce disease will dilute HACCP systems to the point of shifting industry resources away from acute toxicity hazards. No evidence was submitted to support such claims. The pilot HACCP program conducted jointly by FDA and NMFS, the current NMFS voluntary HACCP program, and the NMFS Model Seafood Safety Program all included controls for food additives, primarily a nonacute

food safety hazard, and there has been no diminution of control of acute hazards as a result. Moreover, the agency is convinced that when determining, in accordance with § 123.6(a), what contaminant hazards are ''reasonably likely'' to occur in a particular type of product, most processors will have very few, if any, of these chronic exposure-type hazards to manage through HACCP as opposed to through some other method of control.

FDA intends to monitor the progress of the seafood HACCP program to judge, among other things, whether the application of HACCP to food safety hazards generally, rather than to the most extreme acute hazards, overloads the HACCP system and dilutes its effectiveness for all hazards. Until such an effect is actually found to occur, FDA is persuaded that the systematic application of preventive controls to food safety hazards generally will provide the American consumers with the most effective and efficient food safety system that has been devised to date. If FDA were to determine that HACCP needs to be scaled back in order to make it work, the agency will take appropriate steps to make such a change.

One other factor bears mention in this regard. FDA has long been aware of consumer concern about environmental contaminants in fish and fishery products. As previously mentioned, this concern was expressed in the comments to the proposed regulations. The chance that these regulations will increase consumer confidence in the safety of seafood products would be greatly diminished if these regulations did not require processors to consider the risks from these contaminants as part of their hazard analysis.

56. A comment from a trade association stated that, while there is potential for an unapproved direct or indirect food or color additive to be a health hazard, the use of an additive that has not been listed for use in fish but is routinely used throughout the food industry would not necessarily be likely to cause harm to human health. The comment said that a control for use of the additive should not be required to be included in a HACCP plan.

Under the act, certain products, such as food additives, new animal drugs, including new animal drugs intended for use in aquaculture, and pesticides, require premarket approval before they may be legally used. Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding realization that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, how the product is metabolized in that animal.

Therefore, a food additive that has been approved for use in some foods, but not fish and fishery products, is deemed by the act to be unsafe for use with fish and fishery products. FDA is not in a position to change this aspect of the law through regulations. Consequently, the agency has not created an exemption from the requirement for HACCP controls for safety hazards caused by the presence of unapproved additives or other products that lack premarket approval for fish or fishery products.

The agency is aware that it is possible that some of these products may pose no meaningful risk in fish and fishery products at levels approved or allowed in other foods. It is the obligation of the proponent of the use of the substance to follow applicable statutory procedure to establish this fact to FDA's satisfaction.

57. In the preamble to the proposed regulation, FDA specifically invited comment on whether, in order to reduce the burden of HACCP on the industry, as in the Canadian fishery products HACCP regulation, the agency should limit its HACCP approach to cover only those hazards that are introduced within the confines of the processing plant. This type of limitation would eliminate mandatory control of environmental hazards such as pesticides, natural toxins, industrial contaminants, and aquaculture drugs through the HACCP system.

One comment contended that a processor of fishery products would be in a difficult position attempting to exercise control over problems that occur during harvesting. The comment stated that the purpose of HACCP is to require that each processor be responsible for minimizing those serious hazards that it is in the best position to control, but that the proposed regulations would force the processor to take responsibility for hazards that it may be poorly suited to control. The comment argued that FDA's intent was to deploy HACCP solely as a way of reducing the agency's inspectional burden. The comment further stated that the focus should be on finding those few CCP's within a specific process where a serious hazard can best be controlled. Several other comments expressed confusion about the application of HACCP to environmental hazards.

The preamble to the proposed regulations described the link between environmental hazards, such as natural toxins (e.g., ciguatera toxin, domoic acid, and saxitoxin), histamine, and various viral and bacterial pathogens, and human disease. The NAS' ''Seafood Safety'' report (Ref. 7, p. 1) suggested that the most significant reduction in illness from seafood would come from the control of environmental hazards. To eliminate coverage of such hazards from these regulations would be to eliminate the greatest share of anticipated benefits.

The preamble to the proposed regulations provided a number of ways in which the processor can exercise control over environmental hazards. This control derives from the fact that responsible processors already exercise discretion in obtaining their raw materials. Control is achieved by checking tags on containers of molluscan shellfish to ensure that they are harvested only from approved waters, checking with fishermen to ensure that finfish do not originate from harvest areas that are closed due to the presence of excessive agricultural or industrial contaminants, and physically examining incoming histamine-forming species for evidence of decomposition and insisting that harvest vessels exercise control over the time and temperature of storage for these species. Similarly, processors of aquaculture-raised species can audit or otherwise insist on a producer controls over the use of animal drugs or other hazards resulting from inappropriate husbandry practices. In a HACCP system, these are examples of controls that can be applied at the first CCP, i.e., at the receipt of raw materials.

FDA concludes that the measures that a processor takes to ensure that its raw materials are free of environmental hazards are a critical part of a seafood HACCP program. Responsible processors already exercise the kind of control necessary to ensure that their raw materials do not present such a hazard. If a likely hazard exists, it would not be sufficient to use the price offered for raw materials to be the only measure to protect against the hazard.

For these reasons, FDA has retained environmental hazards in the list of food safety hazards that processors should consider in § 123.6(c)(1). To clarify that there are hazards that occur before receipt of raw materials that can be controlled nonetheless by examination or discretion at the

receiving CCP, FDA has modified § 123.6 by including the following sentence in § 123.6(a), ''Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.''

For consistency, § 123.6(c)(2) needs a space here provides for both types of CCP's, and now reads:

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate: (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment, and (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest.

Because most of the environmental hazards to which fish are exposed will be controlled by the first processor to take possession of the fish from the fisherman or aquacultural producer, whether that processor is located in the United States or in another country, subsequent processors need not focus on these hazards in their HACCP plans. For example, pesticide contamination of inland and near shore finfish can be effectively controlled by the first processor by purchasing from fishermen who do not harvest in areas that have been closed by regulatory authorities, and drug residue contamination can be effectively controlled by the first processor by purchasing from aquaculture producers who use animal drugs properly.

4. When Is a Hazard Reasonably Likely To Occur?

In the proposal, FDA identified nine categories of safety hazards that might occur in fishery products. The agency tentatively concluded that a processor must establish HACCP controls when one or more of the listed hazards is reasonably likely to occur.

58. A number of comments, from processors and a trade association, questioned whether certain of these nine hazard categories by themselves justify a HACCP plan. The comments challenged the likelihood that some of these hazards would cause harm and asked for clarification on how a processor is to determine whether a hazard is ''reasonably likely to occur.'' One comment held that, if the term ''reasonably likely to occur'' is linked to actual incidents of illness caused by a given hazard, it would be inappropriate to define some of the listed hazard categories as reasonably likely to occur. This comment also requested that FDA clarify whether the hazards identified in its draft Guide are those that the agency believes are reasonably likely to occur under all conditions for the listed species and processing methods. The comment further noted that residues of industrial or agricultural chemicals present in seafood are usually not present at levels that are reasonably likely to be a safety hazard, even in many of those species that are listed in the Guide as presenting that hazard.

As discussed in the preamble to the proposed regulations, FDA recognizes that HACCP need not be used to control every theoretical hazard, no matter how remote the likelihood of its occurrence. Moreover, as discussed earlier in this preamble, case law interpreting section 402(a)(4) of the act has held that conditions must be such as to create a reasonable possibility that a hazard will occur in order for product to be adulterated under that section of the law. (See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.,* 339 F. Supp. 140–141.)

Unquestionably, historical occurrence of reported illness is an appropriate starting place for the identification of food safety hazards that are reasonably likely to occur in the absence of controls. For example, illness from scombrotoxin in those species that form the toxin if subjected to time and temperature abuse after harvest is one of the most frequently reported illnesses from seafood. Moreover, the relationship between abuse after harvest and the formation of the toxin is well established. FDA can say with comfort, therefore, that scombrotoxin poisoning is a hazard that is reasonably likely to occur in the absence of appropriate controls for scombrotoxin-forming species of fish.

For some hazards, however, the incidence of reported illness is very low. A good example is illness from the consumption of raw fish species that are prone to parasites. The low number of reported illnesses is probably attributable to underreporting and to the fact that controls for this hazard (e.g., commercial blast freezing that kills parasites) generally exist. However, it is well established that in the absence of controls, infection from parasites is a hazard that is reasonably likely to occur when a species that is prone to parasites is consumed raw.

The incidence of reported illness that is linked to a specific food is virtually nonexistent when the illness is the result of chronic exposure to a chemical contaminant. It is extremely difficult, for example, to link a specific case of cancer to a specific contaminant in food. However, where public health officials have determined that a contaminant represents a chronic health hazard, the standard control strategy to be employed by processors for such contaminants is to ensure that their presence in food remains below specific levels.

Processors are advised of such chronic health hazard determinations through FDA action levels, publications (e.g., Federal Registers at 55 FR 14359, April 17, 1990; 58 FR 11609, February 26, 1993; and 58 FR 48368, September 15, 1993), or other similar guidance documents. If the contaminant is present in food in an amount that is above that level, the food represents a hazard to health that the evidence from the chronic studies shows is reasonably likely to occur. The question, then, is whether the likelihood of finding a fish in which the contaminant is at a higher than acceptable level is an event that is reasonably likely to occur. For open ocean species of fish, for example, a finding of pesticide residues above nationally established tolerances can be a very rare event. For near shore species in certain locations, however, a finding above tolerance can occur often enough so as to warrant controlling for it as a matter of reasonable prudence.

The incidence of reported illness for a particular hazard may also be nonexistent or very low because the hazard may be too new to have generated reported illnesses. The emergence of natural toxins harmful to humans in species or in locales where the toxin has not been found before is a well known phenomenon in seafood. While FDA does not expect that HACCP controls should be in place to control for the possibility of such hazards—the hazard may or may not ever occur—the agency strongly believes that once a hazard does emerge and is identified, HACCP controls are highly appropriate to keep illnesses from occurring. For the duration of the a hazard, it must be treated as one that is reasonably likely to occur.

To provide clarification on the above points, FDA has modified § 123.6 by including the following sentence in new § 123.6(a):

A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information, provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

To reinforce that it was not FDA's intent to suggest that all of the nine hazard categories that it listed in § 123.6(c)(1) are reasonably likely to

occur in all circumstances, the agency has modified the language in this provision to read in part, ''Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:'' (the list of nine categories follows in the text).

The Guide is not intended as a definitive list of the hazards that are reasonably likely to occur, under all conditions, for those species and processing methods listed.

HACCP is a operation-specific process. For this reason, the processor must decide on a case-by-case basis what hazards it needs to address; that is, what hazards are reasonably likely to occur. The purpose of the hazards portion of the Guide is to provide a listing of hazards, by fish species and by finished product type, that FDA knows to have a reasonable potential for occurrence in the product.

FDA encourages processors to use the Guide, as well as any other available information, to decide what hazards need to be addressed in any particular plan. Processors need to recognize that they need to use judgment in applying the Guide to their own particular circumstances. For example, a processor of one species of fish may find that pesticide contamination is listed as a hazard for the species, but may be aware of credible data that demonstrate that the water from which it obtains its fish is free of such contamination. In that case, the processor is free to deviate from the guidance. FDA intends to clarify the Guide on this point by distinguishing between hazards that are reasonably likely to occur all of the time (e.g., histamine in species that are prone to it) and hazards that are reasonably likely to occur under certain circumstances (e.g., certain toxins when a ''bloom'' is occurring).

5. The Plan: Specific Considerations

59. FDA proposed that HACCP plans be specific to each processing location and to each kind of fish and fishery product processed by a processor, except that the plan may group kinds of fish and fishery products together if the hazards, CCP's, CL's, and procedures required to be included in the plan are identical. A few comments from processors and trade associations suggested that production methods should also be allowed to be grouped together so long as the hazards and the control procedures for the production methods are identical. The comments suggested that grouping would reduce the paperwork burden on some processors without altering the benefits attainable through HACCP.

FDA agrees with the suggestion for the reason presented by the comments and has modified § 123.6(b) accordingly, to read, in part:

> A HACCP plan shall be specific to: (1) Each location where fish and fishery products are processed by that processor; and (2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

60. In the proposal, FDA specified that a HACCP plan must identify: The applicable food safety hazards; the CCP's; the CL's; the control and monitoring procedures; and the recordkeeping procedures. A few comments suggested that FDA use the word ''list'' or ''include'' rather than ''identify'' to describe a requirement for an item to appear in the HACCP plan. The comments suggested that it is not clear from the word ''identify'' whether the regulations are intended to require that the plan contain or include the actual values (e.g., the temperature of a refrigerator) or a description of the procedures, or whether it is permissible simply to make reference to their existence in a guideline or other source.

FDA's intent is that a HACCP plan explicitly include the value or a description of the procedures for each of the required HACCP elements. FDA agrees that a word such as ''list'' would be less ambiguous. Therefore, FDA has revised § 123.6 (c)(1), (c)(2), (c)(3), and (c)(4) by substituting the word ''list'' where the word ''identify'' appeared in the proposed regulations.

FDA has also revised § 123.6(c) by making another clarifying change. The agency has added the phrase ''at a minimum'' to the introductory statement to make clear that the required plan contents do not restrict a processor from including additional information in the plan, where it may be appropriate.

61. Two comments requested that FDA specify that decomposition, listed as one of the hazard categories in the proposal, is a hazard only in scombroid toxin-forming species.

These comments stated that decomposition in other species is not a safety hazard but is an economic and aesthetic problem.

FDA agrees with the comments in part. FDA's intent was to require control of decomposition in a HACCP plan only when it represents a food safety hazard. As described in the preamble to the proposed regulations, histamine (scombroid toxin) development as a result of microbiological decomposition in certain species of fish is a well recognized food safety hazard (Ref. 5, p. 24). There are some early indications, however, that the development of putrescine and cadaverine, also byproducts of decomposition of fish, under certain circumstances, may also represent food safety hazards (Ref. 203, p. 240). For this reason, FDA is hesitant to limit the safety concern associated with decomposition to the production of histamine. Accordingly, FDA has modified § 123.6(c)(1)(vi) to read, ''Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition.''

62. Comments from two State government agencies and a trade association stated that FDA should eliminate parasites as a safety hazard that must be considered for inclusion in a processor's HACCP plan. The comments noted that, with respect to pathogens, FDA makes the assumption that raw fish will be further processed by cooking, and that, therefore, that the pathogens will be destroyed and not pose a health hazard. The comments urged that the same rationale be applied to raw fish that may contain parasites. The comments further suggested that the retail level is appropriate point of control for parasites, and that the provisions of the Food Code are adequate to address this issue.

The comments further argued that parasites pose a hazard only in certain species that are consumed raw, and that mandatory control procedures for all fish that are consumed raw would create an enormous economic hardship for some segments of the industry. In particular, one of the comments contended that parasites have never been a problem in the large tunas that are eaten raw, and that it should not be necessary to freeze such fish before they are sold for raw consumption.

FDA's intent is to require control of parasites in a HACCP plan only in those instances when parasites are reasonably likely to occur in the portion of the flesh that is consumed, and the presence of the parasites will present a food safety hazard (e.g., where the fish is offered for raw consumption). To clarify this intent, FDA has modified § 123.6(c)(1)(vii) to read:

> Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to remove the hazard, or where the processor represents, labels, or intends for the product to be so consumed.

With regard to the comparison made by comments that FDA is requiring control of parasites in raw fish but not pathogens in raw fish, the characterization of FDA's policy towards pathogens is inaccurate. The sanitation provisions of these regulations are designed, in large part, to minimize the presence of pathogens in fish and fishery products, whether they are raw or further processed. The major opportunity for the introduction of enteric pathogens to processed fish and fishery products is from the processing environment as a result of insanitary practices rather than by the carcass of the animal (Refs. 3, p. 267; and 7, p. 33). For this reason, sanitation controls designed to prevent contamination of fish flesh are important to minimize the levels of enteric pathogens found on processed fish (Refs. 3, p. 10; 7, p. 27; 204; and 205). The agency is convinced that, if followed, these controls will be effective in minimizing the presence of such pathogens. Moreover, FDA has long enforced a zero tolerance for the presence of *Salmonella* on raw fish, based, in part, on the avoidability of such contamination through the application of CGMP's.

63. One comment stated that the term ''physical hazards'' in the proposal could be interpreted to include nonsafety related hazards.

In § 123.6(c), physical hazards are one of nine listed causes of ''food safety hazards'' that processors should consider for listing in their HACCP plans (§ 123.6(c)(1)(ix)). Thus, the agency believes that the language of this section clearly applies to food safety hazards only, and no modification of the provision is necessary in response to this comment.

FDA proposed that HACCP plans include the CL's that must be met at each CCP. FDA received no significant comment on this section (§ 123.6(c)(3)) and has made no substantive changes to it.

FDA proposed to require that HACCP plans include the procedures for both ''monitoring'' and ''controlling'' the CCP's. FDA recognizes that monitoring and controlling serve different purposes, and that the appropriate HACCP principle is the monitoring of CCP's to ensure conformance with the CL (Ref. 34, p. 197). How a processor exercises control is not critical to product safety so long as the CL is not exceeded. There are many ways to maintain control. No one way or list of ways needs to be stated in the plan so long as monitoring is taking place at an appropriate frequency to ensure that control is occurring and to detect CL deviations when they occur. For this reason, FDA has modified § 123.6(c)(4) to read, ''(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.''

FDA has also eliminated the reference in § 123.6(c)(4) to consumer complaints as a monitoring tool. As explained in more detail in the ''Consumer Complaints'' section of this preamble, FDA has concluded in response to comments that consumer complaints generally do not provide the processor with the kind of immediate feedback about whether the process is under control that monitoring should provide in a HACCP system. Consumer complaints may provide the processor with information that would be useful for verification purposes, however. These regulations therefore require processors to take consumer complaints into account as verification tools (§ 123.8(a)(2)(ii).

Likewise, FDA has moved the reference in the proposed regulations to the calibration of process monitoring instruments to the new ''Verification'' section of these regulations (§ 123.8), and it has eliminated the specific reference to computer software validation. As explained in more detail in the ''Verification'' section of this preamble, FDA has concluded in response to comments that calibration is a verification function that provides the processor with information about whether its monitoring equipment is functioning properly. Computer software validation is a form of calibration and need not be addressed separately in these regulations.

64. In the preamble to the proposed regulations, FDA asked for comment on whether guarantees from suppliers should be considered as an acceptable way of meeting the proposed monitoring requirement. Comments from a number of processors responded that a certificate from a producer that a lot of raw material fish is free from unacceptable levels of pesticide and drug residues should be an acceptable means of monitoring the hazards of animal drug and pesticide residues in aquaculture-raised fish. The comment held that reliance on suppliers' certificates may be necessary because of the logistical problems that could be associated with analyzing raw materials for pesticides and drug residues. Of particular concern, the comments said, is the time necessary to analyze the samples. The comments further stated that the certificates should be based on participation in an industry-wide quality assurance program designed to ensure that the raw materials are free from these hazards.

FDA believes that caution is warranted on the subject of supplier guarantees. Where more direct controls are available, they should be used. In the case of aquaculture-raised fish, more definitive controls than the acceptance of a certificate attesting to the absence of unapproved drug residues alone are available to a processor, and these controls are not unduly burdensome. They include the review of the supplier's animal drug control records when the lot is offered for sale and a system of onsite audits of the supplier, either by the processor or by a third party. Such alternatives are also available for most raw material hazards (e.g., checking container tags and harvester licenses as a means of controlling microbiological contamination in molluscan shellfish, and checking vessel storage records as a means of controlling histamine development in scombroid species). However, the agency recognizes that there may be some instances in which such controls are not possible, and suppliers' certificates or guarantees are the only available monitoring tool. In those cases, verification of the effectiveness of the certificates may be critical. Thus, the extent to which suppliers' guarantees can be relied upon will have to be considered on a case-by-case basis. However, FDA has made no change in § 123.6(c)(4) in response to the comments.

FDA has added § 123.6(c)(5) that describes requirements of the HACCP plan with regard to corrective actions. As explained in more detail in the ''Corrective Actions'' section of this preamble, FDA has concluded in response to comments that these regulations should provide the processor with the option of predetermining corrective actions. Predetermined corrective action procedures have the potential to enable a processor to take faster action when a deviation occurs than would be possible in the absence of such procedures, and to make a more timely response to the deviation when trained or otherwise qualified individuals are not readily available.

FDA has also added § 123.6(c)(6), which describes the requirements of the HACCP plan with regard to verification. As explained in more detail in the ''Verification'' section of this preamble, FDA has concluded in response to comments that a processor needs to specifically include in its HACCP plan the verification procedures that it will use and the frequency with which it will use those procedures. FDA finds

that inclusion of this information in the plan is necessary to underscore that a processor has an ongoing obligation to be sure that the verification steps that it has determined are necessary are readily ascertainable by the processor and its employees as well as by regulatory officials.

FDA proposed to require that HACCP plans provide for a recordkeeping system that documents the monitoring of CCP's. The proposed regulations also provided that the records must include the actual values obtained during monitoring and any consumer complaints that relate to the operation of CCP's or possible CL deviations. FDA has removed the latter provision, relating to consumer complaints, from § 123.6(c)(7). As explained above, these final regulations treat consumer complaints as verification tools rather than monitoring tools. Consequently, consumer complaints need not be included in a recordkeeping system that documents the monitoring of CCP's. A full discussion of issues relating to consumer complaints is presented in the ''Consumer Complaint'' section of this preamble.

6. Positive Versus Negative Recordkeeping

The preamble to the proposed regulations invited comment on whether it was necessary for the results of monitoring (i.e., the actual values) to be recorded regardless of whether a CL was met (positive recordkeeping), or whether it was only necessary to record information when a CL was not met (negative recordkeeping). The agency noted that negative recordkeeping is presumably less expensive than positive recordkeeping.

65. A substantial number of comments addressed this issue. Approximately two-thirds of these comments, including those from trade associations, processors, Federal, State, and foreign government agencies, consumer advocacy groups, and a professional society, supported requiring positive records. The remaining one-third of the comments that addressed this issue, from trade associations, processors, and Federal and State government agencies, argued that records should only be required when a CL deviation occurs, or that positive records should be required or encouraged, but that FDA should be granted access to only the negative records.

In general, the comments supporting the need for positive records recognized that monitoring records serve two major purposes: To facilitate the identification of trends that would lead to a loss of control if not caught in time and to document compliance with, or deviations from, CL's. Comments from a large processor and a trade association stated that, based on their extensive experience with HACCP, positive monitoring records provide a pattern of results and values that is much more meaningful than sporadic negative records alone. Several comments stated that positive recordkeeping facilitates the taking of corrective action before the CL's are exceeded.

Several comments stated that a provision that required only negative records would penalize the firms that already maintain records of all CCP observations. A few comments suggested that neither firm management nor FDA could verify that the monitoring procedures specified in a processor's HACCP plan are being carried out if only records of deviations from CL's are kept, because there would be no records to indicate that the other checks were actually being made. A comment from a consumer group further argued that allowing the use of negative records alone could create the opportunity for processors to limit their monitoring, because no records would be needed to demonstrate that such monitoring was performed.

Most comments that supported the use of negative records alone stated that positive recordkeeping and the review of positive records was overly burdensome for both the industry and the regulator. A few comments stated that positive records generate massive databases that disguise CL deviations, rather than illuminate them. No examples of this phenomenon were provided, however. One comment suggested that since FDA inspects most processors once a year or less, it is questionable whether the agency would be in a position to pick up trends in the data from a review of all the positive records that would be retained. Another comment stated that it is just as unrealistic to expect FDA investigators to review all positive records as it is for FDA to inspect all fish. A few comments argued that the sheer volume of the paperwork produced with positive recordkeeping would result in technical or clerical errors by processors that could result in products being deemed by FDA to be adulterated.

Several comments suggested that a system where CL deviations trigger remedial actions, which are properly documented, should be sufficient for FDA's verification purposes. One comment suggested that because processors can falsify positive records as well as negative records, FDA was mistaken if its motive for proposing to require positive records over negative records was to help prevent unscrupulous processors from circumventing the system. An additional comment supported limiting mandatory HACCP recordkeeping to negative records because FDA could not rule out the possibility that future court decisions or changes in FDA policy might permit the disclosure of HACCP records in FDA's possession, and negative recordkeeping would reduce a company's potential exposure.

FDA's reasons for proposing positive records match those in the comments that support these kinds of records. As the preamble to the proposed regulations noted, recordkeeping is the key to HACCP, enabling the processor and the regulator to see the operation through time. Negative records alone do not allow this assessment over time and do not provide assurance that the appropriate monitoring was even performed.

FDA cannot conclude from the comments that supported negative records that the burden of positive recordkeeping is excessive or otherwise outweighs the benefits. The agency acknowledges that a requirement for positive records may be more burdensome than one that only requires negative records. However, FDA received no new data on this issue. Positive recordkeeping can be extremely simple and need not take much longer to perform than the monitoring necessary to determine whether the process is in control (e.g., noting the temperature of a refrigerator in a logbook located next to the refrigerator). The agency is convinced that this minimal additional effort greatly increases the chances that a processor's HACCP program will be successful.

Based largely on FDA's experience with the positive recordkeeping requirements in the low-acid canned food and the acidified food industries, FDA does not agree that the volume of positive records that a system will generate will defeat the system by hiding CL deviations or trends toward such deviations. FDA's regulations at parts 113 and 114 require that these industries perform positive recordkeeping at identified CCP's. The industry itself requested this requirement.

FDA has found that these processors have no trouble making positive records, and that both the processors themselves and the regulators become adept at reviewing them and deriving benefits from them that would not have been available from negative records. These benefits have included being able to pinpoint with confidence when a

deviation began and ended, being able to react to trends toward a loss of control, and being able to prove that CCP's were actually being monitored as often as necessary to ensure control. The relative volume of records has not served as a roadblock in this regard.

It is unlikely that FDA investigators will review all monitoring records during routine inspections, except in highly unusual circumstances. As has been the case with FDA inspections of low-acid canned foods and acidified foods, the agency will, in most cases, select records to represent the production since the last inspection. This technique has proven to be both effective and efficient.

As for the concern that the agency will declare product adulterated on the basis of technical or clerical errors in positive-type records, the agency advises that it is not its intent to pursue regulatory action against product solely because of clerical or related errors in mandatory records. FDA does not take such actions against processors of low-acid canned foods or acidified foods, and it will not do so against seafood processors. FDA will consider the entire situation, and its potential for impact on human health, in formulating a response to deviations from these regulations.

As for the comment that FDA might as well mandate negative records because positive records can be successfully falsified, FDA advises that the possibility that records will be falsified—and that falsifiers will get away with it—is an issue that involves the fundamental credibility of the system. From FDA's standpoint, the agency's decades-long experience reviewing positive records on low-acid canned foods and acidified foods gives it confidence that its investigators can detect falsifications. However, FDA did not propose positive records for the purpose of catching falsifiers. FDA proposed positive records because this approach confers benefits on both the industry and the regulator that outweigh the additional work of maintaining them. Aside from the view, to which FDA strongly adheres, that most processors are honest and will not falsify records, the agency strongly believes that most processors will quickly see the benefits to themselves of a properly operating HACCP system based on positive records and will insist that their records be accurately completed.

One such benefit should be a more motivated workforce. HACCP monitoring and recordkeeping can and should be done by the workers who operate the system at the CCP's, not by quality control personnel. To the extent that these workers experience a sense of responsibility and pride associated with making accurate daily notations, the processor can expect to benefit.

Regarding public disclosure of records as mentioned by one of the comments, FDA continues to believe that possession of monitoring records by the agency will be more the exception than the rule, and that these kinds of records are protected from public disclosure in any event. The protection of records is addressed in detail in the ''Records'' section of this preamble.

FDA has therefore not modified the requirement that processors' monitoring records include the actual values obtained during the monitoring.

7. Signing the Plan

66. In the preamble to the proposed regulations, FDA specifically invited comment on whether HACCP plans should be required to be signed by a representative of the firm and, if so, by whom. Approximately 30 comments responded to the inquiry. About two-thirds of these comments, from processors, trade associations, professional associations, and Federal, State, and foreign national governmental agencies, supported the need for a signature. The remaining comments, mostly from processors and trade associations, argued that a signature was unnecessary.

Those that favored a requirement for a signature on HACCP plans stated that the signature does the following: Demonstrates formal adoption of the HACCP plan, solidifies responsibility for adherence to the plan, and fosters a sense of management ownership. The comments made the following suggestions with regard to who should be the signatory (in order of preference): Onsite manager, most responsible individual of the firm, any senior manager, HACCP coordinator, and all HACCP team members. Those comments that argued against a mandatory signature on the plan stated that the existence of a HACCP plan itself constitutes management support for the plan.

FDA agrees with the comments that recommended a requirement for HACCP plans to be signed by a representative of the firm. As suggested by the comments, such a signature will provide direct evidence of management's acceptance of the plan for implementation. FDA cannot stress enough that for HACCP to succeed, there must be a clear commitment to it from the top of the firm on down. Management must set a strong example in this regard. A signature requirement will remind management of this important responsibility and will signal to all employees that the firm regards the HACCP plan as a document to be taken seriously. Additionally, the representative's signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist. FDA has concluded that the burden of such a requirement would be minimal, and has added a new paragraph at § 123.6(d), that reads:

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the plan has been accepted for implementation by the firm. (2) The HACCP plan shall be dated and signed: (i) Upon initial acceptance; (ii) Upon any modification; and (iii) upon verification of the plan * * *.''

As will be discussed fully in the ''Verification'' section of this preamble, the adequacy of the HACCP plan must be reassessed, and modified as needed, whenever significant changes in the firm's operations occur, but no less than once per year. These reassessments and modifications are necessary to ensure that the plan remains current and is responsive to emerging problems. The signature of the firm representative will be valuable in documenting that these reassessments and modifications are performed as required. Particularly if no modification of the plan is needed, reassessment can be verified by FDA only if documentation, such as a signature, is maintained by the firm.

8. Relationship to Parts 113 and 114

67. A few comments urged that the final regulations provide that if a processor of low-acid canned fishery products is in compliance with FDA's regulations for these products under part 113, it would also be in compliance with these HACCP regulations with respect to the control of the hazard of *C. botulinum* toxin production. The regulations at part 113 establish HACCP-type controls for this hazard.

FDA agrees that there is no need for a processor to restate in its HACCP plan the requirements of part 113 or 114. It is also not necessary for such a processor to institute controls in addition to those specified in parts 113 and 114 in order to control the hazard of *C. botulinum* toxin production. Consequently, processors who must comply with the requirements of part 113 or 114 need not address this hazard at all in their HACCP plans. However, it is important to note that other hazards may be reasonably likely to occur in an

acidified or low-acid canned fishery product. These hazards must be addressed in the HACCP plan, as appropriate. For example, processors of canned tuna will likely need to identify in their HACCP plans how they will control the development of histamine before the canning process. Accordingly, to clarify what is required of processors of acidified and low-acid canned fishery products, FDA has added § 123.6(e), which reads:

For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

9. Sanitation in the Plan

The question of the role of processing plant hygiene (i.e., traditional sanitation controls) in HACCP is addressed at length in the ''Sanitation'' section of this preamble. As explained in that section, FDA is requiring that processors address plant sanitation by monitoring for certain key sanitation conditions and practices apart from critical control point monitoring activities, or by including sanitation controls as part of the HACCP plan, or by adopting some combination of these two approaches, at the option of the processor. To reflect this approach, in paragraph (f) in § 123.6 on the inclusion of sanitation controls in the HACCP plan FDA has stated: ''(f) Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitoring in accordance with § 123.11(b), they need not be included in the HACCP plan and vice versa.''

FDA recognizes that, in many processing operations (e.g., cooked, ready-to-eat fishery products, smoked fishery products, and molluscan shellfish) sanitation controls, such as hand and equipment washing and sanitizing, are critical to the safety of the food because they serve to minimize the risk of pathogen introduction into finished products that may not be further cooked before consumption (Ref. 3, p. 267). For this reason, some processors may elect to include the control of sanitation conditions and practices in their HACCP plan in addition to, or in place of, monitoring for such conditions and practices apart from the HACCP plan. Based in part on experience gained from the seafood HACCP pilot project operated jointly by FDA and DOC, however, FDA also recognizes that sanitation controls may be difficult to fit in HACCP plans, with appropriate CL's and corrective actions sometimes being elusive. For this reason, some processors may elect to rely exclusively on sanitation controls that are not part of the HACCP plan. FDA considers either approach to be acceptable, so long as whatever approach is chosen is fully implemented and followed.

10. Nonsafety Issues

68. FDA proposed in § 123.6(c) to recommend, but not to require, that HACCP plans include controls for such nonsafety hazards as economic adulteration and decomposition that are not related to safety. Additionally, FDA proposed to append to the regulations at Appendix D guidance on how a processor can use a HACCP-based approach to ensure that fish and fishery products are in compliance with the economic adulteration and misbranding provisions of the act. Approximately 75 comments addressed these proposed provisions. The vast majority of these comments urged that proposed § 123.6(c) and proposed Appendix D of part 123 be eliminated from the regulations. Some of these comments suggested that it might be appropriate for the contents of proposed Appendix D to be included in the Guide.

Those that argued for removal of the recommendation that HACCP be used to control nonsafety hazards from the regulations stated that: (1) HACCP for safety purposes will be a big enough challenge for both the industry and regulators, and that inclusion of nonsafety hazards might be overwhelming; (2) nonsafety hazards, such as economic fraud and decomposition, are covered adequately by existing FDA regulations and standards and by industry quality control programs; (3) inclusion of nonsafety hazards deviates from the internationally recognized NACMCF recommendations; and (4) inclusion of nonsafety hazards, even as a recommendation, would dilute and jeopardize a desirable industry focus on safety. One comment stated that processing plant personnel and supervisors should be trained to expect serious consequences when CL deviations occur because this heightens their attention to monitoring and control. However, the comment further argued, the consequence of violating a nonsafety CL is likely to be relatively minor. The comment argued that, as a result, plant personnel and supervisors will become confused about the significance of CL deviations.

A significant minority of the comments favored the treatment of nonsafety hazards such as economic fraud and decomposition in the same manner in which safety hazards are treated in these regulations, with mandatory HACCP controls. These comments argued that: the same conditions of processing that affect the occurrence of safety hazards affect the occurrence of such nonsafety hazards as decomposition and economic fraud, making the two control systems compatible; an improvement in consumer confidence in seafood cannot be achieved without improvements relative to economic deception and decomposition; decomposition is the number one cause of FDA legal action with respect to seafood; decomposition is a good indication of time and temperature abuse, which has a significant impact on the growth of pathogens; the seafood industry considers economic fraud to be the most significant hazard affecting the marketing of its products; species substitution can be safety related, as in the case of the substitution of a scombroid species for a nonscombroid species; HACCP controls would likely enhance compliance with existing nonsafety standards; and inclusion of controls for economic fraud and decomposition would not significantly increase the costs to industry.

FDA concludes that the HACCP system will have to mature, and much will have to be learned, before it can be determined whether a mandatory HACCP program should include nonsafety matters. Because these regulations reflect a first step in terms of mandating HACCP, the agency is comfortable as a matter of policy that they should initiate a system that focuses on food safety. Additionally, the statutory provisions that form the basis for these regulations are safety provisions. FDA's application of HACCP is intended for the effective enforcement of sections 402(a) (1) and (a)(4) of the act, which apply to products that contain substances that may render the product injurious to health and to processing conditions that are insanitary and that could render a product injurious to health. Thus, the only real issue is whether the final regulations should retain the recommendations with regard to the application of HACCP to nonsafety matters.

FDA is persuaded by the comments that the proposed recommendations for HACCP controls of nonsafety matters, coupled with the presence of proposed Appendix D of part 123, have the potential for causing confusion about the agency's expectations and

enforcement policies. FDA recognizes the point raised by a number of comments that advisory provisions are often confused with or misapplied as requirements. Given this fact and the emerging nature of HACCP, FDA has decided to eliminate proposed § 123.6(c) and Appendix D of part 123. FDA will consider including the concepts that underlay these provisions in the first edition of the Guide, however, because the Guide is understood as being the repository for recommendations relating to seafood HACCP.

The agency's decision to eliminate reference to nonsafety hazards from these regulations notwithstanding, such hazards as economic adulteration, decomposition not normally associated with human illness, general unfitness for food, and misbranding constitute violations of the act and are subject to regulatory action by FDA (see sections 402(a)(3) and 403 of the act (21 U.S.C. 343)). When inspections by FDA investigators reveal violations of these provisions of the act, FDA will take enforcement action as it deems appropriate. Processors who are able to accommodate a HACCP system that covers both safety and nonsafety hazards may find advantage in doing so, in order to better ensure compliance with existing nonsafety regulations and standards.

11. ''Shall Render Adulterated''

FDA proposed to provide that: Failure of a processor or importer to have and implement an HACCP plan that complies with this section or to operate in accordance with the requirements of this part, shall render the products of that processor or importer adulterated under section 402(a)(4) of the act.

The preamble to the proposed regulations explained that the proposed regulations set out those requirements that the agency had tentatively concluded are the minimum necessary to ensure that the processing of fish and fishery products will not result in product that is injurious to health. FDA tentatively determined that such minimum requirements include the establishment of HACCP preventive controls. The preamble further explained that section 402(a)(4) of the act, among other things, deems a food to be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

69. A significant number of comments, primarily from processors and trade associations, opposed the proposed language of this provision. The comments urged that the word ''may'' replace the word ''shall'' in order to establish that instances of noncompliance with the regulations do not automatically constitute adulteration. They contended that, because FDA will not be preapproving HACCP plans, a negative finding on the first FDA inspection could, under the language that was proposed, cause the agency to consider all product produced to that point to be adulterated. The comments stated that each case of noncompliance should be evaluated on its own merits.

FDA fully agrees that each case should be judged on its merits but does not agree that it is necessary to change the regulations in order to establish this principle. The purpose of § 123.6(g), which sets out this language, is not to create a legal presumption that food is adulterated if there is not perfect adherence to these regulations but to make clear that certain types of preventive controls are so fundamental to ensuring the safety of seafood that if there is not adherence to them, the food cannot be considered to have been produced in accordance with section 402(a)(4) of the act.

As a practical matter, FDA expects to exercise broad regulatory discretion in deciding when violations of these regulations warrant regulatory action, just as it does now for other situations. The agency will analyze each case on its merits, based at least in part on the potential for harm that exists.

The agency's primary concern is that processors develop HACCP plans that address the hazards that are reasonably likely to occur. When deficiencies in HACCP plans are detected during FDA inspections, the agency usually will first attempt to seek voluntary correction of the situation. Only when such voluntary correction is not forthcoming is it likely that FDA will elect to pursue regulatory action. It must be noted, however, that, where HACCP plan deficiencies result in significant potential for consumer harm, the agency will evaluate the need for corrective action with respect to the product that has been produced as well as to the HACCP plan itself.

In this regard, FDA notes that a change from ''shall'' to ''may'' in the provision would be more compatible with guidelines than with regulations. Consequently, the agency has retained the term ''shall'' in § 123.6(g). However, to clarify that a decision on whether to take regulatory action will involve discretion based on the public health significance of the violation, a sentence has been added to indicate that when a violation occurs, FDA will evaluate the processors overall implementation of its HACCP plan in deciding how best to remedy the violation.

Consistent with the revisions to the requirements for imported products contained in § 123.12, the word ''importers'' has been eliminated from § 123.6. As described in the ''Imported Products'' section of this preamble, the proposed requirement that an importer develop a HACCP plan (§ 123.11) has been eliminated in favor of a requirement for importer verification procedures. This change eliminated the relevance of § 123.6 to importers.

Consistent with the revision to § 123.6(a) and (b) that processors have HACCP plans only when a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, § 123.6(g) has been amended to state that a processor's failure to have a HACCP plan shall render the fish or fishery products adulterated only when a HACCP plan is necessary.

*F. Corrective Actions*

The fifth HACCP principle, as articulated by the NACMCF, is that processors establish the corrective actions that they will take should monitoring show that a CL has been exceeded. The NACMCF's expectation is that these corrective actions should be predetermined and written into the processor's HACCP plan.

In the proposed regulations, FDA tentatively chose to incorporate the principle of corrective action without requiring predetermined corrective action plans in the processor's HACCP plan. Instead, FDA proposed minimum, generic corrective action procedures for processors to follow. In so doing, FDA was trying to minimize the burden of the mandatory requirements of HACCP, especially for small processors. FDA tentatively concluded that the procedures set out in proposed § 123.7 represented the minimum requirements necessary to ensure that processors respond effectively to deviations that could affect safety, and that if those procedures were followed, specific corrective action plans, although desirable, would not be necessary.

FDA proposed in § 123.7 to require that deviations from CL's trigger a series of actions, including: Segregating and holding the product, making a determination of the acceptability of the product for distribution, taking appropriate remedial action with respect to the product and the cause of the deviation, and documenting the actions taken. In the preamble to the proposed regulations, FDA invited comment on the wisdom of this approach as opposed to requiring that predetermined corrective action plans be made part of the HACCP plan. A large number of comments responded to

that request. Additional comments addressed the specifics of the proposed generic-type requirements in § 123.7.

1. Should Corrective Actions Be Predetermined?

70. Approximately half of the comments supported the corrective action system proposed by the agency or a variation of it, and the other half called for mandatory predetermined corrective action plans. Many of those that supported mandatory corrective action plans urged consistency with the HACCP recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex Alimentarius Commission standards. They predicted that compatibility of the final regulations with such international standards would minimize confusion for processors and importers, smooth international adoption of HACCP principles, and facilitate trade. The comments stressed that predetermining corrective action is an essential component of a processor's HACCP program, with the seven principles being so closely intertwined that overall success is probable only if all are intact.

A number of comments argued that a processor's implementation of a corrective action plan would eliminate indecision and confusion about what corrective action should be taken in the event of a deviation from a CL. For example, one comment pointed out that corrective actions written into the HACCP plan would eliminate the need for employees to substantiate to management the correctness of their response to a deviation, because the corrective action plan would provide the right actions to be taken for each particular deviation. A few comments stated that, if the appropriate corrective actions are detailed in the HACCP plan, responses by employees to CL failures are more likely to be immediate (reducing product losses) and effective (reducing wasted effort). These comments further noted that corrective action plans are particularly necessary when individuals qualified to make product safety evaluations are not readily available.

One comment asserted that the strength of the HACCP system is that it is preventive, and that corrective action plans are fundamental in preventing a product, for which there is a safety concern, from reaching the consumer. The comment further stated that written corrective action plans should provide for the documentation of the following: (1) The cause of the deviation, (2) the action taken to ensure that the deviation does not reoccur, (3) the results of the risk evaluation, and (4) product disposition.

Many comments did not agree that corrective action plans should be required. A few comments argued that developing a corrective action plan is impractical and can be unduly restrictive because of the diversity and complexity of seafood products and of seafood processing operations. One comment noted that many situations exist in which the appropriate response to a CL failure is not apparent until the details of the particular situation are known. Several stated that a corrective action plan is less preferable than having responsible and knowledgeable personnel, adequately trained in HACCP, available to evaluate a deviation from a CL. If such personnel are available, one comment noted, deviations can be handled on a case-by-case basis, with appropriate documentation of the disposition of the affected product.

Several comments argued that the lack of a corrective action plan is not sufficient evidence to demonstrate that a product is adulterated. The comments argued that the proposed requirement that a processor establish CL's and perform and record appropriate corrective actions when these limits are exceeded, provides sufficient demonstration of hazard control.

A number of comments that advocated the concept of predetermined corrective action plans urged that processors be given the option of writing such plans or of following a series of minimum mandatory actions, like those proposed by FDA, when CL failures occur. In the preamble to the proposed regulations the agency did, in fact, encourage processors to predetermine corrective actions as part of the preparation of a HACCP plan.

On this issue, the merits of the various approaches tend to balance. Consequently, FDA agrees with those comments that urged that the regulations provide processors with the option of developing their own corrective action plans as part of their HACCP plans or of following a generic model corrective action plan, provided in the regulations, should a deviation occur.

The agency accepts the view that predetermined plans have the potential to provide processors with benefits, as pointed out by the comments, such as faster action when a deviation occurs, less need to justify to management the appropriateness of the corrective action after it has been taken, and a more timely response to the deviation when trained or otherwise qualified individuals are not readily available to make determinations. On the other hand, FDA has not been provided with information on which it can conclude that these benefits—as desirable as they may be—need to be mandated in order to protect the public health. Processors can build them into their HACCP systems if they so choose, but the public health will be protected so long as shipment of the affected product into commerce does not occur until the significance of the deviation has been assessed and appropriately resolved.

This outcome is assured both with specific predetermined corrective action plans and with the minimum generic model that FDA is requiring as an alternative. Without additional evidence from actual experience, which was not provided by the comments, FDA cannot conclude that the overall success of HACCP depends on whether processors have specific predetermined plans for events that might not necessarily occur.

Consequently, FDA has revised § 123.7 to permit, but not to require, processors to include in their HACCP plans any written corrective action plans that they develop. When a deviation from a CL occurs, § 123.7(a) requires that processors either: (1) Follow a corrective action plan that is appropriate for the particular deviation, or (2) follow the series of actions provided in § 123.7(c). The steps in § 123.7(c) constitute a minimum generic model for corrective actions and, as will be explained below, closely match those that were contained in the proposed regulations.

The final regulations at § 123.7(b) define an appropriate corrective action plan as one that addresses both the safety of the product that was being processed when the CL failure occurred and the cause of the deviation. In this respect, the contents of the corrective action plan are consistent with the views of the NACMCF (Ref. 34, pp. 199–200). The corrective action must ensure that any unsafe product is not distributed.

FDA advises that action necessary to correct the product may involve any one or more of the following steps: Immediately reprocessing the product; diverting the product to another use where it can be used safely; segregating the product, holding it, and having it evaluated by a competent expert; or destroying the product. In order to ensure that subsequent product is not subjected to the same deviation, the corrective action must be sufficient to bring the process back under control (Ref. 34, pp. 199–200). FDA advises that such action may involve, where appropriate: adjustments to those process parameters that have an effect

on the relevant CL (e.g., flow rate, temperature, source of raw materials); temporarily diverting product around a point in the process at which problems are being encountered; or temporarily stopping production until the problem can be corrected.

Section 123.7(c) describes the steps that a processor must take whenever there is a deviation from a CL but no corrective action plan to follow. As stated above, these steps constitute a minimum generic-type corrective action plan. The objectives of these steps are the same as those of a preconceived plan: To ensure that adulterated product does not enter commerce and to correct the cause of the deviation. Because it is a generic-type plan that is intended to be applicable to any situation, some of the steps, such as segregating and holding the affected product (§ 123.7(c)(1)), might not be necessary if the corrective action had been predetermined. This aspect of the generic-type plan may provide processors with an incentive to predetermine corrective actions whenever practical.

Another such incentive is the requirement, at § 123.7(c)(5), that the processor reassess the adequacy of its HACCP plan when a deviation occurs. This requirement does not exist where a corrective action plan exists. The reason for the distinction is that, on one hand, if a processor has assessed its process and decided that CL failures are likely to occur from time to time at particular points, those failures, when they occur, do not represent a failure of the plan but a foreseeable occurrence. On the other hand, if the processor has not made such an assessment, and a failure occurs, it is not possible to say what the failure means. The processor must assess whether the deviation is the result of a system-wide problem that is not being properly addressed by the plan or simply a failure that could be expected to occur in the normal course of things. The failure must be fully assessed, and if it represents a failure of the plan, the plan must be modified to reduce the risk of reoccurrence.

The agency is convinced that the corrective action approach contained in the final regulations (i.e., predetermined corrective action plans at the option of the processor) adheres to the principles of HACCP as recommended by NACMCF (Ref. 34, pp. 199–200) and will not result in undue burden, confusion, or trade difficulties. At the same time, these regulations will provide the flexibility needed to accommodate the varying levels of HACCP sophistication within the industry. FDA is satisfied that employee indecision in responding to CL deviations will not result in a public health problem in the absence of corrective action plans because the final regulations contain a set of well defined actions that are to be followed if a deviation occurs and no predetermined plan exists. The actions outlined in § 123.7(d) ensure that no unsafe product will enter commerce, and that a normalization of processing conditions will be effected as quickly as possible. While the agency sees merit in the argument that predetermined corrective action plans will, in many cases, be economically beneficial to a processor (e.g., minimize product loss and wasted effort), such economic factors will, in and of themselves, motivate processors to predetermine appropriate corrective actions, but they do not mean that the agency needs to require the adoption of predetermined plans.

71. A few comments recommended that FDA review corrective action plans for adequacy during, or in advance of, the first regulatory visit. This review, the comments asserted, would help to avoid a situation in which the processor takes a corrective action in conformance with its HACCP plan, but the agency later determines that the action was inadequate.

FDA agrees that these comments reflect a desirable ideal but must acknowledge that such a review ordinarily will not be feasible. If processors complete their HACCP plans, including any corrective action plans that they choose to develop, before the effective date of these regulations, they may be able to obtain a review of those plans as part of a routine FDA inspection.

In any event, the agency intends to review corrective action plans that a processor includes as part of its HACCP plan during routine regulatory inspections. Where the investigator finds a shortcoming in the corrective action plan, the investigator will discuss it with the processor. As with a failure to meet any other provision of these regulations, in determining its response to such a shortcoming, the agency will consider the totality of the situation and the likelihood that the shortcoming will have an adverse impact on the safety of the product. If a corrective action plan has not actually been used as of the time of the investigator's review, and as a consequence of its review the agency advises the processor that the corrective action plan needs to be improved, it is likely that FDA will advise the processor to follow the alternative procedure in these regulations until the upgrade occurs.

2. Assessing the Product for Safety

72. FDA received comments on specific aspects of the generic-type corrective action plan provided in proposed § 123.7(a). A significant number of comments opposed the provision that would have required an ''immediate'' safety assessment when a CL deviation occurs. One comment stated that, because an appropriately trained individual may not be immediately available to make a determination of the acceptability of the lot, the provision should be modified to require segregation and holding of the affected product until either a timely safety review by a properly trained individual has been completed, or a determination has been made that the appropriate predetermined corrective action plan has been followed. A number of other comments also suggested that the phrase ''immediate review'' be revised to ''timely review.'' One comment recommended that FDA specify a maximum amount of time in which to evaluate the product, for example within 24 hours. Another comment advised that FDA permit processors to cook or freeze fresh product involved in a CL deviation, until an evaluation can be completed.

FDA agrees that immediate review is not necessary. As long as the review occurs before the product is distributed, the public health will be sufficiently protected. Consequently, while § 123.7(c)(2) requires a review to determine the acceptability of the affected product for distribution, it does not require that the review be immediate, nor does it otherwise specify a timeframe for review. If there is a chance that the product is still fit for commerce, FDA expects that economic considerations will dictate the timing of the review. FDA agrees that, in many cases, it would be advantageous for a processor to cook or freeze a product pending results of a safety evaluation. The agency has no objection to such an action as long as the processor maintains the identity of, and its control over, the lot.

FDA has also modified § 123.7(c)(2) from the proposal to require that the review of the product be conducted by someone with adequate training or experience, although FDA is not tying adequate training to training in HACCP (see § 123.10) as it did in the proposal. FDA made this change because, as comments pointed out, a 3-day course in HACCP would not necessarily qualify someone to make many public health determinations of this nature. The basis for this modification is more fully

described in the ''Training'' section of this preamble.

3. Documenting Corrective Actions

In § 123.7(d), FDA is retaining the proposed requirement that records of corrective actions be kept. As with the proposal, such records are subject to the general recordkeeping requirements of § 123.9. The records must document the actions taken in following either a predetermined corrective action plan or the corrective action procedures specified in § 123.7(c).

73. One comment suggested that the absence of written corrective action plans would make it more difficult to document a response to a deviation. It went on to explain that, with a plan, the processor could simply note, for example, that ''the product was recooked in accordance with 'Section B of the Plan.''' It pointed out that more extensive documentation would be necessary if a processor did not have a predetermined plan.

FDA does not agree with this comment. Section § 123.7(d) requires that the corrective action taken by a processor be fully documented. It is the agency's intent that such documentation provide the specifics about the actions that were taken and not simply refer to a written procedure. In the example given, records of the recooking operation, equivalent to monitoring records for such an operation, i.e., cooking, would be necessary to document that the operation was performed in a manner that would render the product safe. Thus, similar documentation would be necessary whether a plan exists or not.

It is worth noting that § 123.7(d) now states that corrective action records are subject to verification in accordance with § 123.8(a)(3)(ii). This requirement is not new but reflects the fact that record review is deemed to be a verification activity in the final regulations but was not classified as such in the proposal. A further discussion of this matter can be found in the section of this preamble that follows.

*G. Verification*

1. Overview

Verification is one of the seven commonly recognized principles of HACCP. In the preamble to the proposed regulations, FDA acknowledged and discussed the recommendations of the NACMCF as they relate to verification. According to the NACMCF, verification essentially involves: (1) Verifying that the CL's are adequate to control the hazards; (2) ensuring that the HACCP plan is working properly, e.g., that it is being followed, and that appropriate decisions are being made about corrective actions; and (3) ensuring that there is documented, periodic revalidation of the plan to make sure that it is still relevant to raw materials as well as to conditions and processes in the plant.

2. Need for Verification Requirement in Regulations

In the preamble to the proposed regulations, FDA encouraged processors to adopt verification practices but did not propose to require that a processor's HACCP plan specify the verification procedures. Rather, the agency tentatively concluded that verification of a HACCP plan would effectively occur through: (1) Comparison of the plan to guidance documents such as FDA's draft Guide; (2) technical assistance provided through trade associations, universities, and government agencies; (3) mandatory review of monitoring and corrective action records by trained individuals before product distribution; (4) mandatory reassessment of the adequacy of the HACCP plan as a consequence of CL deviations; (5) reliance on the recommendations in FDA guidelines that processors of cooked, ready-to-eat seafood products use the expertise of ''processing authorities,'' i.e., third-party experts; (6) mandatory training; and (7) investigator review of the entire HACCP system during routine agency inspections. FDA requested comment on whether this approach is adequate to ensure that the verification principle was being properly addressed.

74. A large number of comments responded to this request. Approximately one-third of these comments stated that FDA's proposed approach to HACCP verification was adequate. The other comments argued that verification should be specifically mandated as a part of a firm's HACCP program.

A few of the comments favoring the proposed approach contended that a HACCP plan lacking verification procedures should not be grounds for FDA to consider a product to be adulterated. Several comments stated that processors will engage in verification activities without a requirement, as a natural outgrowth of a HACCP program, because without such activities, HACCP will not work. For this reason, they argued, it is not necessary to mandate that verification procedures be included in processor's HACCP plans.

Of the comments that supported the need for specifically-mandated verification activities, a significant number urged the agency to adopt such a requirement to be consistent with the HACCP recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex Alimentarius Commission standards. They predicted that compatibility of the final regulations with such international standards would minimize confusion for processors and importers, smooth international adoption of HACCP principles, and facilitate trade. The comments stressed that verification is an essential component of a processor's HACCP program, and that the seven principles are so closely intertwined that overall success is probable only if all are intact.

One of the comments stated that verification should involve a continual review and improvement of the HACCP system. The comment added that verification is a primary responsibility of processors, one that is equivalent in importance to plan development. Several comments stated that the benefits of HACCP verification include: Assurance that all CCP's are identified, assurance that the plan is being followed, a mechanism for third party oversight of the plan development process, a means of measuring the success of a HACCP system, and information on trends in the frequency and reasons for CL deviations. One comment suggested that firms should be required to perform verification activities at least annually.

A few comments stated that although the proposed regulations included some required practices that could be deemed to be verification, such as the calibration of process-monitoring instruments and plan reassessment and modification in response to a CL failure, the entire concept of verification should be addressed more fully in a separate section of the final regulations. One of these comments suggested that the following verification activities be specifically mandated: Calibration of process control instruments, validation of software for computer control systems, and daily review of monitoring records.

One comment stated that, without a requirement for specific verification activities, processors would rely strictly on end-product testing to evaluate the success of the HACCP plan, and that such an approach would diminish the effectiveness of the entire HACCP system. Several comments stated that HACCP plan verification procedures

should include detailed government and industry audits and product analyses.

One comment, from a consumer advocacy organization, challenged whether effective verification would really occur through the measures cited in the preamble. The comment stated that ''third-party technical assistance'' is not a mandatory part of the HACCP program and, therefore, can not be counted on as a verification procedure. It added that such technical assistance would tend to be performed during plan development, and that verification must be an ongoing procedure. The comment stated that a ''review of all HACCP-monitoring records by trained individuals before distribution of product'' is not verifiable by the agency because a firm can cut corners by having their employees sign the records without reviewing them. The comment argued that FDA auditing of consumer complaints and mandatory in-process and end-product testing are important verification procedures.

A few comments suggested that FDA should include a requirement that written verification procedures be in place, but that the agency need not prescribe specific verification activities, or should do so only sparingly.

FDA notes that the proposed regulations contained specific provisions identified by many of the comments as appropriate verification steps. For example, the proposed requirement that the HACCP plan adequately address the food safety hazards that are reasonably likely to occur (§ 123.6(c) in this final rule) is a continuing, rather than a one-time requirement. Thus, to continually be in compliance with it, a responsible processor would have to engage in some form of reassessment. Other provisions in the proposal that comments identified as verification steps included: The required calibration of process monitoring instruments; the required validation of computer software; the requirement that consumer complaints be reviewed to assess whether they indicate a problem at a CCP; and the requirement that HACCP-monitoring and corrective action records be reviewed before distribution of the product. FDA now realizes, however, that by not specifically requiring verification as such, the proposal generated considerable confusion about whether FDA intended to include or exclude the principle of verification from processors' HACCP programs. FDA has concluded, therefore, that verification is important enough to be an explicit part of the regulations. FDA has made it such in the final rule at § 123.6(c)(6) and in a new section for verification, § 123.8.

Section 123.6(c)(6) requires that processors include in their HACCP plans a list of the verification procedures that they will use and the frequency of those procedures. This provision is consistent with the view of the NACMCF that a processor's verification procedures should be addressed in the HACCP plan (Ref. 34, pp. 200–202). FDA does not expect that this requirement will be particularly burdensome for the processor for two reasons. First, the requirement that verification procedures be listed in the HACCP plans is really only a variation of the proposal in that FDA proposed to require a number of the activities that it is now designating as verification activities in § 123.6(b)(4) (e.g., calibration of monitoring instruments and review of consumer complaints). Second, a list of the steps that a processor determines are appropriately a part of the annual reassessment of the HACCP plan need not be extensive or detailed. FDA recognizes that, at least initially, much of the annual verification procedure could take the form of meetings and discussion, and may not lend itself well to a detailed listing of steps. FDA believes that the annual verification procedure should be allowed to evolve, and that a requirement that the listing of steps in the plan be detailed before an annual verification ever occurs could adversely affect that evolution.

The new section on verification, § 123.8, describes the minimum components of a processor verification program. Among other things, the agency has consolidated there those aspects of the proposal that, according to comments, should be designated as verification activities. Section § 123.8 contains little in the way of detail that was not included in the proposed regulations. In addition, it is designed to be generally consistent with the verification concepts expressed by the NACMCF, as requested by comments, and at the same time, not unduly burdensome.

3. Verifying the HACCP Plan

Section 123.8(a) requires that processors with HACCP plans verify two aspects of their HACCP systems: (1) That their HACCP plans are adequate to control food safety hazards that are reasonably likely to occur, and (2) that their plans are being effectively implemented. Verifying these two aspects is, essentially, what the NACMCF refers to as the first and second of the four processes of verification (Ref. 34, p. 201).

Second, § 123.8(a)(1) requires that a reassessment of the HACCP plan occur whenever there are any changes of the type listed in these regulations that could alter the plan, or at least annually. The NACMCF takes the view that verification must occur on a periodic, regular basis (Ref. 34, p. 202), although no specific timeframes are suggested. FDA agrees with the NACMCF and the comments that verification of the adequacy of the HACCP plan should be conducted on a regular basis, even in the absence of a recognized change, to ensure that the plan continues to address all of the reasonably likely food safety hazards with appropriate CL's and monitoring procedures. It is essential that processors verify the adequacy of their plans and that this verification occur on a periodic basis. Processors should conduct the review at intervals that are appropriate for their processes. FDA agrees with one of the comments, however, that this interval be no more than a year in order to ensure that the plan remains adequate to address the hazards associated with the species and processes (Ref. 206, p. 1084).

The regulations at § 123.8(a)(1) provide examples of changes that could trigger a reassessment. These include changes in raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. These examples are derived from the NACMCF materials on the ''five preliminary steps'' that form the basis for the HACCP plan (Ref. 34, pp. 188 and 201). A change in any of these areas could necessitate a change in the plan in order to respond to any new hazards that may have been introduced or to maintain preventive control over existing ones. It is important to recognize that this list is not all inclusive.

Section 123.8(a)(1) requires that the plan reassessment be performed by an individual that has been trained in HACCP in accordance with § 123.10. This requirement is a logical outgrowth of the proposed requirement in § 123.9 that a HACCP-trained individual be responsible for the initial development of, and subsequent modifications to, the HACCP plan. These kinds of activities require an understanding of the principles of HACCP and plan development as obtained through training that is at least equivalent to the course required in § 123.10.

Section 123.8(a)(1) also requires that, where a reassessment reveals that the HACCP plan is inadequate, the processor shall immediately modify the

plan. Failure of a processor to immediately modify its HACCP plan after it has determined that the plan is inadequate would result in the processor operating under a plan that is not in conformance with these regulations.

FDA recognizes that the methods that processors will use to verify that the plan is still adequate will vary, based on individual preferences and past experience. FDA agrees with comments that urged the agency to permit maximum flexibility in the development of verification procedures that are tailored to individual operations. Nonetheless, the agency encourages processors to consider the guidance in the March 20, 1992, NACMCF publication, ''Hazard Analysis and Critical Control Point System.''

Moreover, FDA believes that the best way for the agency to judge the merits of a processor's annual verification will be through its own continuing determinations of whether the processor's overall HACCP system remains appropriate for the circumstances. These determinations will occur as a product of the agency's ongoing inspection program.

On this subject, FDA is sensitive to the comment that the absence of verification procedures from a HACCP plan should not, in and of itself, cause a food to be deemed adulterated under 402(a)(4) of the act. Nonetheless, the absence of verification could jeopardize the likelihood of success of the overall program. For example, monitoring a critical cooking step with a thermometer that has not been calibrated provides little assurance that the CL is actually being met, and failure to review records may allow the absence of monitoring or improper corrective action to go unnoticed for extended periods of time. Should the agency find itself in the position of having to react to the absence of adequate verification procedures in a processor's HACCP plan, in deciding whether to bring regulatory action, the agency will consider the totality of the situation, and the likelihood that it would have an adverse impact on the final food, as it would in considering a processor's failure to meet any specific provision.

4. Verifying the Implementation of the Plan

The regulations at § 123.8(a)(2) and (a)(3) require ongoing verification activities in addition to the annual reassessment. These ongoing activities are in keeping with the NACMCF's view that verification must also take the form of ''frequent reviews'' (Ref. 34, p. 201). Frequent reviews relate primarily to whether the HACCP plan is functioning effectively on a day-to-day basis. It is important to note that, for the most part, the requirements in these sections were proposed in other parts of the regulations and are now being compiled in § 123.8(a)(2) and (a)(3). Several comments on these provisions pointed out that they were verification steps and should be referred to as such. FDA agrees and has brought them together in this new verification section of the final regulations. Section 123.8(a)(2) requires that processors review consumer complaints (proposed at § 123.6(b)(4)), calibrate process monitoring instruments (proposed at § 123.6(b)(4)), and perform periodic end-product or in-process testing, as appropriate, in accordance with written procedures for these activities in the HACCP plan.

Section II H. of this preamble addresses the review of consumer complaints at some length.

The provision on the calibration of monitoring instruments (§ 123.8(a)(2)(ii)) is brought forward with no substantive change from the proposal. Calibration is an important activity and involves readily defined procedures that can easily be provided in the plan.

Calibration can include the validation of computer hardware and software. FDA proposed to require that the HACCP plan detail the methods of computer software validation to be used by the processor. FDA received a small number of comments both for and against computer software validation as a worthwhile part of verification. Two comments supported the need for consumer software verification. But two comments suggested that computer software verification would be an unnecessary expense because it would result in only marginally improved reliability.

The agency has worked extensively with the low-acid canned food industry to verify computer hardware and software that the industry is now using to operate or control various processing functions. That experience has demonstrated to FDA both the desirability and the feasibility of verifying computer hardware and software. For low-acid canned foods, the industry is using computers to perform several functions, including monitoring compliance with CL's, controlling the processing operations, taking corrective actions, and recordkeeping (Ref. 221).

In a HACCP system such as that being established for seafood by these regulations, FDA is interested in ensuring that hardware and software for computers that monitor compliance with a CL be verified. However, when computers are used as process-monitoring instruments, they must be calibrated in accordance with § 123.8(a)(2)(ii). The other functions that a computer can perform, as listed above, can be verified through procedures required elsewhere in these regulations (e.g., recordkeeping can be verified through the review of records by a trained individual in accordance with § 123.8(a)(3)). Consequently, the agency has concluded that it is not necessary for these final regulations to include a specific requirement for computer validation.

Instead, the agency acknowledges that the proper frequency of equipment calibration is entirely dependent upon the type of instrument and the conditions of its use. Therefore, FDA is not being prescriptive in this regard. FDA has, however, provided guidance on the subject in the draft Guide. Additional guidance should be obtainable from the manufacturer of the instrument. The nature and frequency of the calibration effort should be determined at the time of HACCP plan development and should be included in the plan to ensure that it is regularly and appropriately done. The agency is convinced that without such formalization, calibration, which, for some instruments, may be done as infrequently as once per year, may be overlooked.

5. Product Testing

75. Section 123(8)(a)(2)(iii), which lists the performing of end-product or in-process testing, is a new provision. FDA requested comment on what tests, including or in place of end-product testing, should be used to measure the success of the HACCP program, both in terms of individual firms and the national program as a whole, and how frequently such tests should be administered (Ref. 208 at 4183). A large number of respondents addressed FDA's request for comment. Approximately half of these comments supported the need for an end-product testing requirement. The other half objected to such a requirement or suggested that the need should be determined on a case-by-case basis.

A number of consumer advocacy organizations suggested that end product testing is essential because no other verification mechanism provides public confidence that HACCP programs are actually resulting in a safer product. Several comments stated that regular microbiological testing would help a processor determine whether there are sources of contamination that are not being controlled.

A few comments suggested that such testing should be performed more frequently during plan development and validation, and then reduced to some lower level as part of a firm's verification efforts. Another comment suggested that testing should be performed quarterly by those processors with a poor record of compliance and annually by those with a good record.

Several comments suggested that the need for and frequency of product analysis should be established as part of the HACCP plan development process. One of these comments noted that the frequency of testing may fluctuate depending, in part, upon changes in personnel, raw materials, equipment, and product formulation.

A number of comments stated that end-product testing is a questionable method for measuring the success of a HACCP system. One of these comments stated that end-product testing measures the effectiveness of the plan for a small, finite portion of production and has limited value in measuring the success of the HACCP plan overall.

One comment stressed that finished product testing is contrary to the concept of HACCP, i.e., a reliance upon preventive controls at critical points throughout the system. Another comment contended that mandatory microbiological analysis of foods would be inappropriate because: (1) Statistically valid sampling programs for pathogens are not economically feasible because of the low incidence of pathogens in most foods; (2) the use of indicator organisms to predict the presence of pathogens is not always reliable and, where it is not, can become merely a test for aesthetics; and (3) microbiological analysis of foods is often costly, imprecise, and slow, and, therefore, not suitable for real time data generation.

The agency acknowledges the shortcomings of product testing, especially microbiological testing, used for process control as pointed out by the comments. The NACMCF, in its comments in response to FDA's questions about product testing, reiterated its view that, while verification is essential to the success of HACCP, end-product testing has limited value for measuring the success of a HACCP system. Comments also noted that in-process or finished product testing should not normally be a prerequisite for lot release under a HACCP program.

However, FDA recognizes that many processors will find that product testing has a role to play in the verification of HACCP systems, and the agency wishes to encourage incorporation of testing into HACCP plans, where appropriate. Consequently, the regulations at § 123.8(a)(2)(iii) list end-product and in-process testing as a verification activity at the option of the processor.

The agency provided guidance concerning appropriate attributes for product testing in the draft Guide and intends to elaborate on it in the first edition of the Guide.

6. Records Review

Section § 123.8(a)(3) requires that a trained individual review all records that document monitoring of CCP's, the taking of corrective actions, the calibrating of any process control instruments, and the performing of any end-product or in-process testing. The review of HACCP records by a trained individual was included in the proposed regulations at § 123.8(b). In response to comments that urged consistency with the recommendations of the NACMCF, FDA has designated this review a verification function for purposes of the final regulations and has included it in the section on verification. Specifically, the proposed regulations provided that a HACCP-trained individual review the monitoring records, sanitation control records, and corrective action records before distribution of the product to which the records relate. Under the proposal, the individual's review would include records of process monitoring instrument calibration, because the agency characterized these records as monitoring records.

The comments that FDA received on these provisions focused on the proposed requirement that the review by the trained individual occur before the product could be shipped. Several comments objected, stating that such a review before shipment was unnecessary, because under the corrective action provisions of the proposed regulation, any CL deviation caught by the observer/operator would necessitate the segregation and holding of the affected product before shipment until the safety of the product could be assured. One comment further stated that linking lot release to record review before shipment underestimates the level of control attainable through the monitoring and corrective action principles of HACCP.

Comments from several processors and trade associations stated that, for some processors, it would be impractical to withhold the shipment of every lot until HACCP records could be verified and signed. These comments noted that, with the use of today's high speed processing lines, it is normal practice for some processors to begin shipping products before the end of the shift (lot). Several comments also stated that holding a product until the HACCP records could be reviewed could result in a product being subjected to unfavorable conditions during storage, which could compromise both quality and safety.

Several comments urged that processors be permitted to review the HACCP records at the end of the day or at the end of the shift, even if this review occurred after distribution. Others suggested that record review should be performed within a ''reasonable time'' of production of the record.

The agency remains convinced that the coupling of lot release with verification-type record review provides a valuable added level of safety assurance. This kind of record review before shipment is a regulatory requirement for low-acid canned foods and acidified foods. FDA's experience with these industries is that record review before distribution has been instrumental in preventing the introduction of potentially hazardous foods into commerce (Ref. 221). The agency encourages processors to institute such a program whenever possible.

However, FDA accepts from the comments that the proposed requirement would cause certain processors to delay shipping perishable products and thus present an unacceptable burden to them. The agency therefore is not requiring that record review occur before shipment.

Uncoupling record review from lot release leaves as the primary purpose for record review the periodic verification that the HACCP plan is appropriate and is being properly implemented. Record review needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a ''feedback loop,'' with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product.

FDA is convinced that a weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to handle highly perishable commodities without interruption, while still facilitating speedy feedback of information. FDA is reluctant to allow the level of flexibility provided by such language as ''reasonable time,'' out of concern for the confusion that it

would generate. FDA's experience with low-acid canned foods and acidified foods has demonstrated that review of these kinds of records is a critical verification tool. FDA is, therefore, adopting the proposed provision as § 123.8(a)(3) with one revision. As set out in the final rule, it requires that the HACCP-trained individual review the monitoring records of CCP's and the records that document the taking of corrective actions within 1 week of the making of the records, rather than before shipment, as a part of a processor's verification activities (§ 123.8(a)(3) (i) and (ii)).

FDA agrees, on the other hand, that this principle need not apply to the review of records of such verification activities as process control instrument calibration and product testing. The frequency of these activities will be variable and dependent upon the HACCP plan development process. Consequently, setting a specific review frequency for these records is not warranted. Section 123.8(a)(3)(iii) reflects this conclusion. It requires that the HACCP-trained individual review the calibration records within a reasonable time after the records are made, rather than before any additional products are shipped. It also applies the same ''reasonable time'' standard to any end-product testing records that are made.

The proposed regulations did not address the review of end-product testing records by a trained individual. The requirement in these final regulations for a review of such records reflects the principle contained in the proposal that there be a verification-type review by a trained individual of the HACCP records that are being created by the processor. In this respect, the responsibilities of the trained individual are unchanged from those that were contemplated in the proposal, although details relating to those responsibilities have been modified based on the comments.

Section § 123.8(b) requires that processors take appropriate corrective action whenever a review of a consumer complaint, or any other verification procedure, reveals the need to do so. This provision is essentially a restatement of the proposal regarding consumer complaints, expanded to include the results of verification procedures for purposes of emphasis. Verification was not specifically included in the proposal. FDA is including a reference to it here to remind processors not to preclude the possibility that information obtained through verification could lead to the taking of a corrective action. This possibility exists even though, more often than not, verification will not provide the kind of immediate feedback that the processor will receive from monitoring. Corrective actions based on information received through verification will be exceptions to the rule. However, processors should be mindful of the possibility.

7. Verifying the Hazard Analysis

Section 123.8(c) requires that, whenever a processor does not have a HACCP plan because a hazard analysis has not revealed any food safety hazards that are reasonably likely to occur and that can be controlled through HACCP, the processor must reassess the hazard analysis whenever a change occurs that could reasonably affect whether such a hazard exists. FDA has included examples of such changes in § 123.8(c). The list is identical to that provided in § 123.8(a)(1), for when a plan must be reassessed. Consequently, any change in these factors should warrant a reassessment to be certain that a plan is still not needed.

FDA has concluded that, under a mandatory HACCP system, the principle of verification applies equally to a decision that a HACCP plan is not necessary as it does to a decision that the plan continues to be adequate. Circumstances change, and processors must be alert to whether the exemption from the requirement to have a plan continues to apply to them.

Section 123.8(d) requires that processors document calibration and product testing in records that are subject to the recordkeeping requirements of the regulations at § 123.9. The requirement that records be kept of process monitoring instrument calibration was included in the proposed regulations at § 123.6(b)(5). The requirement that records of end-product testing be kept is consistent with the general recordkeeping principles of HACCP. The one exception is that FDA is not requiring records that document the review of consumer complaints. The agency is satisfied that the requirement for a processor to review consumer complaints relating to potential safety concerns will be sufficient for this kind of verification activity. Moreover, as explained in the discussion of consumer complaints elsewhere in this preamble, FDA is persuaded that most consumer complaints will involve matters unrelated to the mandatory HACCP system.

*H. Consumer Complaints*

1. Background

In the proposed regulations, FDA tentatively concluded that each processor's HACCP system had to utilize any consumer complaints that the processor receives that allege a problem with product safety. Several provisions described how consumer complaints were to be used. In one, FDA proposed to require that a processor's monitoring efforts include the use of consumer complaints, and that its HACCP plan reflect how they will be used. In a second provision, FDA proposed to require that, when a processor receives a consumer complaint that may be related to the performance of a CCP or that may reflect a CL deviation, the processor determine whether a corrective action is warranted, and, if so, take one in accordance with the specified corrective action procedures. FDA also proposed to require that the taking of such corrective actions be fully documented in records. Finally, FDA proposed to require that consumer complaints that relate to the operation of a CCP or to a possible CL deviation be included as part of the processor's HACCP records and be available for agency review and copying.

FDA's rationale for proposing these requirements was that consumer complaints may be the first alert that a processor has that problems are occurring that are not being detected or prevented by the processor's HACCP controls. While the goal of a HACCP system is to prevent all likely hazards from occurring, no system is foolproof. The agency tentatively concluded,therefore, that each HACCP system should take advantage of consumer complaints as they relate to the operation of CCP's. FDA also tentatively concluded that it might be necessary for the agency to review those complaints in order to be able to verify whether a processor is taking necessary steps to review its HACCP controls and take corrective actions as necessary in response to consumer complaints. The agency emphasized that it was referring solely to complaints relating to the operation of the HACCP CCP's (i.e., those that allege a problem with human food safety) and not to consumer complaints generally.

2. Consumer Complaints as Verification Tools

76. FDA received a large number of comments on the advisability of handling consumer complaints in the manner that the agency proposed. Generally speaking, the comments

addressed two broad issues: Whether consumer complaints are relevant to a HACCP system, and if they are relevant, how they should be used. The question of whether FDA should have access to consumer complaints was a significant concern that comments found germane to both issues. Approximately one-fifth of the comments supported the proposed system or a variant of the system (i.e., they believed that consumer complaints are relevant to a HACCP system). Some of those who voiced general support urged more comprehensive agency access to consumer complaints, and others urged that some restriction on agency access be put in place. The remaining approximately four-fifths of the comments, principally from seafood and other food processors and trade associations, argued that consumer complaints have no place in a HACCP system.

Those comments that opposed the mandatory use of consumer complaints in a HACCP system provided a variety of reasons. The comments argued that consumer complaints are generally: (1) Unrelated to the safety of the product; (2) not received in a timely manner that would facilitate control of the process and are, in this way, akin to finished product testing; (3) erroneous and sometimes exaggerated or fraudulent; (4) vague; (5) subjective and nonscientific; (6) associated with hazards that develop during transportation, storage, and retail marketing, rather than processing, if they identify food safety hazards of any kind; (7) not traceable to a specific processing plant or lot of product; and (8) not readily associated with a specific CCP or CL failure, even where it is likely that they are the result of a problem during processing. These comments asserted that, therefore, consumer complaints are not an appropriate monitoring tool.

A number of these comments suggested that, given the problems listed above, sorting through the large volume of consumer complaints that are received by most large firms to identify those few that might be able to be linked to the performance of a specific CCP would be a waste of both the processor's and the agency's time. These comments stated that such a review of consumer complaints would divert their efforts from more productive tasks.

Several comments raised additional questions about consumer complaints as a HACCP verification tool. They suggested that there are better, more effective means of verifying that the HACCP plan is working properly. These suggestions are covered in the ''Verification'' section of this preamble. These comments further argued that consumer complaints are not identified in the NACMCF recommendations as a useful verification tool.

A relatively small, diverse group of comments, including those from a seafood processor, a seafood trade association, a State regulatory agency, an individual, and a professional organization, supported the handling of consumer complaints as proposed. One of these comments suggested that consumer complaints could be useful in FDA's efforts to verify that processors' HACCP programs are effective.

Another group of comments, from consumer advocacy organizations and a State regulatory agency, agreed that consumer complaints are an appropriate part of HACCP. One of the comments noted that the consumer performs the final quality control check, and that if a consumer finds a problem egregious enough to take the time to write a letter, the information contained in that letter should be considered in any evaluation of the adequacy of the relevant HACCP plan. The comment further argued that consumer complaints could bring to light unidentified CCP's. This benefit, the comment contended, would not be possible under the proposed regulations because the agency limited consumer complaints in a HACCP system to those that may be related to a CL deviation at an existing CCP. Finally, one of the comments noted that the inclusion of consumer complaint access in the proposed regulations is the one area in which the agency delivers on its ''water to table'' commitment.

FDA is persuaded that consumer complaints generally will not make an effective monitoring tool in a HACCP system, primarily because they tend not to provide the kind of immediate, reliable feedback expected of a HACCP-monitoring system. FDA agrees with the comments that suggested that monitoring procedures under HACCP must provide the processor with immediate feedback on whether the process is under control and be scientifically sound.

FDA is not persuaded, however, that consumer complaints are irrelevant to HACCP systems. The agency received no comments that were able to demonstrate that outside sources of information should not, where appropriate, supplement a processor's own monitoring as a way of determining whether the process is in control. Moreover, a number of comments stated that they go to some lengths to examine the consumer complaints that they receive. The question, then, is whether consumer complaints can serve some legitimate verification purpose in a HACCP system.

While consumer complaints are not specifically addressed in the NACMCF HACCP recommendations, the verification portion of that document states, in part, that verification inspections should be conducted, ''When foods produced have been implicated as a vehicle of foodborne disease.'' This statement is a recognition that information from sources outside the processing plant can and should be considered in the verification of a HACCP plan. In fact, it is FDA's experience that consumer injury or illness complaints to the agency occasionally point out problems traceable to defective controls at the food processing facility (Ref. 207). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA accepts the possibility that many, if not most, consumer complaints that a processor receives will not be germane to safety, that many will turn out not to be valid, and that others will relate to events at retail or that are otherwise beyond the ability of the processor to control. Nonetheless, FDA strongly believes—and the comments support this view—that a responsible processor will at least review consumer complaints to determine their potential value and take steps to correct the product or the process, when such stops are warranted.

FDA has concluded, therefore, that processors should evaluate the consumer complaints that they receive to determine whether the complaints relate to the performance of CCP's, or reveal the existence of unidentified CCP's, as part of their HACCP verification procedures. The agency acknowledges that the absence of consumer complaints does not, by itself, verify the adequacy of a HACCP system. However, after taking into account all the concerns raised by the comments, the agency is of the view that those consumer complaints that a processor does receive, and that allege a safety problem, can be of value as a verification tool and should serve that purpose. This conclusion is reflected in the requirements of § 123.8 of these final regulations (see discussion in the ''Verification'' section of this preamble), which lists the review of consumer complaints as an appropriate verification activity (§ 123.8(a)(2)(i)).

As explained earlier in this preamble, because the agency regards consumer

complaints as a verification tool rather than a monitoring tool, FDA has modified § 123.6(c)(4) to eliminate the proposal requirement that the HACCP plan describe how consumer complaints will be used in the monitoring of CCP's. The agency has also modified § 123.6(c)(7) to eliminate the proposed requirement that consumer complaints be part of a processor's HACCP-monitoring records.

FDA has concluded that when a review of a consumer complaint reveals a need for the processor to take corrective action (e.g., recall, destruction, or reprocessing of the product or modification of the process to reduce the risk of reoccurrence of the problem), such action must be taken in conformance with the applicable corrective action procedures of these regulations. This conclusion is reflected in of § 123.8(b) which states that processors shall immediately follow the procedures in § 123.7 whenever a review of a consumer complaint, or any other verification procedure, reveals the need to take a corrective action. The corrective action provisions are discussed in the ''Corrective Actions'' section of this preamble.

As suggested by several of the comments, records of corrective action relative to consumer complaints need not include the original consumer complaint. However, it is unlikely that a comprehensive record of the corrective action taken could be generated without at least the critical information contained in the complaint, such as the nature of the complaint and identification of the product in question. Identification of the complainant is not likely to be critical.

3. Agency Access to Consumer Complaints

77. Many comments questioned whether FDA should have access to consumer complaints. Several comments argued that no other food industry is required to provide access to consumer complaints. A few specifically cited the absence of such a requirement in the low-acid canned foods regulations (part 113).

One comment noted that FDA has methods other than access to a company's consumer complaint file to obtain information about product defects that affect safety, including direct calls from consumers and health professionals, MedWatch, and reporting to the Center for Disease Control and Prevention (CDC). Another comment suggested that it would be more efficient to devise a system whereby consumers are encouraged to submit complaints about product safety directly to FDA rather than to mandate access to corporate files.

Several comments suggested that consumer complaint files should remain a private company matter, and that open access to these files is likely to result in regulatory abuse. A few comments further argued that, by mandating complaint file access, the agency would penalize those firms with good consumer complaint gathering systems and possibly deter others from developing such systems.

A relatively small, diverse group of comments, including seafood processors, a seafood trade association, and a Federal government agency, submitted that, while it is appropriate for FDA to mandate that processors utilize consumer complaints in assessing the effectiveness of their HACCP program, it is not necessary for the agency to have direct access to the firms' complaint files. The comments suggested two alternatives to providing direct access to complaint files: (1) Allowing processors to prepare Notices of Unusual Occurrence and Corrective Action (NUOCA) that described the action taken in response to consumer complaints that relate to product safety; or (2) allowing processors to prepare a matrix of complaints, as is currently used in the voluntary, fee-for-service HACCP program being operated by NMFS.

Others in this group suggested that FDA have access only to written complaints, or only to consumer complaints, as opposed to trade complaints, which the comment argued are often submitted for commercial advantage only. One comment noted that it would be impossible for processing vessels to retain consumer complaints on board the vessel, and that provision should be made for these to be stored at the corporate office. Other comments urged that FDA access to consumer complaints not include the right to copy them, or that, in some other way, they be protected from public disclosure.

Another group of comments, composed of consumer advocacy organizations and a State regulatory agency, urged that all consumer complaints, regardless of their potential relationship to product safety, be included in a processor's HACCP records and be available for FDA review. These comments suggested that the FDA investigator should make the determination of which complaints are relevant for follow up rather than the firm. They further suggested that the investigator can ignore any complaints that are not relevant to safety controls at the processing facility.

Unquestionably, FDA has an essential role to play as a regulatory verifier of HACCP. As described earlier, the agency received a number of comments that raised concerns about the veracity of a mandatory HACCP system in the absence of adequate regulatory review. Moreover, FDA has concluded that this role cannot be carried out without the ability to review HACCP plans and a narrow category of processor's records (i.e., those that relate to how a processor is controlling the critical safety aspects of its operations). The agency is not interested in expanding this access beyond those records that are the minimum necessary to carry out this responsibility.

With regard to consumer complaints, FDA is persuaded by the comments that, especially when used as HACCP verification records rather than HACCP-monitoring records as originally proposed, the public health benefits that may accrue from agency access to these kinds of records would probably be minimal and are outweighed by the concerns that have been expressed.

FDA is satisfied that agency review of a processor's overall verification scheme, plus access to records that document any corrective actions that were taken as a result of information obtained through consumer complaints, review of those complaints that consumers regularly send to the agency, the ability to conduct unannounced inspections, and access to monitoring records and plans, should be enough for FDA to adequately verify processor's HACCP systems.

FDA also accepts that the burden on processors if they had to segregate complaints that have a potential relationship to product safety from those that relate to product quality, economic issues, customer satisfaction, and other nonsafety issues, would be great and is not warranted by any potential gain in product safety. Many firms would have to take this step to make safety-related complaints available to FDA. Similarly, the agency recognizes that a significant burden would be placed upon its inspectional force if it had to verify that a processor had properly categorized its complaints.

The alternative of FDA having access to all consumer complaints and making its own determinations about which relate to safety, as some comments suggested, is simply not practicable. In addition, it is not the desire of FDA to penalize those firms that have large, expensive complaint gathering systems, by mandating that they provide all information so gathered for agency review, or to discourage others from developing such systems.

In the preamble to the proposed regulations, FDA stated that more than half of the seafood-related consumer complaints that it receives relate to product quality, filth, and economic deception concerns. Access to all consumer complaints is, therefore, unnecessary to ensure product safety.

FDA has, therefore, removed from what is now § 123.9(c) the requirement that consumer complaints relating to safety be available to the agency. The agency reiterates, however, that processors should utilize all available information as they evaluate the adequacy of their HACCP plans and their implementation. Consumer complaints are one potential source of information, and a significant group of comments recognized the value of consumer complaints in the verification process.

*I. Records*

FDA proposed that records required by the regulations: (1) Contain certain information, (2) be completed at the time of the activity, (3) be signed by the operator or observer, (4) be reviewed for completeness and compliance with the HACCP plan and signed and dated by the reviewer, (5) be retained for specified periods of time, and (6) be available for review and copying by FDA.

FDA received a large number of comments that addressed these proposed recordkeeping requirements. These comments were from a diverse group of commenters, including large and small processors, trade associations, individuals, Federal, State, and foreign government agencies, consumer advocacy groups, professional societies, and academics. Several comments provided arguments that support the need in a mandatory HACCP program for records in general, and none specifically argued in opposition to that concept. Most of the comments addressed specific issues that relate to recordkeeping.

Those comments that supported the need for records stated that recordkeeping is a key component of HACCP. One processor's comment noted that HACCP records must be kept in good order so that problems can be easily tracked to their root cause. One comment stated that HACCP records facilitate an evaluation of safety conditions over time, rather than through a ''snap shot'' inspection. Another processor noted that HACCP recordkeeping is not overly burdensome, and that the proposed regulations would not require it to maintain any records in addition to those that it already maintains.

1. Details and Signatures

78. FDA proposed that all HACCP-monitoring records (including records of process-monitoring instrument calibration), sanitation control records, and corrective action records identify the date of the activity that the record reflects. One comment recommended that the final regulations should also require that the time of each observation be recorded, to make it easier to link records to specific lots of product. A comment from a trade association requested that the records be required to identify the establishment where the activity occurred to reduce the potential for confusion in firms with multiple processing facilities.

FDA agrees with both comments that the date and time on records will help to connect information on the records to specific lots of product, and that the name and location of the processor will help link information to a specific processing facility.

The agency has, therefore, modified § 123.9(a)(1) and (a)(2) to state, in part, that the required records must include: ''(1) The name and location of the processor or importer; (2) The date and time of the activity that the record reflects.''

79. FDA proposed to require that HACCP-monitoring records (including records of process-monitoring instrument calibration) and sanitation control records be signed by the observer/operator. A few comments supported the proposed requirement on the grounds that it fosters accuracy and accountability in the recordkeeping process. One comment opposed the proposed requirement, raising concern about the legal liability that it imposed upon the workers that sign the records. A few comments suggested that the observer/operator be allowed to initial, instead of sign, the records.

FDA agrees with the comments that suggested that a signature on monitoring and sanitation control records is necessary to ensure accountability in the recordkeeping process. FDA also hopes that it will enhance workers' sense of responsibility and pride in their participation in the HACCP system of preventive controls. Regarding worker liability, those that deliberately falsify records are liable whether they sign the records or not. In any event, the falsification of records cannot be condoned and should not be tolerated by processors.

FDA further agrees that the purpose for the observer/ operator's signature is achieved if the observer/operator either signs or initials the monitoring records.

FDA proposed to require the signature of the observer/operator on all records involving observations or measurements made during processing or related activities. This specification of the kinds of records in which signatures were required would have had the effect of exempting consumer complaints, which were considered to be monitoring records in the proposal from this requirement. However, the use of consumer complaints as monitoring records has not been carried forward to these final regulations. Consequently, limiting the records that must be signed to involving observations or measurements is no longer necessary, and FDA has deleted it for purposes of clarification (see § 123.9(a)).

FDA has also deleted the proposed provision that the observer/operator need not sign corrective action records. The agency proposed to require that only a trained individual sign these records. FDA is requiring the signature or initials of the observer/operator on corrective action records in order to be consistent with the corrective action provisions of these regulations. In § 123.7, for example, processors may now predetermine their corrective actions in ways that empower observer/operators to take corrective measures, especially in the absence of a trained individual. The likelihood that a trained individual might not be present at the moment when a corrective action must be initiated is enhanced by the fact that such an individual need not be an employee of the processor (see § 123.10). Conversely, the presence of a trained individual during the initiation of a corrective action need not preclude the observer/operator from taking corrective steps, as appropriate. Finally, the agency has concluded that the burden imposed by requiring the signature or initials of the observer/operator whenever that individual participates in the making of a corrective action record is inconsequential.

80. Several comments questioned whether the proposed requirement that monitoring records include the ''identity of the product, product code * * *,'' meant that all fish and fishery products were required to bear a product code.

It was not the intent of the agency to require product codes on such products, only to require that they be listed on appropriate records when they are used. The purpose of the proposed requirement was to facilitate linkage between records and product. To clarify this point, FDA has modified what is now § 123.9(a)(4) to read, ''(4) Where

appropriate, the identity of the product and the production code, if any.''

81. Several comments suggested that FDA not specify the components of required records. These comments argued that many processors have existing forms that can appropriately be used as HACCP records.

It is not FDA's intent in § 123.9(a) to specify record format or content, beyond certain minimum, essential components. Processor's are encouraged to use existing records, making modifications only as necessary to meet the previously described requirements.

2. Retention and Storage

FDA proposed to require that processors retain monitoring (including process monitoring instrument calibration), sanitation control, and corrective action records for 1 year after the date that they were prepared for refrigerated products and for 2 years for frozen or preserved products. FDA also proposed that records used to substantiate the adequacy of equipment or processes be retained for 2 years after the date that they apply to products being processed.

82. Several comments stated that these proposed retention times were too long. Most of these comments suggested record retention times of from 90 days to 1 year for refrigerated products and from 6 months to 1 year for frozen products. One comment argued that 1 year is a sufficient period for record retention unless the records relate to a CL deviation, in which case they should be held for 3 years. Another comment urged that the agency not mandate record retention times but require processors to identify appropriate retention time requirements in their HACCP plans.

FDA rejects those comments that requested a reduction in the proposed mandatory record retention period. While it may be true that most refrigerated products will be unusable within 90 days, as suggested by one of the comments, retention times of less than 1 year do not provide for sufficient access for the processor's or FDA's verification activities. (See revised § 123.8(a)(1) and the accompanying preamble discussion of the minimum 1-year frequency of plan reassessment.) No new, substantive comment was provided relative to record retention times for frozen or preserved products that would warrant a reduction for those products.

Thus, FDA has made no changes to § 123.9(b).

83. FDA proposed that, in the case of processing facilities that close between seasonal packs, records could be transferred to another accessible location between seasonal packs, as long as they were returned during the next active season. Comments from several processors and trade associations urged the agency to modify the requirement to: (a) Allow for permanent transfer from the facility and (b) include both remote processing sites and processing vessels regardless of whether they close seasonally. Comments from operators of processing vessels and remote processing sites and from a trade association requested that FDA allow HACCP records to be kept on the processing vessel or remote site for a period of time and then be transferred permanently to the processor's corporate, or closest business office. The comments argued that the records in those locations would be more easily stored, safer, and more readily accessible to regulators than they would be at remote sites and on processing vessels. Additionally, they argued that corporate verification activities often would be performed at the land-based facilities. Transfer of the records to these facilities would promote verification in these circumstances. Comments opposing the requirement that the records be returned to a seasonally closed facility once the facilities reopened expressed concern that return of the records to the reopened locations could result in lost records.

FDA has been persuaded to accommodate the difficulties associated with record storage on processing vessels and remote processing sites by allowing HACCP records to be moved from such facilities to another reasonably accessible location at the end of the seasonal pack without requiring that the records all be returned for the following season (§ 123.9(b)(3)). Additionally, the agency will, as proposed, allow HACCP records from any facility that is closed between seasonal packs to be permanently transferred to another reasonably accessible location. However, FDA points out that, in most instances, the agency will need to examine processing records onsite in order to conduct an effective verification inspection. For this reason, records must be so stored that they can be promptly returned to the processing facility upon demand by FDA. In order to maintain inspectional efficiency, the time period between an FDA request for the records and their arrival should not ordinarily exceed 24 hours.

84. Several comments urged FDA to provide for the use of computers to maintain HACCP records.

It was not the intent of the agency to preclude such records. To make this fact clear, FDA has added a new paragraph, § 123.9(f), to the final regulation, which reads, ''(f) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.''

In the Federal Register of August 31, 1994 (59 FR 45160), FDA proposed separate regulations at 21 CFR 11 that, if adopted, will become the standard for determining what constitutes appropriate controls for electronic records, electronic signatures, and handwritten signatures executed to electronic records. In the interim, processors are encouraged to look to industry standards for guidance.

3. Confidentiality of Records

85. In the preamble to the proposed regulation, FDA stated that, as a preliminary matter, HACCP plans and monitoring records appear to fall within the bounds of trade secret or commercial confidential information and would, therefore, be protected from public disclosure by section 301(j) of the act (21 U.S.C. 331) and by the Freedom of Information Act (FOIA) and the Department of Health and Human Services (DHHS) and FDA regulations promulgated pursuant to these laws. FDA specifically invited comment on the issue of public disclosure of HACCP records and on whether FDA has any discretion about the releasability of any HACCP records that it may eventually have in its possession. A large number of comments responded to FDA's request for comment, especially in the context of the provision in the regulations (§ 123.9(c) in this final rule), that provides that all required records and plans must be available for review and copying.

A large number of comments, from processors, trade associations, professional associations, State and Federal agencies, and individuals, contended that HACCP records and plans are trade secrets and should under no circumstances be released to the public. Comments from several consumer advocacy groups countered that in many cases HACCP records and plans will not contain trade secret information or will contain only limited trade secret information, and that the nonsecret parts (i.e., most of their contents) should, therefore, be available to the public.

Many of the comments that supported protection from public disclosure urged that the final regulations contain controls over the agency's access to, and

copying of, HACCP plans and records as the only guaranteed way to ensure confidentiality. The comments argued that the potential harm from exposure of HACCP plans and records to competitors or to the public is considerable and carries the threat of increased costs, misuse, and damage to the integrity of a firm and its products.

Several comments contended that HACCP records will be trade secret because they will be process-specific and, therefore, will contain such information as processing times and temperatures. They stated that these processing parameters may differ from company to company based on product formulas.

A few comments argued that there is no precedent for public access to industry-generated records. Some of these comments stated that processing records are regarded as trade secret under the LACF regulations, and they noted that § 108.35(d)(3)(ii) deems processing information submitted to FDA to be trade secret within the meaning of 301(j) of the act and within the meaning of the FOIA. Other comments asked that FDA protect HACCP plans and records in the same way that the agency protects processing and quality control data that are submitted to FDA under cooperative quality assurance agreements (i.e., manufacturing methods or processes, including quality control procedures, are deemed not to be releasable unless the information that they contain has already been released or is otherwise no longer trade secret or confidential commercial per §§ 20.111(d)(2) and 20.114 (21 CFR 20.111(d)(2) and 20.114)).

Several comments suggested that FDA specifically declare that: (1) HACCP plans and records are trade secrets; (2) section 301(j) of the act and the FOIA prohibit disclosure of trade secret or confidential commercial information and give the agency no discretion whether to release these types of records; and (3) § 20.81 provides for disclosure of trade secret or confidential commercial information only if the information has been previously disclosed to the public.

One comment proposed that, if FDA felt obliged to release some HACCP-related information pursuant to FOIA requests, reports of regular inspections be released instead of HACCP plans and records, because such reports are likely to contain less sensitive information. Another comment suggested that, to avoid releasing proprietary information, the agency should describe or explain information that is contained in HACCP plans and records in general terms rather than release the records themselves. The comment asserted that this step would serve to inform consumers about the relative safety of the product and the effectiveness of the HACCP system, while not divulging specific process parameters that are trade secret or confidential commercial.

Conversely, comments from consumer advocacy groups argued that, for the most part, HACCP plans and records are not trade secret or confidential commercial. The comments asserted that much of the information contained in these plans and records involves the application of basic sanitary engineering and is already in the public domain, as evidenced by the draft FDA Guide.

The consumer advocacy groups argued that, given the limited resources that FDA can devote to monitoring HACCP compliance, public access to HACCP records should be as broad as allowed under the law, so that consumer confidence in, and understanding of, the seafood supply can be fostered. One comment asserted that the public's right and need to know about matters involving public health should be the basis from which the agency formulates public access policy. Another comment stated that consumers are the intended beneficiaries of the HACCP seafood proposal and therefore should have the right to determine through record inspection whether processors are properly implementing the HACCP requirements. These comments urged FDA to routinely collect HACCP plans and records from processors to facilitate agency verification activities and public review of the effectiveness of the HACCP system. One comment from a consumer advocacy group asserted that *Public Citizen Health Research Group* v. *FDA*, 704 F.2d 1280 (D.C. Cir. 1983) narrowly defined trade secrets in such a way that HACCP plans and the records at issue in this rulemaking could not be considered trade secret.

Unquestionably, adoption of a mandatory HACCP system will place significant documentation requirements on seafood processors. As a result, they will produce records that reflect processing designs and equipment and certain types of day-to-day operations. They will be available to FDA. FDA strongly believes that it is in the public interest to require that these records be maintained, and that the agency have access to them. Such records and access are necessary to effectuate a mandatory system of preventive controls for safety. As stated in the preamble to the proposed regulations, FDA expects to take possession of records on a case-by-case basis, and only when there is a specific need to do so. The agency categorically rejects the view that FDA should be a collection point for HACCP records and plans so that they may be made publicly available. Nevertheless, the apprehension expressed by many comments about the consequences of public disclosure of these new types of records is certainly understandable.

FDA agrees with the views expressed by consumer advocacy organizations that the public needs ways to be able to judge how and whether it is benefiting from a HACCP system. Neither the agency nor the industry can reasonably expect that the public will simply take the government's word for it. It remains to be seen, however, whether public access to information about processors that processors have traditionally held as protected is the only way, or the best way, to provide the public with information about this system.

FDA is considering how meaningful data can be extracted from the inspectional process and prepared in such a manner that it could be released without jeopardizing trade secret and confidential commercial information and yet be useful to both FDA and the public in evaluating this program. FDA is considering developing standardized reports that would be completed by investigators at the conclusion of routine HACCP-based inspections and become part of agency files. As presently conceived, these reports would contain a summary of the status of the HACCP program in effect at the firm, similar to the suggestion of two of the comments.

Nonetheless, the question is whether, as FDA preliminarily concluded, most plans and records to be generated under this program will be subject to protection under existing law and FOIA regulations. FDA's experience in seafood processing plants, its experience with HACCP, and its understanding from the cost-benefit modeling that has been done in the preparation of these regulations is that HACCP plans will take each processor some time and money to develop. Thus, the agency concludes that HACCP plans generally will meet the definition of trade secret, including the court's definition in *Public Citizen Health Research Group* v. *FDA, supra.* Plans that incorporate unique time-temperature regimens to achieve product safety, or other parameters that are processor-specific and that are the result of considerable research and effort, will surely meet this definition.

Moreover, there is value in a plan to a company that produces it for no other reason than that it took work to write. The equity in such a product is not

readily given away to competitors. FDA knows from its own experience that plant configurations tend to be unique to individual processors, or at least have unique features (Ref. 222). While generic plans will have great utility in many circumstances, they serve primarily as starting points for processors to develop their own plans. FDA expects that its Guide will help serve that purpose, but firms will still need to expend time and money to tailor HACCP to their individual circumstances.

Additionally, the agency has come to the conclusion, as a matter of policy, that records and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.

FDA understands that it cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA, nor does the agency wish to do so in this case. The agency still does not expect that it will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, FDA has concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials. A statement to this effect in the final regulations will help to make this fact as widely understood as possible and will clarify the agency's position on this matter. This fact is codified at § 123.9(d)(1), which reads as follows:

(d) *Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

The agency acknowledges that there could be exceptions to this general rule. The nature of information in HACCP plans and records varies. Some of it could be generally available processing methodology or procedures, based on generic or model HACCP plans or guidelines developed by the agency or some other public source, that is sufficiently reflective of an industry standard that it has little if any proprietary value. In such a case, in response to an FOIA request, there may not be a valid reason for protecting this information. The agency has concluded that there should be a provision that makes clear that it will make information available in appropriate circumstances. Consequently, the final regulations in § 123.9(d)(2), state:

(2) However, these records and plans may be subject to disclosure to the extent that they involve materials that are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

There is precedent for describing in regulations the records that have protected status. The low-acid canned food regulations at § 108.35(l) provide that, except under certain limited situations, filed scheduled processes submitted to FDA are not available for public disclosure. Additionally, § 108.35(d) provides that data submitted to the agency to support these processes are to be treated as trade secret. These materials are analogous to HACCP plans, and their treatment is consistent with the agency's views relative to the protected status of HACCP plans. The comments that suggested that the low-acid canned foods regulations grant trade secret status to the monitoring records that are required to be kept by part 113 are incorrect. These records are not provided any special status in those regulations.

4. Agency Access to Records

86. Several comments suggested that the final regulations should require processors to provide access by FDA to HACCP records only after the submission by the agency of a written request for specific records it deems necessary to review. The comments noted that this approach would be similar to § 108.35(h) in the LACF regulations, because processors are familiar and satisfied with such procedures.

FDA remains convinced that access to HACCP documents is essential to the agency's verification of a firm's HACCP system. A key feature of the HACCP verification process is access by government investigators to the HACCP plan, to monitoring records kept according to the plan, and to records of corrective actions that were taken in response to CL deviations. Examination of HACCP records enables an investigator to see how the processing facility or the importer operates over time rather than how it is functioning at one particular moment in time. Additionally, it will enable the regulator to review the adequacy of the processor's or the importer's preventive control system itself.

FDA rejects the idea of being required to request in writing access to HACCP plans and records. The agency is convinced that it has sufficiently limited its access to those records and plans that are minimally necessary to adequately evaluate the adequacy of a firm's HACCP system. Section 123.9(c) has been modified slightly to clarify to which records FDA is required to be granted access.

The comments are correct that the emergency permit regulations for low-acid canned foods at § 108.35 require that FDA issue a written request for access to monitoring records. However, the written request has proven to be merely a mechanical exercise. It has not in any way served to affect the outcome of FDA access to records, nor is it associated with any managerial control over the activities of FDA investigators, with respect to the kind or numbers of records to which they seek access. Moreover, the bottled water regulations at § 129.80(h), promulgated subsequent to the low-acid canned food regulations, do not contain a requirement for the issuance of a written request for records. FDA is not aware of any undue concerns expressed by the bottled water industry relative to agency abuse of its records access authority as a result of the lack of a written request requirement in those regulations. FDA further notes that its investigators are required to present a written notice of inspection to management of the firm at the start of each inspection. The notice explains the authority of the investigator to conduct an inspection of the facility. The agency has concluded that there is no need to further encumber the efficient enforcement of these regulations with a

written request for those records to which it is entitled to have access. It has chosen to use the more recent regulations, bottled water, as the model for these regulations with respect to records access.

5. Agency Copying of Records

87. A large number of comments opposed the provision in the proposal that provided for FDA copying of HACCP plans and records, mostly because of concern about public disclosure. Several comments stated that the agency should be permitted to obtain copies only to support a regulatory action and only after FDA has obtained a subpoena. Several other comments suggested that FDA be permitted to copy only those records that relate to a CL failure.

Several comments requested that FDA provide safeguards to control potentially abusive regulatory practices by establishing rules to be followed when copying records. The comments stated that the rules should accomplish the following: Identify investigators authorized to copy records, limit copying to records pertaining directly to CCP's, require prior written authorization for copying from the investigator's supervisor, require that the authorization identify the specific records to be copied and the reason that they are needed, require that a responsible company executive receive each request before any copying is permitted, and permit the company to question the purpose for the request before records are copied.

Comments from several consumer advocacy groups, on the other hand, supported the agency's need to copy records.

There are two primary reasons for the agency to copy HACCP plans and records: (1) To facilitate expert review of such issues as the identification of appropriate hazards and CL's in HACCP plans and the evaluation of the adequacy of corrective actions taken in response to CL failures; and (2) to document suspected inadequacies of the HACCP plan or the firm's implementation of the plan for possible regulatory followup.

Limiting the copying of records to those situations in which regulatory action is contemplated or in which a subpoena could be obtained would serve neither the needs of the industry nor the agency. Resolution of differences in food safety control strategies through scientific review and dialog, where possible, is superior to reliance solely upon the legal system for such resolution. Similarly, limiting the copying of records to instances involving CL deviations would inappropriately restrict the agency's ability to evaluate potential problems in the identification of CCP's, the establishment of CL's, and other scientific issues, which, in some cases, may be beyond the expertise of agency investigators.

Industry comments have expressed considerable concern, as discussed in the ''Compliance'' section of this preamble, that there will be no mechanism for dialog with the agency if a firm disagrees with an investigator's findings with regard to the sufficiency of HACCP plans and records. The agency is strongly committed to dialog whenever possible. Provision of a means by which senior reviewers at agency headquarters will have access to HACCP plans and records will facilitate that process.

FDA has concluded that the restrictions on copying of records suggested by the comments would significantly interfere with that access. It would be highly inefficient for FDA to identify a special class of investigators that are permitted to copy HACCP records and plans. FDA investigators are responsible for conducting inspections and investigations to enforce a wide array of regulations, and FDA field managers need the flexibility to assign work in an efficient and effective manner. Copying, like record access, is limited to the records specified in § 123.9(c). It would be highly impractical for supervisory preapproval to be accorded to an investigator for the copying of specific records. Until an investigator has evaluated a HACCP plan and validated the operations of the plant, it is not likely that the investigator will know with any certainty what HACCP records are appropriate for review. Additionally, inspections are often done in remote locations and under highly flexible itineraries that preclude close contact between the investigator and particular supervisor. Certainly, FDA investigators will make every effort to obtain HACCP plans and records from responsible individuals of the firm and will, if necessary, explain the relevance of the requested records to the recordkeeping requirements of these regulations.

The agency is unconvinced of the need to modify § 123.9(c) in response to the aforementioned comments, except that reference to consumer complaints in this section has been eliminated as discussed in the ''Consumer Complaints'' section of this preamble.

88. Several comments questioned the phrase ''duly authorized officers and employees'' used in this section. Some felt that it referred, at least in part, to employees of the firm, and others felt that it excluded officials of State regulatory agencies that may adopt these regulations by reference.

The intent of the proposed regulations was to grant records access to regulatory agency officers and employees, not officers or employees of a firm. The language was intended to be flexible enough to cover State officials if their agency adopted the regulations by reference. FDA has changed the wording of the regulations to address these concerns.

The modified paragraph in § 123.9(c) reads:

(c) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

*J. Training*

A large number of comments addressed the proposed training requirements. FDA proposed to require that each processor and importer employ at least one individual who has successfully completed a training course that has been approved by FDA on the application of HACCP to fish and fishery products processing. FDA also proposed that the trained person or persons be responsible for, at a minimum, developing and modifying the HACCP plan, evaluating the adequacy of corrective actions taken in response to CL deviations, and reviewing monitoring records before shipment.

In the preamble to the proposed regulations, FDA specifically requested comment on: (1) Whether the need for training could be satisfied by different gradations of training (e.g., based on complexity or size of operation or on the degree of risk posed by the products being produced); (2) whether other training formats, such as video tapes, might be effective, at least under some circumstances (e.g., a small business whose processing involved few hazards); (3) whether, assuming the regulations are adopted by FDA, training in HACCP received before they are effective should be ''grandfathered'' as fulfilling the training requirement; and (4) whether some or all of the training requirements should be deleted or modified as a means of reducing the burden on the industry.

1. The Need for Mandatory Training

89. Most of the comments that addressed the question of whether there should be a mandatory training requirement expressed support for it. A significant portion of these comments acknowledged the need for at least one

trained individual at each processing facility. Those that provided reasons for their support contended that properly trained personnel are essential to the development and effectiveness of HACCP controls, and that training is necessary to ensure consistency of approach.

Those few comments that expressed reservations about the overall HACCP training requirement generally acknowledged the need for a trained individual in the plant but opposed a compulsory training program. Two comments, from State governments, expressed concerns about the financial burden of training on small businesses and questioned the need for making such a provision mandatory.

The overwhelming support in the comments for HACCP training is indicative of the nearly universal view that training is essential to the effective implementation of a HACCP system. As stated in the preamble to the proposed regulations, this view is shared by the NAS based on the success of the training requirement in FDA's HACCP-based regulations for low-acid canned foods at part 113 (Ref. 54). The primary concern expressed about mandatory training is the cost.

The agency is convinced that its efforts with the Alliance will facilitate the development and implementation of a low cost training program. As mentioned above, the Alliance is a cooperative effort between Federal and State food regulatory agencies, academia, and the fish and fishery products industry to provide support to the industry in meeting its needs relative to HACCP training, technical assistance, and research. Presently, the Alliance Steering Committee is comprised of representatives of FDA, the U.S. Department of Agriculture (USDA), NMFS, AFDO and its six regional affiliates, the Sea Grant Colleges, the ISSC, the National Fisheries Institute, and the National Food Processors Association (NFPA).

The goals of the Alliance are to develop: a HACCP training course that will meet the requirements of these regulations, a mechanism for delivering the training to the fish and fishery products industry, a compendium of established methods for controlling hazards in the fish and fishery products industry, and a mechanism for coordinating the research efforts of the participating agencies to facilitate the development of improved methods of hazard identification and control.

The training course materials are in an advanced stage of development and are expected to be publicly available shortly after the publication of these regulations. The AFDO regional affiliates have agreed to work within their regions to identify regulatory and industry training needs and qualified trainers who are interested in participating in the Alliance-sponsored training. They have also agreed to serve as the course coordinators for the Alliance-sponsored training, which will be conducted on a cost-recovery basis.

The Alliance is developing a 3-day course, divided about equally among: (1) The fundamentals of HACCP, based on the recommendations of the NACMCF; (2) the requirements of these regulations and the recommendations of the Guide; and (3) a practical exercise in HACCP plan development.

FDA is sensitive to the concerns expressed about the cost of training but is optimistic that training will not be unnecessarily burdensome on small business, either in actual out- of-pocket expenses or in lost productivity. As was previously mentioned, FDA is working with the Alliance to produce a low cost, 3-day HACCP-training course for the seafood industry, that is intended to meet the requirements of these regulations. Current plans are for the course to be offered through a variety of public institutions, including Sea Grant colleges. As indicated earlier, in this setting the course is expected to be offered on a cost recovery basis. It is likely that the course will also be offered by private institutions, using their own fee structure.

The other cost associated with the training requirement is the lost productivity for the duration of the course. FDA is convinced that, with the flexibility in course structure, described elsewhere in this section, training can be taken at times when it would least affect the operations of the firm (e.g., during an off-season, at night). Moreover, FDA is convinced by the comments that, as a general rule, the benefits of training will significantly outweigh the burden. The agency has concluded that with certain modifications from the proposal as described below, training should remain a feature of these regulations.

The agency has made one modification in response to requests that it modify the training requirement to reduce financial burden, especially on smaller processors. FDA acknowledges that a short course in HACCP has its limitations. For example, a 3-day course might not have anything important to offer to an individual who has significant job experience working with or for an individual who is well-versed in HACCP. In such a situation, if the processor loses the trained individual, it should be able to replace him or her with the individual who has, in effect, apprenticed with the trained individual without having to send the apprentice to a course in HACCP training, assuming, of course, that the apprenticeship has imparted a level of knowledge at least equivalent to that that could be provided by the training. The agency has modified the regulations to provide for this kind of situation by permitting adequate job experience to qualify and individual to perform the functions of the trained individual.

Note that all references in this preamble to a trained individual mean an individual who meets the requirements of § 123.10 through either completion of a course or job experience that provides an equivalent level of knowledge.

2. Who Should Provide Training?

90. A significant number of comments identified organizations or individuals that they considered to be qualified to conduct or develop HACCP-training courses. The majority of the comments, which included remarks from processors, trade associations, and State governments, suggested that FDA should either conduct such training or at least approve the relevant course material. A few of the comments that recommended that FDA conduct the courses also recommended that FDA provide the courses at no cost or financially support the training. The comments that endorsed FDA approved courses asserted that this approach would result in a standardized, comprehensive training program that emphasizes the minimum acceptable HACCP requirements.

Other comments recommended that training programs could be conducted by NFPA or other trade associations, ISSC, Sea Grant colleges and other academic institutions, consultants, and State and local regulatory agencies. The comments acknowledged the cost savings that could be realized with trade association- provided training and through the HACCP training experience already possessed by the NFPA. One comment suggested that allowing many training programs would offer hundreds of professionals the opportunity to contribute to the development of HACCP. A few comments suggested that FDA publish a listing of approved training courses.

A comment from the ISSC cautioned that organization does not support the shifting of public health training in the area of molluscan shellfish away from itself. The comment further stated that the organization would work cooperatively with the Alliance in the development of a HACCP-training

course, which it suggested should be Federally subsidized and ISSC endorsed.

A few comments suggested that the Alliance be permitted to develop the standard for HACCP training, and that the results be shared with all prospective trainers. A few additional comments urged that HACCP training be based on the recommendations of NACMCF, because such efforts would result in a training program that was well defined.

FDA generally agrees with these comments. The agency does not intend to run HACCP-training courses for the industry. Rather, FDA must, of necessity, focus its HACCP training on government investigators. The agency anticipates that industry training will be conducted privately and through academia. This division of labor is based on the model that has worked well for the training requirement for low-acid canned foods.

FDA agrees, moreover, that there should be widespread opportunity for conducting HACCP training. It is not the agency's intent to specify or limit the field of qualified trainers.

The training course that is under development by the Alliance is based on the recommendations of the NACMCF. After reviewing the final draft of the Alliance training materials, FDA intends to publish a notice of availability of the documents in the Federal Register. It is the agency's intent to utilize the Alliance materials as the standard against which other course materials may be judged.

The agency strongly encourages trainers to evaluate their courses, past, present, and future, against the Alliance materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance course. Where previously conducted training fails to meet this standard, it may suffice to provide supplemental materials or instruction so that the cumulative training is at least equivalent to the Alliance course. FDA also encourages the fish and fishery products industry to confirm with past or prospective trainers that a particular course is equivalent to and consistent with the Alliance materials. The agency has no plans to publish a list of ''approved'' courses other than the Alliance course materials.

Finally, it should be noted that FDA resources will not be sufficient to fund the training of all appropriate regulators (i.e., State or local regulators). The agency is confident, however, that Alliance training will provide a low cost opportunity for high quality HACCP training for State or local regulators as well as for processors.

Because FDA will not be approving in advance specific courses other than the Alliance curriculum, and in response to comments, the final regulations have been modified at § 123.10 to require that training courses be ''at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration.'' FDA had proposed to require that training courses be ''approved by the Food and Drug Administration.''

3. Should Training Be ''Grandfathered?''

91. A large number of comments addressed the question of whether training in HACCP received before the effective date of these regulations should be ''grandfathered'' as fulfilling the training requirement. All of these comments supported the grandfathering of such training. Many of the these comments recommended specific training courses that FDA should grandfather. Approximately half of these comments requested that those trained under NMFS' HACCP training program be grandfathered. Those that provided reasons referenced the large number that had been trained at the time of the writing of the comment (1,310 domestically and 394 overseas) and stressed that NMFS' training was more comprehensive than that which would be necessary under FDA's HACCP approach, especially because the NMFS program covers nonsafety hazards in addition to safety hazards.

Other comments supported grandfathering HACCP courses conducted by NFPA, Sea Grant colleges, State regulatory agencies and those organizations sanctioned by such agencies to provide HACCP training, and Pacific Fisheries Services. One comment suggested that graduation from a Better Process Control School, as required by parts 113 and 114 for processors of acidified and low-acid canned foods, should be considered to meet the requirements of these regulations. Another comment urged that any training program based on the HACCP principles recommended by the NACMCF should be grandfathered.

One comment suggested that, in order to grandfather courses, FDA would need to develop a system to determine the effectiveness of the training that has been conducted. The comment recommended the use of testing or curriculum review as evaluation tools. The comment further encouraged the development of a formal approval process for previously conducted training.

FDA has concluded that it is not in a position to grandfather HACCP training received before the issuance of these regulations. Blanket grandfathering would pose the risk of sanctioning training that does not fully prepare processors for operating under these regulations, and case-by-case grandfathering would be unduly demanding on agency resources.

On the other hand, the agency will not presume that HACCP training received prior to the issuance of these regulations will have to be repeated. FDA will challenge the adequacy of prior training only when a processor's performance demonstrates a lack of understanding of HACCP principles.

Nonetheless, FDA encourages processors to update any prior training to ensure that they have a thorough understanding of the requirements of these regulations. It may well be that many traditional HACCP courses will need only minimal supplementation to accommodate them to the provisions of these regulations, and that there will be no need for a processor to repeat an entire course. As mentioned above, partial, supplemental courses may be offered, or reading materials developed by the course offerer and sent to the processor may suffice. There are numerous possibilities.

FDA is also not in a position to make determinations in advance about the acceptability of courses that will be offered after the issuance of these regulations. FDA agrees with the comment that, in order to do so, the agency would have to develop a system for course evaluation. Review of course materials, auditing of course presentations, testing, and other evaluation tools that FDA might have to employ are labor intensive and are not the most efficient use of agency resources. Rather, the adequacy of courses will have to be evaluated by FDA on a case-by-case basis, when inspectional or other evidence causes the agency to question whether the course meets the requirements of § 123.10.

The ultimate determination of the success of training is whether processors are operating effective HACCP systems. In the initial stages of the program, at least, FDA's primary focus will have to be on whether HACCP plans are adequate, and the systems are being effectively implemented. FDA's interest in the adequacy of training will increase when plans and systems fail to demonstrate an adequate understanding of HACCP and its application to seafood.

Nonetheless, FDA can state that the Better Processing School curriculum for

acidified and low-acid canned foods will not be adequate to meet the training requirement of these regulations. The Better Processing School was developed to instruct acidified and low-acid canned food processors in how to safely process such products to control the hazard of the development of botulinal toxin in accordance with the requirements of parts 113 and 114. The course does not provide instruction in the principles of HACCP or address other hazards (e.g., histamine development) to which these products might also be exposed.

4. Course Curriculum

92. A few comments suggested that the training be divided into a basic HACCP core and interchangeable segments based on the portions of the industry of interest to the students (e.g., vessels, cooked, ready-to-eat fishery products, molluscan shellfish, and smoked fish).

As mentioned previously, the Alliance course includes three segments: A basic HACCP core, the requirements of these regulations, and the development of a HACCP plan. The first two segments are applicable to the entire fish and fishery products industry. The Alliance has acknowledged the need to develop industry-specific features for the third segment. The agency is in agreement with the Alliance and with the comment in this regard and would encourage the development of such directed courses.

93. In response to FDA's invitation to comment on the advisability of alternate training formats, several comments expressed support for the use of video tapes by small processors of low-risk products. A few additional comments did not specifically address video taped training but stated that, while it is desirable to have uniform training, ultimately training should involve ''whatever it takes.'' One comment suggested that home study courses and education via television might be acceptable alternatives to more formal, for-fee training mechanisms. A few comments opposed courses that consist exclusively of video tapes, based on concern for a potential limitation in the level of understanding that could result from this type of noninteractive training method.

FDA agrees with the comments that expressed concern with teaching methods, such as video tapes, that lack instructor/student interaction. However, in the interest of providing flexibility in meeting the training requirement of these regulations, the agency has concluded that any teaching format is acceptable so long as it provides a level of understanding at least equivalent to that provided by the Alliance training program. FDA is aware that video tape training is widely used for a variety of purposes. The agency cannot conclude that video-based HACCP training will not accomplish the purposes of the training requirement. For remote site processors, video-based training may be the only practical method available.

It is unlikely, however, that two or three 2-hour video tapes, as one comment suggested, will provide an equivalent level of training to the 3-day Alliance course under development. On the other hand, a series of video presentations, perhaps in conjunction with a 1-day workshop, may be adequate.

94. A few comments addressed the length of the training course. One suggested that 3 days would be overly burdensome on small businesses because of the loss of manpower during the course. Another suggested that 3 days was not long enough to furnish the needed information. One comment suggested that the length of training should be based on the level of experience of the student and the level of complexity of the processing operation.

FDA has concluded, based, in part, on its participation in the Alliance, that the 3-day Alliance curriculum is the minimum necessary to develop an adequate understanding of HACCP principles and essentials of HACCP plan development. If the curriculum were reduced any further, processors would risk having to take more time later to implement their HACCP systems as a result of trial and error, and as a result, the quality of their HACCP programs would be jeopardized.

Nonetheless, FDA is not specifying in the regulations how long the course must take, only that it be equivalent in terms of curriculum to the standardized curriculum recognized as adequate by the agency. If true equivalency can be achieved in less time, FDA would have no objection. Moreover, depending upon the circumstances, FDA would have no objection to training that can be imparted in segments at convenient times so as to cause only a minimal disruption to the work schedule.

Section 123.10, therefore, states that the training must be ''at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration.'' This provision will also accommodate the use of food processing experts, who have received training in HACCP that is far more extensive than that planned by the Alliance. FDA recognizes that it would be inappropriate to limit the universe of experts to those who have taken a course based on the Alliance 3-day curriculum. The issue of the use of consultants and other experts will be further discussed later in this section.

5. Do Importers Need Training?

95. A few comments suggested that FDA should provide separate or specialized training aids for importers. Two of these comments noted that importers have not, historically, been involved with the processing of seafood commodities. The comments requested that FDA work with trade associations that represent importers in setting up workshops, developing specialized training materials for importers, and recognizing training provided by foreign institutions.

FDA has reassessed the need for training to accomplish the HACCP functions assigned to importers, especially in light of changes in the imports provisions of these final regulations. These changes are fully discussed in the ''Imports'' section of this preamble. In summary, importers are now required to conduct verification activities but are no longer required to have full HACCP plans of their own unless they also meet the definition of a ''processor.'' FDA has concluded that HACCP training, while desirable, is not essential to the preparation of importers' verification procedures, as specified at § 123.12(a)(2). For this reason, training is not required for importers, and all reference to required training for importer functions has been dropped from § 123.10.

Nonetheless, the agency is aware that importers may be unfamiliar with the technical aspects of fish and fishery product processing and HACCP control procedures. Knowledge about these matters would be helpful for purposes of verification. To meet this need, FDA plans to include in the Guide specific materials relating to importers' verification procedures. In addition, as has traditionally been the case, the agency intends to continue to interact with, and provide information to, the import industry through trade associations and other forums, within the limits of budget constraints. Moreover, importers may want to participate in the training courses that are offered by the Alliance.

Finally, the agency agrees with the comment that suggested that training overseas should be conducted by foreign institutions recognized for their expertise in seafood processing and HACCP control. This issue will be further discussed in the ''Imports'' section of this preamble.

6. Testing and Retraining

96. Several comments supported the mandatory use of testing to assess whether an individual has successfully completed HACCP training. Two comments further recommended that the agency could consider the training requirement to be met if a person successfully passes an examination.

The agency is not opposed to testing at the end of a course but prefers not to mandate that courses include tests. Trainers will be free to include or not include testing as part of their training efforts. The issue of student evaluation is one that is still being debated in the Alliance relative to Alliance-sponsored training courses.

However, testing alone does not provide the kind of exposure to the concepts of HACCP that is necessary to result in company understanding and commitment. The function of training is to prepare industry to meet the requirements of the regulations, not to test competency. The true test will be whether processors are able to implement their HACCP systems. Processors will be judged as plans are reviewed, and plant operations are evaluated, during inspections.

97. A few comments recommended mandatory retraining or continuing education. The comments stated that as new information about the science of fish and fishery products hazards and the technology of their control becomes available, there will need to be some method for introducing this information to previously trained individuals. One comment, on the other hand, urged that training be limited to a single event and not be subject to periodic renewal.

The primary purpose of the training is to teach the fundamentals of HACCP. These are unlikely to change over time. A comprehensive discussion of seafood hazards and controls is far too extensive for inclusion in a 3-day training session. The agency has concluded that information about the technology that is available to control hazards should be made available to the industry through the Guide, the Alliance Compendium of Established Processes, and other modes of technical assistance. FDA supports the idea of continuing education and will encourage it, but the agency is not prepared to mandate it in these final regulations.

98. A comment suggested that the regulations mandate remedial or enhanced training for a first time violator whose infractions have resulted from a misunderstanding of HACCP principles.

Whenever an infraction occurs, the nature of the remedy that is warranted depends on factors such as the public health significance of the infraction. The agency has administrative warnings and, when necessary, a range of regulatory actions available to it. (See the ''Compliance'' section of this preamble for a more thorough discussion of compliance philosophy under HACCP and available remedies.) Ultimately, however, it will be the processor who will be responsible for correcting the deficiencies in its HACCP system. Part of that responsibility will be determining the most appropriate method of resolving any failure to fully understand HACCP principles, whether through remedial training, hiring a consultant, or taking some other step. So long as an appropriate outcome can be obtained, FDA would prefer not to mandate any particular method of remediation in these regulations. Processors certainly may wish to consider additional education as an option, however.

7. Gradations of Training

99. Several comments addressed whether the HACCP training requirement could be satisfied by different gradations of training, depending on the complexity or size of the operation or on the degree of risks posed by the product being produced. The majority of these comments supported the concept of variable levels of HACCP training. Most did not provide the basis of their support. Those that did suggested that small or large scale processing of low-risk products would not likely require any special training, and that small scale processing of even high-risk products would allow for individual examination of every fish, an option that is not possible in large scale processing. One comment further suggested the use of variances to exclude certain industry members from the training requirement, rather than providing a blanket exemption for a segment of the industry.

A minority of the comments on this subject opposed any variations in the level of training. Several of these comments stated that the necessity for HACCP education and training does not vary based on the size of a company, and that a standard training curriculum should be developed for all companies, regardless of their size. Some of these comments stated that smaller processing operations may be inherently less safe, and that, cumulatively, they represent a large amount of the seafood making its way to the consumer. One comment stated that smaller processing operations may actually have a greater need for employee training, compared to some larger processing operations that may already have trained staff.

The agency agrees with the comments that suggested that the need for HACCP training does not vary solely by the size of the processor. An understanding of the principles of HACCP is essential for the successful implementation of a HACCP program, regardless of establishment size. The agency agrees with the assertion that, in many cases, the training needs of small businesses may, in fact, be greater than those of large firms, because they frequently lack the trained quality control and research and development staffs that are common in large firms. Moreover, small businesses comprise a significant portion of certain high-risk segments of the fish and fishery products industry, such as processors of molluscan shellfish and cooked, ready-to-eat products. Training will be critical to ensure the success of HACCP in these segments.

Although the agency expects that the complexity of HACCP plans will vary with the number and type of hazards associated with a processing operation, an understanding of the basic principles of HACCP, and how to apply those principles to the processor's operations, will remain essential. The curriculum under development by the Alliance is designed to provide a very basic grounding in these matters. As stated earlier, the Alliance has acknowledged a need to tailor part of the course so that it can be directed toward specific industry segments. This approach may be the best way to provide flexibility in the program, so that training can match the degree of complexity and risk that is encountered by the processor. FDA will continue to encourage the development of industry-specific training features.

The agency is not persuaded that the ability of a processor to individually examine all fish because of the small scale of operations will reduce the processor's need to understand the hazards associated with seafood and the specifics of a systematic approach for controlling them. FDA has long taken the position that observing each fish on an assembly line is an inappropriate way to ensure seafood safety (Ref. 208, p. 4146). While matters relating to the quality of the fish can be observed in this manner, safety matters often cannot.

8. Duties of the Trained Individual

100. Several comments suggested that a firm be permitted to hire a consultant, or an outside expert, who is not an employee of the firm, to perform the functions required of a trained individual. Two trade associations

argued that contracting for the development of a HACCP plan by a professional consultant could be more efficient and cost effective, especially for many small companies. Related comments pointed out that some of the proposed functions of the trained individual either did not require a person to be onsite continually (e.g., plan development) or required expertise that could not realistically be obtained in a 3-day course (e.g., making decisions about whether product that has been subject to a deviation is safe to release into commerce).

While the agency considers training employees to be preferable to hiring outside consultants in terms of fostering the appropriate corporate culture and commitment to HACCP, FDA recognizes the importance of ensuring the flexibility that firms, especially small businesses, may need to comply with the regulations in a cost-effective manner. The agency also accepts that for some processors, the expertise that may be needed from time to time could best be provided by an expert consultant. Consequently, the agency is modifying § 123.10 to read as follows: ''* * * the following functions shall be performed by an individual who has successfully completed a course of instruction * * *.'' The requirement that processors employ a trained individual has been eliminated. Moreover, FDA has modified § 123.10(c) to state, ''The trained individual need not be an employee of the processor.''

101. A number of comments asked whether the regulations would require a separate trained individual for each processing location of each company or just one per company.

FDA intends that the functions enumerated in § 123.10 be performed by a trained individual. The number of employees a processor must train, or the consultants that must be hired, in order to ensure that trained individuals perform these functions is left to the judgment of the processor. For some firms, one individual will be sufficient. Others will need to secure the services of more than one such individual, either as employees or as consultants. Whether these individuals are located at each facility, at a corporate headquarters, at a consulting firm, or at some combination of these arrangements is to be determined by each individual processor.

102. A few comments were concerned about the logistics of the routine functions that the agency proposed must be performed by someone with HACCP training (i.e., record review and deviation handling). Specifically, they argued that the proposed requirements would actually require each firm to have more than one trained individual because of work weeks that routinely exceed 40 hours, vacations, illnesses, and employee turnover. The consequence, the comments suggested, would drive up the cost of training.

FDA acknowledges that, for certain situations, these comments may be correct. However, the agency has made three changes in the final regulations to minimize this possibility. First, as stated above, a processor may hire trained consultants on an as-needed basis. Second, as discussed in the ''Verification'' section of the preamble, the regulations do not include the proposed requirement that a trained individual review monitoring records before the product to which the records relate is shipped. These final regulations require only a weekly review. As a result, the need to have a trained individual onsite every day has become substantially reduced. Third, as described below, FDA has decided not to require that the trained individual evaluate CL deviations and corrective actions. This modification reduces still further the need to have a trained individual onsite at all times. In addition, as described previously, the agency is allowing processors to employ individuals whose training has been obtained through on-the-job experience. Thus, for example, a processor that needs the services of two trained individuals could satisfy the requirements of these regulations by employing an individual who has been trained in an adequate course and a second individual who has apprenticed sufficiently with the first individual to have mastered the subject.

As a related matter, the provision in the final regulations that provides for the development of corrective action plans (see the ''Corrective Actions'' section of this preamble) could eliminate the need to bring an expert onto the scene in many instances in which corrective action is necessary. The processor may be able to follow the corrective action plan without having to rely on an expert or trained individual. This procedure could permit further savings.

103. Some comments suggested that there should be different categories of trained individuals, with different responsibilities. These comments, from individuals, processors, and trade associations, asserted that a firm should have one HACCP trained person capable of conducting or overseeing the routine operation of the HACCP program, but that this individual should not necessarily be responsible for designing a firm's HACCP plan or making complex scientific evaluations.

Another comment suggested that it was unrealistic to expect that a training program would provide the level of expertise necessary for a person to make a determination on whether a deviation may have rendered a product injurious to health or otherwise adulterated.

FDA generally agrees with these comments. It was never the agency's intent to limit the processor's use of experts to employees whose training included the course prescribed by these regulations, especially in the areas of HACCP plan development and the evaluation of CL deviations and corrective actions (i.e., making evaluations about whether product that has been subject to a deviation is safe to ship). While FDA is convinced that a short course in HACCP principles is important to the success of the overall program, the agency also recognizes that such a course has its limitations.

FDA has deleted the proposed requirement that the HACCP-trained individual be required to evaluate CL deviations and corrective actions to allow for the use of experts in other appropriate scientific disciplines that have not been trained in accordance with these regulations. For example, the agency does not expect that a processor will be able to determine the public health consequences of every possible deviation without the assistance of experts. The kind of expertise necessary would likely involve disciplines other than HACCP. Moreover, the agency agrees that it is unreasonable to expect that successful completion of a 3-day HACCP course alone would qualify an individual to make determinations about the safety of products involved in a CL failure. HACCP training in such a situation could only reasonably be expected to help ensure that appropriate corrective action measures are taken and recorded from a HACCP perspective. Consistent with this change, FDA has modified § 123.7(c)(2) to state that a determination of acceptability for distribution into commerce of products that may have been affected by a deviation must be made by individuals with the expertise to make such a determination, and that such individuals need not be those who meet the requirements of § 123.10.

Nonetheless, FDA expects that, at a minimum, an individual trained in accordance with these regulations will perform the verification function of reviewing records of corrective actions to ensure that they are complete, and that an appropriate corrective action was taken (i.e., one that was predetermined in the HACCP plan, or

one that was determined by a qualified expert to be sufficient to render the product safe). Section 123.10(c) requires that the trained individual perform certain record reviews associated with the verification principle of HACCP, including reviews of corrective action records (see § 123.8(a)(3)(ii)).

FDA has modified § 123.10 from the proposal to clarify and to conform this section to other features of the regulations. A summary of these modifications follows.

FDA has revised § 123.10(a) to clarify that when a trained individual develops an HACCP plan for a processor, this effort may involve adapting a model or generic-type plan for use by that processor. FDA received a significant number of comments on the pros and cons of model or generic-type HACCP plans. This subject is addressed in various places in the preamble, most notably in the section entitled ''Other Issues.'' In summary, the development of model plans can be of great benefit to the industry, especially small businesses, so long as the model plans are tailored by processors to meet their individual situations and are not simply copied verbatim. The agency is convinced that, in most cases, generic or model plans will need to be modified to some extent to fully accommodate the specifics of the processor's operations.

Section 123.10(b) provides, in part, that the trained individual is responsible for reassessing and modifying the HACCP plan in accordance with corrective action procedures specified in § 123.7(c)(5). This requirement is not new. It should be noted, however, that, unlike the proposal, the final rule requires the trained individual to perform these functions only when the processor does not have a predetermined corrective action plan that addresses the specific deviation. As explained in the ''Corrective Action'' section of this preamble, a review and reassessment of the plan should not ordinarily be necessary when a corrective action was anticipated, as reflected by the existence of a predetermined corrective action plan.

Section 123.10(b) also requires that a trained individual perform the annual reassessment of the processor's HACCP plan as required by § 123.8(a)(1). A new feature of the regulations, this requirement parallels the mandate that each processor engage in verification activities (see § 123.8(a)). It is a logical outgrowth of the principle, central to both the proposal and this final rule, that plan development be performed by individuals who possess the knowledge and skills that are obtained through training in HACCP.

Section 123.10(c) requires that a trained individual perform certain record reviews as enumerated in § 123.8(a)(3). This requirement is not new except for the review of records of end-product testing, if any. End-product testing was not addressed in the proposal but, as explained in the ''Verification'' section of the preamble, has been added as an optional verification activity. The review of end-product testing records by a trained individual is a logical outgrowth of the principle that was reflected in the proposal in § 123.8(b) that a trained individual review all HACCP records for completeness and consistency with written HACCP procedures.

Finally, it should be noted that the requirement in the proposed regulations that trained individuals perform certain functions for importers has been dropped entirely. This deletion is consistent with the changes that FDA is making in the provisions that applied to importers in this final rule. These revisions are described elsewhere in this preamble. In summary, importers are given alternatives to having HACCP plans and are not required to take the kinds of actions for which a trained individual has been determined to be essential.

*K. Sanitation*

1. Background

FDA proposed to require that processors conduct sanitation inspections at specified frequencies to ensure that each of up to 18 specified sanitation conditions are maintained in the processing facility where they are relevant to the type of processing being performed. The agency also proposed to require that processors maintain sanitation control records, and that they take and document corrective actions when the specified conditions were not met. In addition, FDA encouraged, but did not propose to require, processors to make use of written SSOP's to ensure that the necessary sanitation measures were implemented.

FDA tentatively concluded that sanitation controls are necessary in these regulations because: (1) Sanitation practices directly affect the microbiological safety of seafood products that are not further cooked by the consumer, such as cooked, ready-to-eat products, smoked products, raw molluscan shellfish, and other fish that are consumed raw; (2) sanitation practices are relevant to the microbiological safety of seafood products even where these products are to be cooked by the consumer; (3) sanitation practices directly affect the chemical and physical safety of seafood products; (4) nearly half the consumer complaints relating to seafood that FDA receives in a typical year are related to plant or food hygiene; and (5) inspections conducted by FDA and NMFS demonstrate that a significant portion of seafood processors operate under poor sanitation conditions.

The MSSP, conducted by NMFS, concluded that sanitation controls could be included in HACCP plans without overloading HACCP. Moreover, the FDA/NMFS HACCP-based seafood pilot program included sanitation CCP's. Nonetheless, FDA tentatively concluded that monitoring and recordkeeping for the 18 specific sanitation conditions specified in the proposal should be permitted to occur outside of a processor's HACCP plan so as not to overload it. Because these sanitation controls relate to an entire facility, not just to a limited number of CCP's, FDA felt that they would not all fit well within an HACCP plan.

FDA took this prescriptive approach to sanitation to assist processors so that they would not have to figure out how, or whether, to include sanitation in their HACCP plans and to help them resolve the sanitation problems that the seafood industry has chronically experienced. By requiring a specific, daily sanitation regime that incorporates HACCP-type features (i.e., monitoring and recordkeeping) to help the processor track sanitation in its plant, FDA hoped to foster a culture of, and commitment to, good sanitation practices that has been lacking in a significant portion of the industry.

2. Should the Regulations Deal With Sanitation?

FDA requested comment on whether sanitation control measures should be addressed by processors in accordance with the proposed approach, or whether the regulations should require that processors address sanitation in their HACCP plans.

More than 250 comments addressed various aspects of the proposed sanitation requirements, more comments than addressed any other aspect of the proposed regulations. Approximately 100 of these comments addressed FDA's questions about the approach to sanitation control in these regulations. The remaining comments focused on specific sanitation provisions.

104. Approximately 10 percent of those that responded to the requests supported the proposed approach. These comments were from processors,

consumer advocacy groups, State, Federal, and foreign government agencies, and a trade association. Approximately five percent of the comments, from processors, trade associations, and State government agencies, objected to the inclusion of any explicit sanitation controls in these regulations. It is not clear, however, whether the latter comments were objecting to sanitation controls as part of HACCP where appropriate for safety or to any sanitation approach beyond HACCP. The remaining approximately 85 percent of the comments, principally from processors, trade associations, and State and Federal government agencies, generally acknowledged the need for these regulations to address sanitation in seafood processing plants but objected to one or more of the specifics of the proposal.

Those that supported the proposed approach argued that sanitation controls are a critical component of the regulations because: (1) Addressing the insanitary practices in the seafood processing industry is essential to improved consumer confidence; (2) effective sanitation controls are a prerequisite to the proper functioning of a HACCP system; and (3) sanitation controls are critical to the management of microbiological hazards in both products that will not be cooked by the consumer and those that will be cooked, the latter because of the potential for cross-contamination in the kitchen. The comments suggested that a prescriptive approach to sanitation is warranted because the FDA and NMFS inspection results cited in the preamble to the proposal documented the failure of a significant percentage of the industry to control key sanitation conditions and practices. Moreover, these comments continued, the enumeration of specific controls relieves the industry of the burden of identifying the most significant areas of concern.

Several comments stated that sanitation requirements for seafood processors are necessary because guidelines do not have the force of regulation and therefore are more difficult to enforce. One comment stated that including sanitation requirements in these regulations would simplify compliance for seafood processors because the HACCP and sanitation requirements would be in one place. One comment stated that some processors would be more inclined to implement sanitation control measures if all processors were subject to the same mandatory requirements.

Many of the comments that objected to the manner in which FDA proposed to treat sanitation acknowledged that effective sanitation controls are essential to the proper functioning of a HACCP system. As with comments that supported the proposed approach, a few of these comments identified sanitation as a prerequisite to HACCP.

The comments that objected to the inclusion of any sanitation requirements in these regulations provided reasons that the agency believes are more relevant to the question of how these regulations should address sanitation than to whether they should address the issue. For this reason, the arguments presented in these comments are addressed later in this section.

FDA accepts the view expressed by the overwhelming majority of comments (i.e., those that advocated the proposed approach and those that advocated other sanitation control mechanisms) that sanitation is relevant to the goals of these regulations and should be addressed in them. The primary source of pathogenic microorganisms for most fish (i.e., wild-caught fish) is the processing plant environment (Ref. 3, p. 267). The control of sanitation in the plant is the most effective way to minimize pathogens, and, for products that are not given a final heat treatment after packaging, it is the only way to minimize them at that stage in the chain of distribution (Refs. 3, p. 10; 7, p. 27; 204; and 205). This situation is nearly the reverse of that for red meat and poultry, where pathogens are likely to have originated from the raw materials before they enter the plant (Refs. 36, p. 197; 209; and 210, p. 1).

A significant body of opinion holds, moreover, that good sanitation is a necessary foundation for HACCP. This view was articulated in comments to this rulemaking and in the proposed rule to establish HACCP and other requirements for the beef and poultry industries issued by USDA (Ref. 211). USDA proposed both SOPs for sanitation as a prerequisite to a HACCP plan and sanitation as part of HACCP where critical for safety (Ref. 211, p. 6789).

FDA concludes, therefore, that these regulations cannot fully address all matters relevant to safety, or significantly contribute to the restoration of consumer confidence in seafood without providing for major improvements in sanitation. Therefore, these regulations address sanitation.

3. Why Isn't Part 110 (21 CFR Part 110) Adequate To Deal With Sanitation Concerns?

105. Some comments asserted that it would be adequate to rely on the existing CGMP's in part 110, which provide guidance of general applicability to all foods. A variation on that concern was the view that the sanitation standards in part 110 need not be codified in these regulations because they are adequately expressed in that part. The NACMCF pointed out that the CGMP's have proven adequate for a wide variety of processed foods under FDA's jurisdiction. Some comments stated that part 110 should be made mandatory for seafood and fully enforced.

Good sanitation is already mandatory for all foods. Section 402(a)(4) of the act deems food to be adulterated if processed under insanitary conditions. The CGMP's in part 110 articulate the kinds of conditions and practices that need to be followed in order to avoid producing an adulterated product under section 402(a)(4) of the act.

Nevertheless, while FDA has been enforcing the sanitation standards contained in part 110 for many years, as indicated earlier, it has not succeeded in developing a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants. The statistics relating to the incidence of insanitation cited in the preamble to the proposed regulations (Ref. 208 at 4161–4162) clearly demonstrate that such a culture is not adequately in place. The following observation about culture in the preamble to USDA's proposed HACCP rules for beef and poultry is applicable here as well:

> * * * Identification of sanitation requirements has been viewed by some establishment owners and personnel as the inspector's responsibility. Such establishments often fail to take the initiative to find and remedy insanitary conditions, relying instead on the inspector to find deficiencies. (Ref. 211, p. 6788)

Moreover, FDA points out that while the CGMP's state that sanitation controls should occur as frequently as necessary, they are silent with regard to monitoring by the processor to ensure for itself that sanitation controls are being followed.

For these reasons, FDA concludes that part 110 alone has not proven to be adequate for the seafood industry. In order to ensure that firms take full responsibility for sanitation in their plants, which is strongly related to the production of safe and wholesome seafood, FDA has concluded that it is necessary to include sanitation requirements in these regulations.

4. Why Isn't the Proposed Approach Appropriate?

106. Many comments that agreed that sanitation should be addressed in the regulations, as well as some that opposed addressing it, objected that the

proposal was too prescriptive. These comments asserted that: (1) The proposed 18 sanitation controls are overly prescriptive and inflexible and are not appropriate for all processors; (2) the codification of prescriptive sanitation requirements as regulations limits the ability of processors to keep pace with advances in science and technology; (3) the proposed sanitation controls have the effect of establishing eighteen CCP's, which are not always appropriate; and (4) the proposed sanitation provisions duplicate or contradict existing State or NSSP requirements. FDA will respond to these criticisms.

Many comments that argued that the 18 specific sanitation controls that FDA proposed were too prescriptive provided examples of how this approach could deny processors the flexibility necessary to develop and implement sanitation programs that are effective for the specific conditions in which they are to be used. Some of these examples are as follows:

(1) A few comments challenged the proposed ''easily cleanable'' standard for equipment, suggesting that in some applications (e.g., at sea processing and old equipment) this standard may not be attainable and may not be necessary as long as the equipment is, in fact, cleaned;

(2) A large number of comments challenged the proposed 4-hour equipment cleaning frequency, suggesting that it is unwarranted in some situations (e.g., refrigerated processing facilities) because it is inconsistent with actual microbiological growth rates. It is unduly burdensome in other situations (e.g., surimi processing facilities), according to the comments, because it would limit shifts to 4 hours, would interrupt production, and would require hours of equipment breakdown time;

(3) A few comments challenged the proposed ''impermeable'' standard for gloves and outer garments that contact food or food contact surfaces, suggesting that in some instances it was impractical (e.g., filleting fish);

(4) A significant number of comments challenged the proposed 4-hour hand sanitizer strength test frequency, suggesting that replacement of dips rather than checking concentration may be appropriate, as may be the use of automated hand washing and sanitizing systems; and,

(5) A number of comments challenged the proposed requirement that hand washing and sanitizing stations be located in processing areas, suggesting that they need only be easily accessible.

These comments have general merit and have persuaded the agency that a less prescriptive approach is appropriate to ensure that the regulations do not impose impractical, unduly burdensome, or excessively rigid requirements.

107. Another concern with FDA's approach was that codifying specific sanitation control procedures would not enable processors to keep their sanitation programs updated with advances in science and technology. As an example, the NACMCF comment cited recent industry experience with other foods that has shown that the proposed requirement of midshift cleaning and sanitizing in packaging rooms for ready-to-eat foods, may with many current sanitation practices actually be counterproductive to the control of *Listeria monocytogenes*. The NACMCF advised that codification of a midshift cleaning requirement would have prevented these industries from modifying their cleaning procedures to adjust to the new information.

FDA agrees that sanitation requirements should be sufficiently flexible to permit the incorporation of new information and better procedures.

108. A number of the comments, including more than half of those that opposed any new form of sanitation controls, argued that the sanitation control approach proposed by FDA would effectively establish eighteen mandatory sanitation CCP's that may not always be appropriate.

These comments may have been the result of a misunderstanding of the relationship between processor HACCP plans and the proposed sanitation controls. While the proposed controls involved monitoring and recordkeeping, they were not proposed as part of a processor's HACCP system. FDA did not intend to designate them as CCP's. FDA believes that the provisions of these final rules make clear that the necessary sanitary controls need not be considered to be CCP's.

109. A large number of the comments that objected to the manner in which FDA proposed to handle sanitation argued that the proposed sanitation provisions are redundant with State and local regulations and, with respect to molluscan shellfish, with the NSSP.

FDA acknowledges that the NSSP and most State seafood control programs include provisions, much like FDA's CGMP's, that are designed to control processing plant sanitation. These other provisions, like the CGMP's, serve as baseline standards for sanitation. However, the rates of noncompliance with existing CGMP standards, as detailed in the preamble to the proposed regulations (Ref. 208 at 4161–4162), demonstrate a need for a system in which processors are responsible for not only meeting these baseline standards but also routinely auditing their facilities and operations to ensure that they are meeting them. In this way, the sanitation requirements of these regulations build upon existing sanitation requirements, at the Federal, State, and local levels.

The more generalized nature of these final regulations with respect to sanitation should mitigate the concerns of the comments that complained about the conflict between, and duplication with, existing sanitation standards.

As discussed elsewhere in this preamble, FDA encourages adoption of these regulations by State and local regulatory agencies. FDA is convinced that, in many cases, the regulations can be quite easily overlaid on existing State, local, and NSSP requirements.

5. What Is the Appropriate Approach to Sanitation?

Based on its review of the comments, FDA has been convinced that a modification of its approach to sanitation is appropriate. FDA concludes that its approach in the proposal was too inflexible and could have made it more difficult in certain circumstances to incorporate new technologies and information.

The comments argued for one or more of several approaches that they identified as being more appropriate than FDA's proposed approach: (1) Requiring that each processor develop and follow a SSOP that is specifically tailored to a processing operation; (2) including sanitation controls in the HACCP plan where they are critical to product safety; and (3) retaining the general approach of the proposed regulations but somehow reducing the number of specific requirements. Approximately 85 percent of those that opposed the way that sanitation was treated in the proposal advocated one or a combination of the first two of the approaches, with the recommendations evenly split between the two. The small number of comments that objected to including any specific sanitation requirements in the regulations may also have been arguing that sanitation should not be part of HACCP but should be controlled solely through CGMP's.

a. *Inclusion of sanitation controls in HACCP plans.*

110. There was strong support in the comments for the inclusion of sanitation controls in HACCP plans, particularly where the controls are necessary to protect the safety of the product. The comments stated that a processor's

hazard analysis may reveal the need to control certain aspects of sanitation in the HACCP plan, especially to control hazards involving microbiological contamination. One comment noted that sanitation controls are likely to be components of the HACCP plans of molluscan shellfish processors.

Given the strong support that sanitation controls should be included in HACCP plans where they are critical to safety, FDA has no objection to processors including sanitation controls in their HACCP plans. Consequently, these final regulations state in § 123.6(f) and § 123.11(d) that sanitation controls for safety may be included in HACCP plans.

The agency has concerns, however, as to whether including sanitation controls in a HACCP plan will be adequate to ensure that appropriate conditions exist in a plant. The conditions that would be addressed in the HACCP plan will likely be those that are most critically and directly related to product safety. Other situations that are relevant to safety, but in a less direct way, would probably not be controlled through HACCP. For example, following the NACMCF recommendations for hazard analysis and HACCP plan development would likely result in the identification of a number of equipment and hand washing controls at CCP's in the HACCP plan for the processing of a cooked, ready-to-eat product to minimize the risk of microbiological contamination but not in the identification of these same controls in the HACCP plan for a raw finished product that would normally be cooked before consumption. In the latter case, however, attention to sanitation would still be important in the processing plant to prevent contamination of the product, given that the ultimate consumer cook may be inadequate, or that the product, once contaminated, could be a source of cross-contamination to other foods.

Likewise, the potential for contamination of either a cooked, ready-to-eat product or a raw product as a result of rodent activity in a processing plant, or as a result of improper use of pesticides on or near the product, would not likely be identified in a HACCP plan. All of these conditions are relevant to the safety of the product and should be addressed by processors. It is not clear whether HACCP can fully succeed in plants that are not in control of general sanitation practices. The inclusion of sanitation in HACCP—as desirable as it may be—will not fully resolve this problem.

b. *SSOP.*

111. As indicated above, a significant number of comments that addressed alternatives to the prescriptive approach to sanitation in the proposal preferred a SSOP, either alone or in combination with critical sanitation controls in HACCP. Significantly, the NACMCF was among those that made this suggestion. NMFS' comment stated that, in its experience, the development of SSOP's by processors in its voluntary program has been associated with marked improvement in sanitation. Many comments stated that much of the seafood processing industry already has SSOP's, and that those that do not should develop them.

FDA agrees that the development by processors of an SSOP would be a beneficial step. FDA therefore is recommending in § 123.11(a) that:

> Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced.

An SSOP places the primary burden for identifying relevant controls on the food processor. To meet this burden, it will be necessary for the processor to think through each operation and identify where, and how frequently, appropriate sanitation measures are necessary. The process of doing so will foster the type of culture that FDA is trying to promote, in which processors assume an operative role in controlling sanitation in their plants.

FDA is adopting § 123.11 pursuant to sections 402(a)(4) and 701(a) of the act to ensure that seafood is not produced under insanitary conditions whereby it may be rendered injurious to health. It grows directly out of proposed § 123.10, but, as stated above, it reflects the agency's efforts to make the sanitation requirements more flexible.

FDA has not elected to make the development of an SSOP mandatory because it recognizes that some processors may be able to achieve satisfactory sanitation conditions and practices without having to commit their sanitation control procedures to writing. The agency remains convinced however, that such satisfactory conditions are unlikely to be achieved without periodic monitoring of the operations. For this reason the agency has retained at § 123.11(b) the mandatory sanitation monitoring requirements proposed at § 123.10(c). Sanitation monitoring will be further discussed in the next section of this preamble.

Where a processor elects to develop an SSOP it should specify how it will meet those sanitation conditions and practices that are to be monitored in accordance with § 123.11(b). These conditions and practices will also be discussed in the next section.

Both § 123.11(d) and § 123.6(f) provide that sanitation controls that are monitored in accordance with § 123.11(b) need not be included in the HACCP plan and vice versa. The purpose of these provisions is to allow processors to incorporate those sanitation controls into their HACCP plans that they believe are appropriately addressed through HACCP, without having to duplicate those controls in a separate sanitation program.

6. Monitoring and Corrective Actions

The regulations no longer contain specific monitoring frequencies to ensure that proper sanitation conditions are being met, as was proposed at § 123.10(c). In keeping with the agency's decision to reduce the prescriptive nature of the sanitation requirements, § 123.11(b) now requires that each processor monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with certain key sanitation conditions and practices as specified in part 110.

112. The agency arrived at this approach in response to the comments. As part of the agency's efforts to achieve flexibility, it examined the 18 sanitation controls that it proposed at § 123.10(a) in light of the comments that argued that they were overly prescriptive. FDA proposed the 18 sanitation controls to ensure that, where relevant to the processing operation, important areas of concern were addressed in each plant. The preamble addressed at some length why each of them was significant and relevant to safety. Moreover, although considerable comment was received that challenged the manner in which a particular processor should address these sanitation conditions and the situations in which they should be considered applicable, only two comments challenged the significance of these conditions or the need for them to be controlled when they are determined to be germane, and neither comment provided a basis for doubting the significance of these controls.

FDA concludes that, where relevant to a processor's operation, the processor should monitor sanitation conditions and practices relating to the general subject areas reflected by the 18 specific sanitation controls because they are important for ensuring the safety of the product. As in the proposal, each processor will be responsible for determining which of the subject areas are relevant to its plant and process. However, unlike the proposal, the

processor will be free to tailor the sanitation controls to the circumstances of its operation, as long as it does so in a manner that ensures the effectiveness of those controls. The regulations do not specify the manner in which control must be achieved. FDA will provide guidance on how to ensure appropriate sanitation control in the Guide. FDA is deferring consideration of the comments that it received on the specific sanitation control measures that it described in the proposal until it prepares the Guide.

In order to ensure that processors monitor the general subject areas reflected by the 18 specific sanitation controls listed in the proposal, FDA has concluded that it is appropriate to list in the regulations the sanitation controls that should be considered. This list will ensure that the most significant sanitation controls are considered by the processor in formulating the measures that it will institute in its plant.

The controls that FDA is listing in § 123.11(b) no longer contain sanitation standards that are beyond part 110 or repeat specific standards that are contained in that part. Instead, § 123.11(b) now states that the processor shall ensure that actions are taken to ensure that those sanitary conditions that are contained in part 110 and that are relevant to the plant are maintained in eight general areas:

(1) The safety of the water that comes into contact with food or food contact surfaces or is used in the manufacture of ice (§ 123.11(b)(1)). This control derives from proposed § 123.10 (a)(1) and (a)(2) relating to water quality and treatment and to cross connections between potable and nonpotable water systems.

Water is used in virtually all seafood processing facilities for washing product, equipment, and employees' hands, for transporting fish in flumes, and as an ingredient. Contaminated water can serve as a vehicle for contamination of the product, both directly and indirectly (Refs. 63; 64; 65, p. 49; 66; 67; and 68, pp. 1 and 2). Cross connections, which include situations that allow for back siphonage into a potable system from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological contamination of the potable water system (Refs. 64; 65, pp. 50 and 51; 68; 71; and 72).

This matter was one of the two, as indicated above, about which FDA received a comment that challenged the need for a sanitation control. A comment suggested that the safety of the water supply is within the jurisdiction of local health authorities, and that a processor should not have to deal with that issue.

FDA acknowledges that many State and local jurisdictions exercise control over both public and private water supplies. In the case of private wells, they often permit and inspect the construction of the well and collect periodic water samples for microbiological and chemical attributes. Where such is the case, it may be reasonable for the processor to rely upon these measures. However, in the absence of appropriate controls by a public authority, FDA has concluded that the processor must exercise whatever control is necessary to ensure that the water supply is safe. To do otherwise would be to subject the product to an unacceptable safety risk from the contaminants that may be introduced by the water.

(2) The condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments (§ 123.11(b)(2)). This control derives from proposed § 123.10 (a)(3) through (a)(5) relating to the design, workmanship, materials, and maintenance of food contact surfaces; the cleaning and sanitizing of these surfaces, including the frequency of cleaning and sanitizing; the impermeability of gloves and outer garments that contact food; and the maintenance of gloves and outer garments.

Utensils, equipment, aprons, gloves, outer garments, and other food contact surfaces can be vehicles for microbial contamination of both the raw and finished products. Food contact surfaces that contain breaks, pits, cuts, or grooves, or that are porous or corroded, may harbor pathogenic microorganisms that can migrate to the product and contaminate it. These kinds of surfaces are difficult to clean (Refs. 65, pp. 20, and 36–48; 72, pp. 166–167; 73; and 83). Where food contact surfaces are constructed of toxic materials, the product may be directly contaminated (Ref. 74). Inadequately cleaned food contact surfaces can serve as a reservoir for pathogenic microorganisms, especially if biofilms are allowed to form, in which microorganisms can be entrapped and shielded from the action of cleaning and sanitizing compounds.

(3) The prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product (§ 123.11(b)(3)). This control derives from proposed § 123.10 (a)(6), (a)(7), (a)(13), and (a)(18), relating to employee practices to prevent contamination, to physical separation of raw and cooked product, and to plant design to prevent contamination.

Employees and food contact surfaces can serve as vectors in the transmission of pathogenic microorganisms to the food. These microorganisms can be introduced to the product from outside areas, rest rooms, contaminated raw materials, waste or waste receptacles, floors, and other insanitary objects. In the processing of cooked products, the raw material may also serve as a reservoir of pathogenic microorganisms. Employees or equipment that touch the raw material can transmit these microorganisms to the cooked product (Refs. 7, 63, 64, 73, 74, 84, and 85). Finally, proper construction of the processing plant is essential if other sanitary measures are to be successful. For example, incompatible operations, such as handling of raw materials and handling of cooked product, should be isolated (Refs. 71, 74, 87, and 88).

(4) The maintenance of hand washing, hand sanitizing, and toilet facilities (§ 123.11(b)(4)). This control derives from proposed § 123.10 (a)(8) and (a)(16), relating to the location and maintenance of hand washing and sanitizing facilities, and toilet facilities.

Employee's hands can serve as a vector for the transmission of pathogenic microorganisms to the food. Hand washing and sanitizing, when performed using suitable preparations are effective means of preventing such transmission. Toilet facilities eliminate from the processing environment pathogenic microorganisms shed in fecal material (Refs. 63, 64, 73, 74, 84, and 85).

(5) The protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants (§ 123.11(b)(5)). This control derives from proposed § 123.10(a)(9), (a)(11), and (a)(12), relating to the protection of food from various microbiological, chemical, and physical contaminants.

The use of toxic compounds (e.g., pesticides, cleaning and sanitizing agents, and lubricants) is frequently necessary in the processing environment. Food and food packaging materials should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from food contact surfaces before processing begins (Ref. 74). Condensate which forms on an insanitary surface and then falls on the

product may carry with it pathogenic microorganisms (Ref. 65, pp. 24–25).

This measure is the second about which FDA received a comment that challenged the value of having a sanitation control. A comment suggested that preventing the formation of condensate on ceilings above processing is, in some situations, physically impossible. The comment did not suggest that condensate is irrelevant to safety.

FDA reasserts that condensate is relevant but acknowledges that there are instances in which it may be impractical for it to be fully eliminated. In these instances, after taking all reasonable measures to minimize the development of condensate, the processor will need to take steps to protect the product from the dripping condensate or to ensure that the surface from which it is dripping is sanitary. The development of a written SSOP processor should tailor its sanitation controls to its particular situation in order to accomplish this objective.

(6) The proper labeling, storage, and use of toxic compounds (§ 123.11(b)(6)). This control derives from proposed § 123.10(a)(10), relating to the overall handling of toxic compounds to protect against contamination of food. Improper use of toxic compounds is a frequent cause of product adulteration throughout the food industry. Proper labeling, storage, and use of the compounds is necessary to minimize the risk of occurrence of such incidents (Ref. 74).

(7) The control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces (§ 123.11(a)(7)). This control derives from proposed § 123.10(a)(15), relating to the exclusion of persons who appear to have an illness, wound, or other affliction that could be a source of microbial contamination.

Employees can serve as a reservoir of diseases, such as salmonellosis, shigellosis, and hepatitis, that can be transmitted to consumers by foods. Additionally, open sores, boils, or infected wounds present the potential for contamination of the food with such pathogenic microorganisms as *Staphylococcus aureus* (Refs. 22, 74, and 84).

(8) Exclusion of pests from the food plant (§ 123.11(b)(8)). This control derives from the proposed requirements at § 123.10(a)(17). Pests, such as rodents, birds, and insects carry a variety of human disease agents, which they can introduce to the processing environment (Refs. 63, 64, 73, and 84).

113. FDA proposed at § 123.10(a)(14) that, ''Refrigeration units that store raw materials, in-process, or finished fish or fishery products that are cooked, ready-to-eat, smoked, or made in whole or in part from scombroid toxin forming species shall be operated at a temperature of 40 °F (4.4 °C) or below.'' The purpose of the proposed requirement was to ensure that processors control the microbiological hazards associated with refrigerated storage for these particularly susceptible products. A significant number of comments argued the control of temperature in refrigerated storage is a processing hazard rather than a sanitation issue, and should be covered by a firm's HACCP plan.

FDA agrees with these comments and has not included a provision on refrigeration in the sanitation section of these regulations. A large number of comments were received relative to the appropriateness of a 40 °F (4.4 °C) limit. These comments are no longer relevant to these regulations but will be addressed in the redrafting of the Guide.

FDA has also incorporated the corrective action requirement relative to sanitation conditions proposed at § 123.10(d) in § 123.11(b). Section 123.11(b) the processor shall, correct in a timely manner those sanitation conditions and practices that are not met. The phrase ''in a timely manner'' did not appear in the language of proposed § 123.10(d). However, it was implicit that corrections should be made as quickly as possible so as not to subject subsequently processed product to conditions that could both jeopardize their safety and render them adulterated. FDA has added the phrase for clarity.

Note that the other corrective action requirements in these regulations, i.e., those in § 123.7, do not apply to sanitation controls that are exclusively addressed in § 123.11. The controls in § 123.7 apply to a processor's HACCP system only.

7. Records

114. FDA received approximately 20 comments that addressed the issue of sanitation records. Many others discussed recordkeeping in general but did not specifically mention records of sanitation controls. These latter comments have already been addressed in the ''Records'' section of this preamble.

Of those that commented specifically on sanitation records, approximately three-fifths, from processors and trade associations, objected to the proposed requirement that processors maintain records that demonstrate compliance with the appropriate sanitation standards. In fact, a number of comments listed this issue as a significant reason for their objection to the overall proposed approach to sanitation control. The comments suggested that sanitation recordkeeping is costly and has not been demonstrated to be effective. None of these comments provided any data in support of their statements. Some argued that, while they accepted the notion of records for CCP monitoring, they opposed records of sanitation monitoring.

The remaining comments that addressed the issue of sanitation records, from consumer advocacy groups, an individual, a Federal government agency, a trade association, and a seafood broker, supported the need for such records. These comments argued that sanitation records are essential to ensure that processors adhere to established sanitary standards, and that they need not be extensive.

FDA does not find the arguments against the requirement for sanitation control records to be compelling. The agency concludes that the burden will be minimal. Checklist type or simple notation records will suffice in most instances. Creating them should be incidental to monitoring. Monitoring to ensure that sanitation is under control is the responsibility of all processors.

Monitoring and recording of sanitation conditions is as much a key to the success in improving those conditions, and, hence, to increasing consumer confidence in the seafood processing industry, as is the development by a processor of an SSOP. As in the case of HACCP records, sanitation records require that processors engage in systematic monitoring of their own sanitation practices and conditions. It enables them to see trends. Moreover, participation in recordkeeping helps empower the work force and foster responsibility. It also allows the regulator to assess a processor's compliance over a period of time, not just at the time of an inspection.

FDA believes that the records bearing on the monitoring of relevant sanitation conditions and practices and FDA's access to such records are all essential if § 123.11 is to be an effective regulatory strategy. Therefore, FDA has concluded that the recordkeeping requirement proposed at § 123.10(b) will be retained. To reflect other modifications in this section, § 123.11(c) has been modified to read, ''Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b)

of this section. These records are subject to the requirements of § 123.9.''

Additionally, FDA has moved the requirement that sanitation corrections be documented from proposed § 123.10 (d) to § 123.11 (b).

Finally, FDA notes that § 123.11 does not contain any mention of importers. The lack of a mention of importers in this section reflects the position that the agency is taking in these regulations that, to the extent that importers are also processors, they would be subject to the sanitation requirements in this section. To the extent that they serve as importers only, the sanitation provisions are not relevant to their operations.

*L. Imports*

1. Background

The majority of seafood consumed in the United States is imported. FDA's surveillance system for imports largely consists of reviewing the customs entries for fish and fishery products being offered for entry into the United States, engaging in wharf examinations and sample collections for laboratory analysis, and placing products with a history of problems on automatic detention. As with domestic inspections, this method is basically a ''snapshot'' approach that places a significant burden on the government to uncover problems. It has failed to result in full compliance or consumer confidence in the safety of imported seafood. Consequently, the agency tentatively concluded that HACCP controls should apply to imported fish and fishery products as well as to domestic products. Among other things, FDA proposed that the definition of ''processor'' explicitly include those who process seafood in foreign countries.

In addition, FDA tentatively concluded that the importer should share some responsibility with the foreign processor for safety. More often than not, it is an U.S. importer, rather than the foreign processor, who actually offers imported fish and fishery products for entry into the United States. The preamble noted that, while many importers are conscientious about the safety of the products that they import, others have little understanding of the potential hazards associated with their products. Thus, the agency tentatively concluded that the existing system of import controls had not promoted a sense of responsibility in the import industry.

Therefore, in addition to proposing to require that foreign processors that export to the United States comply with part 123, FDA proposed that importers of fish and fishery products take steps to ensure that their shipments are obtained from such processors. Specifically, FDA proposed that importers: (1) Have and implement a HACCP plan that describes how the product will be processed while under their control; (2) maintain a copy of the foreign processor's HACCP plan; and (3) take affirmative steps to ensure that the imported fish or fishery product was produced in conformance with the foreign processor's HACCP plan and with the proposed sanitation requirements. The agency also proposed that importers need not take affirmative steps if the fish or fishery product was imported from a country with which FDA has a MOU documenting the equivalency of the foreign inspection system with the U.S. system.

2. Should Imports Be Subject to These Regulations?

115. Approximately 70 comments addressed various aspects of the proposed requirements for imports. Approximately half of the comments that addressed the import provisions argued that it is necessary to subject imported products to the same regulatory requirements as domestically processed products. These comments were submitted by processors, trade associations, State and foreign government agencies, professional associations, and individuals. Many of these comments argued that exempting foreign processors from the requirements of these regulations would put the domestic industry at an unfair economic disadvantage. Other comments stated that the import requirements would increase consumer confidence in seafood because they would ensure that imported fishery products have been produced under the same HACCP requirements and held to the same sanitation standards as domestically produced product. A few comments suggested that imported products are more likely to present safety hazards than domestically-produced products because of a lack of understanding of CGMP's on the part of foreign processors. One comment asserted that a number of countries, including Canada, the EU, Iceland, and Thailand are in varying stages of establishing HACCP programs for their own domestic seafood processors.

Most of the remaining comments (approximately one-half) did not comment on whether HACCP controls should be required for imported fish and fishery products but discussed aspects of the agency's proposed approach. These comments will be addressed later in this section.

FDA did not receive any comments that persuaded it that imports should be exempt from the requirements of these regulations. On the contrary, the comments reflect a nearly universal recognition that the safety of seafood cannot be adequately ensured if the majority of products (that is, imports) are not subject to the same controls as domestic products.

Therefore, the agency has not modified the regulations' basic approach for imports.

116. Only two comments objected to the concept that imported fish or fishery products should meet the same requirements as those for domestic products. One of these comments argued that FDA should be tolerant of a foreign processor that may not have the knowledge or time to develop a HACCP plan before its product is ready for export and urged the agency to develop a temporary waiver system to accommodate such firms.

FDA is convinced that a 2-year implementation period, as discussed in the ''Effective Date and Compliance'' section of this preamble, will provide sufficient time for processors, both within and outside the United States, to develop and implement HACCP plans and otherwise come into compliance with the provisions of these regulations. The comment provided no basis for treating foreign processors any differently than domestic processors in this regard.

117. Another comment suggested that raw material fish and fishery products imported for further processing in the United States should be exempt from the requirements of the regulations but provided no reason to support that position.

The exemption requested by the comment would make it difficult, if not impossible, to control environmental hazards that may be associated with these products. This preamble and the preamble to the proposed regulations fully discuss the conclusions of the NAS, which identified raw material hazards, such as microbiological contamination in molluscan shellfish and natural toxins in both shellfish and finfish, as among the most pressing problems that must be addressed to ensure seafood safety. For the most part, these hazards are best addressed at the time of harvest and by primary processors, through HACCP, at the time of receipt. In many cases, there is little opportunity for control beyond the latter point. Raw material fish and fishery products for further processing comprise a substantial portion of fish

and fishery products imported into the United States (Ref. 212, p. 49). Thus, to exempt foreign processing of such products from the requirements of these regulations would be to greatly diminish the scope and, therefore, the overall effectiveness of these regulations.

118. One comment that supported the need for equitable treatment of imported and domestically produced products urged the agency to provide the same opportunities for processors abroad to familiarize themselves with the requirements of these regulations as it does the domestic industry. The comment argued that just printing the regulations in the Federal Register would not fulfill that responsibility. The comment further suggested that FDA send copies of guidance materials to all known foreign seafood processors, preferably in their native language.

FDA acknowledges the difficulty in reaching foreign processors with information about the requirements of these regulations. However, mass mailings to, and multiple translations of, these regulations and the Guide for all foreign seafood processors that export to the United States would not be practicable for FDA.

The agency intends to reach foreign processors primarily by briefing foreign embassy staffs and by communicating with U.S. importers during public and trade association meetings. Based on experience in disseminating information about U.S. requirements to the import community, the agency expects that these two groups will provide the necessary information and guidance materials (in the appropriate languages) to the foreign processors that they represent. This same approach was used in disseminating information about the proposed regulations. In fact, FDA became aware of a Japanese translation of the proposal shortly after it issued.

In addition, FDA traditionally has provided training and technical assistance for foreign processors and government officials on a variety of food control topics, within the constraints of budget and manpower. These projects have principally been conducted in developing countries, often those in which the agency has become aware of a particular problem that threatens the safety of products offered for entry into the United States. FDA anticipates that these kinds of projects will continue, and that they will focus more closely on HACCP. FDA also expects that HACCP training, performed in accordance with the standardized training materials under development by the Alliance (see the ''Training'' section of this preamble), will provide further opportunity for foreign processors to be exposed to the requirements of these regulations.

3. Should Importers Be Subject to These Regulations?

119. Approximately half of those who commented on the import provisions addressed whether the importer should be required to take steps to ensure that its shipment originates from a foreign processor that operates under HACCP. Approximately half of these comments favored the concept and half opposed it, with both groups being diverse in their representation.

Of those who opposed it, many argued that these requirements should be the responsibility of the government, and that FDA should not require that importers enforce them. A number of these comments further argued that equivalent foreign government inspection systems cannot be presumed to be in place, and that the only way to achieve a ''level playing field'' is for FDA to perform inspections of foreign processors at the same frequency, and using the same standards, that the agency applies to domestic processors. One comment suggested that it may be necessary to obtain legislative authority to perform foreign inspections, as a condition of importation. Another comment suggested that FDA auditing of foreign processor compliance would give importers assurance that the products that they obtain from such sources had been produced in accordance with appropriate U.S. standards.

One comment, while not opposed to mandatory importer responsibilities, nonetheless argued that FDA should spend as much time and effort inspecting foreign processors as it does on domestic processors because over 50 percent of the seafood consumed in the United States is imported. The comment continued that, ''to do any less would be an unfair burden to domestic processors and would not accomplish the stated goal to significantly improve the safety of seafood consumed in the U.S.''

One comment argued that there is no real cost savings in assigning importers the responsibility of verifying foreign processor compliance rather than assigning that responsibility to FDA, because importers will merely pass along the additional costs to the consumer. Another comment noted that many small importers obtain products from over 25 countries, and that they cannot afford to provide the surveillance necessary to ensure compliance.

Another comment argued that many importers function simply as brokers, connecting a buyer with a seller, and that they lack the expertise, manpower, and facilities to evaluate the adequacy of a processor's HACCP controls. One comment stated, ''Many of the people involved in importing never see the product and know nothing about fish—these are people in a small room with a battery of phones!'' Another comment argued against placing reliance for assuring the safety of imported seafood on persons who have a financial interest in the product but lack the required knowledge about seafood safety.

One comment argued that requiring importers to exercise control over their suppliers has no parallel in the proposed domestic HACCP scheme. The comment stated that domestic processors must control the hazards that are introduced during their processing operations but need not be involved in verifying the control of those hazards associated with their supplier's operations. Some comments argued that the responsibility for controlling hazards that are reasonably likely to occur should be assigned to the foreign processor, while others argued that it should be assigned to the U.S. processor to whom the importer sells the product. One comment asserted that importers are not in a position to exercise control over the processing of products in foreign plants any more than they are in a position to exercise control over how the products are handled by their customers.

Most of those comments that supported the concept of importer responsibility provided no reason. However, one comment stated that requirements on importers would ensure that someone in the United States would be legally responsible for the safety and wholesomeness of each imported product.

FDA recognizes that requiring importers to take steps to ensure that foreign processors from whom they purchase seafood products are in compliance with these regulations could necessitate significant changes in the operations of importers who have limited their activities to matching buyers with sellers based on product specifications that may have had little to do with safety. However, for two reasons, FDA cannot agree that responsibility with regard to safety is inappropriate for importers.

First, it has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. It is a prohibited act, under section 301(a) of the act, to introduce into interstate commerce an adulterated food. Thus, an importer would be committing a prohibited act if it failed to ensure that

the food that it is offering for import into the United States is not adulterated under section 402 of the act, including section 402(a)(4), one of the principal provisions on which these regulations are based.

Currently, however, the importer is not required to operate in a proactive manner to ensure that it is meeting this responsibility. Rather, the importer need only offer products for entry into commerce and thereby place the burden on the government to find a problem. Many importers traditionally have purchased ''FDA rejection insurance'' to hedge against that possibility. The government can shift the burden to the importer by placing the importer's products on automatic detention if it finds problems that warrant such a step, but in most instances the burden remains on the government.

Second, responsible importers understand the issues related to the safety of the seafood products that they import and customarily require that foreign suppliers conform to their product specifications and applicable U.S. regulations relating to safety. These importers take various measures to ensure that a foreign processor can comply with their specifications and safety requirements before they agree to purchase products from the foreign processor.

Thus, it is feasible for importers to take steps to ensure that they are not offering adulterated products for entry into U.S. commerce. Requiring such measures will not be a significant added burden for many importers, particularly as HACCP principles become more widely used and understood in international commerce. Foreign processors that want to participate in the export market, not only to the United States but to the EU, Canada, and an increasing number of other countries, will implement HACCP and sanitation control programs and will be prepared to address an importer's needs for verification.

FDA does not agree that there is no parallel in the domestic scheme to the importer's responsibility to ensure that the goods it is offering were produced under HACCP. Domestic processors, like importers must work with their suppliers (e.g., fishermen) to ensure that all reasonably likely hazards (e.g. natural toxins and agricultural and industrial chemical contaminants) are controlled. FDA is confident that importers, like processors, will realize that ensuring that foreign processors institute preventive control systems is a cost effective means of ensuring that the products that they offer for entry into the United States will consistently meet FDA's entry requirements and will be safe for consumption. FDA also disagrees with those comments that suggested that a requirement that importers take steps to ensure that the products they offer for entry have been produced under a HACCP plan is an abrogation of FDA's responsibilities. As stated previously, the industry has a responsibility to ensure that the food that it introduces into interstate commerce is not adulterated. FDA has a responsibility to verify that industry is meeting its obligation and to take remedial action if industry fails to do so. Importers, who are usually the owners of the products that they are offering into commerce, are a part of that industry. FDA cannot accept that importers have no responsibility to ensure that their products are not adulterated.

The agency recognizes that probably the most effective way for a regulatory agency to evaluate a processor's compliance with the HACCP and sanitation requirements is through onsite inspection of facilities, practices, and records. FDA has performed a limited number of inspections of foreign processors and, within its budgetary limitations, will continue to do so to enforce these regulations. However, such inspections are costly, and any attempt to significantly increase their number would require additional resources.

FDA will continue its traditional import surveillance role, utilizing entry document review, wharf examinations, sample collections, and automatic detentions as screening tools. These tools indirectly evaluate the adequacy of HACCP and sanitation controls and will continue to be useful in detecting significant problems. While end-product testing and evaluation are not adequate substitutes for preventive controls in ensuring the safety of a product, they can provide verification where appropriate (Ref. 34, pp. 201–202).

FDA has concluded that requiring HACCP controls, together with import surveillance and periodic inspections of importers to ensure their compliance with the requirements of § 123.12, will better ensure the safety of imports than the current system.

In a related matter, § 123.3(g) makes clear that, under ordinary circumstances, freight forwarders, custom house brokers, carriers, or steamship representatives will not be required to fulfill the obligations of an importer. It is possible, although FDA has no way to know with any certainty, that some of those that objected to being required to fulfill those obligations would, as a result of these clarifications, find that they would not be expected to do so.

4. Memoranda of Understanding (MOU's)

120. Many of the comments that objected to the importer responsibility provisions of the proposal on the grounds that the government is the appropriate entity to ensure foreign processor compliance, stated that the most effective means of ensuring such compliance would be for FDA to enter into MOU's with the governments of exporting nations. Approximately one-third of those that commented in any way on the importer provisions urged FDA make the negotiation of MOU's a high priority. Only one comment objected to the development of MOU's.

Several comments argued that FDA should develop MOU's with all countries from which seafood is imported. One of these comments pointed out that to do otherwise would unfairly cause the obligations of importers to vary considerably. A few comments argued that the existence of an MOU should be a prerequisite for the importation of seafood products from a country. One of these comments stated that mandatory MOU's would reduce the complexity of the present import surveillance situation, reduce the number of countries exporting seafood to the United States, and encourage the development of improved food safety programs in exporting countries. Another comment asserted that MOU development is appropriate because government-to-government relationships and audits can be free of influence from packers and importers, whereas foreign suppliers may be prone to provide false assurances about their programs to prospective importers.

One comment urged FDA to fully describe the process and criteria for developing and evaluating MOU's and expressed concern about the process because of the varying level of sophistication of foreign seafood control programs. One comment stated that the foreign government should be responsible for evaluating the foreign processor's HACCP plan, inspecting the foreign processor, periodically analyzing products produced by the foreign processor, and issuing health certificates. A few comments stated that FDA should monitor the effectiveness of the foreign government's control program in a manner that is authorized in the MOU. These comments stated that, under the MOU's, the foreign government should provide FDA with periodic lists of processors that meet the requirements of these regulations, or, alternately, that all seafood processors

in the country would be required to meet the requirements.

One comment urged FDA to publish periodic reports on the status of MOU's on seafood products and to make them available to all importers. This comment and others argued that it should be FDA's responsibility to notify importers about changes in the status of MOU's, rather than be the responsibility of the importer to find out about any changes. One of these comments noted that, because a change in the status of an MOU could be very detrimental to importers, there must be sufficient lead time to allow importers to develop alternate verification procedures when changes do occur.

Another comment urged FDA to coordinate with U.S. importers and exporters in developing a schedule for MOU development. The same comment urged FDA to assign more resources to the development of MOU's.

On the other hand, one comment stated that the MOU development process is overly open-ended and could result in inconsistencies between domestic and foreign requirements. The comment argued that this inconsistency could result in an economic disadvantage for domestic processors.

FDA agrees with those comments that urged that the agency give high priority to the establishment of MOU's with U.S. seafood trading partners. In the absence of significant numbers of agency inspections of foreign processing facilities, FDA acknowledges that an MOU can be the most efficient and effective mechanism for ensuring that foreign processing plants are operating in compliance with the requirements of these regulations. FDA also agrees that the potential for signing an MOU with FDA is likely to serve as an incentive for the improvement of regulatory food control programs and processing conditions in seafood exporting countries, especially where the existence of an MOU serves to excuse the importer of products from that country from certain verification activities.

FDA has concluded that the development of MOU's or similar agreements with foreign regulatory agencies is an appropriate method for ensuring that foreign processors that export to the United States are in compliance with the requirements of these regulations. Moreover, as suggested by several comments, the agency has determined that, where an MOU exists, there is no need for the importer to perform any independent verification procedures for purposes of these regulations. In this situation, the importer should be able to rely upon the foreign regulatory authority to ensure compliance by foreign processors.

FDA is therefore retaining the provision on MOU's from the proposal but modifying it to provide that, where an importer elects to obtain a fish or fishery product from a country with which FDA has an active MOU or other similar agreement, the importer need not engage in any independent verification activities.

The agency has developed an internal protocol for developing MOU's and is negotiating agreements with several countries. FDA is committed to negotiating as many MOU's as possible. Also in the Federal Register of June 15, 1995 (60 FR 31485), FDA published the notice of availability of a new Compliance Policy Guide on MOU's.

However, it is not reasonable to expect that an agreement could be reached with all countries from which seafood is imported into the United States. The barriers to achieving such a result include the inadequacy of foreign regulatory programs and the lack of interest on the part of some foreign governments in entering into an agreement. The availability of FDA resources also can affect at least how long it takes FDA to enter into a particular MOU.

For these reasons, the existence of an MOU or similar agreement as a requirement of entry of fish or fishery products into the United States would result in an enormous negative economic impact to a major segment of the U.S. seafood industry. Moreover, such a restriction is not warranted from a public health perspective given the alternative means of verifying the existence of HACCP controls that are provided in these regulations.

Experience obtained in part in the international portion of the FDA/NMFS seafood HACCP pilot project has demonstrated that foreign seafood regulatory programs vary considerably, both in their capabilities and in their structures. Likewise, foreign seafood processing conditions are highly variable. Thus, FDA cannot simply follow a boiler plate format in negotiating MOU's. Rather, they must be tailored to the specifics of the situation presented by a particular country. It is possible that some agreements can provide simply for the submission of lists of approved processors to FDA at regular intervals; others may require much more extensive FDA involvement before and after goods flow under the agreement. Some agreements may cover all of a country's seafood processors, while others may be targeted to specific species or product forms, depending on factors such as the capability of the foreign regulatory authority.

In any case, all agreements can be expected to provide for FDA verification of the effectiveness of the foreign programs, including onsite visits. FDA is principally interested in two- way agreements, that is, agreements that acknowledge the acceptability of the U.S. regulatory system to the foreign government as well as the acceptability of the foreign regulatory system to the U.S. government.

The agency will make every reasonable effort to communicate with the industry about changes in the status of MOU's through Federal Register notifications and other means. FDA is open to suggestions about the best ways to communicate in this regard.

Nevertheless, it will ultimately be the importer's responsibility to keep appraised of any changes in the status of MOU's.

The agency is also receptive to the views of the seafood industry and others about how countries should be prioritized for the purpose of negotiating MOU's. Any information that the agency receives on this topic will be coupled with existing information concerning the likelihood of negotiation success and the types and quantity of products typically offered for entry from the country in question.

5. Importer Verification Procedures

121. The remaining comments discussed specific aspects of the proposed importer requirements. Some of these comments argued that the responsibilities that were proposed for importers are onerous, unworkable, and inefficient but offered nothing in support of these assertions.

A number of comments objected to the proposed requirement that all importers have and implement a HACCP plan. Several of these comments contended that an importer's plan can only address the hazards that occur during the time that products are under the importer's control (i.e., from the time the importer takes possession of the product until it is shipped to its customer), and that requiring that the plan cover this point is inconsistent with the principles of HACCP. One comment agreed that an importer should be required to develop a plan if it also processes the product, as in the case of an importer who stores the product. The comment asserted that, in such a case, however, the importer's HACCP plan would be minimal. The comment further asserted that the foreign processor should be the party responsible for developing a HACCP plan that addresses the hazards

introduced during processing in the foreign plant. The comment recommended that, as an alternative to having a HACCP plan, an importer should be able to develop SOP's that outline the steps that it will take to determine whether to purchase the product from a foreign supplier.

A number of comments supported the proposed requirement for importer HACCP plans but provided no reasons for their support.

The agency agrees that it would be inappropriate to require that importers have and implement a HACCP plan regardless of whether they process the products they import. As stated elsewhere in this preamble, HACCP is a system that provides immediate feedback, through the monitoring of CCP's, as to whether a process is under control. Unless an importer is also a processor, there are no CCP's in the classic sense for the importer to monitor, and from which to obtain real-time feedback. Consequently, only where importers also process in accordance with the definition of that term at § 123.3(k) will they be required to have and implement a HACCP plan that meets the requirements of § 123.6. Those food safety hazards that can be controlled by the foreign processor must be addressed in the foreign processor's HACCP plan in accordance with § 123.6.

Consequently, FDA has revised the regulations to limit the responsibilities of importers. Instead of having to maintain their own HACCP plan, under § 123.12(a), in the absence of an MOU or similar agreement, importers only need to maintain and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States have been processed in accordance with the requirements of these regulations. The only exception to this rule would be if the importer itself engages in processing, such as holding food, in which case the importer would, as stated above, also be a processor and subject to § 123.6.

122. In determining the nature of the verification procedures that an importer must have and implement, FDA considered the comments that addressed the appropriate functions and existing procedures of importers. Several comments noted that importers routinely purchase products according to specifications and observed that these specifications could be the basis for reasonable control measures for importers. The NACMCF recommended that importers be required to maintain product specifications that are relevant to product safety for fish and fishery products that they import. The NACMCF listed water activity, pH, histamine content, and, perhaps, pathogen limits as examples of specifications that importers might set in an effort to ensure product safety.

The agency agrees with the comments that product specifications can be useful tools with which importers can exercise some control over the products that they purchase and offer for entry into the United States. In fact, FDA stated in the preamble to the proposed regulations that the purpose of an importer's plan was, in part, to include criteria for how the importer will decide to purchase seafood. FDA is also encouraged by the fact that the comments generally agreed that having product specifications would not constitute a new burden for many importers.

For these reasons, the agency in § 123.12(a)(2)(i), is requiring that the importer's written verification procedures include product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions. These are the adulteration sections that relate to the safety of fish.

In many cases, importers will find existing Federal food safety standards, including tolerances and guidelines, to be useful specifications. In other cases, specifications may need to be tailored to the circumstances. For example, the importer might need to ensure that the temperature of a modified atmosphere packaged product, when it comes off a ship, is 38 °F (in such foods there is a risk of *C. botulinum* type E growth and toxin development which can occur at temperatures as low as 38 °F), although the CGMP's at § 110.80(b)(3)(i) state only that refrigerated foods should be stored at 45 °F or below. The importer is encouraged to seek the advice of qualified experts, as needed, in setting specifications. The same resources available to help domestic processors in setting CL's are available to importers, including the Guide; Sea Grant Institution and other academics; Federal, State, and local food safety regulatory agencies; consultants; the Alliance and other training courses; and published literature.

6. Affirmative Steps: General

As a second part of the importer's verification procedure, FDA is essentially retaining from the proposal, in § 123.12(a)(2)(ii), the requirement that the importer take affirmative steps to ensure that the products being offered for entry are actually being produced under controls that meet the requirements of these regulations. In order for product specifications to be meaningful, importers must take steps to establish that their suppliers are in fact operating in a manner that can reasonably be expected to produce a product that meets those specifications. Effective verification involves scrutinizing the standard, much like evaluating whether the HACCP plan continues to be appropriate, and scrutinizing performance to determine whether the standard is consistently reached, much like reviewing monitoring records (Ref. 34, p. 201). FDA is adopting this approach in § 123.12(a)(2)(ii).

Among the affirmative steps that FDA proposed that a processor take were: (1) Obtaining the foreign processor's HACCP-monitoring records; (2) obtaining a certificate from a foreign government inspection authority certifying that the firm is operating under a valid HACCP plan or certification on a lot-by-lot basis; (3) regularly inspecting a supplier's facilities; (4) periodic end-product testing by the importer or a private laboratory hired by the importer; or (5) other such verification measures as appropriate. FDA listed these affirmative steps as examples of the types of measures that would be acceptable to the agency. FDA does not wish to predetermine all the possible ways that an importer could perform affirmative steps.

123. A number of comments objected to each of the affirmative steps that FDA listed in the proposed regulations, and a few expressed support for each. However, few of the comments provided any reasons for their positions.

One comment suggested that the best means by which an importer can ensure that the conditions at a foreign processing facility are at least equivalent to those required of domestic processors is for the importer to verify the adequacy and implementation of the foreign processor's HACCP plan during a visit to the facility. Another comment stated that, ''without both audits and HACCP records, foreign plants (possibly domestic facilities too) will not adhere to the letter of the FDA regulation and assure safe product in the market.''

Conversely, a number of comments argued that it would be unworkable for importers to conduct inspections of foreign processors. One of these comments stated that to justify the expense of such an undertaking would necessitate that a highly trained, competent individual perform the function.

As stated earlier, FDA remains convinced that importers must exercise

sufficient control over the fish and fishery products that they offer for entry into their country to ensure that the products are produced pursuant to the requirements of these regulations. The agency recognizes that any one of the affirmative steps may not be appropriate or feasible for a particular importer or foreign processor. The regulations allow importers to select an affirmative step that is workable for their circumstances and to develop appropriate affirmative steps other than those listed in the regulations (see § 123.12(a)(2)(ii)(F)). However, such measures must provide at least an equivalent level of assurance of foreign processor compliance as that provided by the listed affirmative steps.

Additionally, FDA has modified the importer requirements to allow for the performance of any of the affirmative steps by a competent third party (§ 123.12(b)). This provision provides even greater flexibility to importers in meeting the requirements of these regulations.

Thus, FDA is not persuaded that the affirmative steps are not feasible or appropriate and has included them in these final regulations.

124. A comment argued that government certificates should not be acceptable unless they are issued by countries with which FDA has signed an MOU or similar agreement. The comment asserted that, especially in developing countries, there may be different interpretations of the regulations, and differences in competency, credibility, infrastructure, intent, and uniformity that might bring the utility of such certificates into question.

FDA acknowledges that it is likely to have a higher level of confidence in certificates received from a government entity with which it has signed an agreement than with one with which no agreement exists. However, as discussed above, it is unlikely that the agency will be able to negotiate an MOU with every country that exports seafood to the United States. Thus, there may be countries that have excellent certification programs with which FDA, for a variety of reasons, simply does not have an opportunity to enter into an agreement. Moreover, if the agency learns, either through its own routine surveillance activities, consumer complaints, or other means, that there is evidence that a country is routinely issuing certificates inappropriately, the agency will try to inform firms that import fish or fishery products from that country that it will expect them to use other means of verification if they want to avoid the appearance that those products are adulterated under section 402(a)(4) of the act (see § 123.12(d)).

125. One comment urged that certification be permitted on a continuing basis rather than requiring lot-by-lot certification.

FDA agrees that continuing certification is appropriate and notes that the language and intent of the proposed regulations would have allowed for it. Nonetheless, in an effort to further clarify this situation, the agency provided in § 123.12(a)(2)(ii)(B) that: ''Obtaining either a continuing or lot-by-lot certificate * * *'' will be one way to satisfy the requirement that an importer take affirmative steps to ensure that the product is produced in accordance with the requirements of this part.

7. Foreign Processor HACCP Plans

126. Approximately 15 comments addressed whether importers should be required to have on file copies of the HACCP plans of each of their foreign processors. Approximately half of these comments supported such a requirement, although for the most part they provided no reasons for their support. The other half objected to the requirement. One of these comments argued that possession of a foreign processor's HACCP plan would be cumbersome for the importer and would provide no assurance that product shipped by that processor was processed in accordance with the plan. One comment cautioned that it would be unrealistic to expect that importers could make any but a rudimentary judgment as to the adequacy of foreign processors' HACCP plans. Such judgments, these comments asserted, should be reserved for the regulator when the plans are assessed during inspections of importers' records.

One comment cited the possibility of breaches in confidentiality because commercially sensitive material would be supplied to importers. A related comment suggested that, to solve the confidentiality problem, the foreign processors' HACCP plans should be filed directly with FDA rather than with importers.

Although the agency continues to believe that a foreign processor's HACCP plan provides a useful basis for verification, FDA is persuaded by the comments that there are logistical and other issues that could render the retention of HACCP plans by importers unmanageable in some cases. FDA has also concluded that, in most cases, affirmative steps such as those listed in § 123.12(a)(2)(ii) (e.g., onsite inspection by the importer and certification by a foreign government agency) will be adequate to enable an importer to verify that the products being imported are safe in accordance with the requirements of these regulations.

As described previously, the NACMCF recommendations describe two primary goals of verification: (1) Ensure that the plan is adequate to address the hazards that are likely to affect the product; and (2) ensure that the plan is being consistently implemented. The affirmative steps listed in § 123.12(a)(2)(ii) are designed to address both of these functions. For example, obtaining HACCP and sanitation monitoring records from the foreign processor (§ 123.12(a)(2)(ii)(A)) enables the importer to confirm that the foreign processor has addressed the relevant hazards and sanitation concerns (i.e., those for which there are monitoring records), and that it is monitoring to ensure that these concerns are under control during the production of lots that are shipped to the importer. Similarly, obtaining governmental or third party certification of foreign processor compliance with the requirements of these regulations (§ 123.12(a)(2)(ii)(B)) or inspecting the foreign processor directly (§ 123.12(a)(2)(ii)(C)) enables the importer to confirm that the foreign processor has an adequate HACCP plan and SSOP, and that the relevant sanitation and safety concerns are being controlled for those lots that are shipped to the importer. The affirmative step options provided for by § 123.12(a)(2)(ii)(D) and (a)(2)(ii)(E) are discussed later in this section.

Consequently, FDA has not included a requirement that importers of fish and fishery products have on file the HACCP plans of each of their foreign suppliers in these final regulations.

Nonetheless, FDA points out that maintaining copies of these plans could be one of several measures that an importer could incorporate into its affirmative steps. Therefore, these final regulations in § 123.12(a)(2)(ii)(D) incorporate the concept as one of the affirmative steps that an importer may choose to use for verification purposes.

127. One comment noted that the plans of foreign processors would normally be prepared in the native language of the country of origin and asked whether FDA would require that these documents be translated into English. On the other hand, another comment recommended that HACCP plans be maintained in both the language of the native country and in English.

FDA agrees with the comment that argued that a copy of a processor's HACCP plan would not, by itself,

provide adequate assurance that a given shipment of imported product was processed in compliance with that HACCP plan or that the sanitation requirements of § 123.11 were met. One additional thing is needed to provide such assurance: a written guarantee from the foreign processor that the products shipped to the importer are processed in accordance with these regulations. The guarantee is necessary to demonstrate that the HACCP and sanitation control systems are being implemented for products shipped to the importer. An importer should be able to make a reasonable judgement about the validity of the guarantee through a rudimentary review of the plan, as described below. Therefore, FDA is including these requirements in § 123.12(a)(2)(ii)(D).

FDA is also providing in § 123.12(a)(2)(ii)(D) that the foreign processors' HACCP plans that are maintained by importers be written in English, so that they will be meaningful to the importer and will allow for regulatory review.

128. As stated above, one comment cautioned the agency about the ability of many importers to evaluate the adequacy of HACCP plans that they might retain.

FDA acknowledges that many importers may not have the technical expertise to evaluate the adequacy of seafood HACCP plans. However, the agency is convinced that, as a result of the importers' assessment of the food safety hazards that are reasonably likely to be presented by the product, the importer should have developed some general expectations about the content of the HACCP plan (e.g., which hazards should be addressed). The importer should be able to spot any obvious shortcomings and to discuss them with the foreign processor. It is not enough that importers simply file away the documents upon receipt. Importers may find it advantageous to make a judgment about the likelihood that their product specifications will be met and to insist that they be given a guarantee that contains assurances that the specifications will be met.

129. Regarding the comment that complained about the potential loss of confidentiality of foreign processor HACCP plans that are provided to importers, since the agency has eliminated the requirement that all importers retain copies of foreign processor plans, the significance of this issue has been minimized. In the case where a foreign processor does not wish to share its plan with the importer, the processor and the importer would need to agree upon another means of providing for importer verification.

130. Regarding the comment that suggested that all foreign processors file their plans with FDA, the resource demands on the agency that would come with such an undertaking would be prohibitive. FDA cannot accept this suggestion.

8. Other Affirmative Steps

As a related matter, FDA has determined that, in the absence of a requirement that importers maintain a copy of the foreign processor's HACCP plan, finished product tests alone are insufficient as an importer affirmative step to ensure that the foreign processor is operating in accordance with these regulations. Finished product testing alone has a small statistical likelihood of detecting defects in a product, especially when the occurrence of such a defect is an uncommon event, as is the case with most seafood hazards (Ref. 213). The proposed requirement for the importer to obtain a copy of the foreign processor's HACCP plan, in addition to performing finished product testing, would have provided indirect evidence that HACCP controls are in place and would have lent support to a conclusion, based upon the analytical findings, that the relevant hazards are under control. In the absence of such evidence, the importer cannot reasonably conclude that the hazards are being controlled based solely on a negative analytical finding. For this reason FDA has required in § 123.12(a)(2)(ii)(E) that such sampling be accompanied by a written guarantee from the foreign processor that products being shipped to the importer are processed in a manner consistent with the requirements of these regulations. The guarantee provides the importer with reasonable assurance that HACCP and sanitation controls are in place and are being implemented, in a manner similar to the way that the foreign processor's HACCP plan would have under the requirements of the proposed regulations. Under this alternative, the importer would not have to maintain a copy of the HACCP plan.

For clarification and consistency within the document, FDA has revised the language of two of the affirmative steps to include reference to the sanitation provisions of the regulations. In both the proposed regulations and these final regulations the stated purpose of the affirmative steps is to enable the importer to verify that the fish or fishery product was processed under conditions that meet both the HACCP and sanitation requirements of these regulations. However, the formulations of two of the affirmative steps in the proposal did not make specific reference to sanitation. To avoid confusion over what the affirmative steps should cover, § 123.12(a)(2)(ii)(A) now reads ''Obtaining from the foreign processor the HACCP and sanitation monitoring records * * *'' and § 123.12(a)(2)(ii)(B) reads ''* * * certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part.''

131. Several comments asked the agency to specify the frequency with which the importer affirmative steps must be taken. A few comments suggested that the frequency should be no greater than the frequency of equivalent FDA verification activities.

It would not be practical for the agency to specify frequencies for affirmative steps that would be appropriate in all circumstances. Consistent with the frequency of monitoring by processors, importers should take affirmative steps to monitor their suppliers with sufficient frequency to accomplish its purpose—that is, to provide the importer with reasonable assurance that the foreign processor is operating in compliance with these regulations.

It would be inappropriate to tie importer affirmative step frequencies to average FDA sampling and inspection frequencies. FDA sample collection and inspection frequencies are determined, in part, by the compliance history of individual firms, agency priorities, and overall agency resources, not simply on a desired average minimum rate of verification. Thus, FDA's rate of inspection has no bearing on how frequently an importer should monitor a supplier.

132. A number of comments urged that the agency permit importers to contract with third parties to perform verification activities on their behalf. Two comments opposed such a provision but did not provide reasons for their position.

Several comments urged that certificates by nongovernmental third parties be accepted as an affirmative step. One of these comments, from a trade association, suggested that an equivalent arrangement has been accepted by FDA in controlling the importation of canned mushrooms from the Peoples Republic of China. This same comment argued that a system where individual importers inspect each of their suppliers is highly inefficient. The comment suggested that a single, technically competent party should perform the inspections. The trade association offered to serve as a

clearinghouse for the reports of such inspections. Likewise, the association offered to serve as a clearinghouse for finished product sample results for imported products, reducing the number of samples needed when the same product is imported by a number of importers. The comment further suggested that the association be permitted to hold foreign processor HACCP plans for its members, and perhaps for nonmembers. The comment argued that acceptance of this suggestion would reduce the number of duplicate records for the same product stored by various importers.

The agency accepts that third party verification can be an appropriate and efficient control mechanism. Such a system is consistent with the use of third parties by processors for plan development, record review, and CL deviation evaluation. Therefore, FDA has added a new provision at § 123.12(b), that reads, ''An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.'' It is worth pointing out that where an importer uses the services of a third party, the importer remains responsible for the verification procedures that are performed. The importers must be able to demonstrate that appropriate verification measures have been performed. This step may involve providing an FDA investigator with a copy of the foreign processor's HACCP plan, results of end-product sampling, results of an onsite inspection, the foreign processor's monitoring records, or the foreign processor's written guarantee. Third parties must, of course, be competent to perform the duties in question, and FDA reserves the right to challenge such competency. The agency has no objection to the use of clearinghouses for importer verification activities, as long as the forgoing requirements are met.

9. Importer Records

As previously mentioned, the proposed regulations would have required that importers develop and implement a HACCP plan. One effect of such a requirement would have been that importers would have had to maintain appropriate records. As has been explained, FDA is adopting only those essential components of the proposed approach that the agency considers to be practicable for importers. One such component is recordkeeping. Recordkeeping is essential in documenting for the benefit of importers and the agency the affirmative steps of importers, in the same way that it is essential in documenting the monitoring, corrective action, and verification activities of processors. For this reason, the agency has retained the recordkeeping aspect of the proposal for importers, in a manner that is consistent with the overall approach for importers in these final regulations. Section 123.12(c), which treats importer records identically to processor records, reads, ''The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.''

133. FDA proposed that importers encourage foreign processors to obtain HACCP training. A few comments urged the agency to make it clear that foreign processors must comply with the same training requirements as are applicable to domestic processors. One comment urged the agency to permit HACCP-training courses for foreign processors to be conducted in the country of origin by ''an official agency.''

FDA agrees that the need for training is the same for foreign processors as it is for domestic processors. The intended benefits of the training requirements are fully discussed in the ''Training'' section of this preamble. Nonetheless, the agency finds that the proposed requirement that importers encourage foreign processors to obtain training is unnecessary. Foreign processors that ship seafood products to the United States are advised of the training requirement of these regulations in the same way that they are advised of the other requirements of these regulations, through publication of the regulations. In addition, as mentioned elsewhere in this preamble, FDA intends to provide the embassies of seafood exporting countries with information concerning these regulations in order that they may in turn provide it to the processors in their countries. Consequently, FDA is not adopting this provision.

FDA has no objection to HACCP training being performed in the country of origin by ''an official agency'' or other entity, as long as the course of instruction is at least equivalent to that provided by the standardized course under development by the Alliance.

10. Determination of Compliance

FDA proposed to require that there be evidence that imported fish and fishery products were processed under conditions that comply with the requirements of these regulations, and that if assurances that this was the case did not exist, the product would appear to be adulterated and would be denied entry. This section of the proposed regulations provided five types of evidence that the agency would consider as adequate to provide such assurance.

134. A few comments supported these provisions. However, a few comments suggested that, if the importer is unable to provide assurance that a HACCP system is in place, the importer should be permitted to conduct finished product testing rather than having the product denied entry. One comment urged that importers be held only to a ''best efforts'' standard in determining whether their suppliers are in compliance with these regulations. This comment suggested that if an importer cannot determine that such compliance exists after using its best efforts, the importer's product should not be banned from the United States.

The purpose of these regulations is to cause processors of fish and fishery products, both domestic and foreign, to develop and implement HACCP systems of preventive controls to ensure the safety of their products. The importer requirements are designed to impose an obligation on importers to ensure that, like domestic products, the products that they are importing are not adulterated within the meaning of section 402(a)(4) of the act. This requirement means that importers must be able to satisfy themselves, and ultimately FDA, that the fish and fishery products that they are offering for import were produced subject to a HACCP system and sanitation controls designed to prevent insanitary processing conditions that may render the food injurious to health. If an importer does not have evidence that shows that the products were produced subject to such controls, it should not offer the product for import into this country. The lack of such evidence creates the appearance of adulteration that cannot be overcome by the collection and analysis of a finished product sample by an importer. Given the problems that can arise in seafood processing if HACCP and sanitation controls are not in place, under sections 402(a)(4), 701(a), and 801(a) of the act, FDA is adopting § 123.12(d), which provides that if evidence does not exist that an imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors, the product will appear to be adulterated.

Section 123.12(d) derives from proposed § 123.12 (a) and (b). FDA has combined these provisions and, as

suggested by a comment, has used terminology consistent with the rest of the regulation in § 123.12(d). While proposed § 123.12 (a)(1) through (a)(5), which described the types of evidence that could be used to demonstrate compliance with the proposed regulations, reflected important principles for the importation of fish, based on the comments, FDA finds that these provisions were causing confusion, and that the statute can appropriately be implemented without including them in the final rule. For this reason, FDA has not adopted these provisions.

135. One comment asked what documents, if any, would have to be presented to FDA at the time of entry concerning the status of the foreign processor. Another comment suggested that importers should note on the entry documents that a HACCP plan is available for the foreign processor. This comment stated that FDA would have an opportunity to review the plan as part of its determination of whether to allow entry of the product.

FDA is not requiring that evidence of the importers' affirmative steps be presented along with the existing U.S. Customs Service entry documents as a matter of routine practice. It is possible that, in some circumstances, such a step will be necessary (e.g., where the agency has reason to believe that inappropriate conditions exist in the foreign processing facility). However, typically, the importer will be able to retain such evidence in its files and to make it available to the agency when FDA performs an inspection at the importer's place of business. Such a system is necessary because of the time that is necessary for the agency to properly review the importer's documentation of its affirmative steps and of the foreign processors' HACCP plans. Nonetheless, the agency is willing to explore alternate methods of implementing the import requirements of these regulations, such as that suggested by the comment. FDA welcomes a continuing public dialog about this matter.

136. One comment asked whether FDA would maintain an approved list of foreign processors.

The agency has no plans to maintain such a list, nor is it apparent upon what basis such a list would be prepared. A possible exception would be as part of an MOU arrangement, where the foreign country would agree to provide a list of ''approved'' firms to FDA. In such a situation, FDA would use reasonable means to inform the import industry of the purpose and contents of the list and update them as rapidly as possible when changes are made.

137. One comment expressed concern that the same foreign processor HACCP plan might be reviewed by different FDA investigators in different ports of entry, and that these investigators might reach different conclusions as to its adequacy. The comment urged that the agency coordinate such reviews, as well as reviews of importers' affirmative steps, in a way that would minimize inconsistencies.

FDA acknowledges that the situation might well arise where different investigators review the same foreign processor HACCP plan as a part of different importer inspections. To minimize inconsistencies in such reviews, the agency intends to train its inspectional staff in the requirements of these regulations and the application of HACCP principles to seafood processing, including training on the Guide. The agency also intends to develop guidance relative to importer verification activities.

*M. Guidelines or Regulations?*

1. Background

FDA recognizes that many processors will need guidance in the preparation of HACCP plans, and that HACCP plans will vary in complexity. The agency is committed to providing the industry with technical assistance that includes general guidelines for HACCP plans and the contents of plans for specific types of products and processes.

As part of FDA's seafood HACCP proposal, the agency included guidelines, in the form of appendices, on how processors of cooked, ready-to-eat products and products involving scombrotoxin-forming species could meet various provisions of the proposed regulations relating to the development and implementation of HACCP plans. FDA regards these products as being high-risk relative to other seafoods. They involve special considerations or special hazards for which additional guidance would likely be useful.

Cooked, ready-to-eat fishery products present an elevated risk of a microbiological hazard compared to most other seafood products. They are cooked as part of processing and might not receive additional cooking by consumers before consumption. Consequently, to be safe, these products must not contain pathogens at a level that will cause disease and must not be subjected to time-temperature abuse that would allow any existing pathogens to grow to unacceptable levels.

Scombrotoxin-forming species are fish that can form a toxin if exposed after death for significant periods to temperatures that permit the growth of certain bacteria. Scombrotoxin can result in a mild to severe allergic response in humans.

The guidelines for these products contained advice about hazards that are reasonably likely to occur and on details for HACCP plans for the control of these hazards. In addition to asking for comments on the substance of the guidelines, the agency asked for comment on whether these guidelines should remain as guidelines, or whether some or all of them should be adopted as regulations. As regulations, they would, essentially, tell processors that certain hazards must be controlled in their HACCP plans, identify in advance critical points in the processing of these products that processors must control to minimize these hazards, and tell processors what they would have to do, at a minimum, to maintain proper control of those critical points.

In another appendix to the proposed regulations, FDA published excerpts from the draft Guide, mentioned earlier in this preamble, for the stated purposes of publicizing the existence of that draft Guide and of providing processors with information about the types of guidance that the agency expected would be available in it.

One of the excerpts that FDA published was guidance on the processing of smoked and smoke-flavored fish. These products represent a significant hazard relative to contamination with *C. botulinum*, especially when packaged in reduced oxygen atmosphere packaging. FDA requested comment on whether this guidance should remain solely within the Guide, whether it should be provided an appendix to the regulations, or whether it should be adopted as regulations. The effect of adopting these materials as regulations would be the same as for the appendices described above.

If these materials remained in the form of guidelines, processors would be free to adopt them or not, so long as measures that provide an equivalent or superior degree of safety are implemented.

138. Approximately 55 comments responded to FDA's request for comment on whether these materials should remain as guidelines or be adopted as regulations. The majority of comments preferred guidelines. A few comments suggested that FDA initially issue guidelines, then possibly convert them to regulations after gaining experience with them as adjuncts to a functioning HACCP system or after pilot testing them. A few comments preferred to retain some of the materials as

guidelines and convert others to regulations.

Over one-third of those who commented on this subject supported guidelines in general, without distinguishing among the three guidelines. They argued that guidelines are in keeping with the general philosophy of HACCP that processors assume responsibility for the safety of their products. Some stated that detailed regulations for processors to follow would not provide an adequate incentive to processors to develop a full understanding of the hazards associated with their products or processes. The result could be the development of rote HACCP plans that might be inadequate for safety in specific situations.

Some comments pointed out that, while guidelines can assist processors to identify controls, guidelines probably could never properly identify the CCP's and limits for all processors given the uniqueness of individual processing methods. In the case of regulations, processors would be obliged to adhere to the presented limits regardless of their appropriateness to the operation. Many of these comments preferred the flexibility that guidelines provide in permitting HACCP controls to evolve with a changing knowledge base and new technologies. Some expressed concern that if the guidelines were adopted as regulations, the industry would bear an unnecessary burden of having to petition FDA for amendments in order to accommodate new products or processes. Modifications to the regulations could take considerable time.

Several comments specifically objected to adopting either the guidelines for cooked, ready-to-eat products or the guidelines for scombroid toxin-forming species, or both, as regulations. The reasons were generally the same as those given by those comments that supported the use of guidelines generally.

One comment did express the concern that adopting the scombroid guideline as regulations would have the effect of adopting a policy action level for histamine as a defacto regulation without a formal notice and comment rulemaking.

Several comments requested that guidelines only appear in the Guide, and not in appendices to the regulations, to alleviate confusion.

However, FDA did receive a number of comments that urged the agency to adopt these guidelines as regulations. These comments cited a need for minimum enforceable standards for these products to ensure the protection of the public health. The comments argued that minimum standards would avoid confusion about what is enforceable, and what is not. They pointed out that as regulations, these provisions could be more readily enforced.

FDA believes that all of these comments have merit. Guidelines can provide flexibility that regulations sometimes lack. Moreover, because they are advisory in nature, guidelines are less likely to be followed by rote.

FDA thus agrees that, ideally, HACCP should serve as a catalyst for processors to develop a full understanding of the relationships between their products and processes and human food safety and to devise controls for ensuring safety. There may well be more than one way to reach an appropriate safety endpoint. Regulations might not always take such alternatives into account.

On the other hand, in those cases involving high-risk products where adherence to scientifically established minimum standards or procedures is necessary to ensure a safe product by design, and those minimums are not likely to change, there is good reason to make those minimums something more than advisories. In those types of situations, it makes no sense to act as if the work that scientifically established the minimum processing conditions had not been done.

2. Cooked, Ready-To-Eat Products and Scombroid Species

These, then, are the considerations that FDA has weighed. In the case of cooked, ready-to-eat products and products made in whole or in part from scombroid toxin-forming species, FDA is persuaded that the guidelines should remain as guidelines, at least until there is enough experience with them to determine whether a change to regulations is warranted. The agency has concluded that processors should be given maximum flexibility, at least initially, to identify the reasonably likely hazards and the CCP's and CL's for those hazards that are most appropriate for their manufacturing processes. FDA will examine over time whether processors are achieving an adequate degree of preventive control for these products under the guidelines, and whether they are doing so by following the guidelines exactly or partially or by relying on alternative approaches.

FDA acknowledges that many comments objected to the details of the appendices. These comments will be addressed when the first edition of the Guide is published. FDA recognizes that these materials will be more easily modified and improved if they remain as guidelines, at least for the time being.

FDA agrees that all of these guidelines should appear solely in the Guide. There are no appendices to these final regulations.

3. Smoked and Smoke-Flavored Fishery Products

The guidance for smoked and smoke-flavored fish contained specific processing parameters (i.e., time and temperature of smoking and finished product salt and nitrite concentrations) to be met in the processing of such products, and control mechanisms for ensuring that they are met. *C. botulinum* toxin production is prevented in smoked and smoke-flavored fish by controlling these interrelated variables, as well as by controlling the temperature of the product throughout the chain of distribution.

139. Approximately 25 comments addressed whether these materials should be regulations or guidelines. About half of the comments, representing State and Federal regulatory agencies, professional associations, and others, urged that the materials be codified as regulations. The remainder, representing processors and trade associations, requested that the guidelines remain as guidelines.

A number of the comments that urged that the smoked and smoke-flavored fish guidelines be issued as regulations asserted that regulations are more easily enforceable, would provide clear direction to the industry, and would provide much needed nationwide uniformity in the processing of smoked fish. One comment from a State regulatory agency observed that processors are not adhering to existing guidelines, such as the 1991 recommendations for these products by AFDO, and are unlikely to change their operations in response to another guideline. Several comments argued that the States need Federal regulations to support their own efforts to regulate the industry and to foster uniformity among the various existing State requirements. One of these comments also stated that such regulations are needed to ensure the safety of smoked fish, because the product has a history of involvement in botulism outbreaks, is handled more than most other products, increasing the risk of microbiological contamination, and is frequently not cooked prior to consumption. One comment suggested that the guidelines be tested in pilot programs before making them mandatory, and that research information on smoked fish be disseminated to industry through

technical bulletins, workshops, and meetings.

Several of the comments that suggested that the proposed guidelines remain as guidelines argued that FDA has not demonstrated that present practices in the smoked fish industry are causing risks that would justify regulations, and that there have been no recent incidents of botulism attributable to smoked fish. Several comments stated that most of the problems with smoked fish in the past have resulted from abuse of the product at retail or by the consumer.

A few comments objected to FDA's contention that large portions of the industry do not conduct final product testing and to the inference that all smoked fish processors do not monitor the composition of their products. The comments stated that responsible companies do conduct product testing on a regular and routine schedule, have scheduled processes, and are aware of what they are doing.

Other comments recommended that FDA enforcement of the current CGMP's, coupled with State and local enforcement of the Food Code for smoked products that are produced in restaurants, retail, and food service establishments, would make it unnecessary to treat smoked fish products any differently than other products under these HACCP regulations. One comment suggested that guidelines would have the same impact as regulations because HACCP plans would be rejected by FDA if they do not contain the recommended controls, and because States would adopt the guidelines as regulations.

One comment argued that the issuance of prescriptive regulations would eliminate the diversity in the types of smoked fish products available and result in a ''homogeneous'' market. Another comment counseled that the issuance of a regulation would cause Alaskan native salmon processors to abandon their traditional trade.

The agency remains convinced that smoked and smoke-flavored fish is a potentially hazardous food. While cases of botulism have not been attributed to commercially prepared smoked or smoke-flavored fish in over 30 years, the outbreaks of the 1960's clearly demonstrate the potential for such occurrence. Virtually all the research that has been conducted establish that processors need to control time, temperature, and salinity (T-T-S) parameters and other matters for these products in order to provide adequate barriers to toxin production (Ref. 214).

As the preamble to the proposed regulations pointed out, FDA and a number of States have longstanding concerns that the actions of a significant portion of the smoked fish industry do not demonstrate a full appreciation for the nature of the risks. FDA and New York State surveys of the smoked fish industry in the late 1980's, for example, showed that many processors did not routinely control their T-T-S parameters.

The comments have not persuaded FDA that, even without regulations, processors will employ preventive controls to ensure the safety of these products as a matter of design and not of chance. Botulism derives from one of the most dangerous toxins known to exist. Controls to prevent the formation of this toxin cannot be left to chance. HACCP controls for this hazard are highly appropriate because HACCP requires that the processor analyze its operation to determine how hazards affecting its product can arise, and that it institute specific controls to prevent those hazards. The majority of comments that addressed smoked and smoke flavored fish products either supported the concept of HACCP controls or did not argue against them.

140. The question, therefore, is whether, in addition to requiring HACCP plans for these products, FDA should mandate specific CCP's, minimum CL's, monitoring frequencies, and other matters that processors would have to include in their HACCP plans. If the agency were to codify draft guidelines as regulations, the agency would be answering that question in the affirmative. The preamble to the proposed regulations identified the T-T-S parameters in the draft guidelines as being scientifically established minimums for ensuring that toxin produced by *C. botulinum* will not be produced over the shelf life of the product under refrigerated conditions and under conditions of moderate temperature abuse. FDA has been urged for years to mandate such T-T-S parameters for these products. In 1988 and 1989, for example, AFDO passed resolutions asking FDA to expedite the development of regulations for the safe processing of smoked fish. The comments to this rulemaking that supported regulations over guidelines support the mandating of specific T-T-S parameters.

However, a significant number of other comments challenged whether some of the parameters in the guidelines were actually minimums, as FDA had contended. They specifically objected to the minimum water-phase salt levels in the draft guidelines for air packaged smoked and smoke-flavored fish. Generally, these comments stated that there is little safety concern with air-packaged smoked or smoke-flavored fish (hot or cold smoked) containing as little as 2.5 percent water phase salt (less than the minimum stated in the guidelines), and requested that FDA reexamine the existing scientific data. A few comments stated that air-packaged smoked fish has a limited shelf life in the refrigerated state and that NMFS research has shown that spoilage occurs before toxin production. One comment stated that NMFS, New York State Department of Agriculture and Markets, and AFDO all consider a minimum water-phase salt content of 2.5 percent to be acceptable for air-packaged products.

A few comments suggested that an alternative to specifying T-T-S parameters would be to require that all processors have a scheduled process for air-packaged products. The comment stated that this requirement has been successful in the State of New York and has enabled industry to produce products with water-phase salt concentrations that are lower than those proposed by FDA. A few comments suggested that the high salt levels proposed by FDA for smoked and smoke-flavored products would be counterproductive to those government programs aimed at reducing salt in the human diet and would be unacceptable, or only marginally acceptable, to consumers. Other comments suggested that the necessary minimum salt levels for smoked and smoke-flavored fish might be reduced by shortening the shelf life of the product or by storing and distributing the product frozen.

The comments have persuaded FDA that it may be possible for processors to use parameters other than those in FDA's draft guidelines and still produce a safe product. Moreover, the NACMCF has recently endorsed AFDO's recommended parameters for smoked and smoke-flavored fish. Most notably, these recommendations differ from those in FDA's draft guidelines in that they provide for a minimum finished product water phase salt content in air-packed product of 2.5 percent, whereas the FDA proposal provided for a range of minimum values of from 2.5 percent to 3.5 percent, depending upon other processing parameters.

The agency acknowledges, therefore, that some recommended T-T-S parameters differ from those in FDA's draft guidelines. FDA acknowledges the possibility that other safe T-T-S parameters exist as well. It is reasonable to suppose that there is more to be learned about how the development of *C. botulinum* toxin is controlled in these products, given the lack of reported illnesses in recent years. Thus, while

FDA strongly believes that the T-T-S parameters in its draft guidelines provide effective controls for botulism, the agency accepts that they are not necessarily the only effective controls, or that all effective controls have been identified.

Consequently, the agency has concluded that, at least for now, the most appropriate place for such guidance on T-T-S parameters and related matters is the Guide, and that it would not be appropriate to adopt specific parameters for the processing of smoked fish by regulation. However, because of the extreme nature of the hazard, and in response to comments, FDA has chosen to codify a rudimentary performance standard for the control of botulism in these products from the draft guidelines (item number 11). As incorporated at subpart B, § 123.16, the performance standard reads:

> In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *C. botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

This requirement responds in part to the comments that proposed that FDA require that all processors scientifically establish scheduled processes for smoked and smoke-flavored fish, rather that mandate specific T-T-S parameters and other matters. It requires processors to establish CL's that are both appropriate to their operation and scientifically sound. Because botulism is undoubtedly a hazard that must be controlled in the production of these products, subpart B of part 123 does not impose a requirement that would not exist in its absence. It has been included for emphasis and as a reminder to processors. The Guide will provide processors with assistance with regard to specific T-T-S parameters and related matters.

141. FDA proposed that, with certain exceptions, fish to be smoked or salted be eviscerated and free of residual viscera. The preamble to the proposed regulations explained that salted or smoked uneviscerated fish present a potential hazard for the development of *C. botulinum* toxin production. The viscera of fish contain the majority of *C. botulinum* normally present.

One comment argued that the entire evisceration provision should be moved to the Guide. Another comment suggested that specific evisceration requirements be codified but not as part of sanitation.

These regulations require in subpart B of part 123 that the processors of smoked and smoke-flavored fish describe in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *C. botulinum*. Specific types of controls will be provided in the Guide. Because evisceration is one form of control for this toxin, it will be covered in the Guide as well and need not be included in the regulations. Consequently, FDA has not included this proposed provision in these final regulations.

*N. Molluscan Shellfish*

1. Background

In addition to the general HACCP provisions in subpart A of part 123, FDA proposed subpart C of part 123—''Raw Molluscan Shellfish,'' which set forth specific requirements for the processing of fresh or frozen molluscan shellfish. Proposed subpart C of part 123 described certain types of controls that processors of these products must include in their HACCP plans in order to meet the requirements of subpart A of part 123.

Specifically, FDA proposed to require that processors of raw molluscan shellfish identify in their HACCP plans how they are controlling the origin of the molluscan shellfish that they process. FDA proposed to require that these controls include accepting only molluscan shellfish that originated from growing waters that are approved by a shellfish control authority, that are from harvesters that are licensed or from processors that are certified by a shellfish control authority, and that are properly tagged or labeled. In addition, FDA proposed to require that processors maintain records to document that each lot of raw molluscan shellfish meets these requirements. FDA also proposed to amend § 1240.60 (21 CFR 1240.60) to provide for a system of tagging for shellstock and labeling for shucked molluscan shellfish as a means of source identification.

It is important to note that shellfish control authorities in the United States are generally agencies of State governments, and that the tagging of molluscan shellfish is an important aspect of State shellfish control programs. As discussed below, reference to aspects of existing State programs in these Federal regulations is not intended to supplant or override the State programs in any way. Rather, these provisions are intended to strengthen the Federal system in ways that will complement, and thereby better support, State programs.

Molluscan shellfish consumed raw or partially cooked pose unique public health risks. As the preamble to the proposed regulations noted, they probably cause the majority of all seafood-related illnesses in the United States. This situation is not unexpected, given the nature of the product and the way that it is consumed. The preamble documented a relationship between the microbiological quality of molluscan shellfish growing waters and the incidence of molluscan shellfish-borne disease. It also noted that naturally occurring toxins may accumulate in molluscan shellfish because they are filter-feeding animals.

The NSSP was established as a cooperative program among FDA, State regulatory agencies, and the molluscan shellfish industry, relying on section 361 of the PHS Act (42 U.S.C. 264), to provide for the classification and patrol of shellfish growing waters and the inspection and certification of shellfish processors. The preamble to the proposal reaffirmed FDA's support for the NSSP but noted the difficulties that are associated with ensuring the safety of these uncooked products. As the preamble stated, FDA tentatively determined that it could strengthen and provide additional support for the cooperative program through these regulations.

2. Should There Be Specific Requirements for Raw Molluscan Shellfish?

FDA received approximately 45 comments about the proposed requirements for raw molluscan shellfish. The responses were from processors, trade associations, State and Federal government agencies, individuals, consumer advocacy groups, and a foreign country. Approximately half of these comments urged FDA to eliminate proposed subpart C of part 123 and the proposed amendment to § 1240.60, while the other half acknowledged the advisability of including these kinds of provisions but commented on, or questioned, various specifics of them.

The comments that generally supported the need for specific requirements for raw molluscan shellfish were from trade associations, molluscan shellfish industry members, consumer advocacy groups, Federal and State government agencies, individuals, and a professional organization. A number of comments noted that special requirements for molluscan shellfish are warranted because of the association of these products with illness. One

comment in particular stated that, with respect to seafood, molluscan shellfish ''serve as the primary source of illness due to ingestion.'' One comment noted that Federal regulations relating to source of origin controls for raw molluscan shellfish would enable FDA to lend support to the States in the administration of the NSSP. Another comment suggested that the proposed regulations would improve FDA's regulatory effectiveness with regard to molluscan shellfish control. The comment from the ISSC stated that ''The Conference has long recognized and supported expansion of FDA authority to assist States in assuring the safety of molluscan shellfish.''

The comments that suggested that subpart C of part 123 and the amendment to § 1240.60 be deleted were from State government agencies and seafood processors. A number of the comments that suggested deletion of the proposed provisions stated that the tagging and labeling requirements of the NSSP are designed not to serve as a control to prevent harvesting from closed areas but to assist States in tracing shellfish that are implicated in illness outbreaks back to the harvest area. The comments went on to state that harvesters who illegally harvest from closed waters do not identify the shellfish as originating from the closed area. The comments maintained that preventing illegal harvesting is the key to reducing the incidence of illness, and that the only known method to achieve this goal is through effective law enforcement, including the patrol of closed waters.

A number of these comments argued that increased FDA funding and support for State molluscan shellfish control and patrol efforts would do more than the proposed rule to deter illegal harvesting, to increase States' compliance with the NSSP, and reduce the number of illnesses caused by molluscan shellfish. The comments went on to state that the proposed regulations unnecessarily duplicate the requirements now in place in the Manual of Operations for the NSSP. They contended that formal adoption of NSSP requirements into Federal regulations would release State agencies from their cooperative relationship with FDA under the NSSP.

One comment noted that the weaknesses in State molluscan shellfish control programs are in areas not addressed by the proposed regulations, such as improperly classified growing waters; the ability of State growing water classification programs to respond to breakdowns at waste water treatment facilities or unexpected climatic events that affect the quality of molluscan shellfish growing waters; and improper handling by caterers and consumers. The comment concluded that the proposed HACCP provisions for molluscan shellfish will, therefore, not reduce the incidence of illness attributable to such products.

As previously mentioned, FDA is a partner with State and foreign regulatory authorities and with industry in the NSSP. The NSSP Manual of Operations provides the standards for State and foreign molluscan shellfish regulatory programs that belong to the cooperative program, as well as for processors. The participating States routinely adopt those standards as law or regulations, but the NSSP itself has neither Federal nor State regulatory stature.

Each participating State and foreign nation classifies and monitors its molluscan shellfish growing waters, controls harvesting, inspects molluscan shellfish processors, and issues certificates for those that meet the shellfish control authority's criteria. FDA evaluates State and foreign molluscan shellfish control programs and publishes monthly the ''Interstate Certified Shellfish Shippers List,'' which lists the molluscan shellfish processors that are certified under the cooperative program. States that are in the program are not willing to receive shellfish from noncertified shippers.

FDA disagrees with the comments that suggest that establishment of the proposed source controls in Federal regulations would supplant the similar and, in some cases more stringent, requirements of participating States and foreign nations or the standards set forth in the NSSP. Rather, the agency is convinced that they will reinforce and support these requirements and standards.

The molluscan shellfish industry is subject to significant regulatory oversight in those States that participate in the NSSP. However, the quality and effectiveness of State laws and enforcement activities can vary considerably as a function of the financial and administrative support available to the responsible State units (Ref. 7, p. 15). For example, FDA documented discrepancies in State enforcement practices during its 1994 evaluation of State programs to determine compliance with the NSSP standards (Ref. 215). Moreover, although all harvesting States participate in the NSSP, many other States do not.

Based on these factors, FDA proposed, and is now adopting, subpart C of part 123 and amendments to § 1240.60 to support and strengthen the shellfish program in two ways. First, these provisions will complement the efforts of the States. FDA recognizes that while States are making significant and important efforts to ensure that all shellfish harvested in their jurisdiction are taken only from open waters and then properly tagged, some shellfish that do not meet these requirements inevitably escape State control. The new provisions will allow FDA to take action against shellfish that are not harvested from open waters or that are not properly tagged if it encounters such shellfish in interstate commerce and make the gravamen of such action the origination from unopen waters or the lack of proper tagging itself, rather than evidence that the shellfish are injurious to health.

Second, the regulations require that processors only use shellfish that originate from growing waters that have been approved for harvesting and that have been properly tagged. Failure to do so can result in Federal regulatory action against the product or against the processor itself. This fact should provide a significant incentive to processors to ensure that they are not receiving shellfish that do not meet these requirements.

Taken as a whole, rather than diminishing in any way the importance of State programs, FDA's regulations elevate the importance of those programs. These regulations make proper origin and tagging—concepts that derive directly from the NSSP—keys to the unimpeded movement of shellfish in interstate, as well as intrastate, commerce.

Moreover, these requirements extend these control measures to imported products, enabling FDA to more efficiently and effectively ensure the safety of imported raw molluscan shellfish. At present, the agency must resort to advising State regulatory authorities of the prospective entry of raw molluscan shellfish from an uncertified source (Ref. 216, part V, p. 5). While States normally take action against uncertified imported raw molluscan shellfish, FDA is aware that uncertified imports enter interstate commerce (Ref. 107).

FDA acknowledges that uniform Federal tagging and record-keeping requirements will not completely eliminate illegal harvesting. The agency agrees with the comments that rigorous enforcement of closed area restrictions by State regulatory agencies will always be needed. Unquestionably, increased funding would help State efforts to classify and patrol growing areas. However, FDA does not have resources for this purpose. Nonetheless, the agency remains convinced that there are

significant, positive steps that can be taken to strengthen source controls as part of HACCP, and thereby to support the cooperative program.

A processor's most significant safety control for raw molluscan shellfish is at the point of receipt. If processors refuse to accept molluscan shellfish for which there is no assurance that they have been legally harvested, the incentive for illegal harvesting would be eliminated. FDA participation in a number of covert investigations into illegal molluscan shellfish harvesting in recent years has convinced the agency that, in many cases, processors are aware of the illegal harvesting activity of their suppliers (Ref. 217). If the provisions of these regulations can help foster a culture change in that respect, shellfish safety will be significantly enhanced.

Based on these considerations, the agency proposed that, as a universal aspect of the HACCP plans for these products, molluscan shellfish processors engage in certain activities to ensure that the products that they receive originate only from waters that have been approved by a shellfish control authority (e.g., checking tags on containers of shellstock, licenses of fishermen, and certification of suppliers). Molluscan shellfish that are clearly improperly tagged or from questionable sources must be rejected by processors as a requirement of their HACCP plans. It is reasonable to conclude that, as more processors adopt HACCP and exercise greater control over their suppliers, the amount of illegally harvested shellfish offered for sale will decrease, because the market for such product will decline.

While it is true that the tagging requirements of the NSSP were primarily designed as a means of tracing back molluscan shellfish involved in incidences of illness to their harvest area, they have also served as a key component in efforts by FDA and State regulators and industry to ensure that molluscan shellfish that are placed in commerce originate from areas that are approved by a shellfish control authority. It is certainly true that the tags on containers of molluscan shellfish that are harvested from closed waters are often falsified to disguise their true origin. However, such falsification carries potential Federal and State penalties and is a focus of current molluscan shellfish control programs.

Regarding the comments that pointed to weaknesses in State programs, at retail, in the classification of molluscan shellfish growing waters, and elsewhere, which are not directly addressed by these regulations, the agency acknowledges that HACCP plans and specific source control requirements cannot serve as a substitute for improvements in the food safety system that directly address these weaknesses. Regulatory systems will always have their strengths and weaknesses, and research to better understand and control hazards will always be needed. Nonetheless, these comments provide no reason for FDA to abandon its efforts to remedy existing agency weaknesses and, in particular, to lend support to the States in those areas to which these regulations do relate.

141. One comment stated that references cited in the preamble to the proposed regulations in support of the tagging requirements (Refs. 102 through 109) do not provide convincing evidence of a need for such a measure. The comment stated that, for the most part, the references that FDA cited document corrective actions taken by State regulatory agencies that would likely be the same measures that FDA officials would take under the proposed regulations. In addition, the comment stated that a failure to have properly tagged shellfish does not always mean that the shellfish were harvested illegally. The comment pointed out that the absence of a tag could mean simply that the tag was lost.

The references in the question contain examples of problems associated with molluscan shellfish tagging, recordkeeping, and harvesting. FDA cited these references to demonstrate that, in some cases, the deterrent effect of existing State tagging requirements and sanctions is inadequate to prevent problems from arising (Refs. 102, 103, and 109). The problems documented in the references helped persuade FDA to propose Federal source control requirements to help deter the interstate shipment of shellfish from unapproved harvest areas. FDA did not intend to imply that the State actions that were documented in these references were incorrect, or that FDA would have responded in a different manner. FDA continues to believe that the references are relevant and supportive to its intended assertion.

A few comments maintained that a better strategy for decreasing illness from the consumption of molluscan shellfish would be to increase the education efforts of FDA and of the ISSC that are directed toward consumers and the medical community to alert susceptible individuals to the risks associated with the consumption of raw molluscan shellfish.

The agency agrees that consumer education can play a vital role in reducing illnesses associated with the consumption of raw molluscan shellfish, particularly in medically compromised individuals. During the period of 1984 through 1994, the agency expended nearly $1 million to alert the public to the risks of raw molluscan shellfish consumption by distributing brochures to consumer groups, groups that represent those with special medical conditions, and consumers; developing a video news release; issuing press releases; and establishing the toll-free, FDA Seafood Hotline. Included in this expenditure is the agency's efforts to inform the medical community about the illnesses associated with the consumption of raw molluscan shellfish by providing informative articles to medical bulletins and journals and by mailing brochures and news articles to target professional groups. The agency will continue its consumer education efforts, but such efforts alone will be insufficient to address the hazards posed by the consumption of raw molluscan shellfish harvested from unapproved growing waters. The existing and planned consumer education efforts are geared toward individuals in high-risk consumer groups, advising them to avoid molluscan shellfish that have not been fully cooked. The risks posed by viruses, toxins, and many bacteria are to the population as a whole. There is little advice that the agency could provide that would enable consumers to protect themselves from these kinds of hazards in molluscan shellfish.

143. Several comments questioned the validity of FDA's statement that molluscan shellfish consumed raw or partially cooked pose unique public health risks and probably cause the majority of all seafood-related illnesses in the United States.

The comments provided no data upon which to conclude that either the NAS or FDA is wrong in this regard. FDA remains convinced that the statements made in the preamble to the proposed regulations are valid, and that the references support these statements.

3. Cooked Versus Raw Molluscan Shellfish

144. Comments from a number of State agencies, trade associations, seafood processors, and the ISSC objected to the use of the terms ''raw'' and ''fresh or frozen'' in the title of part 123 subpart C and the text of the proposed regulations on shellfish. These comments were concerned because these terms would have the effect of exempting canned and any other heat-processed molluscan shellfish from the source control, recordkeeping, and

tagging provisions of subpart C of part 123 and § 1240.60(b).

The comments stated that limiting these provisions to raw products would allow foreign firms to continue to heat-treat or can molluscan shellfish that are harvested from foreign waters that do not meet NSSP standards and to export them to the United States. The comments stated that this situation was not in the best interest of the public health because of the potential for the presence of heat-stable natural toxins, such as paralytic shellfish poison or amnesiac shellfish poison, as well as chemical contaminants. The comments also complained that, because State laws and regulations require that all molluscan shellfish harvested in the United States come from waters approved by a shellfish control authority regardless of whether they are to be consumed raw or cooked, continuing to allow foreign processors who export cooked shellfish to the United States to use molluscan shellfish from unapproved growing waters places the domestic shellfish industry at a competitive disadvantage. Other comments requested that FDA clarify whether canned shellfish were included in subpart C of part 123 but did not suggest that canned and other heat-processed shellfish be included.

FDA has responded to these comments generally in response to comment 34, *supra.* The agency adds the following points:

It is important to recognize that foreign processors who export cooked molluscan shellfish to the United States now will have to have HACCP systems through which they identify and control hazards that are reasonably likely to occur. These hazards include heat stable toxins and chemical contaminants that would cause these products to be adulterated under U.S. law.

To further clarify that the requirements of subpart C of part 123 apply only to the processing of molluscan shellfish that are not heat treated or treated in some other manner by the processor to eliminate microorganisms of public health concern, FDA has modified the language at § 123.20 to read, ''This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.''

4. Shellfish Control Authorities

FDA proposed to require that processors only process molluscan shellfish that originate from waters approved for harvesting by a shellfish control authority. The term ''shellfish control authority'' is defined at § 123.3(o) to include foreign government health authorities that are legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas.

145. Two trade associations questioned how a processor could evaluate the competency of a foreign shellfish control authority. They stated that FDA should require that a foreign country that exports shellfish to the United States have an agreement with the agency that establishes that a competent shellfish control authority exists in that country, and that the foreign shellfish program meets NSSP standards. One comment from a seafood processor argued that it would be unreasonable to require processors to verify that molluscan shellfish from all over the world are caught or cultivated in waters that meet NSSP standards. The comment stated, moreover, that a processor could not keep abreast of which countries have current shellfish agreements with FDA and which countries do not.

FDA acknowledges the merits of requiring that a foreign country that exports shellfish to the United States have an agreement with the agency but has concluded that, given the significance of such a requirement and the agency's failure to raise the possibility of imposing it in the proposal, it is beyond the scope of this rulemaking. Even though FDA is not imposing such a requirement, it is the case that the only means by which a processor can ensure that the molluscan shellfish of foreign origin that it receives are in compliance with the requirements of subpart C of part 123 of these regulations is by determining whether the foreign shellfish control authority is formally recognized by FDA. It is not likely that the processor could employ any other process that would give it assurance that molluscan shellfish harvesting waters that are approved by the shellfish control authority are properly classified. Such a determination is appropriately performed through government to government audit.

5. Shellfish From Federal Waters

146. Comments from a significant number of trade associations and seafood processors stated that a requirement that shellfish originate only in waters ''approved for harvesting by a shellfish control authority'' would preclude harvesting in Federal waters unless the Federal government introduced a formal approval process for waters under its purview through a Federal shellfish control authority.

Under the current system, State agencies are responsible for approving molluscan shellfish growing waters. However, State jurisdiction extends only to waters that are within three miles of the shore. Waters beyond that point but up to 200 miles offshore are under the jurisdiction of the Federal government. The comments pointed out that the harvesting of molluscan shellfish is permitted in all of the oceanic waters under Federal control unless there is a specific Federal action to declare an area unsafe under the provisions of the Magnuson Fishery Conservation and Management Act. The comments further noted that large volumes of molluscan shellfish are harvested in Federal waters.

How Federal waters will be classified, and by whom, has not been fully resolved. The comments are correct that the proposed requirement, if incorporated into the final rule, would pose significant problems for molluscan shellfish processors who receive product harvested from Federal waters. Therefore, FDA has modified § 123.28(b) to allow for the receipt of molluscan shellfish that are harvested in U.S. Federal waters except where such waters are specifically closed to harvesting by an agency of the Federal government. This provision is consistent with the provisions of the Magnuson Act.

It is worth noting that, by allowing Federal waters to be open unless they are specifically closed, this system is the opposite of the State system, under which waters are closed unless they are affirmatively classified so as to be open. This difference is reasonable from a public health standpoint because there is less likelihood that Federal waters will be affected by pollution than will near shore State waters.

Furthermore, because there is no Federal authority to license shellfish harvesters who fish in Federal waters, FDA has modified § 123.28(c) to require only that a harvester be in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish, rather than specifically requiring licensure.

6. Tagging and Recordkeeping Requirements

147. FDA proposed recordkeeping requirements for processors to follow with respect to shellstock and shucked molluscan shellfish in § 123.28 and requirements for the information to be included on the shellstock tag in § 1240.60. A few comments stated that

the proposed molluscan shellfish tag and record requirements were too specific, and that placing such requirements in the form of regulations would make it difficult to make timely changes to these requirements as future needs may dictate. The comments asserted that FDA or the ISSC may wish to modify the content or form of molluscan shellfish tags or records to improve product traceability. They suggested that FDA write the tagging and recordkeeping requirements at § 123.28 and § 1240.60 in general terms and allow the specific form and information required on the tags to be addressed by the NSSP. The comments went on to urge that, if the agency were determined to include specific tagging and recordkeeping requirements as part of the final regulations, they should be fully consistent with current NSSP guidelines.

It is not the agency's intent that the provisions of § 123.28 and § 1240.60 would preclude the ISSC or State agencies from adopting additional recordkeeping or tagging requirements. The recordkeeping and tagging requirements in these regulations are the minimum necessary to ensure that shellfish can be traced through distribution channels, back to the harvest source. FDA explained why each of the specific requirements is necessary in the preamble to the proposed regulations, and the comments did not take issue with the agency's explanation with respect to any of the particulars. Therefore, FDA disagrees with the comments that the recordkeeping or tagging requirements are more restrictive than they need to be, or that they would interfere with the NSSP tagging program.

Moreover, as stated previously, the agency has drafted the regulations broadly enough so as not to conflict with any improvements that the ISSC may wish to make in the form that a tag may take or in how information on tags is to be stored. The definition of the word ''tag'' at § 123.3(t) (added at § 1240.3(u) for consistency) reads, in part, ''a record of harvesting information attached to a container of shellstock * * *.'' This definition is sufficiently broad to include such systems as bar codes, embossed plastic, or other nontraditional methods of identification that may be used by the industry in the future. The agency is supportive of efforts to improve the existing methods of recording harvesting information.

Nonetheless, it is important for the regulations to identify the minimum specific information that must appear on a tag. During past illness outbreaks, FDA, State regulatory agencies, and industry have had difficulty tracing the implicated shellfish to their sources, especially after they have been in the possession of several different processors (Refs. 99; 100; 102–106; 109; 218; and 219, pp. 37–39). These difficulties in tracing the shellfish have occurred because the shellfish were not in compliance with the tagging and recordkeeping provisions of the NSSP. The requirements at § 123.28 will enable FDA to help the States to enforce minimum tagging and recordkeeping requirements for imported and domestic products. Moreover, the agency believes that placing the tagging and recordkeeping requirements in Federal regulations will emphasize the nationwide importance of this information in protecting the public health, as described earlier.

148. One comment noted that the NSSP does not specify that the name of the harvester must be on a molluscan shellfish tag, but that the proposed regulations would require this information.

The NSSP specifies that the number assigned to the harvester by the shellfish control authority must be listed on the tag. The agency recognizes that there may be a variety of effective ways to identify the harvester of the molluscan shellfish, depending on the method of harvest, State requirements, and local tradition. For this reason, the agency has modified § 1240.60(b) to read that the tag shall disclose:

> * * * by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel).

For consistency, FDA has made a similar change in § 123.28(c)(5).

149. A significant number of comments recommended that FDA modify § 1240.60(b) to allow bills of lading or other shipping documents to accompany bulk shipments of shellstock in lieu of tags, as long as they provide the same information. A few comments suggested that bills of lading or other shipping documents be used in lieu of tags on individual containers of shellstock when a shipment consists of a large volume of shellstock in sacks or boxes. Several comments asked for clarification of the impact of the proposed requirements on current repacking operations that commingle shellstock from various harvesters into one container.

FDA recognizes that an inconsistency existed between proposed § 123.28 and proposed § 1240.60 because the former would have allowed shipping documents to provide the required information for bulk shipment, and the latter would not. FDA agrees with the comments that recommended providing for the use of shipping documents and has modified § 1240.60(b) to provide the needed consistency. Under existing industry practice the truck, cage, or vessel hold serve the same purpose as a container for the shellstock, making tagging impractical. In that case, the shipping document serves the same function as the tag.

However, the agency does not agree with the suggestion that containers of shellstock in large shipments be allowed to be covered by shipping documents in lieu of tags. FDA cannot justify treating shellstock in large shipments differently than shellstock in smaller shipments, nor could the terms ''large'' or ''small'' be readily defined. Large shipments can be subdivided, perhaps many times, or commingled with other lots of molluscan shellfish. The source information would, therefore, be necessary on each container to ensure proper identification. Without tags, the identity of individual containers could be lost. FDA is requiring that all shellstock, even after repacking, bear a tag that identifies the prescribed information, including the identification of the harvesters to ensure that all shellstock is readily traceable (§ 1240.60).

7. Other Considerations

150. Comments from a few trade associations and from seafood processors stated that FDA should require a production code on each container of shucked molluscan shellfish. The comments suggested that the code consist of an identifying mark that allows the processor to determine where the remainder of the lot was shipped, and where and when the relevant shellstock was harvested.

FDA agrees that production codes can be useful on containers of shucked molluscan shellfish to facilitate trace back of questionable product. The agency encourages the use of codes by molluscan shellfish processors. However, such a requirement is not within the scope of the proposed regulations. The agency will consider whether such a requirement should be pursued in a separate rulemaking.

151. Comments from several consumer groups stated that if a warning label is not mandated by FDA on raw molluscan shellfish to alert at-risk consumers of the danger to health posed by the product, FDA should require that Gulf Coast oyster processors adequately cook the product to

eliminate risks from *Vibrio vulnificus* during periods when shellfish cannot be harvested free from this bacterium. They further stated that cooking should not be required when the shellfish are free from this bacterium.

FDA agrees that effective controls are needed to protect consumers from the hazard posed by *V. vulnificus* in Gulf Coast oysters during certain times of the year. The agency is evaluating the potential effectiveness of a variety of control mechanisms. Mandating specific mechanisms, however, would be outside the scope of this rulemaking. FDA is therefore taking these comments under advisement.

152. A few comments urged that the word ''processor'' be changed to ''certified dealer and licensed harvester'' throughout § 123.28 to make the terminology consistent with the NSSP and to clarify that these requirements apply to everyone who buys and sells shellfish before the shellfish reach the retail marketplace. The comments also recommended changing the word ''shipper'' to ''processor or packer'' in the provision that is codified at § 123.28(d)(3) in these final regulations to include the shucker, repacker, shipper, reshipper, or depurator.

As mentioned in the ''Definitions'' section of this preamble, the agency has concluded that the definition for ''processor'' covers all NSSP classifications of shellfish dealers, without specifically naming each one. For consistency throughout the regulations, use of the term will remain unchanged.

FDA agrees, however, that the word ''shipper,'' as the agency used it in the proposed regulations, could cause confusion because that term has a different meaning in the NSSP Manual of Operations. Therefore, FDA has changed the language of the final regulations to read ''packer or repacker.'' The certification number of the packer or repacker is readily available to the processor since it is required, under the NSSP standards, on each label of shucked product. For consistency, FDA has modified § 1240.60(c) to also read ''packer or repacker'' where it had previously read ''processor.''

153. A few comments stated that proposed § 123.28(b), which referred to molluscan shellfish that ''originate from growing areas that are approved for harvesting,'' appears to prohibit processors from using products from harvest waters classified under the NSSP as ''conditionally restricted.'' Under the NSSP, shellstock taken from such waters cannot be directly marketed for human consumption but can be ''relayed'' to an open growing area for harvest at a later date. In addition, the comments pointed out that the word ''approved'' is a formal classification designation used in the NSSP. These comments said that harvesting is permitted from areas with other than ''approved'' classifications but would appear to be prohibited under the provisions of proposed § 123.28(b). The comments suggested use of the term ''open'' growing waters, which would apply to several different NSSP harvest area classifications.

FDA agrees that the word ''originate'', as used in proposed § 123.28(b), is too restrictive and has revised this section to say ''harvested from.'' With regard to the word ''approved,'' FDA concludes that no change is warranted. The proposal neither adopted nor referenced the NSSP growing water classification system. The phrase ''approved for harvesting'' should not be construed to be limited to those waters classified by a State under the NSSP as ''approved'' areas. The phrase ''approved for harvesting'' is used in the final regulations for its common sense meaning (i.e., those areas from which harvesting is allowed), which FDA believes is appropriate.

154. For clarification purposes, definitions for the terms ''certification number'', ''shellfish control authority'', and ''tag'' have been added at § 1240.3(s), (t), and (u), respectively. These definitions are taken directly from § 123.3.

155. One comment urged that the regulations be modified to specifically state that a HACCP plan for raw molluscan shellfish that contains the controls specified in subpart C of part 123 is deemed to meet the requirements of § 123.6.

The agency disagrees with this comment. The requirements of subpart C of part 123 are designed to control the environmental hazards associated with the harvest waters from which molluscan shellfish are taken, particularly those relating to sewage-related pathogens, chemical contaminants, and natural toxins. For this reason, they must be included in the HACCP plans of all raw molluscan shellfish processors. However, they are not intended to control process-related hazards resulting from, for example, time-temperature abuse of the product, improper use of food additives, or metal fragments. To control these hazards, the processor needs to follow the general approach set out in subpart A of part 123. The agency has developed the two subparts to be complementary and has strived to eliminate any redundancy in their provisions. Thus, it is theoretically possible that a HACCP plan that contains the controls specified in subpart C alone of part 123 still might not meet all the requirements of § 123.6.

FDA has made two modifications in § 1240.60(b) for clarity only. Where the proposed regulations required that the tag identify the ''* * * place where harvested * * *,'' FDA has added, ''(by State and site).'' This change makes § 1240.60(b) consistent with § 123.28(c)(2). Additionally, where the proposed regulations stated that improperly tagged or labeled product would be ''subject to seizure and destruction,'' FDA has amended the language to read, ''subject to seizure or refusal of entry, and destruction.'' This change is to make clear that, for imported products, the appropriate regulatory procedure is refusal of entry, rather than seizure.

*O. Compliance and Effective Date*

1. Effective Date

FDA proposed that these final regulations be effective and enforced 1 year after the date that they are published in the Federal Register. The purpose of this proposed effective date was to provide processors with enough time to develop and implement HACCP plans. The agency invited comment on whether 1 year would be adequate.

156. FDA received more than 60 comments about the proposed effective date. Virtually all comments agreed that the agency should provide some period before the regulations become effective. The comments either agreed with a 1-year implementation period or requested a longer period of 2 years or more. There were also a number of comments that responded to the agency's question about whether implementation dates should be staggered based on such factors as size of firm and level of risk.

A minority of comments stated that 1 year for implementation is adequate. These comments argued that after 1 year, the industry would have had 3-years notice of the requirements. The comments argued that 3 years was sufficient total time to be informed about impending regulations. Another comment stated that one year might be sufficient for the seafood industry, but other food industries could need considerably more time.

Several comments recommended that FDA provide an implementation period of longer than 1 year but did not recommend a specific alternative. These comments were concerned that HACCP training would not be completed in time for a 1-year implementation date; that foreign processors would need more

time to implement HACCP; and that 1 year after Canada required HACCP for its seafood industry, only half of its firms had complied.

The largest number of comments on this topic recommended that FDA make the regulations effective 2 years after publication. The reason most often cited was that it will be more than 1 year before most of the affected firms can complete HACCP training. The next most frequently cited reason was that firms and trade associations needed more time for HACCP plan development. Several comments also discussed the time required to modify equipment and raise capital; to respond to initial, voluntary reviews of HACCP plans by regulatory agencies; and for Federal, State, and local officials to understand HACCP and how to enforce it and to arrange for cooperative enforcement. A few comments stated that FDA needs sufficient time to develop agreements with foreign countries.

Several comments contended that more than 2 years should be allowed to implement the regulation. These comments mentioned the cultural change that HACCP will require and concern about the impact that the regulations will have on small firms as well as on large firms with multiple products and lines. They also mentioned the time needed for training.

Over 20 comments recommended that FDA stagger effective dates. A majority of these comments stated that such a phased-in start-up should be based on product risk. The remainder of the comments split in favor of either considering both the size of a firm and the risk from the products it makes or just the size of a firm.

A smaller number of comments argued against a staggered start. These comments expressed the view that small firms and foreign products should not be treated differently and pointed out that all firms will already have had 3 years of notice. Some of these comments stated that it would be hard to justify staggering implementation based on risk when the illness data are so incomplete. Others expressed the view that administering a staggered start would use up valuable resources and only result in confusion; that staggering would put some firms at a competitive disadvantage; and that it might encourage procrastination.

After fully considering all of these comments, FDA agrees with the comments that suggested that a 2-year effective date is appropriate. Based on FDA's participation with the Alliance that is developing training materials for this program, FDA has come to realize that 2 years must be provided to establish training programs and to give participants enough time to take them. Two years is also the minimum time necessary to train regulatory personnel. The additional time is also necessary so that the States will have a full opportunity to understand and respond to the effects of these regulations. It will also increase the likelihood that more agreements with other countries will exist.

The additional year will also increase the opportunity for processors to engage in ''voluntary'' HACCP inspections in advance of the effective date in order to obtain preliminary, nonregulatory feedback from the agency on their progress.

The agency acknowledges that it has urged the industry to begin preparing for HACCP well before the issuance of these final regulations. However, as this preamble amply demonstrates, a significant number of questions were raised as a result of the proposal that could not be answered until now. Moreover, the entire support structure for HACCP, including the issuance of the first edition of the Guide and the development of training courses, model plans, and other forms of technical assistance that will be useful to the industry, and especially to small businesses, will not be in place in time to permit a 1-year effective date.

On the other hand, more than 2 years does not appear at this time to be warranted. The agency is concerned that additional time would adversely affect the momentum for this program without adding significantly to the likelihood that it will succeed.

On the other hand, FDA is sensitive to the need to ensure that small businesses will not incur an unreasonable threat to their survival by an effective date that is too short. The agency intends to monitor the progress of the industry after the regulations are published and invites feedback on this subject. If FDA determines that the effective date is placing a significant and unreasonable burden on the industry, particularly on small businesses, the agency would be willing to consider an extension for as much as one additional year or some form of additional technical assistance. The agency would consider whether the delay is needed for training, drafting plans, or taking other measures that directly relate to the installation of a HACCP system, or whether the time is needed to comply with existing CGMP's, which are a prerequisite for HACCP. FDA will likely be reluctant to give firms an extended period of time to achieve compliance with existing requirements.

FDA also finds that there is not an adequate basis at this time for staggering the starts based on size or risk. The arguments for and against staggering generally parallel those for and against exempting firms from these regulations altogether on the basis of either size or risk. These arguments are discussed in the section of this preamble entitled ''Should Some Types of Processors Be Exempt?'' In summary, a good case can be made that implementation by small firms should not be delayed because such firms account for much of the products with significant potential for risk, such as cooked, ready-to-eat products. Moreover, most seafood processors are small firms. Risk-based, as opposed to size-based, criteria for staggering firms would inevitably be arbitrary to some degree because data from foodborne illness reporting systems tend to skew the reports toward more easily diagnosable illnesses.

The comments received on the subject of staggering do not provide a ready way to overcome these problems. Moreover, the 2-year effective date (rather than 1 year as proposed), guidance, technical assistance, and training that will be available to all processors should make staggering much less necessary than it otherwise might have been.

As stated above, however, the agency welcomes feedback on the progress that processors are making to implement HACCP that could have a bearing on whether staggering or an extension of the effective date would be appropriate, especially for small businesses.

157. Several comments asked for a form of staggering based on when an inspection occurs before the effective date. These comments stated that processors who voluntarily submit to inspection under the regulations before the effective date and are advised that their HACCP systems are not yet in compliance with the regulations should have at least a 6-month grace period to correct the problems. The example given in these comments was that of a processor who is so advised 1 day before the effective date and thus is inevitably out of compliance on the effective date.

As reflected in the comments, inspections of HACCP systems before the effective date will occur because a firm desires feedback and volunteers for it when an FDA investigator arrives for an inspection. That feedback will constitute informal advice only and will provide training for the investigator as well as for the processor. There may be some advantage to a processor to obtain feedback and training sooner rather than

later, but the results will have no formal status with the agency and would not warrant an extension of the effective date.

The agency has heard considerable concern that it will automatically seek to seize or otherwise remove from commerce all products being produced under a HACCP system that is determined to be deficient in any respect. That concern is unfounded. The consequence of being out of compliance with HACCP requirements, on the first inspection after implementation or otherwise, is addressed throughout this section. In summary, FDA's reaction will depend, as it does today, on the overall public health significance of the deficiency.

2. Public Meetings

158. One comment suggested that FDA conduct public meetings to explain the requirements of these regulations to the seafood processing industry between the publication date and effective date of these regulations. The comment also encouraged a coordination of research, training, and educational efforts between industry and FDA in order to facilitate the implementation of this HACCP program.

FDA fully agrees with the comment. It is the intent of the agency to engage in a dialog with industry, through a combination of public meetings and discussions at trade association meetings, to facilitate a thorough understanding of the regulations. FDA's affiliation with the Alliance reflects the agency's commitment to a cooperative relationship among industry, government (Federal and State), and academia in the areas of research, training, and technical assistance.

3. Penalties for Noncompliance

159. A significant number of comments, from processors and trade associations, requested that FDA address how noncompliance with the mandatory sanitation control procedures will be handled. Several of these comments also requested that FDA describe the penalties that can be imposed upon a processor and its officers for: Failure of a processor to have and implement a HACCP plan; noncompliance with sanitation control procedures; and failure to meet minor requirements of the regulations, such as the lack of a signature on a document. One comment stated that FDA's legal authorities and enforcement procedures do not provide a means for the agency to respond in a manner that is related to the severity of deficiencies—that is, a less severe response to a less significant deficiency.

FDA has a longstanding practice of tailoring its regulatory response to the facts. A deviation from any of the provisions of these regulations, including those involving the control of sanitation, carries the potential for regulatory action pursuant to section 402(a)(4) of the act. However, FDA intends to enforce these regulations in a manner that focuses on those deviations that have the greatest potential for causing harm. It is not FDA's intent to pursue regulatory action against a product or a processor exclusively for clerical errors or minor errors of omission. To do so would certainly not be an efficient use of agency resources, nor would it be in the best interests of the consuming public.

The penalty provisions for food found to be adulterated are described at ''Prohibited Acts and Penalties,'' in chapter III of the act. The statutory sanctions that FDA may seek include seizure and condemnation of a food and injunction and criminal penalties against a person (i.e., a firm and its responsible management).

FDA may also use existing administrative procedures, such as warning letters and conferences with a processor, to bring instances of noncompliance to the processor's attention as it frequently does under its current inspection programs.

The agency cannot state precisely what type of action it will take when it detects a deficiency because FDA evaluates each deficiency on a case-by-case basis to determine the public health significance of the violation and the appropriate response.

4. Preapproval of HACCP Plans

In the preamble to the proposed regulations, FDA tentatively concluded that HACCP plans would not have to be submitted to the agency or otherwise preapproved before their implementation by processors. The reasons for the agency's tentative conclusion included: (1) HACCP plans should be judged in the context of the processing plant, a process best accomplished during routine FDA inspections of processing facilities; and (2) the agency does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of either HACCP implementation by the processor or the conduct of HACCP-based inspections by FDA.

160. Approximately 20 comments addressed this issue. About two-thirds of these comments, from consumer advocacy groups, processors, trade associations, and State government agencies, contended that a processor should be required to file a HACCP plan and obtain approval from FDA before implementing the plan. The remaining comments, from processors, trade associations, and a foreign government, agreed with FDA's tentative conclusion that HACCP plans need not be submitted to the agency or preapproved before they are implemented.

Some of the comments favoring preapproval argued that FDA should have control over the design of each plan before it is implemented to ensure that all of the CCP's are identified, and that appropriate records will be kept. Other comments contended that, in the absence of a preapproved plan, a processor may implement a plan that FDA would later judge to be inadequate, possibly raising concerns about the product already produced under the plan.

Several comments in opposition to preapproval argued that it would be too expensive and difficult for both FDA and the processors (the latter because implementation would be delayed while processors waited for FDA to preapprove the plan and every subsequent change to the plan). One comment expressed concern that, in formally approving a HACCP plan, regulatory authorities would assume some responsibility for the HACCP system of an individual processor.

A few comments stated that HACCP plans will evolve as operations are adjusted, based on the processor's verification activities. These comments argued that a requirement for the preapproval of HACCP plans would encumber a processor's ability to update its HACCP plan.

The resource situation since the proposal was issued in January, 1994, has not changed in any way that would make the preapproval of HACCP plans by FDA practicable. Thus, FDA's analysis of the comments has focused on whether a lack of preapproval raises significant implementation problems that the agency must address. The comments have not convinced the agency that it does. FDA finds that a preapproval system would unduly burden the agency's resources, without providing significant advantages to the public health. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions.

The preapproval of HACCP plans is distinguishable from the situation for low acid canned foods, where FDA reviews submissions of scheduled processes and revisions to these processes without hinging that review on a visual inspection of the facility. For

low-acid canned foods, the submission relates solely to the adequacy of the cooking process to control one hazard (*C. botulinum*). This process lends itself to a paper evaluation.

FDA agrees with the comments that suggested that a requirement for agency approval of a processor's changes to an existing HACCP plan would unnecessarily slow the process of plan improvement. The ability to modify the plan quickly based on feedback from verification activities is an important aspect of HACCP that could be degraded by a preapproval requirement.

With regard to the concern that the lack of plan preapproval will expose a processor to risk of product loss if a HACCP plan, under which it had been operating, is deemed by FDA to be inadequate, the agency advises that there are several issues that should mitigate this concern. First, the agency is committed to providing guidance, in the form of the Guide, to assist processors in the development of HACCP plans that are likely to be acceptable to the agency. The Guide will be further discussed later in this section.

Second, FDA is convinced that the training requirements of these regulations will serve to inform the regulated industry about the expectations of the agency with respect to HACCP plan content. FDA is working closely with the Alliance to ensure that training reflects FDA policy.

Third, FDA recognizes and accepts that, for HACCP plans to be effective and efficient, they must be tailored to the operating conditions of the individual processor. Of necessity, this fact means that there may be multiple ways to control an individual hazard. Consequently, FDA investigators will be trained to objectively evaluate the processor's HACCP plan from the standpoint of whether it accomplishes its intended function (i.e., hazard control), rather than whether it follows any preconceived model.

Finally, as described earlier, for the HACCP program, FDA intends to respond proportionally to deficiencies that it finds during inspections. The nature of the agency's response will depend on the totality of the situation and on the public health implications of the deficiency. When circumstances permit, the processor will be given the opportunity to make appropriate corrections.

5. Filing Plans With FDA

161. A few comments stated that FDA should require processors to file HACCP plans with the agency, not necessarily to obtain preapproval, but to allow FDA to compile HACCP plans from all seafood processors. The comments suggested that FDA selectively audit a sample of processor HACCP plans from the file copies, perhaps based on product risk, the presence or absence of certain CCP's, or other relevant factors. Some of these comments recommended that FDA request voluntary submission of plans prior to the implementation deadline.

A file, or library, of HACCP plans of all seafood processors would likely present various benefits from the standpoint of trend analysis and program evaluation. The agency finds, however, that the burdens would outweigh the benefits, largely for the same reasons that rule out the preapproval of plans by FDA. For example, the library would have to be updated every time that any processor updated its plan. Therefore, FDA is not requiring that processors file their plans with the agency.

6. Third Party-Approval

162. Several comments urged FDA to include a provision requiring third-party approval of processors' HACCP plans, especially if preapproval by FDA is not required. The comments suggested that the lack of a requirement for a processor to use a disciplinary team approach to develop a HACCP plan, as suggested by the NACMCF, coupled with infrequent FDA inspections, could mean that a processor might operate for years without an appropriate plan. The comments noted that competent processing authorities are available to provide third-party plan approvals and audits.

On the other hand, one comment argued that a requirement for third party HACCP plan approval is not necessary. This comment stated that a nonregulatory first inspection would obviate any form of preapproval.

FDA recognizes that some processors may benefit from obtaining third-party assistance in developing their HACCP plans and in evaluating their implementation. An independent audit is often helpful in locating problems in a system and offers the benefit of bringing in expertise not always possessed by many seafood processors. FDA is aware that some processors have engaged in these kinds of arrangements in the past and encourages their use.

However, the agency cannot agree that third party assistance should serve as an ''approval'' for regulatory purposes. First, to maximize consistency and fair treatment, the responsibility for the initial HACCP plan evaluation (outside of the processor's own verification activities) belongs to FDA, through routine inspections of processing plants. Second, establishing, certifying, and auditing a network of third parties whose approvals FDA would automatically accept would impose significant burdens on the agency that FDA could not accommodate.

As discussed above, FDA is engaging in significant efforts to facilitate the development of appropriate HACCP plans. The overall high level of policy guidance and technical assistance that will be available to processors from FDA and a variety of other sources should minimize the incidence of processors developing and implementing plans that do not address those hazards that are reasonably likely to occur. Therefore, FDA is not providing for third-party approval of HACCP plans.

7. The First Inspection

In the preamble to the proposed regulations, FDA tentatively concluded that, after the effective date of these regulations, FDA's review of processors' HACCP plans and procedures would occur at the time of the routine establishment inspection. FDA requested comment on whether the first HACCP review should be nonregulatory, even though the inspection of the processor would otherwise be regulatory.

163. Approximately 30 comments, mostly representing processors and trade associations, addressed this issue. All but one of the comments asked that the first review of a processor's HACCP plan and procedures be nonregulatory. Approximately one-fourth of these comments further asked that the second such evaluation also be nonregulatory.

The comments stated that a nonregulatory visit by FDA would assist the processor in determining deficiencies in its plan without fear of enforcement action and would provide FDA investigators with hands-on experience in a HACCP-based inspection. The comments suggested that this arrangement would foster a cooperative spirit between the agency and the industry and would provide the time necessary for the investigator to discuss with the processor how the plan should be tailored to address the details of the processor's operation.

One comment stated that the initiation of a sweeping, new program will generate many questions and will necessitate innumerable judgments on the part of both processors and investigators. The comment suggested that it would be preferable for these questions and judgments to occur during nonregulatory visits.

On the other hand, one comment suggested that the first review of a processor's HACCP plan should be

regulatory, because once the effective date has been reached, compliance with the regulations should be enforced.

FDA agrees with the comments that suggested that a smooth transition to a mandatory HACCP system of preventive controls is more likely the result of dialogue than regulatory action. For HACCP to succeed, processors must be committed to it because they perceive benefits to themselves from its use other than simply the avoidance of regulatory sanctions.

FDA has concluded that a 2-year effective date, rather than the 1-year date that was proposed, will provide substantial opportunity for dialogue. Moreover, the proportional response to problems that FDA intends to employ, taking into account the newness of the system, should obviate many of the comments' concerns about excessive regulatory sanctions early in the process. Consequently, FDA concludes that an officially designated, nonregulatory first inspection is not necessary.

FDA has concluded that 2 years is sufficient time for a processor to train employees or secure properly trained consultants, perform a hazard analysis, develop a HACCP plan, and implement and evaluate HACCP control procedures that will comply with these regulations. The additional year will enable the agency's field investigative force and the industry to begin sorting out many of the issues that are likely to develop during implementation.

As stated earlier, the agency intends to perform informal HACCP evaluations of willing processors during routine inspections conducted during the 2-year implementation period. These evaluations should serve to aid the development of both the industry's HACCP programs and the agency's HACCP inspectional skills. They will also largely take the place of the proposed type of nonregulatory inspections.

FDA agrees with the comment that pointed out that the initiation of this program will generate many questions and issues that will have to be worked out between processors and the agency. Moreover, FDA accepts that, despite the years of groundwork and the pilot programs that have been the basis for agency policy decisions to date, there will be details that will have to evolve over time as the program is implemented. It is highly likely that this evolution will continue well after the effective date of these regulations. FDA will take this factor into account in its initial interactions with processors after the effective date. The agency may find it appropriate to use its regulatory discretion when it finds a basis for concern about a processor's HACCP plan or procedures that relate to a matter about which policy is still being formulated.

However, the agency is concerned that there could be significant problems if it officially designated its HACCP review during the first inspection as being nonregulatory. First, such a step could create unfair situations. For example, FDA could find itself in the position of pursuing regulatory action against one processor for failure to adequately control a particular hazard while, at the same time, treating a similar deficiency by another processor as ''nonregulatory.'' Second, it could foster actions by firms to avoid application of the regulations, such as name changes or reorganizations to create the argument that the ''new firm'' is entitled to a nonregulatory inspection. Third, it is not clear how long such a policy should last. Arguably, the reasons in support of a nonregulatory first inspection become much weaker in the case of a firm that goes into business for the first time a number of years after the effective date of the program.

For all of the foregoing reasons, FDA has concluded that it can accomplish the things that led it to inquire about the possibility of, and the comments to support, designating the first HACCP inspection as a nonregulatory inspection without making such a designation and creating the problems that such a designation could cause.

8. Role of the FDA Investigator

164. In the preamble to the proposal, FDA stated its tentative conclusion that its investigators would, among other things, evaluate the adequacy of processors' HACCP plans during routine inspections. A few comments objected to this role for the investigators. These comments stated that investigators should be responsible for verifying that the processor has performed a hazard analysis; developed a HACCP plan where warranted; implemented the HACCP plan; and recognized, corrected, and recorded deviations from the HACCP plan. The comments further stated that investigators should not be in a position to challenge the adequacy or design of a HACCP plan.

The comments pointed out that HACCP plans are tailored for each operation, designed by either a company team or a knowledgeable individual thoroughly familiar with the operation. They questioned whether an FDA investigator would have the expertise to determine the acceptability of the plan.

Many FDA investigators already have considerable training in HACCP and food science, and most have an academic background in the sciences. They will also receive training during the implementation period that focuses on compliance with these regulations. The investigators will be exposed to the Guide, among other sources, for information about potential hazards to be considered for particular products and processes. This exposure, coupled with investigators' experience with the industries with which they work, will give them a sound basis for making screening determinations about the adequacy of processors' HACCP plans. There is little doubt that the caliber of investigator screening decisions will improve with experience with these regulations and with exposure to more and varied processor HACCP programs. FDA is confident that its field investigative staff will quickly adjust to the task of fostering compliance with these regulations, as they have to past initiatives.

Where investigators are unsure about the adequacy of a processor's HACCP plan, they will have ready access to, and will be encouraged to consult with, district, regional, and headquarters experts. Investigators will also be instructed to discuss with plant management the reasons and scientific support for hazard analysis and HACCP plan decisions that are in question. Where, because of the complexity of a particular situation, the investigator cannot reach a decision about the adequacy of a particular aspect of a processor's HACCP plan, the investigator will be instructed to collect as much information, including supporting data, as is necessary in order to facilitate further agency review.

Therefore, FDA concludes that the existing system adequately addresses the concerns of the comments.

9. Disagreements and Appeals

165. A significant number of comments, primarily from processors and trade associations, stated that FDA should have a mechanism to resolve differences between an FDA investigator and a processor regarding the adequacy of the processor's HACCP plan, especially given the subjective nature of the determination as to what the hazards are that are reasonably likely to occur and that therefore must be controlled through HACCP. The comments contended that a cooperative discussion between FDA and the processor's HACCP experts would be preferable to an enforcement confrontation, and that this discussion would allow a processor to explain its decisions and procedures. Other comments urged FDA to formalize an

appeal process in the regulations that would establish a processor's rights to contest any HACCP compliance action by FDA. Moreover, these comments stated that FDA should not take enforcement action based on a disagreement in the field between an investigator and the developers of the plan.

As previously mentioned, agency investigators will be instructed to discuss their concerns about potential inadequacies in processor HACCP plans with the management of the firm in an effort to learn the basis of the firm's decisions. If the investigator retains concern that a plan is inadequate in some regard even after discussing it with the firm, the investigator will list findings on the report that is provided to the management of the firm at the conclusion of the inspection (Inspectional Observations, FDA483). The FDA483 only represents the opinion of the investigator and is not necessarily the final opinion of the agency. The investigator will document the processor's response to, or explanation of, the findings listed on the FDA483 report.

It has been longstanding FDA policy to conduct an internal review of investigators' inspectional findings before initiating regulatory action. There is an opportunity at each stage for discussion between the firm and the agency. These FDA review practices will not change under a HACCP-based system.

Based on the foregoing, the agency concludes that the concern expressed in the comments about possible precipitous compliance action as a result of the findings of FDA investigators is unwarranted. It is worth repeating that the agency intends to engage in conflict resolution through dialogue wherever possible and appropriate. Given these facts, FDA has concluded that a provision for a special appeals process for matters concerning these regulations is not necessary.

10. Status of the ''Guide''

In the preamble to the proposed regulations, FDA discussed the ''five preliminary steps'' to HACCP recommended by the NACMCF. These steps lead a processor through a logical process for identifying hazards that are likely to occur in a product and for developing a HACCP plan. In an effort to facilitate this process, especially for the many small businesses involved in seafood processing, FDA is developing the Guide, a draft of which was made available shortly after publication of the proposed regulations. The draft Guide provides information on hazards and appropriate controls by species and by product type. The preamble said that the information contained in the draft Guide is the kind of information that would likely result in a HACCP plan that is acceptable to the agency. FDA received considerable comment on the contents of the draft Guide and intends to publish a redrafted first edition shortly after the publication of these regulations.

166. A number of comments expressed concern about how the Guide would be used by FDA investigators when evaluating a processor's HACCP plan. The commenters were troubled by the prospect that FDA investigators would not be trained to evaluate HACCP plans that differ from the Guide, and that, therefore, they would take exception to a HACCP plan that deviates from the Guide. The comments stated that industry experience with HACCP demonstrates the need to provide flexibility so that HACCP plans can be tailored to the specific operating conditions of a processor.

Other comments stated that the Guide did not provide express guidance on the meaning of the key phrase ''reasonably likely to occur.'' The comments stated that the Guide should clarify whether it is FDA's intention that the hazards identified in the Guide are the ''reasonably likely'' hazards under all conditions for the specific species and processing operations that are listed.

Several comments cautioned that the Guide should not be characterized as a ''safe harbor,'' i.e., that FDA should not promote strict adherence to the Guide regardless of the circumstances. Such a characterization, they argued, could cause processors to omit the critical hazard analysis step in HACCP plan development and risk developing plans that do not fit the conditions of their processes.

The Guide is, in the agency's opinion, a compilation of the best available information on the subject of hazards and controls in seafood processing. It contains FDA's recommendations as to the hazards that it believes are ''reasonably likely'' to occur in specific species and finished product forms under ordinary circumstances, but it also provides information on rarer hazards as well. FDA recognizes that the first edition of the Guide must clearly distinguish between the two.

The term ''reasonably likely'' is now effectively defined in § 123.6(a). It is worth noting that, under § 123.6(a), whether a hazard is ''reasonably likely'' will depend, at least in part, on the circumstances that exist at the time that the hazard analysis is conducted. For example, a certain toxin might be rare, but if it starts presenting itself in fish and becomes known, it may warrant a new hazard analysis that may identify it as ''reasonably likely'' for a period of time.

FDA also recognizes that circumstances may occur in which hazards will exist that are not identified in the Guide. These hazards may be the result of a previously unidentified phenomenon (e.g., the identification of a natural toxin in a species previously not associated with that toxin) or of unique conditions in the way that the product is handled by a particular processor (e.g., unusual equipment or processing methods). Thus, a definitive determination of ''reasonably likely to occur'' can come only as a result of a carefully conducted hazard analysis performed for a specific product under specific processing conditions.

FDA recognizes that a HACCP approach requires flexibility and will endeavor to make the Guide consistent with such flexibility. FDA will provide training to its investigators so that they will be prepared to evaluate a HACCP plan that is not consistent with the Guide and to evaluate the effectiveness of controls that differ from those suggested in the Guide. The agency agrees that the Guide is not a ''safe harbor'' for all situations. Processors who utilize the Guide should compare it to their own circumstances and make whatever adjustments in the approach suggested in the Guide that are necessary.

11. Trade With the EU

167. One comment suggested that, because of directives issued by the EU, many processors may need early recognition of their HACCP programs by FDA. The comment further suggested that early recognition could be used by the agency as a means of training FDA inspectional personnel.

FDA is aware of the directives of the EU. The agency intends to consider how it can best help processors respond to those directives, among other factors, as it formulates its plans for implementation of these regulations.

12. Measuring Program Success

In the preamble to the proposed regulations, FDA asked for comment on what tests should be used to measure the success of the HACCP program as a whole, and how often those tests should be conducted.

168. A significant number of comments stated that indicators of the success of the seafood HACCP program could include: A reduction in the number of seafood-borne illnesses; improved consumer confidence in

seafood consumption; and a reduction in the number of violative products that enter the marketplace. Several comments stated that periodic inspections of, and sampling at, processors and importers by FDA, State, and foreign officials, coupled with illness reporting from a strengthened CDC program, would provide adequate verification of the effectiveness of the program. However, two other comments stated that the success of the seafood HACCP program cannot be measured solely by a decrease in illnesses, because many food-borne illnesses are the result of problems in the retail sector, which is neither covered by these regulations nor adequately regulated by the States.

The agency agrees with those comments that suggested that the ultimate goal of these regulations should be the improved safety of fish and fishery products—a reduction in the actual number of seafood-related illnesses. FDA will continue to closely monitor the CDC system, as well as reports of illness and death attributable to the consumption of seafood that it receives from other sources, for trends that may indicate an emerging problem or the intensification or modification of an existing problem. However, the agency also agrees with those comments that suggested that, because many of the seafood-related illnesses are attributable to recreational or subsistence fishing or to problems in the retail and food-service sectors (Ref. 7, pp. 2; 15; 27; and 28), improvements in process controls that result from the implementation of HACCP may not be fully reflected by a reduction in the number of illnesses. Additionally, as has been previously discussed, the CDC system encompasses only reported illnesses and is an imperfect means of judging reductions in actual numbers of illnesses. FDA is supportive of a strengthening of the CDC reporting system.

Based in part on the comments received, the agency will be looking at ways to assess a relationship between success of the HACCP program and levels of consumer confidence, levels of violative product in the marketplace, improvements in the quality and quantity of preventive controls throughout the industry; and the results of FDA and cooperating State and foreign inspections. As indicated in the summary of the Regulatory Impact Analysis elsewhere in this preamble, FDA is planning to evaluate key features of this program within the first several years of implementation. This evaluation will include an assessment of its effectiveness.

169. One comment suggested that end-product testing should be used by FDA for program surveillance purposes, particularly for imports. This comment encouraged FDA to conduct statistically reliable baseline and monitoring surveys, modeled after those used in the MSSP, conducted by NMFS, to: (1) Determine how often consumer hazards occur; (2) set specific goals, objectives, and operational strategies for the HACCP program; and (3) provide a means by which the program's success can be measured.

FDA has historically collected and analyzed surveillance samples during and outside the course of its routine inspections. The purposes for these sample collections, in many ways, align with those suggested by the comment. The agency is committed to continued surveillance sampling and intends to use such sampling in an assessment of the HACCP program.

170. Another comment suggested that HACCP will only be successful in improving confidence in seafood if the program is accompanied by a consumer education effort that explains the benefits of HACCP. The comment encouraged FDA to perform a baseline study that assesses the level of consumer anxiety with respect to seafood consumption and compare it to the results of a study that it performs sometime in the future.

FDA agrees that another major goal of these regulations is to increase consumer confidence in the safety of seafood. The agency recognizes that publication and enforcement of regulations aimed at improving seafood safety alone will not achieve that goal. Consumers must be informed of the benefits of producing products under HACCP preventive controls. Within its budgetary constraints, the agency intends to engage in a program of consumer education for that purpose. The prospect of baseline and followup studies of consumer confidence (or anxiety) will also be considered.

*P. Other Issues*

FDA received a number of additional comments that did not address any specific provision of the proposal, although some of them were in response to invitations in the preamble to comment on various subjects.

1. Relationship to Other Programs

In the preamble to the proposed regulations, FDA invited comment on how FDA's HACCP program for seafood processors should mesh with existing State HACCP programs for seafood, in order to avoid imposing inconsistent Federal and State HACCP requirements. In the preamble, FDA acknowledged that many States are under considerable pressure to cut back on programs where there is an overlapping Federal program. Nonetheless, the agency urged States to maintain, if not strengthen, their seafood programs and to work with FDA to develop an integrated Federal/State, HACCP-based seafood control program.

171. Approximately 12 comments, representing processors, trade associations, and State government agencies, recommended that FDA coordinate its HACCP program with existing State and Federal seafood control programs. Several comments emphasized that a coordinated effort would ensure uniform application and interpretation of HACCP principles, while preventing duplication of effort that wastes limited enforcement resources. One comment stated that such a coordinated effort would be facilitated if only a single HACCP plan were required for each processing facility, rather than one that was designed to meet FDA requirements and another that would meet State requirements. Another comment noted that a multitude of differing HACCP regulations would only serve to confuse processors and dilute the effectiveness of the Federal program. The comment further recommended that FDA work with AFDO to promote State laws and regulations that are compatible with FDA's HACCP program.

One comment suggested the formation of a task force representing the food industry, FDA, USDA, and DOC to work towards the goal of reducing regulatory duplication.

The agency agrees that there is a need for Federal/State partnership to facilitate the efficient implementation of HACCP programs. FDA believes that coordination with the States would permit both the agency and the States to leverage their inspectional resources. FDA, as well as the States, would benefit by dividing the workload and sharing data and other information. Such coordination would also benefit industry through consistent inspections and regulatory requirements.

The agency has already begun to coordinate its efforts with the States on seafood. The formation of the Alliance, to which AFDO is a member, is one such endeavor. The Alliance is described in detail in the ''Training'' section of this preamble.

With FDA's support, AFDO passed a resolution supporting the development of FDA/State partnership agreements at its 1994 meeting in Portland, ME (Ref. 220). The resolution specifically recommended that HACCP be the basis of such partnerships and noted the

shared roles of FDA and State regulators in seafood safety, the limited resources of both levels of government, and the existence and the potential impact of the Alliance.

Meanwhile, FDA is increasing its use of partnership agreements with State enforcement agencies. For instance, the Northeast Region of FDA has entered into a threeway partnership agreement with the Northeast Food and Drug Officials Association and individual States to provide industry with HACCP training at the retail level. FDA also expects to enter into partnership agreements with States to implement HACCP pilot programs for foods other than seafood. FDA's Northeast Region has already signed such an agreement with the Commonwealth of Massachusetts, and more are anticipated.

These initiatives demonstrate the agency's desire to coordinate its efforts with the States. The agency's cooperative efforts in the area of HACCP reflect a trend. The agency has used cooperative efforts in other areas, such as pesticide sampling and workplan sharing. FDA will continue to explore ways to coordinate the Federal and State role in the regulation of seafood.

172. A number of comments recommended that States act as the primary enforcement agencies for these HACCP regulations, while FDA's responsibility would be to evaluate the States' compliance with HACCP inspection protocols. Some of these comments suggested that such a program could be patterned after the NSSP.

FDA is adopting these HACCP regulations to implement and enforce the act. While FDA plans to work cooperatively with the States in all ways possible, the agency cannot delegate its authority under the act. It is possible that in some aspects of seafood processing, the States will serve as the primary enforcement agencies, with FDA serving primarily an auditing function. However, responsibility for enforcing the act and these regulations must remain with FDA.

173. A number of comments, from processors, trade associations, and one consumer advocacy group, maintained that FDA's HACCP regulations should preempt any existing State HACCP programs. The comments contended that Federal preemption would ultimately reduce confusion caused by conflicting State programs, reduce costs, and promote uniformity. Examples of the specific areas of conflict were not provided by the comments.

As was previously stated, FDA intends to work through AFDO and through Federal/State partnerships to seek consistency in State regulatory approaches to HACCP for seafood inspection and through the NSSP process and the ISSC to attain this goal specifically for molluscan shellfish. Moreover, processors in each State must comply with Federal HACCP requirements if their product moves in interstate commerce. For these reasons, the agency has concluded that there is no need for Federal preemption of State regulatory requirements.

174. Several comments encouraged FDA to work closely with NMFS to coordinate FDA's program with the existing NMFS' HACCP program. The comments noted that cooperation with NMFS would help the two agencies avoid wasteful duplication of effort and would reduce the burden on those firms already operating under the NMFS program.

FDA agrees with these comments and notes that FDA and NMFS are coordinating their HACCP programs to ensure compatibility. Nonetheless, FDA advises that the NMFS program is a voluntary, fee-for-service program and is likely to continue to include features that go beyond the requirements of these regulations, especially in the area of preventive controls for economic fraud and plant and food hygiene.

A 1974 MOU between FDA and NMFS recognizes the respective roles of the two agencies and commits the two agencies to consistency and cooperation. FDA will continue to work with NMFS to maintain a coordinated Federal effort.

2. ''Whistleblower'' Protection

175. A few comments urged that these regulations include ''whistleblower'' protection for employees of seafood processors. Whistleblower protection is designed to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers. The wrongdoing in this case, presumably, would likely involve the falsification of HACCP records. The comments argued that: ''Whistleblowers are iispensable as the eyes and ears for overextended FDA personnel making limited spot checks. The public's line of defense will be no stronger than the shield protecting industry worker's rights to obey and help enforce this law.''

One concern that FDA has heard about the credibility of a HACCP system is that important records can be falsified. It is alleged that, without whistleblower protection, it is much less likely that the agency will know about falsifications.

While the agency is confident, based in part on its experience reviewing records in the low-acid canned food program, that it can detect falsification, FDA also expects from experience that it will be alerted to possible wrongdoing from time to time by employees of processors even in the absence of whistleblower protection. FDA has received, and acted upon, confidential information from employees of regulated firms for decades. This assistance has proven invaluable on many occasions. The only protection to these employees available from FDA has been confidentiality.

The question raised by the comments is whether, in addition to the actions against the product or the processor that would be available to FDA as a result of violations of the requirements of the act and these regulations, there must be specific protection for employees in order for the program to succeed. The agency has concluded that, like other FDA programs, this program can be successful in the absence of specific whistleblower protection, and that congressional action would be necessary to provide protection other than confidentiality.

FDA cannot provide whistleblower protection in these regulations. FDA believes—and case law bears out—that there must be a nexus between the conduct being required by regulations and the focus of the underlying statute, in this case primarily section 402(a)(4) of the act. An analysis of the application of section 402(a)(4) of the act to these regulations can be found in the ''Legal Basis'' section of this preamble.

While FDA has determined that an assessment of processing risks and a plan that ensures that these risks are minimized has the requisite nexus to section 402(a)(4) of the act, and that this nexus justifies adopting these regulations, the agency does not see a sufficient nexus between whistleblower protection and the prevention of adulteration of food. If a firm retaliates against an employee who brings complaints or other information about the firm to FDA, the implication of such an action is that there is a condition at the firm that may need investigation, not that the products produced by the firm are necessarily adulterated. It may be the case that the products are adulterated, but such a conclusion does not flow as directly from section 402(a)(4) of the act as does the conclusion that seafood products not produced under a HACCP plan have been produced under insanitary conditions whereby they may have been rendered injurious to health. For this reason, FDA concludes that it lacks

clearcut authority to provide whistleblower protection in these regulations.

3. Separation of Quality Control (QC) and Production

176. A few comments requested that the regulations mandate structural independence within a processing firm between ''HACCP QC [quality control] personnel'' and ''production'' personnel. Otherwise, according to the comments, ''HACCP QC personnel could still be hired and fired by a production supervisor.''

FDA does not believe that a change in the regulations would be beneficial in this regard. It is important to recognize that, under HACCP, production personnel are the observer/operators who perform the initial monitoring of CCP's as well as the recordkeeping that documents the results of this monitoring. The operation of the HACCP system must involve the whole organization, not just QC personnel.

However, it is reasonable to expect that, where practical, verification activities should be performed by individuals other than those who made the records in the first place. For verification, the agency encourages the kind of organizational separation that is being urged in the comments.

The agency recognizes, however, that many seafood companies will not be large enough to have distinct, independent organizational units that can verify each other's work. The seafood industry is characterized by small businesses. FDA has concluded that such a requirement is not practical for this industry.

It is worth noting that the regulations at parts 113 and 114 for low-acid canned foods and acidified foods contain recordkeeping requirements and some verification requirements that are similar to the provisions of these regulations. In certain respects, parts 113 and 114 served as models for the seafood HACCP program. Those regulations have succeeded even though they do not require a separation between QC personnel and production personnel. Given this history, the agency is reluctant to mandate the internal structure of seafood processors.

4. Education

177. FDA received a number of comments on the subject of seafood safety education. These comments were in response to an invitation in the preamble to the proposed regulations for comments on risk reduction activities that could be regarded as complementary to HACCP, primarily directed toward postprocessing handling. In addition, FDA asked for comment on appropriate education and information that should be directed toward consumers and recreational fishermen, even though education aimed at these groups is actually outside the scope of this rulemaking. FDA made this request based on a recognition that HACCP cannot reasonably be expected to solve every problem. The agency recognizes that HACCP must be integrated into a comprehensive program for seafood safety. Education is another important component of that program. As one comment noted:

> * * * the responsibility for seafood safety should be met at every level of seafood distribution, from harvesters to processors to retailers, restaurants and, finally, the consumers themselves. Regulations are not a substitute for informed and responsible behavior and it is impractical to extend the scope of the proposed regulations to everyone involved in handling and consuming seafood.

The comments overwhelmingly endorsed the value of education. They strongly supported education for: (1) Consumers on the handling and purchasing of seafood, especially through brochures at the point of purchase and information available at pharmacies, and on the significance of HACCP, especially with regard to the government's verification role; (2) recreational fishermen, provided by the State during licensure (with guidance from the Federal government) and through articles in popular fishing and outdoors magazines; (3) subsistence fishermen; (4) retailers, including food service and restaurants.

FDA greatly appreciates these comments. The agency agrees that education is an essential complementary activity to HACCP as well as to other aspects of FDA's overall seafood program. The comments will be taken into account as the agency develops its educational program.

178. FDA also invited comment on whether the agency should consider proposing to require handling instructions for consumers on the labeling of seafood. Any action that FDA were to take along these lines would be as part of a separate rulemaking.

The agency received about 20 comments on this issue. Approximately half of those comments supported the notion of mandatory safe handling instructions. One business noted that safe handling instructions would help to ensure the safety of a product through the distribution chain, while another business said that such instructions had a real potential to decrease seafood-related illness. One individual commented that safe handling instructions would increase consumer confidence in these products. One industry comment noted that a task force composed of industry, Federal and State agencies, and consumers should agree on the appropriate statement. Some comments indicated that safe handling instructions might be appropriate for high-risk products.

The remainder of the comments on this issue disagreed that safe handling instructions for seafood should be required by FDA. Many of these comments noted that most seafood products include such instructions voluntarily. One trade association commented that such a requirement would limit retailers' flexibility and creativity and impose significant new costs on retailers and consumers. Most of those comments noted that requiring new information would detract from other labeling requirements.

FDA appreciates these comments and the different points of view that they represent. The agency will use the comments in its deliberations on this issue.

179. Finally, FDA described some of its educational efforts aimed at medically compromised individuals about avoiding raw molluscan shellfish and invited comment on types of education and information activities that might be useful in this regard. The agency received about a dozen comments on this subject.

Most of these comments addressed whether there should be mandatory warning labeling for raw molluscan shellfish. A majority of the comments stated that the agency should require warning labeling. Three comments from consumer groups stressed the need to protect high-risk individuals. One State government commented that warnings for raw molluscan shellfish should be tied to specific locations and times of year. One professional association requested that the warning state that the shellfish should only be eaten if it is certified and tagged.

Three comments stated that warning labels would be inappropriate. One comment noted that shellfish are not consumed in enough quantity to be a problem. Another comment stated that warning labels would unduly alarm those not at risk and that better channels exist for educating those at risk.

A few comments did not specifically address warning labels but recommended that FDA target advice directly to compromised individuals. Those comments suggested that FDA direct information to the medical community involved in the treatment of those individuals.

Again, FDA thanks the comments for providing views on a matter that is outside the scope of this rulemaking. FDA is working to provide information to at-risk populations and its strategy on how best to do so is evolving. The agency will take the comments into account as it develops policy in this area.

In summary, the agency agrees that education is an essential complementary activity to HACCP as well as to other aspects of FDA's overall seafood program. The comments relating to education will be useful to the agency as it develops its education programs.

5. Traceback Mechanisms

180. One comment recommended that FDA develop and incorporate methods to trace back fish and mandate such traceback in these regulations. The comment described the use of bar codes and computer-based tracking numbers by a meat products company that enable it to trace a specific cut of meat from a store or restaurant to its source.

The agency acknowledges that traceback to the water would be useful for certain species of fish associated with certain hazards, e.g., ciguatoxin. On the other hand, traceback to the water for scombrotoxin would not be particularly useful, although traceback through the distribution chain to find out the source of mishandling would be useful. The agency urges the industry to consider this comment. FDA advises that it is willing to explore this idea further, although not as part of this rulemaking.

6. Tribal Governments

181. FDA received a few comments on the effect of these regulations on tribal governments. The preamble to the proposed regulations noted that Executive Order 12875 of October 26, 1993, requires, among other things, consultation with tribal governments before the formal promulgation of regulations containing unfunded Federal mandates. While FDA does not believe that these regulations impose an unfunded Federal mandate, the agency wishes to foster consultation on matters that might significantly affect tribal communities. Consequently, FDA requested comment on the economic effect of the regulations on tribal governments.

FDA received no comments from tribal governments. One comment, from a tribal business, stated that the impact of the regulations on tribal governments will be beneficial because they will result in safe products, positive consumer perceptions, and positive market impacts. The other comment that mentioned this subject was from an academic, who expressed the view that the regulations will have a major impact on tribal groups involved in fisheries and contains unfunded Federal mandates. The comment did not elaborate. Neither of these comments justifies any change in these regulations.

The agency remains interested in fostering consultation with tribal communities as they see fit and encourages correspondence from tribal governments.

7. HACCP System Improvements

182. A comment urged that there be a process to continually amend or update these regulations.

FDA points out that such a mechanism exists in its regulations. Under § 10.30 (21 CFR 10.30), interested persons are provided with a process by which they can petition the agency to amend and update these regulations.

From a less mechanistic viewpoint, the agency recognizes that these regulations represent a pioneering program that has not been attempted before. While the agency believes that sufficient groundwork has been laid to adopt these regulations and to begin to implement them, FDA also acknowledges that full scale implementation will reveal modifications that may be necessary, both in the short and long terms. Consequently, the agency will be highly receptive to feedback from all parties who are affected by these regulations and will remain open to changes that are necessary in the regulations. The ''Verification'' section of this preamble reflects the agency's interest in evaluating this program.

183. A number of comments asked for improvements in the foodborne-illness reporting system operated by CDC. Some comments urged collaboration between FDA and CDC. One comment advocated the creation of an active reporting system.

These comments are essentially outside the scope of this rulemaking. Nonetheless, the agency recognizes that the strength of the foodborne-illness reporting system bears directly on the ability of the agency to measure the public health impact of HACCP. Both FDA and CDC agree that underreporting is an undesirable feature of the current system. FDA and CDC have been collaborating on an active-type reporting system. The limiting factor, however, will always be resources. Significant improvements in the current system will involve considerable expense.

184. One comment provided views on factors that would limit the effectiveness of HACCP. The comment cited:

> [P]oor commitment by company management and lack of allocation of necessary resources; improper training; lack of understanding and planning in all stages of implementation of a plan[,] and failure to recognize the need to understand the corporate culture change which must accompany an effective HACCP program.

FDA agrees with this comment but hopes that company management will embrace HACCP and recognize the benefits that it offers to the firm.

III. Paperwork Reduction Act of 1995

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections are shown below along with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* Reporting and recordkeeping requirements for processors and importers of fish and fishery products under the provisions of 21 CFR parts 123 and 1240. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.

*Description:* This regulation implements the use of Hazard Analysis and Critical Control Point (HACCP) methodology to ensure that processed and imported fish and fishery products are safe within the meaning of sections 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and 342(a)(4)).

*Description of Respondents:* Businesses or other for profit organizations.

Although the January 28, 1994, proposed rule provided a 60 day comment period (extended to 90 days in the April 7, 1994, Federal Register, 59 FR 16578) under the Paperwork Reduction Act of 1980, and this final rule incorporates the comments received, as required by 44 U.S.C. section 3507(d), FDA is providing additional opportunities for public comment under the Paperwork Reduction Act of 1995, which applies to this final rule and was enacted after the expiration of the comment period.

Therefore, the agency solicits public comment on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit comments on the information collection requirements by February 16, 1996, and should direct comments to FDA's Dockets Management Branch (address above).

Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register when the information collection requirements in this rule are submitted for OMB approval, and again when OMB makes a decision to approve, modify or disapprove the information collection requirements.

Sections of this final rule require that certain businesses collect information and keep records. Under Public Law 104–13 Federal agencies are required to estimate the hours and costs attributable to collections of information, as defined in 44 U.S.C. 3502(3), that are required by Federal regulation. Table 1 sets forth an estimate of the hours that are required annually for compliance with each section in part 123 that requires regulated entities to collect or record information.

TABLE 1.—ESTIMATED AVERAGE ANNUAL INFORMATION COLLECTION AND RECORDKEEPING BURDEN

| 21 CFR | No. of respondents | No. of responses per respondent [1] | Hours per response [2] | Total hours |
|---|---|---|---|---|
| 123.6(a),(b),(d) | 4,850 | 1 | 16 | 77,600 [3] |
| 123.6(c)(5) | 4,850 | 4 | 0.3 | 5,280 |
| 123.8(a)(1),(c) | 4,850 | 1 | 4 | 19,400 |
| 123.12(a)(2)(ii) | 1,000 | 80 | 0.2 | 16,000 |
| 123.6(c)(7) | 4,850 | 280 | 0.3 | 470,400 |
| 123.7(d) | 1,940 | 4 | 0.1 | 1,940 |
| 123.8(d) | 4,850 | 47 | 0.1 | 22,795 |
| 123.11(c) | 4,850 | 280 | 0.1 | 135,800 |
| 123.12(c) | 1,000 | 80 | 0.1 | 8,000 |
| 123.12(a)(2) | 20 | 1 | 20 | 4,000 [3] |
| 123.10 | 24 | 1 | 24 | 116,400 [3] |
| First year total burden hours | ..... | ..... | ..... | 877,615 |
| Annual recurring total hours | ..... | ..... | ..... | 679,615 |

[1] Based on an estimated average of 280 working days per year.
[2] Estimated average time per 8 hour work day unless one time response.
[3] Nonrecurring burdens.
The above estimates include the information collection requirements in the following sections:
123.16 Smoked Fish—process controls (see 123.6(b))
123.28(a) Source Controls—Molluscan Shellfish (see 123.6(b))
123.28(c),(d) Records—molluscan shellfish (see 123.6(c)(7))
123.9 Records control general (see recording and records)

The time and costs of these activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using the typical small seafood processing firm as a model because these firms represent a significant proportion of the industry.

The burden estimate in Table 1 includes only those collections of information under this rule that are not already required under current statutes and regulations and are being added by this rule. For example, the current good manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures.

In addition, the estimate does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labelling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in Table 1 accounts only for new information collection and recording requirements attributable to part 123.

There are no additional capital costs associated with this regulation that are not also attributable to the preexisting requirements of part 110.

FDA estimated in the proposal that the total burden to all respondents would be 2,826,850 hours. That estimate, however, significantly overestimated the burden because it included activities performed by domestic processors that are not related to information collection and recordkeeping, and, more significantly, did not account for existing regulatory requirements and usual and customary business practices, as described above.

The agency has recalculated the recordkeeping burden in a manner that is more consistent with the intent of Public Law 104–13. Therefore, the burdens presented in Table 1 are those actually associated with collecting and recording the pertinent HACCP information. The burdens for HACCP plan development, plan reassessment, and record review are also included in the recalculated burden. In estimating the time for the preparation of a HACCP plan, the agency believes that a significant portion of the training hours can also be characterized as time spent on preparation of the plan.

Additionally, the agency recognizes that the regulations will place a burden on seafood importers. For this reason, FDA has included in the burden

estimate the time necessary for importers to develop a written verification plan, verify compliance of imports, and keep records of their verification activities.

Few comments provided information on the number of hours that a processor would expend on information collection and recordkeeping, as described in the preamble to the proposed regulation. One comment estimated that the annual burden would vary from 200 to over 700 hours, depending on the type of product, and another comment suggested that one hour per day, or 365 hours per year, would be required. One comment stated that the agency's estimate of 650 hours per year was reasonable. Another comment estimated four to five hours per day, or 1,820 hours per year as the likely burden. None of these comments provided information to support how the commenters arrived at their estimates.

It seems likely that the estimates suggested by the comments were calculated based on the same errors that the agency made in the proposal, that is, by combining the burdens associated with HACCP data collection and recordkeeping with other HACCP activities unrelated to information collection and recordkeeping, with usual and customary information collection and recordkeeping practices, and with collections of information required by the provisions of the Federal Food, Drug, and Cosmetic Act and implementing regulations. This conclusion is supported by the fact that some of the comments expressed agreement with the agency's calculations. For these reasons, FDA concludes that no changes in its corrected calculations are necessary to respond to the comments.

## IV. Economic Impact

### *A. Introduction*

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, FDA has examined the impacts of the final rule. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses.

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation). The Unfunded Mandates Reform Act also requires (in section 205) that the agency identify and consider a reasonable number of regulatory alternatives and, from these alternatives, select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. Even though FDA finds that the costs of this final rule may be below $100 million a year, estimating these costs is a difficult task involving uncertainties. This analysis, together with the preamble published in the Federal Register and supporting analysis and materials, constitutes a final RIA. Therefore, FDA has treated the final rule as an economically significant regulatory action under Executive Order 12866. Consequently, the agency has completed this full RIA which demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866. FDA has concluded that the net benefits of this rule (benefits minus costs) are largest for the regulatory option selected as specified by Executive Order 12866. FDA has also concluded that, pursuant to the Unfunded Mandates Act, the regulatory option selected is the least burdensome option to accomplish the goal of controlling all physical, chemical, and microbiological hazards reasonably likely to be present in seafood.

As a part of the preamble to the proposed regulation, FDA published a summary of the Preliminary Regulatory Impact Analysis (PRIA) and placed on file with FDA's Docket Managements Branch the complete PRIA. In addition, FDA has placed the full final Regulatory Impact analysis on file at Dockets Management Branch (address above).

FDA has fully reviewed the information on which the PRIA was based, the comments on the PRIA, and other available information on the costs and benefits of HACCP for the seafood industry. Based on this review, FDA has arrived at two estimates of the costs in this final rule as well as upper and lower estimates of benefits. As can be seen in the agency's summary of costs and benefits are summarized in Table 2, FDA believes that the costs of the final rule will range from $677 million to $1.488 while the benefits will range from $1.435 to $2.561 billion. In its final analysis, the agency maintains that the total benefits of this mandatory seafood HACCP rule will exceed the total costs.

### Regulatory Options

The agency raised and received comment on a number of regulatory options in the PRIA. The most significant two options raised were regulating only high risk products or the most serious hazards and providing regulatory relief for small businesses. The first option is inconsistent with the objective of this regulation, to control all physical, chemical or microbiological hazards reasonably likely to be found in seafood products. Although FDA has not granted relief only for small business, the agency has extended the compliance date for all firms from 1 year to 2 years.

TABLE 2.—SUMMARY OF TOTAL COSTS AND BENEFITS

| Year | Costs from FDA models (millions) | Costs adjusted from NMFS model (millions) | Benefits lower (millions) | Benefits upper (millions) |
|---|---|---|---|---|
| 1 | $69 | $162 | $73 | $108 |
| 2 | 42 | 9173 | 108 | |
| 3 | 41 | 83 | 85 | 156 |
| 4 | 38 | 80 | 87 | 158 |
| Total[1] | 677 | 1,482 | 1,435 | 2,561 |

[1]The total defines the total discounted costs and benefits beyond the 4th year and discounted at 6 percent.

*B. Costs*

In the PRIA, FDA was reluctant to rely only on results of the limited experience with HACCP in the seafood industry. FDA balanced the reports of some seafood firms, which showed that the costs of HACCP were low, with a study of the costs of HACCP that had been done under contract with NMFS by A. T. Kearney, Inc. (Contract No. NA88AA–H–SK006). This study showed significantly higher costs (as reflected in the range of cost estimates summarized above) but had several flaws that engender skepticism about its results as well. For example, none of the plants that were the subjects of the study had actually implemented HACCP, and the system whose costs were studied was significantly more demanding than the system embodied in the 21 CFR part 123. Despite these facts, the cost estimates in the PRIA were based on the results of the NMFS study because FDA considered it to represent the best evidence available at that time.

As explained more fully below, FDA used modeling technique and the experience reported about seafood firms to produce estimates that are in general agreement and that are approximately one-fourth of those estimated in the NMFS study reported in the PRIA.

In estimating the costs in this PRIA, there are three checks that have helped ensure the accuracy of the costs that would be imposed by adoption of this regulation. The first is the cost comments, but these, the agency's analysis revealed, were in most cases rather general, not well supported, and of only marginal assistance. The second is modeling by FDA experts based on their experience with the use of HACCP in the seafood industry; working with aquatic species and the public health problems that they present; inspecting and studying both seafood plants and low acid canned food plants (which have operated under HACCP principles for almost two decades); and participating in the FDA–NMFS seafood pilot. The results of this modeling are detailed below. The third source is information that FDA received from firms that have actually implemented HACCP. Even though FDA finds that the costs of this final rule may be below $100 million, estimating these costs is a difficult task involving some uncertainties. The agency recognizes that the rule may affect in a material way a sector of the economy. Therefore, FDA has treated the final rule as a significant regulatory action under Executive Order 12866. Consequently, the agency has completed a full Regulatory Impact Analysis.

The agency received approximately 230 comments on issues involving the PRIA. These comments are fully summarized and addressed in the full RIA which is included in the record as Reference 229. However, because of the problems with these comments noted above, FDA did not generally use them in the revised estimates reported here and in the full RIA. The reasons for this are more fully explained in the full RIA.

These adjusted NMFS model cost estimates result in per plant costs for domestic manufacturers of $23,000 in the first year and $13,000 in subsequent years. Total costs for compliance with these regulations using the adjusted NMFS data are shown in Table 3. FDA has also concluded that the PRIA represents a reasonable upper estimate of the costs of HACCP. Table 3 also summarizes the specific cost estimates that FDA arrived at using data from the NMFS model with cost refinements received from commenters and FDA seafood industry experts.

TABLE 3.—DISAGGREGATED COSTS FROM ADJUSTED NMFS MODEL

| | Million |
|---|---|
| 1st Year: | |
| Domestic manufacturers and Importers | $112 |
| Major plant repair and renovation | 13 |
| Sea Grant expertise | 1 |
| Repackers and warehouses | 14 |
| Harvesters for rejected raw product | 1 |
| Shellfish vessels | 3 |
| Foreign processors | 18 |
| Total | 162 |
| 2d Year: | |
| Domestic manufacturers | 65 |
| Sea Grant expertise | 1 |
| Repackers and warehouses | 14 |
| Shellfish vessels | 1 |
| Foreign processors | 10 |
| Total | 91 |
| 3d Year: | |
| Domestic manufacturers | 65 |
| Sea Grant expertise | 1 |
| Repackers and warehouses | 14 |
| IQF Shellfish plants | 3 |
| Total | 83 |
| 4th Year: | |
| Domestic manufacturers | 65 |
| Sea Grant expertise | 1 |
| Repackers and warehouses | 14 |

TABLE 3.—DISAGGREGATED COSTS FROM ADJUSTED NMFS MODEL—Continued

| | Million |
|---|---|
| Total | 80 |

Total discounted costs beyond the 4th year and discounted at 6 percent, the costs are $1,482 million.

1. Alternative Model for Estimating the Costs

In addition to the cost estimate based on the NMFS modeling, FDA is presenting a second cost estimate for these regulations. The uncertainties associated with the choices made by seafood processors to control hazards justify providing a range of potential costs based on more than one model.

In examples created by seafood experts within FDA, the cost of compliance with these regulations was estimated for two small hypothetical seafood processors that the agency believes to be representative of a significant portion of the seafood industry. One of the plants is assumed to be in substantial compliance with existing CGMP requirements. Therefore, the costs experienced by that plant are attributable exclusively to the establishment and maintenance of a HACCP system. The other plant has some CGMP deficiencies that the agency believes are typical of those displayed by seafood processors. This plant is identical to the first plant except for the CGMP deviations. The costs calculated for this second plant represent the cost associated with the establishment and maintenance of HACCP as well as costs associated with the correction and monitoring of sanitation conditions.

The models concern two plants that cut and package tuna which is received frozen and that also distribute orange roughy fillets. The complexity of the processing operations, and the nature and number of hazards, are assumed to be roughly equivalent to that of the other types of operations. FDA recognizes the difficulty in validating these assumptions. Nonetheless, the results demonstrate that processors may have costs that are significantly below the averages estimated by means of the NMFS report. As discussed later, data received from firms that have implemented HACCP are generally supportive of the results of this modeling.

a. *Small plant cost example 1.* This is the example of a firm that is a processor of frozen tuna steaks and distributor of imported orange roughy fillets who receives all fish frozen. This plant is

located in a major seafood processing region, so there is no need for plant personnel to travel to other cities to receive training as it would be available locally. This processor operates 280 days per year. The plant manager is paid $15 per hour and production workers are paid $8.50 per hour. No food safety hazards are reasonably likely to occur in orange roughy, so a written hazard analysis shows hazards for tuna only. This processor has no need to make CGMP improvements so the plant costs are limited to the following:

(1) Training—($760). This is calculated as follows: $400 tuition plus the opportunity cost of training time ($24 hours x $15 per hour). The processor is expected to do most of the hazard analysis during the class.

(2) HACCP Plan Refinement—($240). This is calculated by taking 16 hours billed at $15 per hour using the FDA Fish and Fishery Products Hazards and Controls Guide.

(3) Plant Sanitation Audit—($0). This is done 3 times daily for 20 minutes each time. However, because the firm is modeled as being in compliance with existing CGMP's, it is assumed that these audits are already being done. It is assumed that there is a negligible cost for recordkeeping.

i. *Critical Control Points (CCP).* (4) Receiving CCP (histamine)—($3,200). This processor gets a freezing log from the tuna harvester and makes a visual check of the fish to see that they are frozen. The processor keeps a copy of the freezing log and makes a note of the visual check. The fish are then transferred to a plant freezer. The monitoring takes 15 minutes per lot for 4 lots per day. Similar monitoring is already occurring and the marginal cost for the recordkeeping is negligible.

The processor drills a representative sample of each lot and performs an organoleptic examination for decomposition of the tuna. It is assumed that this monitoring is not being done previous to this regulation and takes 20 minutes per lot for 4 lots per day. Monitoring is billed at $8.50 per hour. Also, there is a cost for a new drill ($50) and it is assumed that recordkeeping costs are negligible.

(5) Cutting CCP (metal fragments)—($0). A worker checks the saw blade at every break to look for broken saw teeth and keeps a log of checking on the teeth. Monitoring takes a few minutes per break. It is assumed that there is a negligible marginal cost for the monitoring and recordkeeping. Fish is weighed, packed, labeled and returned to the freezer.

ii. Corrective actions. (6) Problems with incoming product—($0). It is expected that product rejects in the first year would be higher but they would return to current levels in the second year as harvesters became aware of the processor's new requirements. The total cost for the industry is $1 million for the first year and zero in the following years. Because harvesters and not processors bear the cost of rejected raw product, this cost is included in Table 4 as a separate line item and not in Table 3 which includes only costs borne by processors.

(7) A saw tooth breaks every two years—($20). A worker needs to examine potentially affected product every 2 years. This is expected to take 4 hours billed at $8.50 to check two hours worth of cutting.

iii. *Verification.* (8) Record review—($400). This involves a review of five sanitation records, five receiving records, and a log book for the cutting operation. These are expected to be very simple (e.g., check mark records). Consequently, this review is expected to take 30 minutes per week billed at $15 per hour.

(9) Review hazard analysis & HACCP plan—($60). This is expected to take 4 hours per year at $15 per hour.

(10) Administrative changes—20 percent of all of the other costs in the first year and 10 percent in the second year.

b. *Small plant cost example 2.* The categories of costs that are different from Example 1 are explained below.

(1) Plant Sanitation Audit—($2,800). This will need to be done 3 times daily taking approximately 20 minutes for each audit. It is assumed that some minimal sanitation assessment is already being done once per day, but an additional 40 minutes would be required to perform three adequate audits. Again, it is assumed that there is a negligible cost for recordkeeping.

(2) Extra Equipment Cleaning and Sanitizing—($2,480). This is assumed to take 1 hour per day billed at $8.50 per hour. Also, additional water, and cleaning and sanitizing materials are assumed to cost $100.

(3) Eliminate Fly Infestation—($330). Torn screens need to be repaired taking 2 hours billed at $8.50 per hour. Also, screening materials assumed to cost $15 are needed. An exterminator to apply pesticides costs $300.

Table 4 represents the models described above in tabular form.

TABLE 4.—FDA MODELS OF SMALL PLANTS

| Category | Small plant 1 (no GMP costs) | | Small plant 2 (GMP costs) | |
|---|---|---|---|---|
| | Year 1 | Year 2— | Year 1 | Year 2— |
| Training | 760 | 0 | 760 | 0 |
| HACCP plan refinement | 240 | 0 | 240 | 0 |
| Sanitation audit | 0 | 0 | 2,800 | 2,800 |
| Receiving CCP | 3,200 | 3,200 | 3,200 | 3,200 |
| Cutting CCP | 0 | 0 | 0 | 0 |
| Sawtooth monitoring | 20 | 20 | 20 | 20 |
| Record review | 400 | 400 | 400 | 400 |
| HACCP plan review | 60 | 60 | 60 | 60 |
| Equipment cleaning | 0 | 0 | 2,500 | 2,500 |
| Eliminate pests | 0 | 0 | 330 | 0 |
| Administration | 940 | 370 | 2,100 | 900 |
| Per plant costs | $5,600 | $4,000 | $12,400 | $9,900 |

In order to estimate an average plant cost from these FDA model plants, FDA assumed that, based on the results of the agency's 1990/1991 survey of the seafood industry, 20 percent of small firms are similar to the model plant that requires some GMP improvements (Small Plant 2) and that 80 percent of the small firms are similar to the model plant that is in compliance with current CGMP's (Small Plant 1). The agency has also assumed that the cost of

compliance for large firms is the same as that of small firms. There are offsetting considerations that have led the agency to make this assumption in this model. For example, agency experience suggests that it is likely that small firms will, on average, have larger sanitation costs and thus incur greater expenses to rectify existing CGMP deviations. Large firms, on the other hand, are more likely to have a greater number of products and processing lines, resulting in greater costs of plan development and monitoring. However, the agency believes that large firms are more likely to already have preventive controls, formalized sanitation programs, and record keeping systems in place than small firms. Additionally, large firms are more likely to take on new monitoring regimes with their existing quality control and production staffs than are small firms. The agency believes that these considerations would counteract each other and should result in fairly equal costs for large and small firms.

To complete the FDA model, FDA assumed that exporters (one- half of the 1,000 large firms) would only need to spend $1,000 in order to comply with this rule. Combining the two plant total costs as reported in Table 4 and weighting the proportion of the industry they are assumed to represent, average plant costs are estimated to be $6,400 in the first year and $4,800 in subsequent years.

The foreign processor costs associated with this rule and passed on to U.S. consumers are estimated to be 13 percent of the average domestic plant costs. The total cost of this regulation using this method of cost modeling is $71 million in the first year and $38 million in the fourth year and beyond.

Total costs for compliance with these regulations using the FDA model are shown in Table 5.

TABLE 5.—DISAGGREAGATED COSTS FROM FDA MODEL

| | |
|---|---|
| 1st Year Costs: | |
| Domestic manufacturers and importers | $32 million. |
| Major plant repair and renovation | 13 million. |
| Sea Grant expertise | 1 million. |
| Repackers and warehouses | 14 million. |
| Harvesters for rejected raw product | 1 million. |
| Shellfish vessels | 3 million. |
| Foreign processors | 5 million. |
| Total | 69 million. |
| 2d Year Costs | |
| Domestic manufacturers | $ 23 million. |
| Sea Grant expertise | 1 million. |
| Repackers and warehouses | 14 million. |
| Shellfish vessels | 1 million. |
| Foreign processors | 3 million. |
| Total | 42 million. |
| 3d Year Costs: | |
| Domestic manufacturers | 23 million. |
| Sea a grant expertise | 1 million. |
| Repackers and warehouses | 14 million. |
| IQF Shellfish plants | 3 million. |
| Total | 41 million. |
| 4th Year (and subsequent years) Costs | |
| Domestic manufactures | 23 million. |
| Sea Grant expertise | 1 million. |
| Repackers and warehouses | 14 million. |
| Total | 38 million. |
| Total Discounted Costs: | |
| Beyond the 4th year and discounted at 6 percent, the costs are $677 million. | |

There are a number of explanations that would account for the uncertainty between the FDA and NMFS models. Virtually all of the difference can be explained by the two different estimates of what it would take to come into compliance with 21 CFR part 110 (FDA's CGMP regulations). In the case of the NMFS study, the contractors estimated the cost of coming into full compliance with all CGMPs. Using this methodology, they found that approximately 80 percent of the plants were out of compliance. On the other hand, the FDA model uses the results of FDA's own survey of the industry, which only listed plants as being out of compliance if the CGMP violations were related to potential contamination of the seafood product. In this case, FDA found that only about 20 percent of the firms were out of compliance. In addition, the FDA cost model assumes the simplest, least expensive corrective action to solve the CGMP violation. The NMFS model did not use the same approach in all cases.

2. Other Cost Reports

Reports received by FDA on the cost of implementing HACCP discussed below appear generally to support the results of FDA modeling across the seafood industry. While the modeling was limited to certain types of small operations, the firms for which FDA has information on reported costs represent a cross section of processing operation types, including canned, fresh, frozen, smoked/salted, molluscan shellfish, and cooked, ready-to-eat products as well as warehouses and repacking operations. It should be noted that these costs are reported only as an additional source of information. They were not used to generate FDA's model plants.

The cost information obtained from industry includes responses to a 1991 evaluation questionnaire from four firms that participated in the FDA/NOAA seafood HACCP pilot in 1990–1991. It also includes information provided to FDA from seven firms through the assistance of the National Food Processors Association. (These 7 firms operate a total of 44 processing plants.) It further includes information from two seafood trade associations, the National Fisheries Institute and the New England Fisheries Development Association

(NEFDA), which provided FDA with summary information about member firms that had implemented HACCP systems. The 2 seafood trade associations provided information on 16 firms. NEFDA operated a HACCP pilot with member firms through a Federal grant. All of this information was received by FDA before the publication of the proposed regulations and was reported in the PRIA. After the publication of the proposal, FDA received information from a large processor-exporter on its HACCP start-up costs. This processor reported start up costs of $1,000 per plant. In total, FDA has information on 86 plants (Refs. 129 and 223).

Many of these firms have implemented HACCP as participants in either pilot programs, the NOAA fee-for-service program, or the State of Alaska program, and therefore their HACCP systems have been subject to some form of third party verification. Virtually all of these plants have developed HACCP plans, many of which included critical control points for quality or economic fraud or both in addition to safety. In this respect, many firms implemented a more extensive form of HACCP than is being mandated by FDA.

More complete information on start-up costs received from 22 firms who have implemented HACCP is summarized in Table 6. Some of these costs are for multi-plant firms and some for firms operating only one plant.

TABLE 6.—START-UP COSTS

| No. of firms | Start-up costs ($) |
|---|---|
| 4 | <1,000 |
| 15 | 1,000–5,000 |
| 1 | 5,000–10,000 |
| 1 | 10,000–15,000 |
| 1 | >20,000 |

FDA notes that there are several uncertainties with these data. The agency does not have sufficient information to extrapolate the costs observed by these firms to the entire industry. FDA also does not know the extent of previous HACCP-type activities in these firms so that they may have different incremental costs than the industry average. Additionally, for subsequent year costs, some of the firms reported costs that exceeded the start-up costs shown in the table although some were below, and it is not clear if costs that might be incurred in order to comply with CGMP's are represented.

Nevertheless, the range of reported costs, are consistent with the FDA model for a processing operation that does not incur such costs. Notably, the estimates developed for NMFS of the costs of operating HACCP systems for small businesses are consistent with the FDA model and with the reports to FDA by trade associations discussed above.[1] Thus, three independent sources of information suggest that annual HACCP costs, at least for small businesses, are within a range of $3,000 to $6,000 per plant if sanitation costs are not included. Although the HACCP cost estimates made for NMFS did not include certain aspects of a HACCP system such as HACCP plan development, plan verification, and taking corrective actions, the estimates did include the costs of operating HACCP systems for quality and economic adulteration in addition to safety. These costs were not included in the NMFS cost estimates reported here. The FDA HACCP system involves safety only and is therefore less expensive.

It is also worth noting that three independent sources (FDA's own inspection experience, NMFS inspection experience with plants purchasing its voluntary inspection services, and the contractor's report for NMFS) confirm the existence of sanitation deficiencies in some seafood plants. Because FDA holds that these conditions must be corrected under existing requirements, the costs associated with these corrections will be borne by processors regardless of whether sanitation provisions are included in the seafood HACCP regulations or somewhere else. Sanitation controls for processors may address a number of enteric pathogens discussed elsewhere in this analysis including Salmonella, *Shigella*, hepatitis A, *L. monocytogenes*, *campylobacter*, and *C. botulinum*. Contamination may come from either the raw product or from poor hygiene practices such as insufficient control of vermin (flies and rodents) or insanitary water. In addition, poor sanitation may cause contamination of the product with pesticides, lubricants, cleaning compounds, or other toxic substances because of improper labeling, storage or use. The system in the seafood HACCP regulations is based on the monitoring of sanitation conditions by processors. FDA is not aware of any method for processors to take control of the sanitation conditions within their plants other than by a method that involves routine monitoring. Recording the results of these observations, as required by the regulations, need involve only minimal additional cost.

[11] The costs referred to here are those estimated for NMFS for the type of HACCP system it was studying. For the purposes of the PRIA and RIA, FDA made adjustments to the costs estimated for NMFS so as to be consistent with FDA's own regulation. These adjusted costs from the NMFS models are the estimates presented earlier in this document.

3. Seafood Prices

A number of comments referred to the effect that the regulation will have on the price of seafood that consumers experience at the retail level. In the PRIA, it was presumed that most of the cost of compliance of the proposed regulations would be passed on to consumers. In the PRIA, it was calculated that if the domestic industry passed on to consumers all of the costs estimated in the PRIA, prices for domestically produced seafood would increase by less than 1 percent in the first year and less than one-half of 1 percent in succeeding years. It was noted in the PRIA that price changes of such magnitude are unlikely to have a significant impact on general seafood purchases.

Some commenters claimed that all of the cost of the regulation would be born by processors, and that none of the increase in cost would be passed on to consumers. These commenters explained that seafood is currently at a disadvantage compared to other flesh foods for consumers' food dollars because seafood has a higher price per pound. If the relative price of seafood were to increase further, consumers would eat less seafood. The commenter also explained that domestic seafood processors are at a competitive disadvantage compared with seafood that can be imported at low cost (i.e., lower wages). If domestic processors were to raise their prices, seafood imports would take an even larger part of the seafood market away from domestically produced seafood.

Other comments said that processors will pass on all of the cost of the regulation, and that the regulation will cause the consumer price of seafood to rise. Some said that the price increase would be large enough to cause a decrease in seafood consumption.

Both theories have some merit, although neither is completely correct. The agency agrees that, all other things remaining the same, an increase in the price of seafood will decrease seafood consumption and increase the consumption of other fresh foods. However, the decision of a consumer to purchase a product depends on a number of factors.

Seafood includes many invertebrate and vertebrate species which vary in price per pound, often by over 100 percent, for a particular species (depending, in part, on seasonal supply). Such diversity, compared with

meat and poultry, makes it clear that there is not perfect substitution among the flesh foods. Nevertheless, data bases on food consumption are equally clear at showing that as people have increased their consumption of various seafood products, they have reduced their consumption of meat and poultry.

There are other nonprice factors in the consumption decision. A consumer survey found that taste, quality, and freshness were rated above price (''moderately important'') in decisions to order seafood in a restaurant or to purchase for preparation at home. In a survey of retailers' experiences, consumers ranked quality ahead of price in making seafood selections and rated the need for information on cooking as a concern equal to price (Refs. 244 and 225).

Another relevant consideration is the fact that a disproportionate percentage of seafood is consumed in restaurants as a luxury item where the cost of the raw material is not as important a factor in the purchasing decisions made by these consumers.

All of this information is consistent with other data in this analysis that suggests that a 1 percent change in price results in less than one-half of one percent change in seafood consumption.

Another major factor that lessens any competitive cost advantage meat and poultry products might experience from an increase in seafood cost is that USDA is proposing similar HACCP regulations for meat and poultry. USDA's proposal, if finalized for meat and poultry products, suggests that all segments of the flesh food market may face cost increases in the near future. It is entirely possible that the price of seafood relative to meat and poultry will not change. The agency agrees that some seafood imports have a cost advantage over domestically produced seafood, primarily due to lower labor and capital costs of production. However, because the regulation applies to imports as well as domestic products and because importers from EU member nations will soon be under HACCP requirements and experiencing increased costs, it is reasonable to assume that the price of imported seafood relative to domestic seafood will not change.

In the short run, the ability of producers to pass on cost increases is largely determined by the elasticity of demand (the degree to which consumers reduce their consumption of a good in response to a given increase in price) and the elasticity of supply (the degree to which producers increase their production of a good in response to a given increase in price). The elasticity of demand is determined in turn by, among other things, the presence or absence of close substitutes. Thus, for example, if there are close substitutes and the price of a good goes up, consumers will not continue to consume the higher priced good but switch to one of the substitutes.

If manufacturers know that consumers will not switch to a substitute when there is a price increase, then they are free to pass along all of the increased costs (from complying with the regulation) in the form of price increases. However, where there are close substitutes for seafood, such as other flesh foods, consumers respond to price increases by reducing their consumption of the high priced good. Rather than attempting to pass on all of the costs of the regulation in the form of higher prices, producers must accept reduced profits and bear some, if not all, of the burden of the cost increase.

In very competitive markets, such as the market for flesh food, where meat, fish, and poultry are considered substitutes, producers bear the entire burden of any increases in fixed costs. Fixed costs are costs that do not change, despite the size of the firm and changes in the level of output. Examples of fixed costs are costs of plant, equipment, and management; much of these costs are expected to be borne by processors. Because large firms spread fixed costs over larger output, they may be able to pass on these costs when smaller firms cannot.

In addition, also in the short run, producers may bear some portion of the variable costs that cannot be profitably passed on to consumers. Variable costs are costs that vary with changes in the amount of output. Examples of variable costs are costs of raw materials and hourly labor. However, it is likely that much of the variable costs will be passed on to consumers.

When firms in a competitive market cannot pass on all of a cost increase in the short run, profits decline. Beyond some point profits become either so low or negative that the firm is forced to close (discussed more fully in the Regulatory Flexibility Analysis below). In the long run, the exit of these marginal firms reduces the industry supply (of seafood) and permits the remaining firms to raise prices to cover the full costs of production, both variable and fixed costs. Thus, in the long run, seafood prices will rise by the full cost of the regulation.

A few comments requested a better analysis of price changes. These commenters criticized the approach used to estimate price increases in the Executive Summary of the PRIA. Rather than dividing the estimated domestic cost of the regulation by the total domestic production, the commenters suggested estimating price changes for each market segment. The advantages of this approach are that different types of seafood are treated separately (the change in the price of raw tuna might be very different from the change in the price of ready-to-eat shrimp cocktail) and that different sized firms are treated separately (small firms may be forced to raise prices more than large firms).

FDA agrees that this method of determining price changes is more legitimate than the method employed in the PRIA. However, FDA did not receive any information from commenters that would enable the agency to calculate prices in this manner. It is worth noting, however, that the contractor that performed the study upon which many of the estimated costs in this RIA are based did take product type into account when estimating cost increases. That contractor estimated a range of cost increases from negligible to 1.3 percent, depending on the product. Again, it is important to note that that study included costs for the control of types of hazards not covered by this final regulation.

Finally, while the methodology used in the PRIA might not produce accurate price changes, it suggests that overall price increases due to this regulation could well have a negligible effect on demand.

*C. Benefits*

In the PRIA, FDA estimated that the proposed option, which is being adopted in this final rule, would: (1) Reduce the amount of foodborne illness that results from consumption of seafood and; (2) generate significant nutrition benefits as a result of the increased consumption of seafood (brought about by a decrease in consumer anxiety) with a concomitant decrease in the consumption of meat and poultry; (3) reduce the amount of rent seeking (rent seeking is a term economists have applied to activities which do not contribute to societal welfare but only seek to transfer resources from one party to another); and (4) generate export benefits by allowing U.S. exporters to continue to export to countries requiring HACCP.

The last benefit, the export benefit, is characterized as the benefit to firms exporting to countries that require federal oversight and certification of HACCP programs. In addition to the benefits cited in the PRIA, the agency is addressing benefits derived from reduced enforcement costs, and is discussing other unquantified benefits of adopting the seafood HACCP

regulations. The agency has fully considered all of the comments on benefits. These estimates are more fully explained in the full RIA. What follows is FDA's conclusion as to how these benefits should be valued.

1. Safety Benefits

In the tables below, FDA presents revised estimates of the benefits of mandatory HACCP for seafood processors. Several changes from the preamble to the proposal are noteworthy. First, based on the comment that said that FDA had underestimated the number of cases, FDA has reestimated the baseline numbers of cases for certain illnesses (Ref. 226). Next, some changes were made to the valuations of particular cases, as better information was obtained concerning the probabilities of death per type of illness. Finally, as mentioned above, some changes have been made to the estimates of the percentages of the illnesses reduced.

Although Canada, for example, has mandatory HACCP for its seafood processors, no data exist on the efficacy of HACCP. Therefore, for the percentages of the illnesses reduced, FDA used three different types of its experts (seafood experts, epidemiologists familiar with microbial hazards, and microbiologists) to address the efficacy of seafood HACCP. Each of these experts reviewed the literature on each type of hazard as well as the requirements of HACCP. The ranges reflect likely upper and lower bounds on how effective HACCP will be at controlling production deficiencies by processors, including indirect controls exerted by processors on the owners of harvesting vessels. In addition, the tables reflect the fact that some of the cases of illness are not addressable by this rule as they are caused by either consumer or restaurant mishandling or poor fishing practices by recreational fishermen.

In order to calculate the number of cases (annual cases resulting from exposure to hazards associated with seafood consumption) that would be reduced by HACCP, each of the four experts followed a series of methodical steps. The first was to determine the types of seafood associated with each hazard. The second step consisted of reviewing the various aspects of the rule to determine the areas of seafood harvesting and processing that the rule could affect. The third step was to eliminate those cases that could not be affected by the rule.

These would be cases that seafood processors could neither eliminate through processing nor prevent from being introduced, either by their own staff or by control over raw materials. Cases caused or controlled by factors outside of the HACCP system include recreational harvest (approximately 20 percent of all seafood harvested) that does not pass through processing plants and problems caused by restaurant, supermarket or consumer improper cooking or mishandling. In addition, there will be some types of hazards that will not, for the foreseeable future, be controllable by means other than avoiding contaminated waters, which will not be 100 percent effective (ciguatera, for example). Until rapid, inexpensive tests are developed, HACCP cannot be 100% effective at controlling these hazards.

Once each expert had accounted for those cases that could not potentially be reached by this rule, the experts then assessed the likely effectiveness of control steps associated with broad sanitation improvements and mandatory controls on specific hazards and specific species.

*Ciguatera:* Both the lower and upper bound reductions in illness are relatively small in the near term because there does not yet exist a rapid, inexpensive test for this toxin. Processors and commercial fishermen must rely on information about whether geographic areas are ciguatoxic. Moreover, many illnesses are attributable to recreational harvest.

*Hepatitis A virus:* This illness derives mostly from molluscan shellfish. For molluscan shellfish, the controls are harvesting from approved waters and good sanitation in the plant. These regulations specifically involve both types of controls. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish.

*Norwalk virus:* This illness derives from raw molluscan shellfish that are contaminated from human pollution in harvesting areas. Control involves harvesting from approve waters. These regulations include this kind of control. The upper bound number is 50 percent of the total estimated number of illnesses largely because of the problems that states have in patrolling and controlling illegally harvested molluscan shellfish and because of the uncertainty of the control of sewage from harvesting and recreational vessels.

*Vibrio vulnificus:* This illness essentially derives from eating raw molluscan shellfish from the Gulf of Mexico. Vibrio vulnificus is a naturally occurring, ubiquitous, marine organism. The lower and upper bound numbers reflect the fact that controls are newly emerging for this organism and still have uncertainties associated with them.

Table 6a sets out the new estimates of baseline cases of foodborne disease related to HACCP and the range of cases averted by HACCP.

TABLE 6a.—ESTIMATE OF ANNUAL CASES AVERTED

| Hazard | Estimated number of cases [1] | Number of cases averted (lower) [2] | Number of cases averted (upper) [1] |
|---|---|---|---|
| Anasakis | 100 | 25 | 60 |
| Campylobacter jejuni | 200 | 100 | 150 |
| Ciguatera | 1,600 | 96 | 200 |
| Clostridium botulinum | 10 | 3 | 5 |
| Clostridium perfringens | 200 | 100 | 150 |
| Diphyllobothrum latum | 1,000 | 250 | 600 |
| Giardia | 30 | 15 | 23 |
| Hepatitis A Virus | 1,000 | 150 | 500 |
| Other Marine Toxins | 20 | ..... | 1 |
| Norwalk Virus | 100,000 | 15,000 | 50,000 |
| Other Vibrio's | 1,000 | 200 | 500 |
| Paralytic Shellfish Poisoning | 10 | ..... | 1 |
| Salmonella non typhi | 200 | 100 | 150 |
| Scombrotoxin | 8,000 | 4,000 | 6,000 |

TABLE 6a.—ESTIMATE OF ANNUAL CASES AVERTED—Continued

| Hazard | Estimated number of cases [1] | Number of cases averted (lower) [2] | Number of cases averted (upper) [1] |
|---|---|---|---|
| Shigella | 200 | 100 | 150 |
| Vibrio vulnificus (3d year) | 60 | 12 | 30 |
| Total | 113,630 | 20,151 | 58,520 |

[1] These numbers were determined in consultation with representatives from the Centers for Disease Control and Prevention.
[2] The upper and lower bounds were determined by a panel of scientists at CFSAN (Dr. George P. Hoskin, Dr. Karl C. Klontz, Dr. Kaye I Wachsmuth and Dr. Thomas C. Wilcox.

Table 7 reflects revised estimates of the total cost of seafood illness.

TABLE 7.—ANNUAL COST OF SEAFOOD ILLNESS

| Hazard | Value per case | Total cost of seafood illness |
|---|---|---|
| Anasakis | $1,703 | $170,332 |
| Campylobacter jejuni | 9,390 | 1,877,924 |
| Ciguatera | 15,247 | 24,395,438 |
| Clostridium botuli num | 223,252 | 2,232,524 |
| Clostridium perfrin gens | 6,551 | 1,310,164 |
| Diphyllobothrum latum | 2,753 | 2,752,617 |
| Giardia | 6,104 | 183,112 |
| Hepatitis A Virus | 22,669 | 22,668,870 |
| Other Marine Toxins | 269 | 5,380 |
| Norwalk Virus | 575 | 57,500,000 |
| Other Vibrio's | 2,955 | 2,954,842 |
| Paralytic shellfish poisoning | 92,356 | 1,200,628 |
| Salmonella non-typhi | 8,199 | 1,639,756 |
| Scombrotoxin | 339 | 2,708,755 |
| Shigella | 16,750 | 3,349,961 |
| Vibrio vulnificus | 2,008,917 | 120,535,039 |
| Total | ..... | 245,485,342 |

Table 8 shows the estimates of the efficacy of mandatory seafood HACCP at reducing foodborne disease in the third year following the date of implementation (undiscounted).

TABLE 8.—ESTIMATE OF THE EFFICACY OF MANDATORY HACCP AT REDUCING FOODBORNE DISEASE IN THE THIRD YEAR

| Hazards | Lower bound estimate (3d year) | Upper bound estimate (3d year) |
|---|---|---|
| Anasakis | $42,583 | $102,199 |
| Campylobacter jejuni | 938,962 | 1,408,443 |
| Ciguatera | 1,463,726 | 3,049,430 |
| Clostridium botulinum | 558,131 | 1,116,262 |
| Clostridium perfringens | 655,082 | 982,623 |
| Diphyllobothrum latum | 688,154 | 1,651,570 |
| Giardia | 91,556 | 137,334 |
| Hepatitis A Virus | 3,400,331 | 11,334,435 |
| Other Marine Toxins | ..... | 269 |
| Norwalk Virus | 8,625,000 | 28,750,000 |
| Other Vibrio's | 590,968 | 1,477,421 |
| Paralytic Shellfish Poisoning | ..... | 46,178 |
| Salmonella non-typhi | 819,878 | 1,229,817 |
| Scombrotoxin | 1,354,377 | 2,031,566 |
| Shigella | 1,674,981 | 2,512,471 |
| Vibrio vulnificus (3d year) | 24,107,004 | 60,267,519 |
| Total | 45,010,733 | 116,097,537 |

Finally, in response to the comments, FDA has attempted in Table 9 to associate particular hazards with categories of seafood (to the extent the data allow).

TABLE 9.—ASSOCIATION OF PARTICULAR HAZARDS WITH CATEGORIES OF SEAFOOD

| Hazards | Estimated number of cases | Affected species |
|---|---|---|
| Anasakis | 100 | Raw Finfish. |
| Campylobacter jejuni | 200 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Ciguatera | 1600 | Tropical, reef associated species of finfish. |
| Clostridium botulinum | 10 | Vacuum Packaged Fish, Smoked and Salted Fish. |
| Clostridium perfringens | 200 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Diphyllobothrum latum | 1000 | Raw Finfish. |
| Giardia | 30 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Hepatitis A Virus | 1000 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Other Marine Toxins | 20 | Molluscan Shellfish. |
| Norwalk Virus | 100,000 | Molluscan Shellfish. |
| Other Vibrio's | 1,000 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Salmonella non-typhi | 200 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Scombrotoxin | 8,000 | Scombroid Species of Finfish. |
| Paralytic Shellfish Poisoning | 10 | Molluscan Shellfish. |
| Shigella | 200 | Cooked Ready-to-Eat Fish, Smoked Fish, Molluscan Shellfish. |
| Vibrio vulnificus | 60 | Molluscan Shellfish. |
| Total | 113,630 | |

2. Summary of Safety Benefits

The safety benefits are shown by year in Table 10 (undiscounted).

TABLE 10.—SAFETY BENEFITS

| Year | Lower bound benefits | Upper bound benefits |
|---|---|---|
| 1 | 32,957,233 | 67,897,751 |
| 2 | 32,957,233 | 67,897,751 |
| 3 | 45,010,733 | 116,097,537 |
| 4 and beyond | 45,010,733 | 116,097,537 |

3. Nutrition Benefits From Mandatory Seafood HACCP and Increased Consumer Confidence

In the PRIA, FDA estimated what the potential nutrition benefits might be if reduced consumer anxiety over seafood safety led to increased sales. FDA hypothesized that this might lead to consumers eating lower fat meals (on average) as they replaced higher fat meat and poultry with lower fat seafood.

The agency has considered this issue in greater detail in the full RIA. FDA acknowledged in the PRIA that the entire estimate of nutrition benefits resulting from increased sales of seafood at the expense of meat and poultry sales is speculative. Although the agency believes that increased consumer confidence would result from having a state-of-the-art HACCP system in place for the seafood industry, no data were received to confidently predict the ultimate increase in the quantity of seafood sold as a result of this regulation. Sales data of this type were also not available before or after the agency initiated its low acid canned food regulations. Finally, the agency was unable to determine if any increase in consumer confidence would offset a price increase resulting from HACCP costs.

The agency was equally concerned about possible nutrition benefits as to whether there would be an exact exchange in the nutrient profile between fish as prepared and meat and poultry. The agency finds that some fish dishes as consumed are eaten fried or served with heavy sauces, and that different species of fish have different fat profiles. Thus, for some consumers who make substitutions of fish meals for meat and poultry, it is not totally clear if there will be a favorable decrease in fat intake. Because there are too many unknown variables surrounding these substitutes and the lack of sales data, the agency is unable to quantify this benefit.

4. Rent Seeking

Rent seeking activities were characterized in the proposal as ''public and private resources (which) have been expended in attempts to alter the level of regulatory effort toward seafood safety, as well as alter which Federal agency should oversee the industry.'' ''Rent seeking'' is a term economists have applied to activities that do not contribute to societal welfare but only seek to transfer resources from one party to another. An example often given is lobbying to change the ownership of a government granted special privilege so that profits change hands. In many cases, however, it is difficult to distinguish between activities that ultimately indirectly benefit society from those that only transfer profits. The proposal hypothesized that one benefit of the regulation was to reduce the social costs of rent seeking.

One commenter noted that the reason large firms support HACCP is because they must have HACCP to export to Europe. The commenter noted that mandated HACCP would ''ensure that all domestic processing firms face the same costs, thereby reducing any competitive disadvantage.''

FDA does not agree that this is a justification for HACCP. The reason for implementing HACCP is to reduce the incidence of foodborne disease. However, FDA agrees that this ''rent-seeking'' argument may explain some support for HACCP by larger exporting firms. It is important to note, however, that there are small firms who export to Europe as well.

5. Export Benefits

In the PRIA, FDA asserted that one benefit (unquantified) of the rule was to allow firms now exporting to the EU to continue to do so because of the EU requirement for a federally overseen voluntary HACCP program. Several commenters noted that some countries that import seafood from the United States are beginning to require HACCP. One commenter noted that more than 30 percent of seafood produced in the United States is exported. The same commenter noted the disruption in trade when French authorities did not coordinate their seafood safety requirements with ''other officials.'' Several commenters noted the need for more Memoranda of Understandings (MOU's) between the United States and other countries for seafood. One suggested that such MOU's be based upon HACCP as defined by various international bodies. Finally, one commenter noted that FDA ''should take into account how the international

community is implementing HACCP before the agency imposes regulations that may create unnecessary trade barriers.''

As discussed in the PRIA, this program will benefit those seafood processors who are exporting to nations requiring HACCP. However, as also noted in the PRIA, there is in place a federally overseen HACCP program, specifically, the program being offered to processors by the National Marine Fisheries Service (NMFS).

FDA has made an estimate of the cost savings to exporting firms of being in FDA's mandatory program in lieu of the NMFS program. The alternative to NMFS review (if FDA were not to adopt this regulation) would be inspection of product that is offered for entry into the EU on an entry-by-entry basis and the payment of a significant fee for these inspection services. With approximately 2 billion pounds being exported each year, this savings of resources amounts to, at a minimum, $20 million per year.

In addition, although the EU has announced the requirement that HACCP be in place by January 1, 1996, adoption of a U.S. plan reduces some of the uncertainty for U.S. firms and firms exporting to the United States concerning the ultimate form of an internationally agreed upon HACCP requirement.

6. Reduced Enforcement Costs

Comments qualitatively mentioned other benefits including fewer product recalls and other enforcement actions. FDA agrees that there will be fewer product recalls, seizures, injunctions and detentions of seafood and seafood products. As examples of what benefits could have accrued in 1994, the agency has calculated the value of each of these actions and addressed them below.

a. *Seizures.* A seizure is a civil action designed to remove violative goods from consumer channels. Table 11 shows the actions and their associated costs that follow a determination that a violation exists and that goods should be seized.

TABLE 11.—SEIZURE STEPS

| Action | Hours/Other | Cost |
|---|---|---|
| Federal personnel collect and analyze samples, write up recommendations (program and general counsel), review the case and make recommendations to the U.S. attorney. | 120 | $12,840 |
| U.S. attorney files complaint and Court orders goods arrested | 16 | 1,712 |
| U.S. Marshal and other federal official seizes goods at location | 8 | 856 |
| | Travel | 200 |
| Firm hires attorney to contest/accept action | 16 | 1,712 |
| Food is reconditioned by firm | 16 firm | 1,712 |
| | 16 Federal lower valued food [2] | 1,712 |
| Food is denatured (converted to a non-food use) or; | 16 firm | 1,712 |
| | 8 Federal lower valued food [2] | 856 |
| Food is destroyed | 8 firm | 856 |
| | 8 Federal lost food [1] | 856 |

[1] The rate of $107 per hour represents the cost of a loaded (including equipment and benefits) employee plus headquarters support of approximately 70 percent.
[2] Total seizure costs are calculated in Table 12.

Table 12 shows the seizures in 1994. Assuming that half of all seizures are prevented each year, the benefits are expected to be approximately $290,000 each year.

TABLE 12.—SEIZURES IN 1994

| Problem | No. | Administrative costs [1] | Action [2] | Total |
|---|---|---|---|---|
| Decomposition (Destroy) | 5 | $17,320 | $46,565 | $320,925 |
| Filth (Denature) | 3 | 17,320 | 8,709 | 78,087 |
| Chemicals (Destroy) | 2 | 17,320 | 10,108 | 54,856 |
| Other (Destroyed) | 4 | 17,320 | 14,212 | 126,128 |
| Total | 14 | | | [3] 579,996 |

[1] Costs of items (1) through (4) in the preceding Table totaled are $17,320.
[2] The actions that are typically taken for each type of hazard are listed in the PROBLEM column. Costs include the value of destroyed food multiplied by the number of actions or, in the case of denaturing, it is assumed that 10 percent of the value of the product is retained. No food was reconditioned.
[3] This number may well underestimate the benefit. FDA recently completed a seizure proceeding (not filed in 1994) in which $5 million of product was condemned. Thus, preventing seizure can have a significantly higher value than that reflected in this table.

b. *Detentions.* A detention is a procedure for preventing violative products from entering the United States. Table 13 shows the actions and their associated costs that follow a determination that a sample is violative, the following actions take place.

TABLE 13.—DETENTION STEPS

| Action | Hours/other | Cost [2] |
|---|---|---|
| Federal personnel send a detention notice to the importer with an opportunity to introduce testimony | 2 | $214 |
| Importer hires attorney and introduces evidence. Submits response application | 16 | 1,712 |
| Determination of action to take | 24 | 2,568 |
| Reshipment allowed, or | 10 | 1,070 |
| | Travel, Cost to Reship | 200 |

TABLE 13.—DETENTION STEPS—Continued

| Action | Hours/other | Cost [2] |
|---|---|---|
| Product is denatured, or | 8, Loss of value,[2] Cost of denaturing,[2], Reselling costs [2]. | 856 |
| Goods are destroyed under Federal supervision | 16, Loss of product [1]. | |

[1] These costs are calculated in table 14 which gives estimates of the numbers and estimated costs for detentions in 1994.
[2] Seizure can have a significantly higher value than that reflected in this table.

TABLE 14.—DETENTIONS IN 1994

| Reason | Number of detentions | Quantity [1] | Dollars [1] | Detention disposition [2] | Detention admin [3] |
|---|---|---|---|---|---|
| Borates | 25 | 21,484 | 1,827,173 | 183,017 | 112,350 |
| C. botulinum | 1 | 113,790 | 363,434 | 363,434 | 4,494 |
| E.coli/coliforms | 14 | 254,774 | 742,786 | 149,413 | 62,916 |
| Histamines | 2 | 98,023,014 | 1,361,714 | 273,199 | 8,988 |
| Lead | 2 | 102,188 | 87,440 | 9,044 | 8,988 |
| Listeria/Other Pathogens | 51 | 2,792,808 | 21,369,692 | 4,274,794 | 229,194 |
| Mercury | 11 | 7,338,900 | 12,720,272 | 1,272,327 | 49,434 |
| Poisonous/Deleterious sub-nec | 7 | 180,000 | 446,025 | 446,025 | 31,458 |
| Salmonella/arizona | 129 | 221,543,300 | 76,137,973 | 15,228,451 | 579,726 |
| Staphylocci | 6 | 55,810 | 199,550 | 40,766 | 26,964 |
| Sulfites | 23 | 713,653 | 8,100,620 | 810,362 | 103,362 |
| Unsafe food additives—NEC | 5 | 67,160 | 540,201 | 540,201 | 22,470 |
| Total | 276 | | | 23,591,033 | 1,240,344 |

[1] Quantity and dollars include the total amount of both detentions and automatic detentions and are shown to illustrate how detentions were calculated.
[2] Disposition included reshipping which was estimated to be 10 percent times the number of shipments (quantity) times the value per shipment (dollars/quantity); reconditioning which was estimated to be 20 percent of the value of the shipment (dollars) or destruction which was estimated to be 100 percent of the value of the shipment.
[3] Administrative costs are estimated to be $4,494 per detention, the sum of the first three rows of the previous table.

Assuming just half of these detentions are prevented by HACCP, benefits to the federal government and industry would be approximately $12 million per year.

c. *Automatic detentions.* Automatic detentions place each lot of imported products on detention upon arrival at the border until the importer has demonstrated that the products do not violate the Federal Food, Drug, and Cosmetic Act. This is normally done by the importer hiring independent labs to sample each lot. Table 15 shows the number and types of relevant automatic detentions that took place in 1994.

TABLE 15.—AUTOMATIC DETENTIONS IN 1994

| Reason | Number of automatic detentions | Sample cost[1] | Storage cost[2] |
|---|---|---|---|
| Borates | 53 | $132,500 | $182,717 |
| C. botulinum | 104 | 260,000 | 36,343 |
| E.coli/coliforms | 8 | 20,000 | 74,279 |
| Histamines | 63 | 157,500 | 136,171 |
| Lead | 1 | 2,500 | 8,744 |
| Listeria/Other Pathogens | 236 | 590,000 | 2,136,969 |
| Mercury | 397 | 992,500 | 1,272,027 |
| Pesticide chlorothalanil | 1 | 2,500 | 50 |
| Poisonous and Deleterious sub-nec | 4 | 10,000 | 44,603 |
| Salmonella/arizona | 759 | 1,897,500 | 7,613,797 |
| Staphylocci | 0 | 0 | 19,955 |
| Sulfites | 12 | 30,000 | 810,062 |
| Underprocessed | 3 | 7,500 | 15,454 |
| Unsafe food additives—NEC | 3 | 7,500 | 54,020 |
| Total | 1,644 | 4,110,000 | 12,405,191 |

[1] 1 Calculation of costs assumes that, for each product placed on automatic detention, 10 lots per year will be analyzed with 1 sample each at a cost of $250 per sample.
[2] Assumes storage costs equals 10 percent of the stated value of the goods.

Again assuming that half of the above automatic detentions are eliminated each year, then the benefits will be approximately $6 million per year.

d. *Recalls.* The costs of recalls to a firm vary from inexpensive notification

of consignees to several million dollars, depending on the nature of the hazard, the type of seafood, the cost and amount of product involved, and the distribution chain of the product. The costs of a recall include searching for the recalled products, removing them from retail and wholesale outlets, replacing the adulterated product, effectiveness checks, and disposal or reconditioning. In some cases recalls cause marketing disruptions, loss of shelf space, and subsequent losses in sales via publicity.

FDA costs include investigative and analytical time and expenses, administrative costs, cost of samples, and auditing time.

FDA assumes that the costs of recalls borne by firms are directly related to the distribution costs associated with the products and to the size of the contaminated lots. Distribution costs account for about one-third of the final value of seafood. FDA assumes that the firm must bear the full amount of the distribution costs of the recall. In addition, the other costs listed above raise the total cost of recalls borne by firms to one-half the value of the product. FDA uses one-half the value of the product as the base for the estimate of total recall costs. The total recall cost of seafood processing firms in 1994 is estimated to be $2,461,906, as shown in table 16. FDA audit checks for seafood took 474 hours in 1994. FDA assumes that total FDA costs per recall were proportional to audit hours. The cost per hour of an audit check is $107, giving an FDA audit cost of $50,718 (474 x 107). FDA collected 72 samples at $250 per sample, giving sample costs of $18,000 (72 x 250). FDA thus estimates additional costs due to recalls to be $68,718 ($50,718 + $18,000). The total recall cost is estimated to be $2,530,624 ($2,461,906 + $68,718). Again, the estimate for the purpose of this benefits analysis assumes that half of all recalls will be prevented or about $1,250,000.

TABLE 16.—RECALLS IN 1994

| Fish | Hazards | Amount | Total |
|---|---|---|---|
| Canned tuna | Filth, decomposed, punctured cans, short weight. | 6,599 cases | $150,687 |
| Crab | L. monocytogenes | 16,156 lbs | 64,624 |
| Escolar fish | Decomposed, sc ombroid, illness | 1,719 lbs | 1,614 |
| Herring, salted Schmaltz | L. monocytogenes | 1,200 lbs | 1,740 |
| Hilsha fish | Salmonella | 2,000 lbs | 2,100 |
| Lobster | L. monocytogenes, salmonella | 25,920 lbs | 243,648 |
| Mahi mahi, fresh | Decomposed | 575 lbs | 834 |
| Nova chips | L. monocytogenes | 54 lbs | 157 |
| Oysters, shellstock | V. vulnificus | 9,219,430 lbs | 1,843,886 |
| Oysters, shucked | V. vulnificus | 21,944 lbs | 87,776 |
| Sardines, flat fillets | Rusty, leaky, decomposed | 33,600, 13 oz cans | 50,400 |
| Smoked catfish, salmon, sturgeon, tuna | L. monocytogenes | 1,060 lbs | 2,963 |
| Tuna steaks | Decomposed | 7,110 lbs | 11,477 |
| Total | | | 2,461,906.00 |

e. *Injunctions.* Injunctions are the most severe form of domestic penalties whereby a firm is enjoined from producing/distributing a product until a violation is remedied. There are approximately 5 injunctions by FDA against seafood products each year costing the firm an average of about $70,000 and FDA an average of about $30,000 each or about $500,000 per year. These costs include court costs, analytical testing costs, inspections costs, and lost production costs. Again, if this rule reduced injunctions by half, societal savings would be $250,000.

Total enforcement benefits are the sum of all of the reduced enforcement costs estimated to be approximately $20 million per year.

7. Other Benefits

Commenters also mentioned benefits including better process control (resulting in lower production costs) and improved employee morale.

FDA believes that there may be ''re-engineering'' types of benefits associated with these regulations. For both seafood and other foods for which HACCP has been implemented, FDA has received information that firms have found cost-saving innovations in other areas as they implement HACCP. These innovations are considered trade secrets by firms and thus, their description (actual process innovations) and quantification is impossible as firms have not released this data into the public domain. This phenomenon involves unexpected savings and efficiencies as a result of establishing a new system in a processing operation. The majority of firms that have previously instituted HACCP reported that they believed that the advantages they derived from HACCP were worth the costs to them in terms of better control over their operations, better sanitation, and greater efficiencies, such as reduced waste. Virtually all foresaw long-term benefits from operating under HACCP.

Improved employee morale depends on how HACCP is implemented. If, for example, employees are (1) participating in day-to-day monitoring of critical control points, (2) allowed through corrective action plans to participate in corrective actions including shutting down a line when a critical limit has been exceeded, and (3) are rewarded for this decision rather than penalized or forced to rigorously defend their actions, then employee morale may increase. Such an increase in morale, if valid, may lead to greater productivity. However, it is in the direct financial interest of every company to maintain employee morale such that any additional benefit from this regulation is likely to be small.

A final benefit will be realized for finfish where processing plants and vessels, in an effort to control for histamine formation, keep fish cooled from harvest to retail. This will simultaneously decrease the decomposition rate that causes seafood to be thrown out because of organoleptic problems. The same situation exists relative to cooked, ready-to-eat products and smoked fish. One retailer cited losses of 4 percent to 8 percent of all seafood because of decomposition. If some of this decomposition begins prior to arrival at the retail level and is reduced in any degree by this

regulation, benefits could potentially be large.

However, FDA recognizes that there is also a short term cost (e.g., as molluscan shellfish harvesters attempt to supply processors with untagged shellfish or from vessels without sanitary facilities aboard and find the harvest rejected). The same will also be true for finfish which have not been properly temperature controlled from harvest to processor. These harvests will be discarded although this behavior is not expected to occur often, or more than once in any instance.

*D. Costs and Benefits of Sanitation*

A portion of the costs and benefits of this rule derive from the improvements in the facilities and CGMP's in seafood plants. Although all food manufacturing plants are required to produce food under sanitary conditions now, FDA's experience, and that of others, indicate that many seafood processors are not producing seafood under those conditions. The sanitation, monitoring, and recordkeeping provisions of this rule are expected to drive processors to improve their sanitation conditions and thus reduce the need for FDA to enforce CGMP's through regulatory actions. These provisions will produce net increases in societal welfare with accompanying costs and benefits.

Current goods manufacturing practices include such things as cleanliness and habits of personnel, the conditions of buildings and facilities, equipment, production and process controls, and conditions of warehousing and distribution of the product. It is difficult to differentiate between costs and benefits that are HACCP-related and those that are sanitation-related. For example, processors are required under HACCP to keep records that show that CGMP's such as ''Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling $a_w$ that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act'' are being followed (see 21 CFR 110.80(a) (2) and (4)). However, the benefits derive from making plant and processing changes, uncovering problems in processing due to recordkeeping and taking corrective action which prevents hazardous seafood from being sold. Thus, HACCP and CGMP's are inextricably intertwined and it is difficult to calculate the marginal benefits and marginal costs of each.

*E. Costs and Benefits Attributable to Foreign Governments*

FDA has reported the portion of the increased costs that are expected to be passed on to U.S. consumers by foreign processors. The justification for this action is that FDA has not included safety benefits that foreign consumers may enjoy when foreign firms that export to the United States introduce HACCP into their plants. FDA has also included, as a benefit of this regulation, reduced enforcement actions toward products produced by foreign firms and reduced illnesses that U.S. consumers suffer from imported seafood.

In a benefit-cost analysis, costs and benefits are attributable to choices made among competing options. However, in this rule, there are difficulties in assigning the costs and benefits to choices made by FDA to require HACCP of domestic and foreign seafood processors. This difficulty arises because other countries either already require HACCP or have indicated that they will do so in the near future—for both their domestic and imported seafood products. No costs or benefits should be ascribed to choices made by the U.S. Government in this rule that affect firms already complying with foreign regulations, if the regulations are the same and no changes need to be made to be in compliance with the U.S. regulation.

Thus, foreign firms in those countries who export to the United States may be required to comply first with the U.S. plan or first with their own country's plan; the timing is impossible to predict. However, FDA does have evidence from the European Union that the seafood produced by the following countries (at least seafood for export) have met the EU standard for HACCP— Albania, Australia, Austria, Belgium, Brazil, Canada, Chile, Columbia, Denmark, Ecuador, England, Faro Is., Finland, France, Germany, Greece, Holland, Iceland, Indonesia, Ireland, Italy, Japan, Luxembourg, Mexico, Morocco, New Zealand, Norway, Peru, Philippines, Sweden, Taiwan, Thailand, and Turkey.

*F. Conclusion*

As the above analysis demonstrates, FDA finds that the estimated benefits exceed the estimated costs. The estimated costs are approximately one third of those in the PRIA, ranging from $677 million to $1.488 billion. These estimated costs were based primarily on the reports of some seafood firms and modeling done by FDA experts based on their experience with HACCP but also considered the study done under contract with NMFS. The benefits range from $1.435 billion to $2.561 billion and include benefits from safety, nutrition, increased consumer confidence, rent seeking activities, exports, and reduced enforcement costs.

*G. Final Regulatory Flexibility Analysis*

The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses. In the PRIA, FDA listed for comment a series of regulatory options on how to grant regulatory relief for small firms. In that document, FDA defined small firms as having less than $1 million in annual gross revenue (for non-shrimp processors) and less than $2 million for shrimp processors. In the PRIA, regulatory options for small business relief included:

(1) Requiring HACCP-type controls for those critical control points in individual plants that have a history of failure.

(2) Exempting very small processors from the requirements in the proposed regulatory option.

(3) Allowing a longer implementation period such that HACCP requirements may be phased in over a longer period of time.

(4) Providing generic HACCP plans (without mandatory control points) for certain types of operations, providing federal verification, or less frequent monitoring of critical control points.

FDA received a large number of comments on these options and on the costs that small businesses would incur as a result of the proposed option.

The agency has fully considered all of the comments received on its regulatory flexibility analysis and has responded to these comments in the full RIA. What follows is a summary of FDA's major conclusions from the analysis.

FDA received comments on whether there should be exemptions for processors based on either the size of the processor or the degree of risk associated with the product or process. For example, one commenter supported the exemption of small firms on the basis that small firms that represent 75 percent of the industry in terms of the number of plants, produce less than 10 percent of the seafood consumed.

FDA has concluded that there should be no exemptions for small firms. Small processors often engage in relatively high risk seafood processing, and an exemption based on size could inappropriately exempt high risk operations. An exemption based on risk might entail knowing which seafood might be responsible for a reported and confirmed illness. The agency finds however that because underreporting and skewed reporting of foodborne

illnesses occurs it is not always directly possible to relate the reported illnesses to risk. This subject is also discussed at length in the preambles to both the proposed and final rule.

One comment recommended that no firms be completely exempt, but that some firms be subject to different HACCP requirements depending on size. The smaller the firm, the less strict the record-keeping, testing, and monitoring requirements. The use of a short form for recordkeeping and informal monitoring was supported in some comments.

Again, this is a topic that is extensively covered in the preamble to the final rule. FDA notes that HACCP depends on the degree of risk and complexity of processing and that HACCP requirements for each plant are calibrated based on these factors. Whether the plant is large or small, if there are few hazards and simple processes, HACCP requirements are inherently minimal. If there are no hazards, no HACCP plan is required. Overall, however the agency believes that many smaller firms are associated with simpler processes and that the HACCP system already accommodates the commenter's concern.

In the long run, as processors adopt HACCP and attempt to pass costs on to consumers, the retail price of seafood will rise by less than 1 percent. In the absence of an increase in consumer demand that may result from this regulation, as the price of seafood rises, consumers will purchase less seafood. As producers fail to sell all of the seafood offered at the higher price, output must fall. Moreover, output must decrease in the highest cost sector of the industry, generally small processors. Although it is possible that small processors will cut back production but stay in business, the small profit margins of some small seafood producers strongly imply that the reduction in output will come about because small processors go out of business. For every one percent increase in the price of seafood, approximately 140 small processors could go out of business. The estimated number comes from the following calculation. FDA has estimated that as costs are passed on, HACCP will raise the price of seafood to consumers. The price elasticity of demand, which is the percentage change in quantity purchased divided by the percentage change in price, is estimated to be −0.37 for seafood (Ref. 227). A one percent increase in the price consumers pay for seafood should therefore reduce the quantity purchased by 0.37 percent (1 percent times −0.37). FDA believes that the entire reduction in output attributable to HACCP will be borne by small processors who go out of business. Although close to 80 percent of seafood processors are classified as small, small processors account for only 10 percent of total industry output (Ref. 228). In the case of a 0.37 percent decline in total processing output represents a decline in the output of small processors of 3.7 percent (0.37 percent divided by 0.10). If the decline in the number of processors were proportional to the decline in the output of small processors, the reduction in the number of processors would be 3.7 percent in the case of a 1 percent price increase. FDA is uncertain as to what price increase will actually occur.

The agency finds that the number of small seafood processors that go out of business will be determined by the cost per unit (or per plant) of implementing HACCP, the effect of HACCP on seafood prices, the ability of small plants to pass costs on to consumers, the current practices of the plants and the implementation time. The analysis has assumed that the regulation will have no positive effect on the demand for seafood. If the regulation in fact increases consumer confidence in seafood sufficiently to increase the demand for seafood, then the effect on small business would be less.

Although the economic impact on small firms is difficult to predict, many small firms should be able to implement HACCP at low cost, as they have already fulfilled many of its basic requirements. The closer a firm's current practices are to HACCP, the lower the cost of HACCP and the more likely is firm survival. Some small firms occupy market niches that allow them to pass on more of their costs than the industry average, increasing their likelihood of survival.

The effect of HACCP on small seafood processors depends on their costs of compliance and on the changes in the relative price of seafood. FDA expects the relative price increase attributable to HACCP to be small. For many small firms, the flexibility built into the regulation strongly implies that HACCP costs will be low. In consideration of small firms, the agency has extended the effective date to 2 years from publication. FDA will also be publishing a Guide that will provide small processors with valuable information for developing and implementing HACCP. Additionally, the agency, in cooperation with Sea Grant Universities and others through the Seafood HACCP Alliance, will be providing to small firms assistance on training and other needs.

FDA recognizes that HACCP is an innovative regulatory system that has not been applied on a large scale to ongoing commercial enterprises in the United States. For this reason all of the agency's estimates of firm behavior, costs and benefits necessarily involve substantial uncertainty. As explained in this Regulatory Impact Analysis, FDA has used modeling techniques and informed judgements rather than firm empirical data to estimate many effects. In order to determine the accuracy of these estimates, and also to assist in possible mid-course corrections, FDA and HHS plan to conduct an evaluation study during the first few years after the effective date of these regulations. This study could focus on each major type of one-time or continuing compliance cost, on different types of firms, on different sizes of firms (with particular attention to the smallest firms), and on both costs required by the regulation and on costs that firms may incur unnecessarily. It could also address the ability of firms to understand and implement HACCP properly, and any other problems that may impede rapid and inexpensive implementation. This study could also include an exploratory analysis of benefits, addressing both improvements in processing as measured by elimination of hazards and, to the extent permitted by existing data systems, early trends in reported incidence of illness caused by seafood.

## V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (59 FR 4142, January 28, 1994). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment, and that an environmental impact statement is not required.

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List of Subjects

*21 CFR Part 123*

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

*21 CFR Part 1240*

Communicable diseases, Public health, Travel restrictions, Water supply.

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

1. New part 123 is added to read as follows:

## PART 123—FISH AND FISHERY PRODUCTS

### Subpart A—General Provisions

Sec.
123.3 Definitions.
123.5 Current good manufacturing practice.
123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.
123.7 Corrective actions.
123.8 Verification.
123.9 Records.
123.10 Training.
123.11 Sanitation control procedures.
123.12 Special requirements for imported products.

### Subpart B—Smoked and Smoke-Flavored Fishery Products

123.15 General.
123.16 Process controls.

### Subpart C—Raw Molluscan Shellfish

123.20 General.
123.28 Source controls.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242l, 264).

## Subpart A—General Provisions

### § 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(d) *Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) *Fishery product* means any human food product in which fish is a characterizing ingredient.

(f) *Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g) *Importer* means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) *Preventive measure* means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) *Process-monitoring instrument* means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) *Scombroid toxin-forming species* means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) *Shall* is used to state mandatory requirements.

(o) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of

molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) *Shellstock* means raw, in-shell molluscan shellfish.

(q) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(r) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(s) *Smoked or smoke-flavored fishery products* means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

**§ 123.5 Current good manufacturing practice.**

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

**§ 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan.**

(a) *Hazard analysis.* Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with § 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with § 123.8(a)(1).

(e) *Products subject to other regulations.* For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) *Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

**§ 123.7 Corrective actions.**

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

**§ 123.8 Verification.**

(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 123.6(c).

(2) *Ongoing verification activities.* Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) *Corrective actions.* Processors shall immediately follow the procedures in § 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) *Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

(d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of § 123.9.

**§ 123.9 Records.**

(a) *General requirements.* All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) *Record retention.* (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the

results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) *Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) *Tags.* Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

(f) *Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

**§ 123.10 Training.**

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3); The trained individual need not be an employee of the processor.

**§ 123.11 Sanitation control procedures.**

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) *Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.

(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

**§ 123.12 Special requirements for imported products.**

This section sets forth specific requirements for imported fish and fishery products.

(a) *Importer verification.* Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate

foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.

(d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

## Subpart B—Smoked and Smoke-flavored Fishery Products

### § 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

### § 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

## Subpart C—Raw Molluscan Shellfish

### § 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

### § 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in § 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in § 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by State and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with § 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

## PART 1240—CONTROL OF COMMUNICABLE DISEASES

2. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

### § 1240.3 General definitions.

* * * * *

(r) *Molluscan shellfish.* Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, by

redesignating the existing text as paragraph (a) and adding the word ''molluscan'' before the word ''shellfish'' the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

**§ 1240.60 Molluscan shellfish.**

* * * * *

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Dated: October 3, 1995.

David A. Kessler,

*Commissioner of Food and Drugs.*

Donna E. Shalala,

*Secretary of Health and Human Services.*

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December 18, 1995

# Part III

# Department of Justice

## Bureau of Prisons

## 28 CFR Part 540

## Correspondence Between Confined Inmates; Final Rule

**DEPARTMENT OF JUSTICE**

**Bureau of Prisons**

**28 CFR Part 540**

**[BOP–1042–F]**

**RIN 1120–AA38**

## Correspondence: Correspondence Between Confined Inmates

**AGENCY:** Bureau of Prisons, Justice.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Bureau of Prisons is amending its regulations on correspondence to provide unit managers with the authority to approve correspondence in certain circumstances between inmates in different federal institutions. These amendments are intended to provide for the continued efficient and secure operation of the institution.

**EFFECTIVE DATE:** December 18, 1995.

**ADDRESSES:** Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

**FOR FURTHER INFORMATION CONTACT:** Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 514–6655.

**SUPPLEMENTARY INFORMATION:** The Bureau of Prisons is amending its regulations on correspondence (28 CFR part 540, subpart B). A final rule on this subject was published in the Federal Register October 1, 1985 (50 FR 40109) and was amended on February 1, 1991 (56 FR 4159).

Current provisions in § 540.17 specify that in instances where correspondence is permissible between inmates confined in separate institutions, the Wardens of both institutions must approve of the correspondence. In order to make better use of staff resources, the Bureau is revising the introductory text and paragraph (b) of this section to designate the unit managers in both institutions as the approving officials in instances where both inmates are housed in federal institutions and both inmates are either members of the same immediate family or are parties or witnesses in a legal action in which both inmates are involved. As revised, paragraph (b) designates the Wardens of both institutions as the approving officials where one of the inmates is housed in a non-federal institution or if approval is being granted on the basis of exceptional circumstances. As a conforming change, reference in the introductory text to the Warden as the approving official in exceptional circumstances has been removed.

Because the circumstances permitting the approval by the unit manager of correspondence between inmates are ordinarily fact specific (i.e, the other inmate is either a member of the immediate family, or is a party or witness in a legal action in which both inmates are involved), no adverse impact on inmates is anticipated. Approval based upon other exceptional circumstances remains with the Warden.

The Bureau of Prisons has determined that this rule is not a significant regulatory action for the purpose of E.O. 12866, and accordingly was not reviewed by the Office of Management and Budget. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (Pub. L. 96–354), does not have a significant impact on a substantial number of small entities.

The Bureau is publishing this regulation as an interim rule in order to implement streamlining measures through more efficient use of staff while still soliciting public comment. Members of the public may submit comments concerning this rule by writing to the previously cited address. These comments will be considered before the rule is finalized.

List of Subjects in 28 CFR Part 540

Prisoners.

Kathleen M. Hawk,

*Director, Bureau of Prisons.*

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(p), part 540 in subchapter C of 28 CFR, chapter V is amended as set forth below.

**SUBCHAPTER C—INSTITUTIONAL MANAGEMENT**

## PART 540—CONTACT WITH PERSONS IN THE COMMUNITY

1. The authority citation for 28 CFR part 540 is revised to read as follows:

Authority: 5 U.S.C. 301, 551, 552a; 18 U.S.C. 1791, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

2. In § 540.17, the introductory text and paragraph (b) are revised to read as follows:

### § 540.17 Correspondence between confined inmates.

An inmate may be permitted to correspond with an inmate confined in any other penal or correctional institution if the other inmate is either a member of the immediate family, or is a party or witness in a legal action in which both inmates are involved. Such correspondence may be approved in other exceptional circumstances, with particular regard to the security level of the institution, the nature of the relationship between the two inmates, and whether the inmate has other regular correspondence. The following additional limitations apply:

* * * * *

(b)(1) The appropriate unit manager at each institution must approve of the correspondence if both inmates are housed in Federal institutions and both inmates are members of the same immediate family or are a party or witness in a legal action in which both inmates are involved.

(2) The Wardens of both institutions must approve of the correspondence if one of the inmates is housed at a non-Federal institution or if approval is being granted on the basis of exceptional circumstances.

[FR Doc. 95–30641 Filed 12–15–95; 8:45 am]

BILLING CODE 4410–05–P

federal register

Monday
December 18, 1995

# Part IV

# Environmental Protection Agency

**Workshop on Trace Metals Analysis; Notice**

**40 CFR Parts 136 and 141**

**Method Flexibility and Streamlining Approval of Analytical Methods; Public Meeting; Proposed Rule**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–5346–4]**

## Workshop on Trace Metals Analysis

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Notice of meeting.

**SUMMARY:** The Office of Water is sponsoring two workshops to aid attendees in resolving the problems associated with the sampling and analysis of trace metals, including the difficulty in precluding contamination. These workshops will be held in conjunction with the Public Meetings on Method Flexibility and Streamlining Approval of Analytical Methods at 40 CFR Part 136 announced concurrently in the Federal Register.

**DATES:** EPA will conduct the Trace Metals Workshops on Wednesday, January 24, 1996, in Boston, Massachusetts and on Tuesday, February 13, 1996, in Chicago, Illinois. Registration for each workshop will begin at 10:00 AM. Each workshop will be held from 12:00 PM to 5:00 PM.

**ADDRESSES:** The workshop on January 24, 1996, will be held in the O'Neill Auditorium, Thomas P. O'Neill Jr. Federal Building, 10 Causeway Street, Boston, Massachusetts. The workshop on February 13, 1996, will be held in the Morrison Room, Metcalfe Building, 77 West Jackson, Chicago, Illinois

**FOR FURTHER INFORMATION CONTACT:** Questions concerning this notice can be directed to Marion Thompson by phone at (202)260–7117 or by facsimile at (202)260–7185.

**SUPPLEMENTARY INFORMATION:** Meeting arrangements are being coordinated by DynCorp, Inc. For information on registration, contact Cindy Simbanin, 300 N. Lee Street, Suite 500, Alexandria, VA 22314. Phone: (703)519–1386. Facsimile number: (703)684–0610. Space is limited and reservations are being taken on a first come, first served basis. No fees will be charged to attend.

Hotel reservations for Massachusetts may be made by contacting the Holiday Inn-Government Center in Boston at (617)742–7630. Guest rates are $101 single and $121 double occupancy, including tax. Reservations must be made by January 5, 1996, and you must specify that you are affiliated with USEPA/TM to qualify for the quoted rate.

For the Chicago meeting, hotel reservations may be made by contacting Marriott Reservations at (800)228–9290. Guest rates are $91 single and double occupancy. These rates are subject to applicable state and local taxes. Reservations must be made by January 20, 1996, and you must reference the event as the EPA TM Meeting and request the Chicago Marriott-Downtown in order to qualify for the group rate.

Accommodations are limited at each location, so please make your reservations early. The hotels are within walking distance of the meeting facilities.

### Background

The USEPA Office of Water's interest in trace metals determinations has been driven by the development of ambient water quality criteria (WQC) in response to Congressional mandates in the 1987 Water Quality Act. Ambient water quality criteria require determinations of metals at levels significantly lower than those required by technology-based effluent limits or achievable by routine environmental laboratory analyses.

### Agenda Topics

The Office of Water's purpose in sponsoring these workshops is to assist State and Regional authorities, regulated community, and commercial laboratories in understanding the requirements and techniques necessary to determine trace metals at EPA's ambient WQC levels. These workshops will focus on sampling and analysis techniques, data review, and quality assurance measures necessary to support reliable trace metals measurements for data gathering and compliance monitoring purposes.

Tudor T. Davies,

*Director, Office of Science and Technology.*

[FR Doc. 95–30570 Filed 12–15–95; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 136 and 141

**[FRL–5346–3]**

### A Public Meeting on Method Flexibility and Streamlining Approval of Analytical Methods

**AGENCY:** U.S. Environmental Protection Agency (EPA).

**ACTION:** Notice of meeting.

**SUMMARY:** The Office of Science and Technology within EPA's Office of Water is conducting two public meetings on approaches to method flexibility and streamlining the proposal and promulgation of analytical methods at 40 CFR Part 136 under Section 304(h) of the Clean Water Act and 40 CFR Part 141 of the Safe Drinking Water Act. These 304(h) streamlining public meetings will be held in conjunction with the Trace Metals Workshops announced concurrently in the Federal Register.

These two public meetings follow the first public meeting on this topic held on September 28, 1995, in Seattle, Washington. The Seattle meeting was announced in an FR notice titled, ''A Public Meeting and Availability of Documents on Streamlining Approval of Analytical Methods at 40 CFR Part 136 and flexibility in Existing Test Methods'' [FRL–5294–6]. This FR notice provided extensive supplementary information regarding the 304(h) streamlining effort and made available several supporting documents. The supporting documents and a summary of the Seattle meeting can be obtained through the address given in this notice.

**DATES:** EPA will conduct the public meetings on 304(h) streamlining on Thursday, January 25, 1996, in Boston, Massachusetts and on Wednesday, February 14, 1996, in Chicago, Illinois. Registration for each meeting will begin at 8:00 AM. Each meeting will be held from 9:00 AM to 5:00 PM.

**ADDRESSES:** The meeting on January 25, 1996, will be held in the O'Neill Auditorium, Thomas P. O'Neill Jr. Federal Building, 10 Causeway Street, Boston, Massachusetts. The meeting on February 14, 1996, will be held in the Morrison Room, Metcalfe Building, 77 West Jackson, Chicago, Illinois.

**FOR FURTHER INFORMATION CONTACT:** Questions concerning this notice can be directed to Marion Thompson by phone at (202) 260–7117 or by facsimile at (202) 260–7185.

**SUPPLEMENTARY INFORMATION:** Meeting arrangements are being coordinated by DynCorp, Inc. For information on registration, contact Cindy Simbanin, 300 N. Lee Street, Suite 500, Alexandria, VA 22314. Phone: (703) 519–1386. Facsimile number: (703) 684–0610. Space is limited and reservations are being taken on a first come, first served basis. No fees will be charged to attend.

Hotel reservations for Massachusetts may be made by contacting the Holiday Inn-Government Center in Boston at (617) 742–7630. Guest rates are $101 single and $121 double occupancy, including tax. Reservations must be made by January 5, 1996. When making reservations, you must specify that you are affiliated with USEPA/TM to qualify for the quoted rate.

For the Chicago meeting, hotel reservations may be made by contacting Marriott Reservations at (800) 228–9290. Guest rates are $91 single and double occupancy. These rates are subject to applicable state and local taxes. Reservations must be made by January 20, 1996, and you must reference the event as the EPA TM Meeting and request the Chicago Marriott-Downtown in order to qualify for the group rate.

Accommodations are limited at each location, so please make your reservations early. The hotels are located within walking distance of the meeting facilities.

#### Background

Under Section 304(h) of the Clean Water Act, EPA is responsible for promulgating analytical methods at 40 CFR Part 136 for use in monitoring pollutant discharges. EPA uses these methods to support development of effluent guidelines promulgated at 40 CFR Parts 400–499, and both EPA and the regulated community use the methods for establishing compliance with National Pollutant Discharge Elimination System (NPDES) permits and other monitoring purposes. The methods approved for use at 40 CFR Part 136 have been developed by EPA, by industrial associations such as the American Society for Testing Materials, and by other governmental agencies such as the U.S. Geological Survey. In the past, the methods proposal and promulgation process has been cumbersome, and has not provided the flexibility to take advantage of new analytical technologies in a timely manner. In response to the Administration's Environmental Technology Initiative, EPA is proposing a comprehensive Section 304(h) streamlining initiative to increase method flexibility to allow use of emerging technologies and to expedite the method approval process, to encourage development of new methods and technologies by organizations outside of EPA.

#### Agenda Topics

The purpose of the public meetings on 304(h) streamlining is to outline plans for method flexibility and for streamlining proposal and promulgation of new methods at 40 CFR Part 136 under Section 304(h) of the Clean Water Act, and to elicit stakeholder views regarding these plans. The following topics will be addressed at the public meetings:

- Increasing method flexibility to allow use of new technologies and to identify modifications that are acceptable within the scope of existing methods and do not require proposal of an alternate method—
  - —Interpretation of flexibility in existing 40 CFR part 136 methods
  - —Advantages and disadvantages of method flexibility (no flexibility, limited flexibility, and unlimited flexibility)
  - —Proposal to allow nearly unlimited ''front-end'' method modifications as long as the determinative technique is not changed and method performance is demonstrated to be equivalent
- Establishing standardized quality control (QC) and QC acceptance criteria to support determination of method equivalency
- Streamlining the method proposal process to take advantage of emerging analytical technologies in a timely manner—
  - —Standardized format for preparing new methods
  - —Three-tiered method validation process based on method use
  - —OST coordination of method submission and approval
- Harmonization of 40 CFR Part 136 methods with other EPA methods to allow standardization of methods across EPA programs
- Other streamlining issues—
  - —Standardized data elements for reporting, to allow access to Agency databases in a standardized data format
  - —Withdrawal of 40 CFR Part 136 methods that contain outdated technologies
  - —Incorporating new methods into the Federal Register by reference and making them available through other suitable venues, to reduce publication expense

The Office of Ground Water and Drinking Water, which is within EPA's Office of Water, is also developing approaches to increasing method flexibility and streamlining the approval of analytical methods at 40 CFR Part 141

under sections 1401 and 1445 of the Safe Drinking Water Act (SDWA). To better coordinate these efforts within the Office of Water, EPA will discuss flexibility and streamlining approaches for 304(h) and drinking water methods at these two public meetings. EPA believes the public will benefit from a joint meeting, because the flexibility and method approval issues, the regulated contaminants and the methods currently approved at Parts 136 and 141 are very similar. EPA notes, however, that the supporting documents that are available with this notice were developed only for 304(h) methods and within the requirements of the CWA. The approaches and specifically allowing unlimited ''front-end'' modifications might not be appropriate for methods approved under the SDWA. In contrast to the 304(h) documentation, less front end flexibility in sample collection and work-up procedures and more flexibility in the determinative measurement steps may be appropriate for SDWA compliance methods. Despite these potential differences in method flexibility approaches between 304(h) and SDWA methods, EPA believes there is a significant benefit in conducting public meetings on the perspectives of both programs.

Tudor T. Davies,

*Director, Office of Science and Technology.*

[FR Doc. 95–30555 Filed 12–15–95; 8:45 am]

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federal register

Monday
December 18, 1995

# Part V

# Department of Transportation

## Research and Special Programs Administration

## 49 CFR Part 106

## Direct Final Rule Procedure; Petitions for Rulemaking; Proposed Rule

**DEPARTMENT OF TRANSPORTATION**

**Research and Special Programs Administration**

**49 CFR Part 106**

**[Docket No. RSP–1, Notice No. 95–15]**

**RIN 2137–AC75**

## Direct Final Rule Procedure; Petitions for Rulemaking

**AGENCY:** Research and Special Programs Administration (RSPA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** To further the goals of Executive Order 12866 on Regulatory Planning and Review, and in response to the recommendations of the National Performance Review and the Administrative Conference of the United States, RSPA is proposing to implement a new and more efficient procedure for adopting noncontroversial rules. This ''direct final rule'' procedure involves issuing a final rule that provides notice and an opportunity to comment, with a statement that if RSPA does not receive a significant adverse comment or notice of an intent to file a significant adverse comment, the rule will become effective on a specified date without further publication of the text of the rule. RSPA would publish a subsequent document in the Federal Register to confirm that no significant adverse comment was received, and reiterate the effective date. If a significant adverse comment or notice of an intent to file a significant adverse comment were received, RSPA would publish a document in the Federal Register before the effective date of the direct final rule withdrawing the rule or a part of the rule.

RSPA also proposes to amend its rulemaking procedures to: Specify in more detail the required contents of a petition for rulemaking; and provide that petitions for rulemaking and petitions for reconsideration will be reviewed and acted upon by the Associate Administrator and that decisions of the Associate Administrator may be appealed to the Administrator.

**DATES:** Comments must be submitted no later than February 16, 1995.

**ADDRESSES:** Address comments to the Dockets Unit (DHM–30), RSPA, U.S. Department of Transportation, Washington, DC 20590–0001. Comments should identify the docket and notice number and be submitted, when possible, in five copies. Persons wishing to receive confirmation of receipt of their comments should include a self-addressed, stamped postcard. The Dockets Unit is located in Room 8421 of the Nassif Building, 400 Seventh Street S.W., Washington, DC 20590–0001. Office hours are 8:30 am to 5:00 pm Monday through Friday, except on public holidays when the office is closed.

**FOR FURTHER INFORMATION CONTACT:** Nancy E. Machado, Office of the Chief Counsel, RSPA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001; Telephone (202) 366–4400.

**SUPPLEMENTARY INFORMATION:** In Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735; October 4, 1993), the President set forth the Administration's regulatory philosophy and principles. The Executive Order contemplates an efficient and effective rulemaking process, including the conservation of limited government resources for carrying out its regulatory functions. Furthermore, ''Improving Regulatory Systems,'' an Accompanying Report of the National Performance Review, recognized the need to streamline the regulatory process and recommended the use of ''direct final'' rulemaking procedures to reduce needless double review of noncontroversial rules.

The former Administrative Conference of the United States (ACUS) adopted Recommendation 95–4, ''Procedures for Noncontroversial and Expedited Rulemaking,'' which endorses direct final rulemaking as a procedure that can expedite rules in appropriate cases. (*See* 60 FR 43108; August 18, 1995.) ACUS studied the efficiency, adequacy and fairness of the administrative procedures used by Federal agencies in carrying out administrative programs, and made recommendations for improvements to the agencies, collectively or individually, and to the President, Congress, and the Judicial Conference of the United States. ACUS found direct final rulemaking appropriate where a rule is expected to generate no significant adverse comment. ACUS defined a significant adverse comment as one where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change.

Under the direct final rulemaking procedure, an agency would issue a final rule with a statement that, if the agency received no significant adverse comments, the rule becomes effective automatically at a specified time after publication of the direct final rule without going through another round of intra- and inter-agency review. If a significant adverse comment were received, the agency would withdraw the rule before the effective date and issue a notice of proposed rulemaking. As noted in the report, ''this approach avoids the second round of clearances and review, which otherwise delays rules, wastes time, and should be superfluous * * * Theoretically, the second review ought to be very quick, but clearing any document through numerous government offices takes time. The paper shuffling also wastes reviewers' time by requiring them to look at something twice when once would have sufficed.'' (''Improving Regulatory Systems,'' p. 42.)

In responding to both the letter and the spirit of the Executive Order and the NPR Recommendations, the Secretary of Transportation has directed administrations within the Department of Transportation to focus on improvements that can be made in the way in which they propose and adopt regulations.

RSPA is proposing to adopt a new § 106.39 that provides for the use of direct final rule procedures for noncontroversial rules, such as minor, substantive changes to regulations; incorporation by reference of the latest edition of technical or industry standards; extensions of compliance dates; and other noncontroversial rules. RSPA intends to continue issuing certain final rules with no opportunity for comment; these include editorial changes and designation of hazardous substances as hazardous materials, as required by the Comprehensive Environmental Response, Compensation, and Liability Act. RSPA solicits comment on the advisability of using direct final rules for these categories of rules, as well as suggestions for other types of rules that could be issued as direct final rules.

When RSPA believes that a rulemaking in these categories is unlikely to result in significant adverse comment, it would use the direct final rule procedure. The direct final rule would advise the public that no significant adverse comments are anticipated and unless significant adverse comment or intent to submit a significant adverse comment is received, in writing, within a certain period of time (generally 60 days), the rule will become effective on a specified date (generally 90 days after publication). If no significant adverse comments are received, RSPA would issue a subsequent document advising the public that no significant adverse comments were received, and that the

rule will become, or did become, effective on the date previously specified in the direct final rule. Direct final rules would not be subject to petitions for reconsideration under 49 CFR 106.35.

If RSPA received a significant adverse comment or notice of intent to file a significant adverse comment, RSPA would publish a document in the Federal Register withdrawing the direct final rule, in whole or in part. If RSPA believed it could incorporate the adverse comment in a subsequent direct final rulemaking, without generating further significant adverse comment, it could do so. If RSPA believed that the significant adverse comment raised an issue serious enough to warrant a substantive response in a notice-and-comment process, it could publish a notice of proposed rulemaking, following the procedures provided in 49 CFR 106.11–106.29. Publishing the rule as a proposal gives an opportunity to comment to persons who may not have commented earlier because they wanted the rule to go into effect immediately. If a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule (for example where a rule deletes several unrelated regulations), RSPA would adopt as final those parts of the rule that were not the subject of a significant adverse comment.

RSPA is proposing to adopt ACUS's definition of ''significant adverse comment.'' (The U.S. Coast Guard adopted this definition in its recently issued final rule on direct final rulemaking, 60 FR 49222; Sept. 22, 1995.) Specifically, a significant adverse comment would be one that explains why the rule would be inappropriate, including a challenge to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. Comments that are frivolous or insubstantial would not be considered adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the commenter states why the rule would be ineffective without the additional change.

RSPA would amend § 106.3 to clarify that RSPA's Chief Counsel has the delegated authority to conduct rulemaking proceedings. This authority has been delegated to the Chief Counsel in RSPA Order 1100.2A (May 19, 1992.) Specifically, the Chief Counsel has been delegated authority to ''develop and issue rulemaking documents, other than final rules, for procedural rules, such as enforcement, preemption, general definitions, etc.''

RSPA also proposes to amend § 106.17 to clarify the procedures for participation by interested parties in the rulemaking process.

RSPA also is proposing to amend § 106.31 to specify in more detail the required contents of a petition for rulemaking. In this way, RSPA hopes to provide clear guidance to those who would like to participate in the rulemaking process by availing themselves of this mechanism. Establishing clear procedures will reduce the number of incomplete petitions filed with RSPA; furthermore, well-prepared, detailed petitions will ease RSPA's job and enable it to process petitions in a timely and efficient manner. In particular, proposed § 106.31(c) would state that, if the proposed action has a potential impact on the regulated industry or other entities, the Associate Administrator may request the petitioner to submit information and data concerning that impact to assist in rulemaking analyses required under Executive Orders 12866 and 12612, the Regulatory Flexibility Act, the Paperwork Reduction Act and the National Environmental Policy Act. This proposal is consistent with ACUS Recommendation 86–6, Petitions for Rulemaking, which suggests how agencies may improve the handling of petitions for the issuance of rules. *See* 51 FR 46985; Dec. 30, 1986.

RSPA also proposes to amend 49 CFR 106.31, 106.33, 106.35 and 106.37 to provide that petitions for rulemaking and petitions for reconsideration be filed with the appropriate Associate Administrator, who will review and issue determinations granting or denying the petitions in whole or part. RSPA also proposes to add a new § 106.38 to provide that any interested party may appeal a decision of the Associate Administrator, issued under § 106.33 or § 106.37, to the Administrator.

Rulemaking Analyses and Notices

*Executive Order 12866 and DOT Regulatory Policies and Procedures*

This proposed rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and was not reviewed by the Office of Management and Budget. The rule is not considered a significant rule under the Regulatory Policies and Procedures of the Department of Transportation [44 FR 11034]. Because of the minimal economic impact of this proposed rule, preparation of a regulatory impact analysis or a regulatory evaluation is not warranted.

*Executive Order 12612*

This action has been analyzed in accordance with Executive Order 12612 (''Federalism''), and RSPA has determined that preparation of a federalism assessment is not warranted.

*Regulatory Flexibility Act*

I certify that this proposal will not, if promulgated, have a significant economic impact on a substantial number of small entities. This certification is subject to modification as a result of a review of comments received in response to this proposal.

*Paperwork Reduction Act*

There are no information collection requirements in this proposed rule.

*Regulation Identifier Number (RIN)*

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 106

Administrative practice and procedure, Hazardous materials transportation, Oil, Pipeline safety.

In consideration of the foregoing, 49 CFR Part 106 is proposed to be amended as follows:

## PART 106—RULEMAKING PROCEDURES

1. The authority citation for part 106 would continue to read as follows:

Authority: 33 U.S.C. 1321; 49 U.S.C. 5101–5127, 40113, 60101–60125; 49 CFR 1.53.

**§§ 106.31, 106.33, 106.35, 106.37 [Amended]**

2. Sections 106.31(a), 106.33, 106.35(b), (c), and (d) and 106.37 would be amended by adding the word ''Associate'' immediately before the word ''Administrator'' wherever it appears.

3. In § 106.3, a new paragraph (d) would be added to read as follows:

**§ 106.3 Delegations.**

* * * * *

(d) Chief Counsel.

4. In § 106.17, paragraph (a) would be revised to read as follows:

**§ 106.17 Participation by interested persons.**

(a) Any interested person may participate in rulemaking proceedings by submitting comments in writing containing information, views or arguments in accordance with instructions for participation in the rulemaking document.

* * * * *

5. In § 106.31, paragraph (b) would be revised and new paragraphs (c) and (d) would be added to read as follows:

**§ 106.31 Petitions for rulemaking.**

* * * * *

(b) Each petition filed under this section must—

(1) Summarize the proposed action and explain its purpose;

(2) State the text of the proposed rule or amendment, or specify the rule proposed to be repealed;

(3) Explain the petitioner's interest in the proposed action and the interest of any party the petitioner represents; and

(4) Provide information and arguments that support the proposed action, including relevant technical, scientific or other data as available to the petitioner, and any specific known cases that illustrate the need for the proposed action.

(c) If the potential impact of the proposed action is substantial, and information and data related to that impact are available to the petitioner, the Associate Administrator may request the petitioner to provide—

(1) The costs and benefits to society and identifiable groups within society, quantifiable and otherwise;

(2) The direct effects (including preemption effects) of the proposed action on States, on the relationship between the Federal Government and the States, and on the distribution of power and responsibilities among the various levels of government;

(3) The regulatory burden on small businesses, small organizations and small governmental jurisdictions;

(4) The recordkeeping and reporting requirements and to whom they would apply; and

(5) Impacts on the quality of the natural and social environments.

(d) The Associate Administrator may return a petition that does not comply with the requirements of this section, accompanied by a written statement indicating the deficiencies in the petition.

6. Section 106.35 would be amended by revising the first sentence of paragraph (a) to read as follows:

**§ 106.35 Petitions for reconsideration.**

(a) Except as provided in § 106.39(d), any interested person may petition the Associate Administrator for reconsideration of any regulation issued under this part. * * *

* * * * *

7. Part 106 would be amended by adding a new § 106.38 to read as follows:

**§ 106.38 Appeals.**

(a) Any interested person may appeal a decision of the Associate Administrator, issued under § 106.33 or § 106.37, to the Administrator.

(b) An appeal must be received within 20 days of service of written notice to petitioner of the Associate Administrator's decision, or within 20 days from the date of publication of the Associate Administrator's decision in the Federal Register.

(c) It is requested, but not required, that three copies of the appeal be submitted to the Administrator.

(d) Unless the Administrator otherwise provides, the filing of an appeal under this section does not stay the effectiveness of any rule.

8. Part 106 would be amended by adding a new § 106.39 to read as follows:

**§ 106.39 Direct final rulemaking.**

(a) Where practicable, RSPA will use direct final rulemaking to issue the following types of rules:

(1) Minor, substantive changes to regulations;

(2) Incorporation by reference of the latest edition of technical or industry standards;

(3) Extensions of compliance dates; and

(4) Other noncontroversial rules where RSPA determines that use of direct final rulemaking is in the public interest and that a regulation is unlikely to result in adverse comment.

(b) The direct final rule document that is published in the Federal Register will state that unless RSPA receives a significant adverse comment, or notice of intent to file a significant adverse comment, within a specified time, generally 60 days after publication, the rule will become effective on a specified date, generally 90 days after publication.

(c) For purposes of this section, a significant adverse comment is one which explains why the rule would be inappropriate, including a challenge to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. Comments that are frivolous or insubstantial will not be considered adverse under this procedure. A comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the commenter states why the rule would be ineffective without the additional change.

(d) If no significant adverse comment or notice of intent to file a significant adverse comment is received, RSPA will issue a subsequent document advising the public of that fact and that the rule will become, or did become, effective on the date previously specified. Direct final rules issued under this section are not subject to petitions for reconsideration under § 106.35.

(e) If RSPA receives a significant adverse comment or notice of intent to file a significant adverse document, RSPA will publish a document in the Federal Register withdrawing the direct final rule in whole or in part, and may incorporate the adverse comment into a subsequent direct final rule or may publish a notice of proposed rulemaking. A notice of proposed rulemaking will provide an opportunity for public comment, generally a minimum of 60 days, and will be processed in accordance with §§ 106.11–106.29.

Issued in Washington, D.C. under the authority delegated in 49 CFR part 1.53 and RSPA Order 1100.2A (May 19, 1992).

Dated: December 12, 1995.

Judith S. Kaleta,

*Chief Counsel.*

[FR Doc. 95–30669 Filed 12–15–95; 8:45 am]

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federal register

Monday
December 18, 1995

# Part VI

# Department of the Treasury

## Office of the Under Secretary for Domestic Finance

## 17 CFR Parts 400 and 420

## Government Securities Act Regulations: Large Position Rules; Proposed Rule

**DEPARTMENT OF THE TREASURY**

**Office of the Under Secretary for Domestic Finance**

**17 CFR Parts 400 and 420**

**RIN: 1505–AA53**

## Government Securities Act Regulations: Large Position Rules

**AGENCY:** Office of the Under Secretary for Domestic Finance, Treasury.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of the Treasury (''Department'' or ''Treasury'') is publishing for comment proposed rules that would establish a new Part 420 providing recordkeeping and reporting requirements pertaining to large positions in certain Treasury securities. The proposed regulations are being issued pursuant to the Government Securities Act Amendments of 1993, which authorized the Secretary of the Treasury to prescribe rules requiring persons holding, maintaining or controlling large positions in to-be-issued or recently-issued Treasury securities to keep records and file reports of such large positions.

The proposed recordkeeping rules require any person or entity that controls a position equal to or greater than $2 billion in a Treasury security to maintain and preserve certain records that enable the entity to record, compile, aggregate and report large position information. The proposed reporting rules require entities to file a large position report with the Federal Reserve Bank of New York if their reportable position equals or exceeds the large position threshold in a particular Treasury security as specified by the Treasury in a notice requesting large position information. The Department's proposed large position rules are intended to provide the Treasury and other securities regulators with information on concentrations of control that would enable them to better understand the possible reasons for apparent significant price distortions and the causes of market shortages in certain Treasury securities.

**DATES:** Comments must be received on or before February 16, 1996.

**ADDRESSES:** Comments should be sent to: Government Securities Regulations Staff, Bureau of the Public Debt, Department of the Treasury, 999 E Street, N.W., Room 515, Washington, D.C. 20239–0001. Comments received will be available for public inspection and copying at the Treasury Department Library, Room 5030, Main Treasury Building, 1500 Pennsylvania Avenue, N.W., Washington, D.C. 20220.

**FOR FURTHER INFORMATION CONTACT:** Ken Papaj, Director, or Don Hammond, Assistant Director, Government Securities Regulations Staff, at 202–219–3632. (TDD for the hearing impaired is 202–219–3988.)

**SUPPLEMENTARY INFORMATION:**

### I. Background

*Statutory Authority*

In response to certain events that occurred in the government securities market in 1990–1991—short squeezes in the two-year Treasury notes issued in April and May 1991 and bidding improprieties in several auctions of Treasury securities in 1990–1991 [1]—Congress included in the Government Securities Act Amendments of 1993 (GSAA) [2] a provision granting the Department the authority to write rules for large position reporting in certain Treasury securities. Specifically, Section 104 of the GSAA, which amended Section 15C of the Securities Exchange Act of 1934,[3] authorizes the Treasury to adopt rules requiring specified persons holding, maintaining or controlling large positions in to-be-issued or recently-issued Treasury securities to maintain records and file reports regarding such positions.[4] This provision is intended to improve the information available to the Treasury and other regulators regarding very large positions of recently-issued Treasury securities held by market participants and to ensure that regulators have the tools necessary to monitor the Treasury securities market.

The GSAA gave the Department wide latitude and discretion in determining several key features and conditions that would form the underpinnings of the large position recordkeeping and reporting rules. Among the most significant of these features were: defining which persons (individually or as a group) hold, maintain or control large positions; determining the minimum size of positions to be reported; determining what constitutes ''control'' for the purposes of the rules; prescribing the manner in which positions and accounts are to be aggregated; identifying the types of positions to be reported; determining the securities that would be subject to the rules; and developing the form, manner and timing of reporting. The proposed rules address these points.

*Participation in Rulemaking Process/ Solicitation of Comments*

In formulating the process to be used to develop large position rules, the Department, early on, made a decision to obtain the views of the market participants who would be directly affected by such regulations. We also decided that it would be useful to explain the Department's initial thoughts on the structure and purposes of the rules, to explore various conceptual approaches to designing a large position recordkeeping and reporting system and to obtain industry comment and feedback before actually drafting proposed rules. We believed that market participant involvement in the rulemaking initiative from its outset would facilitate greater understanding of, and support for, the final rules when implemented.

Accordingly, in order to involve market participants and other interested parties at the earliest phase of the rulemaking process, the Department issued an Advance Notice of Proposed Rulemaking (ANPR) on January 24, 1995.[5] The ANPR addressed several key issues, concepts and approaches to be considered in developing large position recordkeeping and reporting rules, and solicited comments, suggestions and recommendations regarding how the requirements should be structured. Rather than repeating that information here, readers are encouraged to review the ANPR to familiarize themselves with these issues. The ANPR also contains a detailed historical background that provides a fuller understanding of the events and circumstances that resulted in the establishment of this regulatory authority, the purposes and objectives to be achieved from large position rules, and the Congressional intent behind this legislation.

The 90-day comment period on the ANPR was extended, in response to an industry request, for an additional 30 days through May 24, 1995.[6] In response to the ANPR, the Department received seven comment letters which are summarized in the next section of the preamble.

[1] For a discussion of the events that gave rise to the establishment of large position reporting authority, see the *Joint Report on the Government Securities Market*, Department of the Treasury, Securities and Exchange Commission and Board of Governors of the Federal Reserve System, (1992); Salomon Brothers Inc. Press Releases dated August 9 and 14, 1991; S. Rep. No. 103–109 (July 27, 1993); H.R. Rep. No. 103–255 (September 23, 1993); and 60 FR 4576 (January 24, 1995).

[2] Pub. L. No. 103–202, 107 Stat. 2344 (1993).

[3] 15 U.S.C. 78o-5.

[4] Pub. L. No. 103–202, Sec. 104; 107 Stat. 2344, 2346–2348; 15 U.S.C. 78o-5(f).

[5] 60 FR 4576 (January 24, 1995).

[6] 60 FR 20065 (April 24, 1995).

In addition to considering the views expressed by the commenters to the ANPR, Department staff has also consulted with various regulatory agencies (i.e., staff of the Securities and Exchange Commission (SEC), the Commodities Futures Trading Commission, the Board of Governors of the Federal Reserve System and the Federal Reserve Bank of New York (FRBNY)) in developing this proposal. We intend to continue to involve interested market participants and the regulatory agencies in the development of the large position regulations through the completion of the rulemaking process. Accordingly, the Department welcomes and strongly encourages market participants to submit comments on the proposed rules and any suggestions for reducing burdens on the industry while still achieving the objectives of the rules.

*Balancing of Regulatory and Market Needs*

The Department has attempted to strike a balance between achieving the purposes and objectives of the statute and minimizing costs and burdens to those entities affected by the regulations. For the following reasons, we believe that the rules being proposed successfully achieve this balance.

First, the proposed rules envision reports to be submitted only in response to a specific request by the Treasury for large position information on a particular Treasury security issue. Under this approach, reporting should be an infrequent event required primarily in response to pricing anomalies in a specific Treasury security rather than a regular, on-going process resulting from a certain pre-determined large position threshold being exceeded in a broader range of securities.

Second, the proposed rules establish a minimum large position threshold of $2 billion below which the Treasury would not request large position reports. As a result, we believe that very few entities would be required to file large position reports.

Third, the recordkeeping requirements would generally not apply to any reporting entity (as defined in the rules) that did not control a position that equalled or exceeded $2 billion in a Treasury security.

Fourth, for those entities currently subject to recordkeeping rules of the SEC, the Treasury or the bank regulatory agencies, the proposed rules impose only minor additional recordkeeping requirements and only if certain conditions are present. Finally, the proposed rules adopt several concepts from the Treasury's auction rules (e.g., positions to be included in a reportable large position, definition of a reporting entity and method of aggregating positions) which have been in effect since March 1993 and are understood by many of the major participants in the Treasury securities market.[7] This should reduce the time and costs that affected entities will need for training their employees on the large position rules.

*Scope of Large Position Rules*

It is important for all market participants to recognize that large position rules create a requirement to maintain records and report information about such positions. However, these requirements only apply to entities that hold or control (i.e., exercise investment discretion) large positions, as determined by the Department, in specific Treasury security issues. Accordingly, there is no obligation on executing brokers and dealers to report large trades nor is there an affirmative duty to inform their customers of the large position recordkeeping and reporting requirements being proposed as part of this rulemaking.

The Department reiterates that large positions are not inherently harmful and there is no presumption of manipulative or illegal intent on the part of the controlling entity merely because a position is large enough to be subject to the Treasury rules. In addition, the proposed rules do not establish trading or position limits or require the identification of large traders or the reporting of large trades. Finally, the GSAA specifically provides that the Department shall not be compelled to disclose publicly any information required to be kept or reported for large position reporting. In particular, such information is exempt from disclosure under the Freedom of Information Act.[8]

## II. Comments Received in Response to ANPR

Seven comment letters were received in response to the ANPR. The letters were submitted by two trade organizations, one primary dealer, a Federal Reserve Bank, a bank regulatory agency, a commercial bank and an insurance company.[9] While all comments are summarized below, each letter did not necessarily address all aspects of the ANPR.

Six commenters were largely supportive of a large position reporting system provided that such a reporting system would not be overly burdensome for market participants. However, one commenter opposed the concept of large position reporting entirely. This party believed that ''the current auction reporting rules have already addressed adequately the prior problems with market manipulation,'' and that an unintended consequence of large position rules could be fewer participants in the government securities market, which, in turn, would result in higher borrowing costs.

*On-Demand vs. Automatic Reporting*

Five commenters supported an on-demand reporting system which would be triggered by specific requests from the Treasury for large position information on a particular Treasury security. One respondent, however, favored an automatic, regular reporting system triggered whenever a reporting entity's holdings in a security reached a certain threshold.

The primary reason expressed by those commenters favoring an on-demand reporting system was that this approach would be significantly less burdensome and costly than an automatic reporting system. Many commenters noted that an automatic reporting method would impose more complex systems development requirements and greater operational costs due to the need for daily monitoring of positions across multiple securities. In addition, automatic reporting could create a disincentive to buy and hold large positions that exceed a fixed reporting threshold. Finally, on-demand reporting was viewed by several respondents as being better able to address price distortions and provide more useful information since the request for large position information would be targeted to specific market situations and security issues.

The respondent favoring an automatic reporting system argued that on-demand reporting ''would be difficult and costly to communicate to all relevant parties.'' The commenter also felt that on-demand requests might trigger unwanted market reactions, while a regular reporting system ''would provide more consistent monitoring of the market and would be less confusing to the market over time.''

*Definition of Reporting Entity*

Six commenters were in agreement that the definition of ''reporting entity'' should conform with the definition of ''bidder'' as defined in the uniform

[7] Uniform Offering Circular for the Sale and Issue of Treasury Bills, Notes and Bonds, 31 CFR Chapter II, Subchapter B, Part 356.

[8] 5 U.S.C. 552(b)(3)(B).

[9] Public Securities Association, Investment Company Institute, Chemical Securities Inc., the Federal Reserve Bank of New York, the Board of Governors of the Federal Reserve System, Chemical Bank, and CNA Insurance Companies, respectively.

offering circular.[10] The aggregation rule with regard to affiliates, for example, is a concept with which many market participants are already familiar and provides an appropriate model for a large position reporting rule. Similarly, the commenters supported a process, similar to the ''separate bidder'' process provided for in the uniform offering circular, by which separately managed entities within a corporate or partnership structure can request that Treasury recognize them as separate reporting entities.

*Definition of ''Control''*

There was similar concurrence on the definition of ''control.'' Nearly all parties that addressed this issue expressed the view that control should be evidenced by either proprietary ownership or investment discretion over a Treasury security. The commenters were in similar agreement that the concept of ''control'' should not be extended to merely beneficial ownership or custodians. Specifically, the commenters held that entities acting as custodians should not be required to report positions in Treasury securities over which they have no investment discretion.

*Definition of ''Large'' Position*

The commenters generally felt that the large position threshold should be large enough to both detect concentrations of control and avoid overly burdensome, frequent reporting by market participants. Opinions were fairly evenly divided on whether a securities position should be defined as ''large'' based on a percentage of the total outstanding issue size or a specific dollar amount.

Those preferring a percentage standard commented that this method is a better indicator of concentration of control than a straight dollar standard, given the large range of issue sizes among various maturities. Suggested percentages ranged from 10 percent to 25 percent of a particular issue. One commenter felt that, if an automatic reporting system is implemented, the percentage should be consistent with the Treasury's auction rules, i.e., ''large'' should be defined as 35 percent of the securities awarded in an auction.

Those favoring a fixed-dollar threshold did so on the basis of clarity, ease of administration, and, consequently, improved compliance. Suggested dollar thresholds ranged from $2 billion, to correspond to the net long position reporting threshold for auctions,[11] to $4–5 billion. Some commenters also expressed the view that the threshold should be larger under an automatic reporting system than under an on-demand system to minimize the compliance burden associated with automatic reporting. One commenter said that there is no need to define ''large position'' in advance under an on-demand reporting system (the large position threshold would be specified in the Treasury notice requesting large position reports), and there may be no ''one-size-fits-all'' threshold.

*Definition of ''Recently-Issued''*

The scope of Treasury's large position reporting authority is limited to recently-issued and to-be-issued Treasury securities. Discretion to define the term ''recently-issued'' was given to the Treasury. Although the commenters differed somewhat on the specifics of the preferred meaning of ''recently-issued,'' all agreed that it should include the ''on-the-run'' [12] (most-recently issued) security of a particular type. Opinions were fairly evenly divided on whether ''recently-issued'' also should include only the most recent ''off-the-run'' issue or the two most recent ''off-the-run'' issues. One commenter said that there is no need to define ''recently-issued'' under an on-demand reporting system.

*Types of Securities Covered*

Based largely upon the presumption that Treasury note and bond issues are more likely to be ''on special'' [13] (in short supply) than bills, two commenters said that bills should be excluded from large position reporting. One such commenter also cited the complexity, burdens and costs ''associated with implementing systems to track positions on weekly-issued securities * * *.'' One commenter, however, said that all types of Treasury securities (bills, notes and bonds) should be eligible for reporting, ''since any type of Treasury security could be the subject of a concentration of control.'' Another commenter took a more neutral position, saying that excluding bills may be appropriate, ''but a good case will need to be made that short interest is always small relative to the net supply, or that supply conditions and price movements preclude sustained and possibly injurious squeezes.''

*Components of a Position*

The four commenters addressing this issue agreed as a starting point that net long settled cash positions should be included in a ''large position.''

Two commenters said that the definition of ''large position'' should be consistent with the definition of ''net long position'' in the uniform offering circular.[14] Both felt that financing transactions (repos, securities borrowed, etc.) should be excluded from the large position calculation since it is too difficult to apply the concept of control to securities used in such transactions. Calculating a net financing position is particularly difficult, according to one of the commenters. Examples provided included the problems of differentiating deliver-out from hold-in-custody and tri-party repurchase agreements, and of separating overnight repos from term repos, particularly those with mandatory substitution provisions. Both of these commenters, however, could support a requirement to report financing transactions on a gross basis if Treasury believes financings need to be included.

The other two commenters felt that financing transactions should be included in the definition of a reportable position to encompass a wider range of transactions from which an entity can exert immediate control over a Treasury security. Both advocated reporting such transactions on a gross basis. One commenter noted that a position that might look flat on a net basis may in fact be exposed if fails become a problem. Moreover, the commenter contended, matched-book and tri-party repo activity might result in a small net position, and yet be used as a tool to achieve a short squeeze.

*Recordkeeping Requirements*

The issue of what records should be kept by reporting entities was largely unaddressed except that the commenters felt that these records, and their associated retention periods, should closely correspond to records already required to be maintained by reporting entities under existing securities and banking laws. Most respondents stated that reporting entities should not be required to keep records in electronic form, since such a

[10] 31 CFR 356.2 and Appendix A.

[11] 31 CFR 356.13(a).

[12] A Treasury security is considered to be ''on-the-run'' when it is the newest security issue of its maturity (e.g., in October the two-year note issued September 30 would be ''on-the-run'' while the two-year note issued August 31 would be ''off-the-run''). An on-the-run security is normally the most liquid issue for that maturity.

[13] When securities are ''on special,'' market participants desiring to borrow the particular security must accept an interest rate significantly lower than the prevailing repo rate for unspecified collateral. Conversely, the owners of the securities can finance their position at exceptionally low interest rates.

[14] 31 CFR 356.13(b).

requirement could be burdensome for entities that do not have systems for electronic recordkeeping.

III. Section-by-Section Analysis of Proposed Regulations

*A. Section 400.1. Scope of Regulations*

A new paragraph is proposed to be added to Part 400 to describe the statutory basis for the large position rules. The paragraph also states that the large position rules are located in Part 420.

*B. Part 420. Large Position Reporting*

1. Section 420.1

Applicability. This section sets out the scope of the large position recordkeeping and reporting rules by identifying the types of Treasury securities covered and by defining the universe of entities potentially affected. Section 420.1 reflects the Department's initial determination that all marketable Treasury securities—bills, notes and bonds—should be included within the scope of the rules. However, arguments have been made that features and characteristics of the bill market, such as the frequency of issues (i.e., weekly) and reopenings, the size of bill auctions and the availability of several instruments that are close substitutes for bills (e.g., various money market instruments), make it more difficult to accumulate concentrations of ownership of Treasury bills. Comments are specifically requested on whether Treasury bills should be included in the large position recordkeeping and reporting rules.

On its face, part 420 applies to any type of entity, foreign or domestic, that might control a large position in a specific Treasury security. This broad construct of potential application is consistent with the statutory purpose: ''Large position reporting also would be useful in assuring that regulators can monitor the positions of major market participants other than government securities brokers or dealers under certain circumstances. In particular, it will provide assurance that the government can compel disclosure of position information when necessary from all large market participants, including a group of relatively unregulated entities called 'hedge funds.' '' [15] As described in the preamble discussion of sections 420.3 and 420.4, the number of entities that may actually be affected by large position rules is significantly narrowed when the minimum size for a large position is applied.

We believe it is appropriate to exclude certain entities from the application of the rules based on the existing availability of position information on these organizations and/or concerns about the confidentiality of this information. Accordingly, paragraphs (b) and (c) of section 420.1 provide exemptions from part 420 to the holdings of foreign central banks, foreign governments, international monetary authorities and Federal Reserve Banks (FRBs). The exemptions for the foreign entities are limited to their respective positions maintained at the FRBNY. The exemptions are also consistent with the position expressed by the Senate and House during consideration of the legislation.[16]

One commenter, responding to the ANPR, expressed concern about granting exemptions specifically to these foreign entities. However, the Department believes the proposed approach is appropriate since the exemptions are limited in their scope by applying only to the portion of the organization's position that is maintained at the FRBNY. Any positions held by the exempt entities at locations other than the FRBNY are not exempted and will be subject to the large position recordkeeping and reporting rules. The proposed exemption for those Treasury securities that FRBs hold and control for their own accounts is also based on the Department's access to this information.

The Department recognizes that on rare occasions it may be necessary to request large position information on Treasury securities that are not within the parameters of the proposed definition of recently-issued (paragraph 420.2(g)) but that are within the scope of the intent of the statute. For example, in August 1991, Treasury might have sought large position information on the April 1991 two-year note, given that the security was still ''on special'' in the repurchase agreement market and there was a significant concentration of ownership. While this security, at that time, would have been outside the scope of the currently proposed definition, the Department believes it is necessary to reserve the right to collect large position information in such circumstances. Accordingly, we have included within the rule a reservation to request information on additional Treasury security issues consistent with the purposes of the GSAA.

2. Section 420.2

Definitions. This section provides for the definitions of terms that are integral to the large position rules. Unless otherwise defined in this section, terms used in part 420 have the same meanings provided in section 400.3.

''Control''—The concept of control revolves around three elements: beneficial ownership, possession (custody) and investment discretion. The beneficial owner is the party with the actual ownership interest in the Treasury security. The beneficial owner may or may not always be aware of its ownership position in a given security if it does not manage its own investments and it may not have possession of the Treasury securities even if it makes its own investment decisions (especially likely with book-entry Treasury securities). Possession or custody is evidenced by an organization's ability to service the securities directly (e.g., transfer the securities, receive interest and principal payments). The beneficial owner may perform this function for its own holdings, but the mechanics of book-entry Treasury securities require that a depositary institution act in this capacity on behalf of others at some level in the custody chain for all Treasury securities. Additionally, book-entry Treasury securities may involve more than one custodian in the holding of a specific security entitlement.[17] Investment discretion is the authority to make and execute decisions about the purchase, sale and retention of securities. In the institutional market for Treasury securities, which is of critical importance in developing large position reporting rules, the granting of investment discretion to an investment adviser to manage all or some portion of an entity's portfolio is common.

It is our view that, for the purposes of large position reporting, the most important criterion in the definition of control is that of investment discretion. While beneficial owners receive the economic benefit of holding a Treasury security, frequently, they do not make the decision to purchase/sell/retain the Treasury security and, as mentioned, may not, on a day to day basis, be aware

[15] H.R. Rep. 103–255, September 23, 1993, at pg. 25.

[16] 139 Cong. Rec. H–10967 (daily ed. November 22, 1993) Statement of Chairman Dingell on S. 422.

[17] The Federal Reserve Banks maintain book-entry security accounts for depository institutions and other entities such as government and international agencies and certain foreign central banks. In their book-entry accounts at the Federal Reserve, the depository institutions may maintain their own security holdings and holdings for customers, which may include other depository institutions, dealers, brokers, institutional investors and individuals. In turn, the depository institution's customers may maintain accounts for their customers. This creates a tiered chain of custodial relationships.

of their ownership interest. Since a purpose of large position reporting is to understand better any pricing anomalies for a particular Treasury security issue in a timely fashion, defining control based on beneficial ownership would not be particularly useful because a reporting entity could have difficulty assembling the information needed to file a large position report and would be potentially unaware of the reasons why the security involved was purchased.

Likewise, custody (without investment discretion) does not provide a good basis for determining control. A definition based on custody would most certainly involve multiple reporting of the same security position since each tier in the custody chain would be required to report. This approach would diminish the value of any large position reports received. Also, because under these circumstances the custodian would not be a party to the investment decision, reporting on the positions held in safekeeping would shed very little light on the objectives of the investor.

Therefore, Treasury has decided to define control as the authority to exercise investment discretion. This definition is supported in six of the seven comment letters. Investment discretion can be exercised by the beneficial owner, a custodian or an investment adviser. The party responsible for making investment decisions, regardless of where it is in the tiered system, is the most relevant reporting entity for large position reporting since the actions and objectives of the decision maker are what we are trying to determine. A single party exercising investment discretion for multiple beneficial owners could control a potentially large amount of Treasury securities without any single beneficial owner having a reportable position. Additionally, such investment advisers could possibly distribute custody of the securities in a manner that would keep any individual custodian below the reporting threshold. However, using the exercise of investment discretion as a measure of control, an investment adviser's aggregate positions would be reportable regardless of the number of beneficial owners or custodians involved and would be treated separately from any positions over which the beneficial owners had retained investment discretion. Finally, a definition of control based on investment discretion is consistent with the treatment of investment advisers under the uniform offering circular.[18]

Following this definition, an investor would only be responsible for reporting its proprietary holdings if it retained investment discretion over the positions. This approach would avoid double reporting of these positions. Additionally, a custodian would only have responsibility for reporting on any large positions for which it had investment discretion. A custodian would not have any obligation to report on positions for which it maintained securities solely in a safekeeping capacity.

''Reporting Entity''—This term is defined to be consistent with the definition of a bidder in the uniform offering circular.[19] This concept provides for the treatment of all affiliated entities as a single entity for purposes of determining the quantity of Treasury securities controlled. Additionally, the definition permits specific affiliates to be treated separately or ''carved-out'' from the reporting entity based on stated principles of separateness.

Applying this approach, a ''reporting entity'' will aggregate each of the positions in a specific Treasury security that is held by itself and all affiliates that control positions, and will report a single position to the FRBNY. Any affiliate that exercises independent investment discretion, and whose position information is not available to other affiliates, will be permitted to report separately from the overall entity provided it has requested such a ''carve-out'' and received written recognition from the Treasury. Merely establishing ''Chinese walls'' or similar procedures is not sufficient. If an entity has already received such written recognition under the uniform offering circular, it will not have to reapply for the purposes of large position reporting.

Defining the term ''reporting entity'' based on the bidder concept from the auction rules has the advantage of relying on an existing body of regulations, thus minimizing confusion and the need for market participants to learn new rules. The bidder definition is well known to most large participants in the Treasury market (from their auction participation) and has functioned effectively since March 1993 when the rules were implemented. This approach was also endorsed in four comment letters.

This definition also introduces a new term, ''aggregating entity,'' which is defined separately. An aggregating entity is a single legal entity (e.g., a parent company or affiliate within a reporting entity) that may control elements of a large position. If an aggregating entity has no affiliates, then it is also a reporting entity. Each component of a reporting entity is individually an aggregating entity.

''Reportable Position''[20]—The scope of the definition of reportable position directly affects the complexity of calculating such a position and the amount of time needed to file a large position report. The definition of a reportable position should be broad enough to encompass the most significant ways that an investor may control a Treasury security issue, balanced against the difficulty and cost of compiling the information. Additionally, because of the complexity in defining this term, it is useful to base the definition, to the maximum extent feasible, on concepts familiar to market participants.

For participants in the Treasury securities market, a familiar concept is that of ''net long position'' in the uniform offering circular.[21] The uniform offering circular definition includes the par amount of: (1) Immediate (cash) positions; (2) when-issued positions for to-be-issued and reopened issues; (3) forward settling positions; (4) positions in futures contracts requiring delivery of the specific security; and (5) STRIPS (Separate Trading of Registered Interest and Principal of Securities) principal components of the specific security. This is an appropriate place to begin development of a reportable position because it is not only familiar to many market participants but also includes the most common elements of control in the cash market. The combination of these five elements is defined as the net trading position—the first component of a reportable position.

The Department is requesting that commenters specifically address the treatment of forward positions. While forward positions are a component of the net long position defined in the uniform offering circular, there may be reasons to exclude them from the definition of reportable position because forward positions may be less effective in controlling a security or may act to conceal settled positions. For example, the proposed large position rules permit a reporting entity to reduce the size of its settled position by the amount of a

[18] Treasury intends to clarify this treatment in a proposed rule in the near future.

[19] *See supra* note 10.

[20] A reportable position for the purposes of the large position rules differs from a reportable position for purposes of the uniform offering circular. In the uniform offering circular, a reportable net long position is a position that has met the necessary criteria to be reported on a tender. In the context of the large position rules, a reportable position defines the components of a potential large position.

[21] See supra note 14.

short forward settling position. Should this treatment be permitted? Treasury especially welcomes the views of market participants on this subject.

Options and certain futures contracts (i.e., cash-settled or those requiring delivery of securities other than the specific security that is the focus of large position reporting) continue to be excluded because they do not provide the holder with either immediate control or an effective way to manipulate the price of a specific security. For options, an entity would only gain control of the security at the time the position is exercised, at which time the security would become a component of a reportable position. Large positions in the excluded futures contracts are already reported to the Commodity Futures Trading Commission.[22] Thus, this information will be available to the Department and other regulatory agencies, if needed, without imposing additional reporting requirements.

Financing transactions are proposed to be included in a reportable position because of the important influence they have on the available supply of a Treasury security. The legislative history behind the large position reporting authority supports the inclusion of financings, especially repurchase agreements.[23] The approach for including financing transactions is addressed below in the definition of a gross financing position. The gross financing position is the second component of a reportable position.

Finally, the Department believes that a third component—''fails''—should be included in the definition of reportable position. An investor's net fails position (fails to receive less fails to deliver) indicates ownership rights to a security without the cost of financing. All fail positions should be included without differentiating between types of counterparties (i.e., broker-dealers, customers). A large ''fail-to-receive'' position may exacerbate, or benefit from, a squeeze by maintaining high demand for a specific security. In analyzing existing market discontinuities, the knowledge of the existence of any large net fail-to-receive positions could help determine the cause and potential resolution of a tight supply condition.

Commenters are also requested to address the treatment of fails. Specifically, the Department is interested in receiving comments on whether the proposed treatment of fails positions is more appropriate than excluding fails from the determination of a large position and instead requiring submitters of large position reports to disclose information about fails as a memorandum entry. Since a position that remains unsettled after its scheduled settlement date is not included in the computation of a net trading position, including fails may act to artificially increase the size of the reported position. This result is apparent if fails-to-deliver were to be a positive addition to a reportable position since a past settlement date short trade, unlike a short forward position, would not reduce the size of an entity's reportable position. Additionally, commenters are asked to consider whether fails should be treated differently from forwards given their similarities.

The sum of the net trading position, gross financing position and the net fails position is a reporting entity's total reportable position.

''Gross Financing Position''—To achieve the statutory intent, financing transactions should be included in a reportable position. The more difficult question is how to include them. Within the generic construct of financing transactions, there are multiple types of transactions including: repurchase and reverse repurchase agreements, securities borrowed and loaned, securities pledged and received in pledge, and any other form of credit collateralized by Treasury securities.

Since the intent of large position reporting is to obtain information about the control of Treasury security positions, an effective approach for incorporating financing transactions is to include them on a gross basis (no netting) in the reportable position of the entity that has received the securities. Under this approach, the seller/lender of the securities would not include the financing transaction in its calculation of the gross financing position since it would already have reflected the positions that provided it with control of the securities (i.e., cash positions, reverse repos) in the calculation. Reporting in this manner would provide regulators with information about the broader universe of market participants that had possible control of the Treasury security, regardless of how they might have subsequently financed or transferred it.

No differentiation is made in the computation between the types of financing transactions (e.g., repos, securities lending) since, despite different legal frameworks, they are generally equally effective ways of obtaining control. The first part of the gross financing position computation also does not differentiate between types of repos (e.g., overnight, term). As an example, a security that has been received through a reverse repo and contemporaneously repoed out to a third party will be included at the gross par amount of the reverse in the entity's long position. Gross reporting yields this result even though the security was no longer in the possession of the reporting entity since it had been contemporaneously repoed out. The proposed approach will result in the potential for multiple entities including a position for the same specific Treasury security in their respective computations and reportable positions. However, the resultant double counting is not considered to be a problem because it provides additional information about entities that have various legal claims to the security and that may potentially benefit from any possible market disruptions.

An optional exclusion is proposed that will permit a reporting entity to voluntarily exclude from the computation of its gross financing position certain securities received through financing transactions. This exclusion would apply to situations in which the securities received were subject to a right of substitution on behalf of the delivering counterparty, tri-party custodial relationships, or custody of the securities being retained by the party granting the legal interest in the securities (hold-in-custody). These Treasury securities would be eligible for exclusion based on a presumption that the receiving organization did not have effective control of the securities despite having ''received'' them. The exclusion is optional because its use, while benefiting the entity taking advantage of it, does not diminish the usefulness of the resultant large position reports. If it were made mandatory, many potential reporting entities might find it too costly and burdensome to differentiate information on financings at this level of detail. If the amount excluded is large enough to cause the reporting entity to fall below the reporting threshold, then a report should not be filed.

The gross financing position is then combined with the other two components of a reportable position to determine the total reportable position held by a reporting entity. For purposes of the calculation, all positions would be valued at the par amount of the securities involved.

''Large Position Threshold''—The large position threshold is the dollar amount of a reportable position at or above which the requirement to file a large position report is triggered. Since

[22] 17 CFR Parts 15 to 18.

[23] *See supra* note 15 at pg. 44.

the large position rules take an ''on-demand'' approach to reporting, the specific large position threshold for any given Treasury security issue may vary. However, since the threshold would not be known in advance, we believe that it will be beneficial to provide some certainty to market participants by setting a minimum dollar amount (''floor'')—$2 billion—below which reports would not be requested. Establishing a floor should minimize compliance costs. For example, many entities, based on this level of the floor, may decide that no modifications would be needed to their computer systems or trading strategies since the rule would not apply to them (i.e., the firms would not expect their positions ever to reach the floor amount). Of the six commenters who addressed this issue, three endorsed a variable threshold method (one respondent actually supported a fixed percentage method, which would lead to a variable dollar level since it would be based on the amount issued of a specific security).

''Recently-Issued''—Despite the determination that any large position reporting would be done on an on-demand basis, the Department believes that it is useful to set out a general description of which Treasury securities would be within the scope of the rule. For convenience, the definition of recently-issued includes when-issued securities from the time of announcement of the issue. Thus, when-issued securities would be considered the most recent issue of a security type. In response to the commenters and in consideration of the Treasury securities that could be of most interest to regulators, we have proposed that as a regular matter, recently-issued would be limited to the three most recent issues of a Treasury security (bill, note or bond) if issued quarterly or more frequently and the two most recent issues if issued less frequently. Currently, this latter condition exists only for the 30-year bond. The definition of recently-issued for this security, which is currently issued semi-annually, was limited to the two most recent issues because a three-most-recent definition would have, on a regular basis, encompassed a time period of nearly a year and a half. As discussed earlier, the Department intends to reserve the right to broaden the scope of this definition, on a limited exception basis, consistent with the purposes of the GSAA.

3. Section 420.3

Reporting. The provisions of this section require large position reports to be filed by the designated filing entity of any reporting entity that has a reportable position that equals or exceeds the large position threshold in a particular Treasury security issue as specified by the Department. This section also specifies the method by which Treasury will provide notice to the marketplace requesting large position reports, the specific information that must be provided on the large position reports, where they must be filed and the time frame for their submission. This section also permits either the Treasury or the FRBNY, acting as the Treasury's agent, to request additional information from a reporting entity if either organization, after analyzing the large position reports, requires further data to gain a more complete understanding of the extent and nature of the concentration of positions in a particular Treasury security. A sample reporting format for large position information is illustrated in Appendix B to the rule.

*Analysis of Alternative Reporting Methods*

The method of reporting large positions is a central issue in the development of large position rules, since the method selected will significantly affect the compliance burdens of, and costs incurred by, the entities subject to the large position regulations.

The Department evaluated two distinct approaches for reporting large position information: an ''automatic'' or regular reporting method and an ''on-demand'' reporting method. Under an automatic, regular reporting process, large position reports would be required to be filed whenever a reporting entity equalled or exceeded the large position threshold stated in the rules for any covered Treasury security. Depending upon the particular method used in a regular reporting system, reports could either be required on a one-time basis or they could continue to be required each day the entity exceeded the large position threshold and would cease only when its positions in the Treasury security fell below the threshold level. In contrast, in an on-demand reporting system, reports would be triggered by a notice from the Treasury requesting large position information on a specific issue of a Treasury security from those reporting entities whose positions at that time equalled or exceeded the large position threshold specified in the notice.

In evaluating the method of reporting that should be employed, the Department took into consideration the events that gave rise to Congress' grant of authority to prescribe large position reporting rules as well as the purposes and objectives of the statutory authority underlying such rules. The main focus of our analysis involved selecting the approach that best balanced the purposes of the statute and any new regulatory burdens that would be created. (Readers are referred to the ANPR for a more detailed discussion of these issues and other background information pertaining to large position reporting.)[24]

The primary purpose of any large position reporting system is to enable the Treasury and the other regulators to understand better the possible reasons for apparent significant price distortions and the causes of market shortages in certain Treasury securities. Large position reports are also intended to provide regulators with information on concentrations of control for market surveillance purposes and for enforcement of the securities laws, as well as to enable Treasury policy makers to make better decisions concerning any possible government actions that might be taken in response to apparent price anomalies. A critical factor in evaluating the two alternative large position reporting methods was the extent to which they would meet the overriding legislative and policy objective of strengthening the ability of the regulatory agencies to deter possible manipulation of the Treasury securities market.

*On-Demand Reporting System*

The requirements outlined in paragraph 420.3(a) reflect the Department's decision to propose an on-demand reporting system for large position information. Reports would be required in response to a specific request, issued by the Treasury, for large position information.

An on-demand reporting approach will enable the Department to target large position reporting to a specific issue of a Treasury security in response to particular circumstances or unusual market activity. This would ensure the availability of information for market surveillance and enforcement purposes in those specific instances where it is most needed, thus satisfying the primary objective of this regulatory authority, while obviating the need to collect information on securities that are not of interest. In contrast, under a regular reporting system, reports would be required when the large position threshold had been exceeded; therefore, reports would be filed even in situations where there were no price distortions, anomalies or evidence of possible

[24] *See supra* note 5.

market manipulation. This would result in unnecessary costs for, and burdens on, both market participants and the government. In addition, a regular reporting method could increase the possibility that investors would take deliberate actions to reduce their holdings of Treasury securities to avoid exceeding the ''large'' position reporting threshold. This could result in decreased market participation, reduced liquidity and increased borrowing costs.

An on-demand reporting system would avoid the need to set a uniform large position threshold that would apply to some or all Treasury issues as would be required under an automatic reporting approach. The Treasury would have the flexibility and latitude to establish a tailor-made large position threshold each time it requests large position reports. This permits a large position threshold to be based on the latest supply of, and market conditions for, a specific Treasury security, which can vary considerably.

On-demand reporting should be less onerous and costly for market participants. Any modifications to existing computer systems to compile, summarize, compare and report the positions would be less complex than for the required continual review of multiple securities positions under a regular reporting method. Under a regular reporting approach, firms would need to modify existing computer systems or develop entirely new systems to continuously collect, monitor and report positions in when-issued and recently-issued Treasury securities. Since reports would need to be filed whenever positions equalled or exceeded the large position threshold, the systems would have to be designed to compute the overall positions in a large number of separate Treasury security issues (approximately 23 separate CUSIPs [25] based on the definition of recently-issued in paragraph 420.2(g)) and then compare the amount of the positions to the large position threshold on a daily basis to determine if reports would have to be produced. There would be an even greater burden on those entities that would manually compile this information.

Recognition of the costs that would be imposed on market participants has been a critical consideration in our attempt to develop large position rules that strike a balance between regulatory oversight and market efficiency. We believe that an on-demand reporting system significantly minimizes the regulatory costs and burdens on market participants compared to those that would be incurred if the Treasury were to require regular reporting.

In analyzing the different reporting models, the Treasury also took into consideration the fact that a large segment of market participants who are likely to be subject to Treasury's large position reporting rules—the 37 primary dealers—already submit regular position reports to the FRBNY on a voluntary basis for on-the-run Treasury notes and bonds. By adopting an on-demand reporting system, we have attempted to minimize, as much as possible, any duplicate reporting by these entities.

*Triggering Event: Treasury Request for Information*

The provisions of paragraph 420.3(a) propose that the requirement to report large position information would be triggered by a notice issued by the Treasury specifically requesting such information. The notice would identify the specific Treasury security issue to be reported, the applicable large position threshold (in no case less than $2 billion) for that issue and the date or dates [26] as of which the large position information must be reported.

The notice requesting large position reports would be communicated by issuing a press release and subsequently publishing the notice in the Federal Register. Given the relatively short reporting deadline in the proposed rules, this two-pronged notice approach satisfies the dual objectives of operational efficiency and legal sufficiency. A Treasury press release has the advantage of achieving wide, timely distribution of the notice without a significant time lag. Although this approach relies on third-party services over which the Treasury has no control, it is reasonable to expect that the major news and financial publications and the various electronic financial wire services (e.g., Telerate, Reuters, Bloomberg, Knight-Ridder) would disseminate the Treasury notice as quickly as their respective technological capabilities allow. The electronic financial wire services and news publications can also be relied upon to accurately present the Treasury's request for large position information. We believe that any market participant, including a foreign entity, that may control a large position in a Treasury security is likely to subscribe, or have access, to one or more of the electronic financial wire services. Thus, the likelihood that the Treasury notice requesting large position reports would fail to come to the attention of a potential reporting entity is extremely remote.

The press release would include information about how to obtain a sample large position report and the name and telephone number of a Departmental contact person to answer questions about the report.

Since the Federal Register is the designated federal publication for providing official notice, publishing the Treasury notice in that document is legally sufficient for ''constructive notice'' of the request despite lagging the issuance of the press release.

*Designated Filing Entity*

Under paragraph 420.3(b), the designated filing entity is responsible for preparing and submitting the large position reports on behalf of a reporting entity in response to a Treasury notice requesting large position information. The identity of the designated filing entity must be given on any large position report submitted.

Each reporting entity, as defined in paragraph 420.2(i), whose reportable position equals or exceeds the large position threshold, must have one, and only one, designated filing entity. A reporting entity that consists of only one component is the designated filing entity. For those reporting entities that consist of multiple affiliates or aggregating entities, one entity must be selected to be the designated filing entity. That entity is responsible for receiving and compiling the large position information from each of the aggregating entities, computing the reportable position and preparing and filing the large position report.

An official authorized to file reports on behalf of the designated filing entity shall sign the large position report and certification attesting to the accuracy, completeness and reliability of the information being reported. This official must be one of the following: the chief financial officer, the chief operating officer, the chief executive officer, or the managing partner or equivalent of the designated filing entity. The contact person named on the large position report should also be a representative of the designated filing entity but need not be the authorized official.

Further, any designated filing entity is required, under the applicable provision in section 420.4, to make and maintain

[25] The CUSIP number is the unique identifying number assigned to each separate security issue and each separate STRIPS component.

[26] To understand the price and supply dynamics of the security under scrutiny better, the Treasury reserves the right to request that entities submit positions covering a multi-day, historical time frame rather than just one day.

additional records on behalf of the entire reporting entity.[27]

*Information Required on Large Position Reports*

Paragraph 420.3(c), together with Appendix B, sets forth the specific information that must be provided in the large position report. For those reporting entities that have a number of aggregating entities or affiliates, the amount to be reported for each of the positions is the total, combined net amount. All positions are to be reported as of the close of the business/transaction day for the date specified. In those instances where Treasury requests positions covering multiple dates, separate reportable position calculations must be submitted for each date. The rule does not require, nor does the Treasury intend, for firms to calculate their positions as of some specific point during the trading day. However, in order to meet the deadline for reporting, the designated filing entity may need to determine a cut-off time for foreign entities.

The following administrative information must be provided on the large position report:

(a) The name of the reporting entity;

(b) The address of the principal place of business of the reporting entity;

(c) The name and address of the designated filing entity;

(d) The description of the Treasury security being reported, including the CUSIP number;

(e) The date or dates for which the information is being reported (which should be the same date(s) as that (those) stated in the Treasury notice requesting the large position reports);

(f) The date the report was submitted;

(g) The name and telephone number of a contact person of the designated filing entity to whom questions can be directed regarding any information on the report;

(h) The name and title of the person authorized to submit the report (as previously described);

(i) A certification statement attesting to the accuracy, completeness and reliability of the information being submitted; and

(j) The signature of the authorized official specified in (h).

The following large position information must be reported in the exact order as noted:

(a) Line 1, cash/immediate net settled positions;

(b) Line 2, net when-issued positions for to-be-issued and reopened issues;

(c) Line 3, net forward settling positions, including next-day settling positions;

(d) Line 4, net positions in futures contracts that require delivery of the specific security that is the subject of the large position report (but not futures contracts for which the security that is the subject of the large position report is one of several securities that may be delivered and not futures contracts that are cash-settled);

(e) Line 5, net holdings of STRIPS principal components of the specific security that is the subject of the large position report;

(f) Line 6, the gross financing position, which is the sum of the gross par amounts of a security issue received from financing transactions (e.g., reverse repurchase transactions, bonds borrowed, securities received in pledge and collateralized credit extended);

(g) Line 7, net fails position, which is fails to receive less fails to deliver in the specific security issue; and

(h) Line 8, Total Reportable Position, which is the sum of lines 1–7.

All amounts must be reported in millions at par value. See Appendix B for a sample reporting format.

The large position report provides for two memoranda entries. Memorandum Entry #1 is the sum of the gross par amounts of a security issue delivered as part of a financing transaction (e.g., repurchase agreements, securities loaned, securities pledged and collateralized loans). This amount should not be included in the gross financing position (line 6) as noted in item (f) above. Memorandum Entry #1 is required.

Memorandum Entry #2 is to be reported by those entities that take the voluntary exclusion pursuant to paragraph 420.2(c) to reduce the gross financing position reported on line 6. The amount shown is the amount of securities received from financing positions over which the reporting entity does not have effective control due to arrangements such as third-party custodial structures, hold-in-custody relationships or substitution rights. This amount should not be included in the amount reported on line 6.

Lines 1–5 of the large position report are consistent with the items that determine the net long position for auction reporting purposes.[28] As with the auction rules, the amounts to be reported for each of the items on lines 1–5 are the net of any long and short positions, so that the entry can be a positive number (long position), a negative number (short position), which should be shown in parentheses, or zero (flat position). Only securities trades that have actually settled should be included in line 1, cash/immediate net settled positions. Accordingly, auction purchases that have not yet been settled or issued should be included in the total reported on line 2, when-issued positions.

For line 6, Gross Financing Position, netting of these positions is not permitted although certain items may be excluded. (See paragraph 420.2(c).) For reporting entities that take advantage of this limited exclusion, the gross financing position should not include the amount of security issues received from financing positions over which the reporting entity does not exercise control. Rather, the amount associated with the exclusion should be reported in the Memorandum Entry #2.

Line 7, Net Fails Position, can only be reported as a positive number (which indicates fails to receive exceed fails to deliver) or zero (which reflects fails to receive are totally offset by, or are less than, fails to deliver).

*Reporting Format*

Rather than designing and mandating a specific reporting form, the Treasury is proposing to allow the reporting entities to develop their own large position reports, provided the reports contain all of the required information as prescribed in the rules, in the order stated in Appendix B. By permitting the reporting entities to design their own large position report, firms will be able to integrate the report into their existing systems as they see fit and avoid the unnecessary burden of transferring the information from internally generated reports to a Treasury-mandated form. While firms will have a certain amount of latitude and discretion in designing a large position report, the information on the various positions that constitute the total reportable position must be reported in the order shown in paragraph 420.3(c) and in the sample/prototype report in Appendix B. This will facilitate analysis of the data. Failure to include any of the required information, including administrative information, on the large position report will constitute non-compliance with the rule.

*Filing of Large Position Reports: Where, When and How*

Pursuant to paragraph 420.3(d) the large position report must be submitted to the FRBNY. The report must be received before 12:00 noon, Eastern time, on the second business day after

[27] Since designated filing entities are also aggregating entities, they would also be required under §§ 420.4(b) or (c) to maintain records pertaining solely to their own securities transactions.

[28] *See supra* note 14.

the issuance of the Treasury press release requesting large position reports. Given that large position reports would generally be requested by the Department in response to certain market conditions or activity, the proposed rule has a fairly short response time for submission of the reports. The one and one-half day reporting deadline balances the need for timely information with the recognition that some time is required to compile the information. The reporting time frame should not present significant problems since the information would be derived from records required to be maintained by the reporting entities. Additionally, we understand that most large firms engaged in the securities business compile their positions on a daily basis. Finally, since reporting is ''on-demand,'' the filing of a large position report will be an exceptional event not requiring regular preparation.

The Treasury requests comments from market participants on the proposed reporting time frame, specifically concerning any potential obstacles, burdens or other factors that would make meeting the deadline problematic, and the extent of any extra costs that would be incurred.

The rule, in paragraph 420.3(d), also provides that the large position report may be filed in any manner or media (i.e., hard copy, facsimile or other electronic transmission) that is acceptable to the FRBNY. As mentioned earlier, the reporting entities are permitted to produce or generate their own large position reports.

*Follow-Up Inquiries*

The requirement to file a large position report in response to a specific Treasury notice requesting this information is expected to be an occasional event. The requirement is satisfied upon receipt of the report by the FRBNY within the required time frame and in the required format as prescribed in paragraph 420.3. The proposed rule does not impose a continuous reporting requirement. However, the Treasury and the FRBNY staff may contact a designated filing entity after receiving a large position report to discuss any aspect of the report, seek clarification of the information provided or request additional documents or information. The purpose of such inquiries or requests for data would be to understand the concentration of positions better. The Treasury or the FRBNY staff may also request further detail on any position reported, such as breaking out the gross financing position into its component parts or identifying repurchase agreements by their terms or types (e.g., overnight repos, term repos, tri-party repos, hold-in-custody repos). Reporting entities are required to make good faith attempts to respond to inquiries and provide any additional data requested in an expeditious manner.

*Testing of Large Position Reporting Systems*

The Department wishes to underscore the importance of accurate, reliable and timely reporting of large position information by affected market participants. As the agency of the Federal government most concerned with minimizing the interest cost on the public debt, the Treasury believes that the United States is best served by a liquid and efficient market for Treasury securities that is not overburdened with regulation, but, at the same time, is not viewed as being subject to manipulation. In developing these proposed rules, the Treasury has attempted to pursue a modest approach that balances the need for additional regulation with a desire to minimize the burdens on, and costs to, the industry and to preserve the efficiency of the Treasury securities market.

Compliance with these large position rules—the maintenance of reliable records and the accurate and timely reporting of large position information—is essential to preserving and strengthening the integrity of the Treasury securities market. One of the primary concerns with an on-demand reporting system is the increased potential for inaccurate or incomplete information on large positions due to unfamiliarity by market participants with the reporting requirements. Large position information will be extremely important for policymakers at Treasury, in consultation with other regulatory officials, in determining whether, and what course of, action should be taken to alleviate a concentration of control in a particular Treasury security. Thus, it is imperative that market participants fully understand and comply with the large position recordkeeping and reporting requirements.

To ensure that market participants remain knowledgeable about the rules, specifically how to calculate and report a reportable position, the Treasury intends to ''test'' the reporting system by requesting large position reports at least annually, regardless of market conditions for a particular security. The Treasury does not intend to notify market participants that its request for large position reports is merely a test. Commenters are asked to address this proposed treatment of ''test'' reporting. The notice and reporting requirements are proposed to be identical to a call for large position information in which the Department is concerned about price anomalies and concentrated ownership. ''Test'' reporting is consistent with the statutory purpose since the Department believes it is both necessary and appropriate to help ensure that an on-demand program of large position reporting is conducted effectively.

4. Section 420.4

Recordkeeping. Section 15C(f)(2) of the Securities Exchange Act of 1934 authorizes the Secretary to promulgate rules requiring large position holders to make and preserve records related to large position reporting requirements. Section 420.4 sets forth the proposed recordkeeping rules supporting large position reporting under that authority. The proposed recordkeeping rules are divided into two classes: (1) records required for entities that are currently subject to recordkeeping rules of federal securities or federal bank regulators (paragraph 420.4(b)); and (2) records required for all other entities, such as hedge funds, insurance companies, and pension funds (paragraph 420.4(c)).

Under paragraph 420.4(a)(1), the recordkeeping rules would apply to all aggregating entities that may control components of their respective reporting entity's reportable position as of the effective date of the final large position rules, but only if the aggregating entities' respective reporting entity had a reportable position in any Treasury security equal to or in excess of $2 billion (the minimum large position threshold) at any time during the prior two-year period ending 90 days after publication of the final rule. Thus, all reporting entities (through their respective aggregating entities) will be responsible for determining whether they have controlled a reportable position of at least $2 billion in a Treasury security during the two-year period. For some firms, this will necessitate a thorough review of their records to determine if their reportable positions reached that level.

In addition, under paragraph 420.4(a)(2), in instances where a reporting entity controlled a reportable position of at least $2 billion in a Treasury security during the two-year period, its designated filing entity will be required to submit a letter to the FRBNY certifying that it has in place, or will have in place by the effective date of the final rules, a recordkeeping system (including policies and procedures) capable of making, verifying the accuracy of, and preserving the requisite records. This

letter must be signed by one of the following officials of the designated filing entity: the chief financial officer, the chief operating officer, the chief executive officer, or the managing partner or equivalent. The letter must be received by the FRBNY within 120 days after publication of the final rule.

The Department believes this requirement would ensure that entities having a history of controlling large Treasury securities positions would have supporting records in place in the event their reportable positions reach an announced large position threshold for a specific issue, thereby triggering the submission of a large position report. These potential large position holders would have several months to develop methods to meet the proposed recordkeeping requirements since there will be a delayed effective date for the rules. Subsequent to the effective date of the rules, aggregating entities within a reporting entity that had not previously had a reportable position in a Treasury security equal to or greater than $2 billion but whose reportable position reaches or exceeds $2 billion would be subject to the large position recordkeeping requirements from that point forward.

Regardless of the date aggregating entities become subject to the recordkeeping rules, their being subject to the rules is based on whether the reportable position of their reporting entity reaches the large position threshold, not on whether the position of the aggregating entity itself reaches that threshold. Thus, an aggregating entity may be subject to the recordkeeping rules even though its own position has been substantially below the threshold.

*Entities Subject to Recordkeeping Rules of Federal Securities or Federal Bank Regulators (Paragraph 420.4(b))*

In developing the proposed recordkeeping rules, the Department sought to strike an appropriate balance between ensuring that large position holders maintain records that document and facilitate the generation of accurate reports and minimizing recordkeeping burdens on large position holders. Accordingly, the Department examined existing securities-related recordkeeping rules of the SEC, the Treasury, and the bank regulatory agencies to determine if the records required under those rules include the type of information necessary to create large position reports.

Specifically, the Department examined the following recordkeeping regulations: SEC recordkeeping regulations applicable to registered broker-dealers, registered investment advisors, and registered investment companies; Treasury recordkeeping rules applicable to registered government securities broker-dealers, financial institutions that have filed or should file notice as government securities broker-dealers, and depository institutions that hold government securities as custodians; and bank regulatory agency recordkeeping rules applicable to banks that conduct securities transactions for customers.[29]

The Department has determined that all of these recordkeeping rules require the affected entities to make and keep records of original entry (i.e., journals, blotters, or similar records) containing itemized records of all of the entities' securities transactions, including information pertaining to the amount and identification of each security or instrument. Records of original entry are basic, detailed records that cover, among other things, all transactions related to the components of a reportable position. Most of the existing regulations of the federal securities and federal bank regulators also require the affected entities to maintain order tickets or memos and various ledgers containing much of the same information required in the records of original entry.[30]

The proposed treatment of depository institutions that exercise investment discretion warrants specific discussion with respect to recordkeeping requirements because such entities are potential reporting entities. Depository institutions that exercise investment discretion are generally subject to the securities recordkeeping requirements of the bank regulatory agencies (12 CFR 12, 12 CFR 208, or 12 CFR 344), regardless of whether or not they exercise investment discretion within their trust departments.

In addition, for those rare cases in which depository institutions exercise investment discretion and act as custodians of government securities outside of their trust departments, the recordkeeping provisions of paragraph 450.4(c) of the GSA regulations also apply.[31] The Department views the information required by the recordkeeping rules of paragraph 450.4(c) as comparable to the basic information required in the records of original entry under the existing rules of the SEC, the Treasury, and the bank regulatory agencies.

The Department believes that reportable positions can be constructed relatively easily from the aforementioned records required by the federal regulatory agencies. As a result, the Department has decided, with respect to large position rules, not to propose any new recordkeeping rules for aggregating entities that are: (1) subject to the existing federal recordkeeping requirements, and (2) not designated filing entities.

However, an aggregating entity that is also a designated filing entity would be required to maintain specific large position-related records in addition to its existing securities-related records. (Each reporting entity would have only one designated filing entity.) First, the designated filing entity would be required to make and maintain copies of all of the large position reports it filed. Also, since the designated filing entity, in some cases, would have to collect and combine information received from other aggregating entities within its reporting entity, the designated filing entity would be required to make and maintain supporting documents or schedules (e.g., worksheets) that are used to compute the reportable position and to prepare large position reports. The designated filing entity would also be required to make and keep a chart showing the organizational entities (e.g., aggregating entities, if applicable) whose data is combined for purposes of calculating a reportable position.

The Department believes that requiring supporting schedules would enhance the ability of the designated filing entity to produce accurate and timely large position reports. Moreover, the retention of supporting schedules and organizational charts would be indispensable in responding to follow-up inquiries from the regulatory agencies and in the course of any in-depth review or reconstruction of a reporting entity's reportable position conducted by the Treasury, the FRBNY, or the SEC.

[29] 17 CFR 240.17a–3, 240.17a–4, and 240.17a–7 (for registered brokers and dealers); 17 CFR 275.204–2 (for registered investment advisers); 17 CFR 270.31a–1, 270.31a–2, and 270.31a–3 (for registered investment companies); 17 CFR 404.2 and 404.3 (for registered government securities brokers and dealers); 17 CFR 404.4 (for noticed financial institutions); 17 CFR 450 (for depository institution custodians that exercise investment discretion); and 12 CFR Part 12, Part 208, or Part 344 (for banks conducting securities transactions for customers), respectively.

[30] Most of the existing recordkeeping rules also require affected entities to maintain position records, which provide a composite listing of the long and short positions in each security for which the broker-dealer or other entity is responsible. However, position records do not include information on positions resulting from certain unsettled and off-balance sheet transactions (e.g., when-issued trades and futures).

[31] Recordkeeping requirements for depository institutions acting solely as custodians were not considered because these entities do not meet the proposed definition of having control under paragraph 420.2(b).

Designated filing entities would be required to retain the additional records for the same period specified in their existing securities-related recordkeeping rules.[32] In instances where recordkeeping rules contain more than one retention period (e.g., SEC Rule 17a-4), paragraph 420.4(b)(4) of the proposed rule specifies that the longest retention period will apply.

*Other Entities (Paragraph 420.4(c))*

Certain entities that have the potential to control large positions, or portions thereof, in Treasury securities within a reporting entity (e.g., hedge funds and insurance companies) are not currently subject to federal requirements to make and preserve securities-related records. To ensure that such entities make and preserve records that document and facilitate the generation of accurate large position reports—while minimizing the burden on these entities—the Department proposes that all aggregating entities (within their respective reporting entities) in this category make and maintain records of original entry (the equivalent of blotters or journals). These documents should be relatively easy for large, sophisticated investors to implement. In fact, it is our understanding that most such investors already produce and maintain such records as part of their on-going business and accounting control systems.

Like the recordkeeping system applicable to entities that are subject to federal securities-related recordkeeping rules, an aggregating entity that is also a designated filing entity would be required to make and maintain the following large position-related records in addition to its records of original entry: copies of all of the large position reports it filed, supporting documents or schedules (e.g., worksheets) used to prepare large position reports, and a chart showing the organizational entities (e.g., aggregating entities, if applicable) whose data is aggregated in order to calculate a reportable position. Such records would have to be preserved by the designated filing entity for at least six years, the first two in an easily accessible place.

5. Section 420.5

Effective Date. Section 420.5 sets out the effective date for both the recordkeeping and reporting provisions of the large position rules. The rule provides for a delayed effective date approximately six months after publication of the final rule. This period of time is provided in order to give affected entities sufficient time to make the necessary preparations for compliance. Only subsection 420.4(a) is not subject to this date but instead contains its own specific dates for compliance.

IV. Special Analysis

The proposed rules reflect the Treasury's interest in meeting regulators' informational needs while minimizing the costs and burdens on market participants. The rules propose to adopt an on-demand reporting system, which will significantly minimize operational and compliance costs for market participants compared with the costs that would have been incurred if a regular reporting system were required. Further, in an effort to avoid imposing new requirements, the proposed regulations adopt, for the most part, existing federal recordkeeping requirements for the largest segment of market participants that would be subject to the rules. The proposal requires limited records to be maintained by those entities that are not currently subject to federal rules to make and preserve securities-related records. Additionally, the establishment of a minimum floor of $2 billion for the large position threshold will also greatly reduce the number of market participants potentially subject to the proposed rules. Therefore, based on the very limited impact of the proposal, it is the Department's view that the proposed regulations are not a ''significant regulatory action'' for the purposes of Executive Order 12866.

In addition, pursuant to the Regulatory Flexibility Act,[33] it is hereby certified that the proposed regulations, if adopted, will not have a significant economic impact on a substantial number of small entities since the proposal establishes a minimum large position threshold of $2 billion. This assures market participants that the Treasury would not request large position reports for positions below that minimum amount. The Department does not believe that small entities will control positions of $2 billion or greater in any Treasury security. Accordingly, the inapplicability of the proposed regulations to small firms indicates that there is no significant impact. As a result, a regulatory flexibility analysis is not required.

The Paperwork Reduction Act of 1995 requires that collections of information prescribed in the proposed rules be submitted to the Office of Management and Budget for review and approval.[34] In accordance with this requirement, the Department has submitted the collection of information contained in this notice of proposed rulemaking for review. Under the Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Comments on the collection of information may be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Department of the Treasury, Washington, D.C. 20503; and to the Government Securities Regulations Staff, Bureau of the Public Debt, at the address specified at the beginning of this document.

The collection of information in this proposed regulation is contained in proposed §§ 420.3 and 420.4. The proposed reporting requirements in § 420.3 would require the designated filing entity of any market participant, whose position equals or exceeds the announced large position threshold for a specific issue of a Treasury security, to report information to FRBNY. Although the Treasury cannot be certain of the number of market participants that would have large reportable positions for a specific issue on which information is requested, we believe that very few entities would likely have to file reports because the proposed minimum reporting threshold is $2 billion. Further, Treasury expects that its requests for information will be relatively infrequent, and estimates that there will only be an average of five reports filed in response to any particular request.

The proposed recordkeeping requirements in § 420.4 require any aggregating entity to make and preserve certain records as of the effective date, but only if it has, during a specified period, controlled a portion of its reporting entity's reportable position in any Treasury security when that reportable position is equal to or in excess of the $2 billion minimum large position threshold specified in § 420.2(d). For each reporting entity subject to the recordkeeping rules as of the effective date, the designated filing entity will be required to submit a letter, on a one-time basis, certifying that it has in place, or will have in place, a recordkeeping system capable of making, verifying the accuracy of, and preserving the requisite records. As mentioned above, while Treasury expects that very few entities would likely control positions in excess of the stated threshold that would require reporting, a larger group of entities will

[32] *See supra* note 29.

[33] 5 U.S.C. 601, *et seq.*

[34] 44 U.S.C. 3507(d).

be required to submit the one-time letter.

For aggregating entities currently subject to, and in compliance with, recordkeeping rules of federal securities or federal bank regulators, and subject to the large position recordkeeping rules, there are no additional recordkeeping requirements, with one exception. If the aggregating entity is the designated filing entity for its reporting entity, then it is required to make and maintain copies of any large position reports filed; supporting documents or schedules used to compute data for such large position reports, including any information received from aggregating entities within the reporting entity; and an organizational chart showing the entities that are aggregated in developing a reportable position.

Those aggregating entities that must comply with the proposed rules but are not subject to paragraph 420.4(b) must make and preserve journals, blotters or other records of original entry containing an itemized record of all transactions that fall within the definition of a reportable position. This provision accounts for the greatest percentage of estimated recordkeeping burden hours. However, this requirement is significantly less than the full range of books and records requirements currently applicable to entities subject to federal securities-related recordkeeping requirements. If the aggregating entity is also a designated filing entity, the requirements for a designated filing entity are also applicable.

The collection of information is intended to enable the Treasury and other regulators to understand better the possible reasons for any apparent significant price distortions and the possible causes of market shortages in certain Treasury securities. The collection of information will help ensure that the Treasury securities market remains liquid and efficient, and is not viewed as subject to manipulation. The proposed rules apply to all market participants controlling large positions, as defined in the rules. Per paragraph 420.3(c), it is a mandatory requirement that reporting entities with reportable positions that equal or exceed the specified threshold in a Treasury notice respond through their designated filing entities by filing a report in the required format and within the specified reporting time frame.

In developing the proposed rules, we have consulted with affected entities and regulatory agencies, and expect that this process will continue through the development of a final rule. As previously mentioned, Treasury published an ANPR[35] which requested comments on a number of specific issues, including the approach and structure for a large position recordkeeping and reporting system. The estimated reporting and recordkeeping burden hours are based on a review of tenders submitted in Treasury auctions, position reports that primary dealers already complete and voluntarily submit to FRBNY, recordkeeping requirements that are already in place for federally-regulated participants in the government securities market and discussions with the industry and other regulators.

Treasury invites further comments on: (1) Whether the proposed collection of information is necessary for the proper performance of functions of the Treasury, including the practical utility of the information; (2) the accuracy of the Treasury's estimate of the burden; (3) enhancement of the quality, utility, and clarity of information to be collected; and (4) minimizing the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Estimated total annual reporting and recordkeeping burden: 4,940 hours.

Estimated annual number of recordkeepers: 100.

Estimated annual number of respondents: 10.

Estimated annual frequency of response: On occasion.

List of Subjects

*17 CFR Part 400*

Administrative practice and procedure, Banks, banking, Brokers, Government securities, Reporting and recordkeeping requirements.

*17 CFR Part 420*

Foreign investments in U.S., Government securities, Investments, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 17 CFR Chapter IV, subchapter A is proposed to be amended as follows:

## PART 400—RULES OF GENERAL APPLICATION

1. The authority citation for part 400 is revised to read as follows:

Authority: 15 U.S.C. 78*o*–5.

2. In § 400.1, paragraph (e) is added as follows:

[35] *See supra* note 5.

**§ 400.1 Scope of regulations.**

* * * * *

(e) Section 104 of the Government Securities Act Amendments of 1993 (Pub. L. 103–202, 107 Stat. 2344) amended Section 15C of the Act (15 U.S.C. 78*o*–5) by adding a new subsection (f), authorizing the Secretary of the Treasury to adopt rules to require specified persons holding, maintaining or controlling a large position in to-be-issued or recently-issued Treasury securities to report such a position and make and keep records related to such a position. Part 420 of this subchapter contains the rules governing large position reporting.

* * * * *

3. Part 420 is added to read as follows:

## PART 420—LARGE POSITION REPORTING

Sec.
420.1 Applicability.
420.2 Definitions.
420.3 Reporting.
420.4 Recordkeeping.
420.5 Effective Date.

Appendix A to Part 420—Separate Reporting Entity

Appendix B to Part 420—Sample Large Position Report

Authority: 15 U.S.C. 78*o*–5(f).

**§ 420.1 Applicability.**

(a) This part, including the Appendices, is applicable to all persons that participate in the government securities market, including, but not limited to, government securities brokers and dealers, depository institutions, registered investment companies, registered investment advisers, pension funds, hedge funds and insurance companies, that may control a reportable position in a recently-issued Treasury bill, note or bond as those terms are defined in § 420.2.

(b) Notwithstanding paragraph (a) of this section, foreign central banks, foreign governments and international monetary authorities are exempt from this part for the portion of any reportable position they control that is held at the Federal Reserve Bank of New York.

(c) Notwithstanding paragraph (a) of this section, Federal Reserve Banks are exempt from this part for the portion of any reportable position they control for their own account.

(d) Notwithstanding the definition of recently-issued, the Department reserves the right to collect large position information on Treasury security issues that are older than those specified, provided that such action is consistent

with the purposes of the Act (15 U.S.C 78*o*–5(f)).

**§ 420.2 Definitions.**

For the purposes of this part:

(a) ''Aggregating entity'' means a single entity (e.g., a parent company or affiliate) that is combined with other entities, as specified in paragraph (i) of this section, to form a reporting entity. In those cases where an entity has no affiliates, the aggregating entity is the same as the reporting entity.

(b) ''Control'' means having the authority to exercise investment discretion over the purchase, sale, retention or financing of specific Treasury securities. Only one entity should be considered to have investment discretion over a particular position.

(c) ''Gross financing position'' is the sum of the gross par amounts of a security issue received from financing transactions, including, but not limited to, reverse repurchase transactions, bonds borrowed, securities received in pledge, and collateralized credit extended. In calculating the gross financing position, a reporting entity may not net its positions against repurchase transactions, securities loaned, securities pledged or other deliveries of the security issue. However, a reporting entity may elect to reduce its gross financing position by the par amount of the security received in transactions: in which the counterparty retains the right to substitute securities; that are subject to third party custodial relationships; or that are hold-in-custody reverse repurchase agreements.

(d) ''Large position threshold'' means, with respect to a reportable position, the dollar par amount such position must equal or exceed in order for a reporting entity to be required to submit a large position report. The large position threshold will be announced by the Department and may vary with each notice of request to report large position information and with each specified Treasury security. However, under no circumstances will a large position threshold be less than $2 billion.

(e) ''Net fails position'' is the net par amount of ''fails to receive'' less ''fails to deliver'' in the same security. The net fails position, as reported, may not be less than zero.

(f) ''Net trading position'' is the net sum of the following respective positions in the specific security issue:

(1) Cash/immediate net settled positions;

(2) Net when-issued positions;

(3) Net forward positions, including next-day settling;

(4) Net futures contract positions that require delivery of the specific security; and

(5) Net holdings of STRIPS principal components of the security.

(g) ''Recently-issued'' means:

(1) With respect to Treasury securities that are issued quarterly or more frequently, the three most recent issues of the security (e.g., in early April, the January, February, and March 2-year notes).

(2) With respect to Treasury securities that are issued less frequently than quarterly, the two most recent issues of the security.

(3) With respect to a reopened security, the entire issue of a reopened security (older and newer portions) based on the date the reopened security is reissued by the Department (or scheduled to be reissued for when-issued securities).

(4) For all Treasury securities, a security announced to be issued or auctioned but unissued (when-issued), starting from the date of the issuance announcement. The most recent issue of the security is the one most recently announced.

(h) ''Reportable position'' is the sum of the net trading positions, gross financing positions and net fails positions in a specified issue of Treasury securities collectively controlled by a reporting entity.

(i) ''Reporting entity'' means any corporation, partnership, person or other entity and its affiliates. For the purposes of this definition, an affiliate is any: entity that is more than 50% owned, directly or indirectly, by the aggregating entity or by any other affiliate of the aggregating entity; person or entity that owns, directly or indirectly, more than 50% of the aggregating entity; person or entity that owns, directly or indirectly, more than 50% of any other affiliate of the aggregating entity; or entity, a majority of whose board of directors or a majority of whose general partners are directors or officers of the aggregating entity or any affiliate of the aggregating entity.

(1) Subject to the conditions prescribed in Appendix A, one or more aggregating entities, either separately or together with one or more other aggregating entities, may be recognized as a separate reporting entity. Any entity that previously has received recognition from the Treasury as a separate bidder in Treasury auctions pursuant to Appendix A of 31 CFR Part 356 is also recognized as a separate reporting entity without further action.

(2) Notwithstanding this definition, any persons or entities that intentionally act together with respect to the investing in, retention of, or financing of, Treasury securities are considered, collectively, to be one reporting entity.

**§ 420.3 Reporting.**

(a) A reporting entity is subject to the reporting requirements of this section only when its reportable position equals or exceeds the large position threshold specified by the Department for a specific Treasury security issue. The Department shall provide notice of such threshold by issuance of a press release and subsequent publication of the notice in the Federal Register. Such notice will identify the Treasury security issue to be reported; the date or dates (as of close of business) for which the large position information must be reported; and the applicable large position threshold for that issue. It is the responsibility of a reporting entity to take reasonable actions to be aware of such a notice.

(b) A reporting entity shall select one entity from among its aggregating entities (i.e., the designated filing entity) as the entity designated to compile and file a report on behalf of the reporting entity. The designated filing entity shall be responsible for filing any large position reports in response to a notice issued by the Department and for maintaining the additional records prescribed in the applicable paragraph of § 420.4.

(c) (1) In response to a notice issued under paragraph (a) of this section requesting large position information, a reporting entity with a reportable position that equals or exceeds the specified large position threshold stated in the notice shall compile and report the amounts of the reporting entity's reportable position, as follows:

(i) net trading position comprising:

(A) cash/immediate net settled positions,

(B) net when-issued positions,

(C) net forward positions, including next-day settling,

(D) net futures contracts that require delivery of the specific security, and

(E) net holdings of STRIPS principal components of the security;

(ii) gross financing position; and

(iii) net fails position.

(2) The large position report should include the following two additional items as memoranda:

(i) A total that includes the amounts of securities delivered through repurchase agreements, securities loaned, securities pledged, and collateralized loans and other securities deliveries. This total should not be reflected in the gross financing position; and

(ii) If the reporting entity has elected to exercise the option available in

§ 420.2(c) to reduce the amount of the gross financing position by the par amount of securities received but over which the reporting entity did not have effective control, the amount not included. The total amount of reduction should be deducted from the gross financing position prior to determining the reportable position.

(3) An illustration of a sample report is contained in Appendix B. Each of the net trading position elements shall be netted and reported as the applicable positive or negative number (or zero). The gross financing position and net fails position should each be reported as a single entry. If the amount of the net fails position is zero or less, report zero. All of these items should be reported in the order specified above. All position amounts and their components should be reported at par in millions of dollars.

(4) All balances must be reported as of the close of business of the reporting date(s) specified in the notice.

(5) Each submitted report must include the following administrative information in addition to the reportable position: the name of the reporting entity, the address of the principal place of business, the name and address of the designated filing entity, the Treasury security that is being reported, the CUSIP number, the report date or dates for which information is being reported, the date the report was submitted, the name and telephone number of the person to contact regarding information reported, and the name and position of the authorized individual submitting this report. The report must also be signed by the authorized individual, who must be one of the following: the chief financial officer, the chief operating officer, the chief executive officer, or the managing partner or equivalent of the designated filing entity. The designated filing entity must also include in its report, immediately preceding the signature, a statement of certification as follows:

> The reporting entity submitting this report and the person(s) by whom it is executed hereby certify that all information contained in the report is accurate and complete and that the reporting entity is in compliance with the requirements of 17 CFR Part 420.

(6) The report must be filed before noon Eastern time on the second business day following issuance of the press release.

(d) A report to be filed pursuant to paragraph (c) will be considered filed when received by the Federal Reserve Bank of New York. The report may be filed in any manner acceptable to the Federal Reserve Bank of New York.

(e) A reporting entity that has filed a report pursuant to paragraph (c) shall, at the request of the Department or the Federal Reserve Bank of New York, timely provide any supplemental information pertaining to such report.

**§ 420.4 Recordkeeping.**

(a)(1) Notwithstanding the provisions of paragraphs (b) and (c) of this section, an aggregating entity must make and maintain records pursuant to this part as of its effective date, but only if the aggregating entity has controlled a portion of its reporting entity's reportable position in any Treasury security when such reportable position of the reporting entity has equaled or exceeded the minimum large position threshold specified in § 420.2(d) (i.e., $2 billion) during the prior two-year period ending [90 days after publication of the final rule]. Subsequent to the effective date, an aggregating entity that controls a portion of its reporting entity's reportable position in a recently-issued Treasury security, when such reportable position of the reporting entity equals or exceeds the minimum large position threshold, shall be responsible for making and maintaining the records prescribed in this part.

(2) In the case of a reporting entity whose reportable position in any Treasury security has equaled or exceeded the minimum large position threshold during the prior two-year period ending [90 days after publication of the final rule], each such reporting entity's designated filing entity shall submit a letter to the Federal Reserve Bank of New York certifying that it has in place, or will have in place by the effective date, a recordkeeping system (including policies and procedures) capable of making, verifying the accuracy of, and preserving the records required pursuant to this section.

(3) The letter specified in paragraph (a)(2) of this section must be signed by one of the following: the chief financial officer, the chief operating officer, the chief executive officer, or the managing partner or equivalent of the designated filing entity and must be received by the Federal Reserve Bank of New York no later than [120 days after publication of the final rule].

(b) Records to be made and preserved by entities that are subject to the recordkeeping provisions of the Commission, the Department, or the appropriate regulatory agencies for financial institutions. As an aggregating entity, compliance by a registered broker or dealer, registered government securities broker or dealer, noticed financial institution, depository institution that exercises investment discretion, registered investment advisor, or registered investment company with the applicable recordkeeping provisions of the Commission, the Department, or the appropriate regulatory agencies for financial institutions shall constitute compliance with this section, provided that if such entity is also the designated filing entity it:

(1) Makes and keeps copies of all large position reports filed pursuant to this part;

(2) Makes and keeps supporting documents or schedules used to compute data for the large position reports filed pursuant to this part;

(3) Makes and keeps a chart showing the organizational entities that are aggregated (if applicable) in determining a reportable position; and

(4) With respect to recordkeeping preservation requirements that contain more than one retention period, preserves records required by paragraphs (b)(1)-(3) of this section for the longest record retention period of applicable recordkeeping provisions.

(c) Records to be made and kept by other entities. (1) An aggregating entity that is not subject to the provisions of paragraph (b) of this section shall make and preserve a journal, blotter, or other record of original entry containing an itemized record of all transactions that fall within the definition of a reportable position, including information showing the account for which such transactions were effected and the following information pertaining to the identification of each instrument: the type of security, the par amount, the CUSIP number, the trade date, the maturity date, the type of transaction (e.g., a reverse repurchase agreement), and the name or other designation of the person from whom sold or purchased.

(2) If such aggregating entity is also the designated filing entity, then in addition it shall make and preserve the following records:

(i) copies of all large position reports filed pursuant to this part;

(ii) supporting documents or schedules used to compute data for the large position reports filed pursuant to this part; and

(iii) a chart showing the organizational entities that are aggregated (if applicable) in determining a reportable position.

(3) With respect to the records required by paragraphs (c) (1) and (2) of this section, each such aggregating entity shall preserve such records for a period of not less than six years, the first two years in an easily accessible place. If an aggregating entity maintains its records at a location other than its principal place of business, the aggregating entity must maintain an

index that states the location of the records, and such index must be easily accessible at all times.

**§ 420.5 Effective Date.**

The provisions of this part, except for § 420.4(a), shall be first effective on [180 days from the date of publication of the final rule. If the date does not fall on the last day of the month, then move the date to the end of the month.].

Appendix A to Part 420—Separate Reporting Entity

Subject to the following conditions, one or more aggregating entity(ies) (e.g., parent or subsidiary) in a reporting entity, either separately or together with one or more other aggregating entity(ies), may be recognized as a separate reporting entity. All of the following conditions must be met for such entity(ies) to qualify for recognition as a separate reporting entity:

(1) Such entity(ies) must be prohibited by law or regulation from exchanging, or must have established written internal procedures (i.e., Chinese walls) designed to prevent the exchange of information related to transactions in Treasury securities with any other aggregating entity;

(2) Such entity(ies) must not be created for the purpose of circumventing these large position reporting rules;

(3) Decisions related to the purchase, sale or retention of Treasury securities must be made by employees of such entity(ies). Employees of such entity(ies) who make decisions to purchase or dispose of Treasury securities must not perform the same function for other aggregating entities; and

(4) The records of such entity(ies) related to the ownership, financing, purchase and sale of Treasury securities must be maintained by such entity(ies). Those records must be identifiable—separate and apart from similar records for other aggregating entities.

To obtain recognition as a separate reporting entity, each aggregating entity or group of aggregating entities must request such recognition from the Department pursuant to the procedures outlined in § 400.2(c) of this title. Such request must provide a description of the entity or group and its position within the reporting entity, and provide the following certification:

''[Name of the entity(ies)] hereby certifies that to the best of its knowledge and belief it meets the conditions for a separate reporting entity as described in Appendix A to 17 CFR part 420. The above named entity also certifies that it has established written policies or procedures, including ongoing compliance monitoring processes, that are designed to prevent the entity or group of entities from:

''(1) Exchanging any of the following information with any other aggregating entity (a) positions that it holds or plans to acquire in a Treasury security; (b) investment strategies that it plans to follow regarding Treasury securities; and (c) financing strategies that it plans to follow regarding Treasury securities, or

''(2) In any way intentionally acting together with any other aggregating entity with respect to the purchase, sale, retention or financing of Treasury securities.

''The above-named entity agrees that it will promptly notify the Department in writing when any of the information provided to obtain separate reporting entity status changes or when this certification is no longer valid.''

Any entity that previously has received recognition as a separate bidder in Treasury auctions from the Department pursuant to 31 CFR Part 356 is also recognized as a separate reporting entity without further action.

Appendix B to Part 420—Sample Large Position Report.

## Formula for Determining a Reportable Position

[$ Amounts in millions at par value]

| | |
|---|---|
| Date For Which Information Is Being Reported: _____ | |
| 1. Cash/Immediate Net Settled Positions | $____ |
| 2. Net When-Issued Positions for To-Be-Issued and Reopened Issues | +$____ |
| 3. Net Forward Settling Positions Including Next Day Settling | +$____ |
| 4. Net Positions in Futures Contracts Requiring Delivery of the Specific Security | +$____ |
| 5. Net STRIPS Principal Components of the Specific Security | +$____ |
| 6. Gross Financing Position (Includes total of securities received through reverse repos, bonds borrowed, securities received in pledge, collateralized credit extended.) | +$____ |
| 7. Net Fails Position (Fails to Receive less Fails to Deliver. If equal to or less than 0, report 0.) | +$____ |
| 8. Total Reportable Position | =$____ |

## Formula for Determining a Reportable Position—Continued

[$ Amounts in millions at par value]

| | |
|---|---|
| Memorandum #1: Report one total which includes the gross par amounts of securities delivered through repurchase agreements, securities loaned, securities pledged, and collateralized loans. Not included in item #6 (Gross Financing Position) as reported above. | $____ |
| Memorandum #2: If the optional exclusion was taken to reduce the amount of the Gross Financing Position by the amount of securities received but that the reporting entity did not have effective control over (e.g., third party custodial structures, hold-in-custody relationships, counterparty retained contractual right to substitute), indicate the total amount of reduction here. Deduct from item #6 (Gross Financing Position). | $____ |

Administrative Information To Be Provided in the Report

Name of Reporting Entity:

Address of Principal Place of Business:

Name and Address of the Designated Filing Entity:

Treasury Security Reported on:

CUSIP Number:

Date or Dates for Which Information Is Being Reported:

Date Report Submitted:

Name and Telephone Number of Person to Contact Regarding Information Reported:

Name and Position of Authorized Individual Submitting this Report (Chief Financial Officer, Chief Operating Officer, Chief Executive Officer, or Managing Partner or Equivalent of Designated Filing Entity):

Statement of Certification: ''The reporting entity submitting this report and the person(s) by whom it is executed hereby certify that all information contained in the report is accurate and complete and that the reporting entity is in compliance with the requirements of 17 CFR Part 420.''

Signature of Authorized Person Named Above:

* * * * *

Date:

Darcy Bradbury,

*Deputy Assistant Secretary (Federal Finance).*

[FR Doc. 95–30766 Filed 12–14–95; 1:59 pm]

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federal register

Monday
December 18, 1995

# Part VII

# The President

## Proclamation 6859—To Modify the Tariff-Rate Quota on Italian-Type Cheeses From Poland

Federal Register
Vol. 60, No. 242
Monday, December 18, 1995

# Presidential Documents

Title 3—

The President

Proclamation 6859 of December 13, 1995

## To Modify the Tariff-Rate Quota on Italian-Type Cheeses From Poland

By the President of the United States of America

A Proclamation

1. On May 17, 1995, the United States and Poland signed a Record of Understanding Between Poland and the United States of America on Agricultural Items, which provides for an increase in the allocation to Poland of the in-quota quantity of the tariff-rate quota on Italian-type cheeses.

2. Section 404(d)(3) of the Uruguay Round Agreements Act (''the URAA'')(19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a tariff-rate quota for any agricultural product among supplying countries or customs areas and to modify any allocation as the President determines appropriate.

3. Accordingly, pursuant to section 404(d)(3) of the URAA, I have determined that it is appropriate to proclaim an increase in the allocation to Poland of the in-quota quantity of the tariff-rate quota for Italian-type cheeses.

4. Section 604 of the Trade Act of 1974, as amended (''the 1974 Act'')(19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (''the HTS'') the substance of the relevant provisions of that Act, and of other Acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction. The modification of the allocation to Poland of the in-quota quantity of the tariff-rate quota for Italian-type cheeses is such an action.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including but not limited to section 404(d)(3) of the URAA (19 U.S.C. 3601(d)(3)) and section 604 of the 1974 Act (19 U.S.C. 2483), do proclaim that:

(1) Additional U.S. note 21 to chapter 4 of the HTS is modified by deleting the quantity ''1,100,000'' set out opposite Poland and inserting ''1,325,000'' in lieu thereof.

(2) This proclamation is effective with respect to goods entered or withdrawn from warehouse for consumption on or after the date of signature of this proclamation.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of December, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

William J. Clinton

[FR Doc. 95–30819
Filed 12–15–95; 8:45 am]
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| 400–499 | (869–026–00065–4) | 34.00 | Apr. 1, 1995 |
| 500–End | (869–026–00066–2) | 34.00 | Apr. 1, 1995 |
| **21 Parts:** | | | |
| 1–99 | (869–026–00067–1) | 16.00 | Apr. 1, 1995 |
| 100–169 | (869–026–00068–9) | 21.00 | Apr. 1, 1995 |
| 170–199 | (869–026–00069–7) | 22.00 | Apr. 1, 1995 |
| 200–299 | (869–026–00070–1) | 7.00 | Apr. 1, 1995 |
| 300–499 | (869–026–00071–9) | 39.00 | Apr. 1, 1995 |
| 500–599 | (869–026–00072–7) | 22.00 | Apr. 1, 1995 |
| 600–799 | (869–026–00073–5) | 9.50 | Apr. 1, 1995 |
| 800–1299 | (869–026–00074–3) | 23.00 | Apr. 1, 1995 |
| 1300–End | (869–026–00075–1) | 13.00 | Apr. 1, 1995 |
| **22 Parts:** | | | |
| 1–299 | (869–026–00076–0) | 33.00 | Apr. 1, 1995 |
| 300–End | (869–026–00077–8) | 24.00 | Apr. 1, 1995 |
| **23** | (869–026–00078–6) | 22.00 | Apr. 1, 1995 |
| **24 Parts:** | | | |
| 0–199 | (869–026–00079–4) | 40.00 | Apr. 1, 1995 |
| 200–219 | (869–026–00080–8) | 19.00 | Apr. 1, 1995 |
| 220–499 | (869–026–00081–6) | 23.00 | Apr. 1, 1995 |
| 500–699 | (869–026–00082–4) | 20.00 | Apr. 1, 1995 |
| 700–899 | (869–026–00083–2) | 24.00 | Apr. 1, 1995 |
| 900–1699 | (869–026–00084–1) | 24.00 | Apr. 1, 1995 |
| 1700–End | (869–026–00085–9) | 17.00 | Apr. 1, 1995 |
| **25** | (869–026–00086–7) | 32.00 | Apr. 1, 1995 |
| **26 Parts:** | | | |
| §§ 1.0-1–1.60 | (869–026–00087–5) | 21.00 | Apr. 1, 1995 |
| §§ 1.61–1.169 | (869–026–00088–3) | 34.00 | Apr. 1, 1995 |
| §§ 1.170–1.300 | (869–026–00089–1) | 24.00 | Apr. 1, 1995 |
| §§ 1.301–1.400 | (869–026–00090–5) | 17.00 | Apr. 1, 1995 |
| §§ 1.401–1.440 | (869–026–00091–3) | 30.00 | Apr. 1, 1995 |
| §§ 1.441-1.500 | (869-026-00092-1) | 22.00 | Apr. 1, 1995 |
| §§ 1.501–1.640 | (869–026–00093–0) | 21.00 | Apr. 1, 1995 |
| §§ 1.641–1.850 | (869–026–00094–8) | 25.00 | Apr. 1, 1995 |
| §§ 1.851–1.907 | (869–026–00095–6) | 26.00 | Apr. 1, 1995 |
| §§ 1.908–1.1000 | (869–026–00096–4) | 27.00 | Apr. 1, 1995 |
| §§ 1.1001–1.1400 | (869–026–00097–2) | 25.00 | Apr. 1, 1995 |
| §§ 1.1401–End | (869–026–00098–1) | 33.00 | Apr. 1, 1995 |
| 2–29 | (869–026–00099–9) | 25.00 | Apr. 1, 1995 |
| 30–39 | (869–026–00100–6) | 18.00 | Apr. 1, 1995 |
| 40–49 | (869–026–00101–4) | 14.00 | Apr. 1, 1995 |

| Title | Stock Number | Price | Revision Date |
|---|---|---|---|
| 50–299 | (869–026–00102–2) | 14.00 | Apr. 1, 1995 |
| 300–499 | (869–026–00103–1) | 24.00 | Apr. 1, 1995 |
| 500–599 | (869–026–00104–9) | 6.00 | [4] Apr. 1, 1990 |
| 600–End | (869–026–00105–7) | 8.00 | Apr. 1, 1995 |
| **27 Parts:** | | | |
| 1–199 | (869–026–00106–5) | 37.00 | Apr. 1, 1995 |
| 200–End | (869–026–00107–3) | 13.00 | [8] Apr. 1, 1994 |
| **28 Parts:** | | | |
| 1-42 | (869–026–00108–1) | 27.00 | July 1, 1995 |
| 43-end | (869-026-00109-0) | 22.00 | July 1, 1995 |
| **29 Parts:** | | | |
| 0–99 | (869–026–00110–3) | 21.00 | July 1, 1995 |
| 100–499 | (869–026–00111–1) | 9.50 | July 1, 1995 |
| 500–899 | (869–026–00112–0) | 36.00 | July 1, 1995 |
| 900–1899 | (869–026–00113–8) | 17.00 | July 1, 1995 |
| 1900–1910 (§§ 1901.1 to 1910.999) | (869–026–00114–6) | 33.00 | July 1, 1995 |
| 1910 (§§ 1910.1000 to end) | (869–026–00115–4) | 22.00 | July 1, 1995 |
| 1911–1925 | (869–026–00116–2) | 27.00 | July 1, 1995 |
| 1926 | (869–022–00114–1) | 33.00 | July 1, 1994 |
| *1927–End | (869–026–00118–9) | 36.00 | July 1, 1995 |
| **30 Parts:** | | | |
| 1–199 | (869–026–00119–7) | 25.00 | July 1, 1995 |
| 200–699 | (869–026–00120–1) | 20.00 | July 1, 1995 |
| 700–End | (869–026–00121–9) | 30.00 | July 1, 1995 |
| **31 Parts:** | | | |
| 0–199 | (869–026–00122–7) | 15.00 | July 1, 1995 |
| 200–End | (869–026–00123–5) | 25.00 | July 1, 1995 |
| **32 Parts:** | | | |
| 1–39, Vol. I | | 15.00 | [2] July 1, 1984 |
| 1–39, Vol. II | | 19.00 | [2] July 1, 1984 |
| 1–39, Vol. III | | 18.00 | [2] July 1, 1984 |
| 1–190 | (869–026–00124–3) | 32.00 | July 1, 1995 |
| 191–399 | (869–026–00125–1) | 38.00 | July 1, 1995 |
| 400–629 | (869–026–00126–0) | 26.00 | July 1, 1995 |
| 630–699 | (869–026–00127–8) | 14.00 | [5] July 1, 1991 |
| 700–799 | (869–026–00128–6) | 21.00 | July 1, 1995 |
| 800–End | (869–026–00129–4) | 22.00 | July 1, 1995 |
| **33 Parts:** | | | |
| 1–124 | (869–026–00130–8) | 20.00 | July 1, 1995 |
| 125–199 | (869–026–00131–6) | 27.00 | July 1, 1995 |
| 200–End | (869–026–00132–4) | 24.00 | July 1, 1995 |
| **34 Parts:** | | | |
| 1–299 | (869–026–00133–2) | 25.00 | July 1, 1995 |
| 300–399 | (869–026–00134–1) | 21.00 | July 1, 1995 |
| *400–End | (869–026–00135–9) | 37.00 | July 5, 1995 |
| **35** | (869–026–00136–7) | 12.00 | July 1, 1995 |
| **36 Parts** | | | |
| 1–199 | (869–026–00137–5) | 15.00 | July 1, 1995 |
| 200–End | (869–026–00138–3) | 37.00 | July 1, 1995 |
| **37** | (869–026–00139–1) | 20.00 | July 1, 1995 |
| **38 Parts:** | | | |
| 0–17 | (869–026–00140–5) | 30.00 | July 1, 1995 |
| 18–End | (869–026–00141–3) | 30.00 | July 1, 1995 |
| **39** | (869–026–00142–1) | 17.00 | July 1, 1995 |
| **40 Parts:** | | | |
| 1–51 | (869–026–00143–0) | 40.00 | July 1, 1995 |
| 52 | (869–026–00144–8) | 39.00 | July 1, 1995 |
| 53–59 | (869–026–00145–6) | 11.00 | July 1, 1995 |
| 60 | (869-026-00146-4) | 36.00 | July 1, 1995 |
| 61–71 | (869–026–00147–2) | 36.00 | July 1, 1995 |
| 81–85 | (869–022–00145–1) | 23.00 | July 1, 1994 |
| 86–99 | (869–022–00146–9) | 41.00 | July 1, 1994 |
| 87–149 | (869–026–00150–2) | 41.00 | July 1, 1995 |
| 150–189 | (869–026–00151–1) | 25.00 | July 1, 1995 |
| 190–259 | (869–026–00152–9) | 17.00 | July 1, 1995 |
| *260–299 | (869–026–00153–7) | 40.00 | July 1, 1995 |
| 300–399 | (869–026–00154–5) | 21.00 | July 1, 1995 |
| 400–424 | (869–026–00155–3) | 26.00 | July 1, 1995 |
| 425–699 | (869–026–00156–1) | 30.00 | July 1, 1995 |
| 700–789 | (869–026–00157–0) | 25.00 | July 1, 1995 |
| 790–End | (869–026–00158–8) | 15.00 | July 1, 1995 |
| **41 Chapters:** | | | |
| 1, 1–1 to 1–10 | | 13.00 | [3] July 1, 1984 |
| 1, 1–11 to Appendix, 2 (2 Reserved) | | 13.00 | [3] July 1, 1984 |
| 3–6 | | 14.00 | [3] July 1, 1984 |
| 7 | | 6.00 | [3] July 1, 1984 |
| 8 | | 4.50 | [3] July 1, 1984 |
| 9 | | 13.00 | [3] July 1, 1984 |
| 10–17 | | 9.50 | [3] July 1, 1984 |
| 18, Vol. I, Parts 1–5 | | 13.00 | [3] July 1, 1984 |
| 18, Vol. II, Parts 6–19 | | 13.00 | [3] July 1, 1984 |
| 18, Vol. III, Parts 20–52 | | 13.00 | [3] July 1, 1984 |
| 19–100 | | 13.00 | [3] July 1, 1984 |
| 1–100 | (869–026–00159–6) | 9.50 | July 1, 1995 |
| 101 | (869–026–00160–0) | 29.00 | July 1, 1995 |
| 102–200 | (869–026–00161–8) | 15.00 | July 1, 1995 |
| 201–End | (869–026–00162–6) | 13.00 | July 1, 1995 |
| **42 Parts:** | | | |
| 1–399 | (869–022–00160–4) | 24.00 | Oct. 1, 1994 |
| 400–429 | (869–022–00161–2) | 26.00 | Oct. 1, 1994 |
| 430–End | (869–022–00162–1) | 36.00 | Oct. 1, 1994 |
| **43 Parts:** | | | |
| 1–999 | (869–022–00163–9) | 23.00 | Oct. 1, 1994 |
| 1000–3999 | (869–022–00164–7) | 31.00 | Oct. 1, 1994 |
| 4000–End | (869–022–00165–5) | 14.00 | Oct. 1, 1994 |
| **44** | (869–022–00166–3) | 27.00 | Oct. 1, 1994 |
| **45 Parts:** | | | |
| 1–199 | (869–022–00167–1) | 22.00 | Oct. 1, 1994 |
| 200–499 | (869–022–00168–0) | 15.00 | Oct. 1, 1994 |
| *500–1199 | (869–026–00172–3) | 23.00 | Oct. 1, 1995 |
| 1200–End | (869–022–00170–1) | 26.00 | Oct. 1, 1994 |
| **46 Parts:** | | | |
| 1–40 | (869–022–00171–0) | 20.00 | Oct. 1, 1994 |
| 41–69 | (869–022–00172–8) | 16.00 | Oct. 1, 1994 |
| 70–89 | (869–022–00173–6) | 8.50 | Oct. 1, 1994 |
| 90–139 | (869–022–00174–4) | 15.00 | Oct. 1, 1994 |
| 140–155 | (869–022–00175–2) | 12.00 | Oct. 1, 1994 |
| 156–165 | (869–022–00176–1) | 17.00 | [7] Oct. 1, 1993 |
| 166–199 | (869–022–00177–9) | 17.00 | Oct. 1, 1994 |
| 200–499 | (869–022–00178–7) | 21.00 | Oct. 1, 1994 |
| 500–End | (869–022–00179–5) | 15.00 | Oct. 1, 1994 |
| **47 Parts:** | | | |
| 0–19 | (869–022–00180–9) | 25.00 | Oct. 1, 1994 |
| 20–39 | (869–022–00181–7) | 20.00 | Oct. 1, 1994 |
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| 80–End | (869–022–00184–1) | 26.00 | Oct. 1, 1994 |
| **48 Chapters:** | | | |
| 1 (Parts 1–51) | (869–022–00185–0) | 36.00 | Oct. 1, 1994 |
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| 15–28 | (869–022–00191–4) | 32.00 | Oct. 1, 1994 |
| 29–End | (869–022–00192–2) | 17.00 | Oct. 1, 1994 |
| **49 Parts:** | | | |
| 1–99 | (869–022–00193–1) | 24.00 | Oct. 1, 1994 |
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| 178–199 | (869–022–00195–7) | 21.00 | Oct. 1, 1994 |
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| 1000–1199 | (869–022–00198–1) | 19.00 | Oct. 1, 1994 |
| 1200–End | (869–022–00199–0) | 15.00 | Oct. 1, 1994 |
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| 1–199 | (869–022–00200–7) | 25.00 | Oct. 1, 1994 |
| 200–599 | (869–022–00201–5) | 22.00 | Oct. 1, 1994 |
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| Title | Stock Number | Price | Revision Date |
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1995. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1995. The CFR volume issued July 1, 1991, should be retained.

[6] No amendments to this volume were promulgated during the period January 1, 1993 to December 31, 1994. The CFR volume issued January 1, 1993, should be retained.

[7] No amendments to this volume were promulgated during the period October 1, 1993, to September 30, 1994. The CFR volume issued October 1, 1993, should be retained.

[8] No amendments to this volume were promulgated during the period April 1, 1994 to March 31, 1995. The CFR volume issued April 1, 1994, should be retained.