AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

2-9-94
Vol. 59 No. 27

federal register

Wednesday
February 9, 1994

United States
Government
Printing Office
SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for private use, $300

SECOND CLASS NEWSPAPER

Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097-6326)

2-9-94
Vol. 59 No. 27
Pages 5929-6212

federal register

Wednesday
February 9, 1994

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, Tucson, AZ, and Oakland, CA, see announcement on the inside cover of this issue.

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and 24x microfiche format. The annual subscription price for the **Federal Register** paper edition is $444, or $490 for a combined **Federal Register**, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the Federal Register Index and LSA is $403. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $6.00 for each issue, or $6.00 for each group of pages as actually bound; or $1.50 for each issue in microfiche form. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 59 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–783–3238**
Assistance with public subscriptions	**512–2303**
Single copies/back copies:	
Paper or fiche	**783–3238**
Assistance with public single copies	**512–2457**
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	**523–5243**
Assistance with Federal agency subscriptions	**523–5243**

For other telephone numbers, see the Reader Aids section at the end of this issue.

THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC
(TWO BRIEFINGS)

WHEN: February 17 at 9:00 am and 1:30 pm
WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

TUCSON, AZ

WHEN: March 23 at 9:00 am
WHERE: University of Arizona Medical School, DuVal Auditorium, 1501 N. Campbell Avenue, Tucson, AZ
RESERVATIONS: Federal Information Center 1–800–359–3997 or in the Tucson area, call 602–290–1616

OAKLAND, CA

WHEN: March 30 at 9:00 am
WHERE: Oakland Federal Building, 1301 Clay Street, Conference Rooms A, B, and C, 2nd Floor, Oakland, CA
RESERVATIONS: Federal Information Center 1–800–726–4995

Printed on recycled paper containing 100% post consumer waste

Contents

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

Agricultural Marketing Service
RULES
Dairy products; grading, inspection, and standards:
Fee increases, 5933–5934

Agriculture Department
See Agricultural Marketing Service

Air Force Department
NOTICES
Environmental statements; availability, etc.:
Owyhee County, ID; training range; correction, 6041
Meetings:
Scientific Advisory Board, 6007

Army Department
NOTICES
Environmental statements; availability, etc.:
Base realignment and closure—
Pueblo Depot Activity, CO, 6007–6008

Civil Rights Commission
NOTICES
Meetings; State advisory committees:
Arizona, 5984
South Carolina, 5984

Coast Guard
RULES
Drawbridge operations:
Virginia, 5953–5954
Ports and waterways safety:
Chesapeake Bay, MD; regulated navigation area, 5954
Safety and security zones, etc.; list of temporary rules, 5950–5951
San Pedro Bay, CA; regulated navigation area, 5951–5953
PROPOSED RULES
Drawbridge operations:
Washington, 5970–5971

Commerce Department
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration
See National Telecommunications and Information Administration
See Travel and Tourism Administration

Committee for the Implementation of Textile Agreements
NOTICES
Export visa requirements; certification, waivers, etc.:
India, 6006–6007

Corporation for National and Community Service
NOTICES
Grants and cooperative agreements; availability, etc.:
Summer of Safety Learn and Serve America program, 6206–6211
Summer youth corps programs, public or nonprofit, 6196–6203

Defense Department
See Air Force Department
See Army Department
See Navy Department
RULES
Security protective force; CFR Part added, 5948–5950
NOTICES
Agency information collection activities under OMB review, 6007

Defense Nuclear Facilities Safety Board
NOTICES
Meetings; Sunshine Act, 6082

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Environmental statements; availability, etc.:
Foreign research reactor spent fuel containing uranium enriched in U.S.; urgent-relief acceptance, 6008–6009
Grant and cooperative agreement awards:
Idaho; new business development activities, 6009

Environmental Protection Agency
RULES
Air pollution; standards of performance for new stationary sources:
Kentucky; revised categories, implementation and enforcement, 5955–5956
Air quality implementation plans; approval and promulgation; various States:
Illinois, 5955
Toxic substances:
Preliminary assessment information and health and safety data reporting rules—
List additions, 5956–5962
PROPOSED RULES
Pesticide programs:
Total release foggers; flammability labeling requirements, 5971–5972
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Aluminum tris(O-ethylphosphonate), 5972–5974
NOTICES
Pesticide, food, and feed additive petitions:
Janssen Pharmacuetica et al., 6019–6020
Pesticide registration, cancellation, etc.:
Aerosect contains pyrethrum, etc., 6014–6017
Dow Chemical Co., 6018
Ortho Malathion 50 Insect Spray, etc., 6020–6021
SKW Trotberg AG, 6023
Pesticides; emergency exemptions, etc.:
Oxytetracycline, 6021–6022
Propazine, 6022–6023
Pesticides; permanent tolerances:
Clofentezine, 6017–6018
Pesticides; temporary tolerances:
Fenbuconazole, 6018–6019
Toxic and hazardous substances control:
Testing consent orders—
Sodium cyanide; mallard reproductive study; deletion request, 6024
Water pollution control:
Clean Water Act—
Class II administrative penalty assessments, 6024

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
PROPOSED RULES
Airworthiness directives:
Airbus Industrie, 5964–5965
Beech, 5965–5966
Canadair, 5966–5968
Fokker, 5968–5970
NOTICES
Meetings:
Centers of Excellence in Airport Pavement Research, 6080

Federal Communications Commission
NOTICES
Agency information collection activities under OMB review, 6024–6029

Federal Energy Regulatory Commission
RULES
Natural gas companies (Natural Gas Act):
Project cost limits under blanket certificates, 5946–5947
NOTICES
Electric rate and corporate regulation filings:
Western Resources, Inc., et al., 6009–6011
Environmental statements; availability, etc.:
Alaska Aquaculture, Inc., 6011
Applications, hearings, determinations, etc.:
Arkla Energy Resources Co., 6011
Great Lakes Gas Transmission Limited Partnership, 6011–6012
Texas Eastern Transmission Corp., 6012–6013
Trunkline Gas Co., 6013–6014
Trunkline LNG Co., 6014
Williston Basin Interstate Pipeline Co., 6014

Federal Highway Administration
NOTICES
Ferryboat equipment and machinery; Buy America general material requirements, 6080–6081

Federal Maritime Commission
PROPOSED RULES
Maritime carriers in foreign commerce:
Coloading practices by non-vessel-operating common carriers; shipper affiliate access to service contracts, 5974

Federal Register, Administrative Committee
See Federal Register Office

Federal Register Office
NOTICES
[**Editorial Note:** For a list of Acts requiring publication in the **Federal Register**, see the Reader Aids section at the end of this issue.]

Federal Reserve System
NOTICES
Agency information collection activities under OMB review, 6029–6031
Applications, hearings, determinations, etc.:
Capitol Bancorp Ltd., 6031–6032
First Bankshares of West Point, Inc., 6032
Klefstad, Harlan A., et al., 6032

Food and Drug Administration
RULES
Food additives:
Polymers—
Polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers, 5947–5948
PROPOSED RULES
Human drugs:
Oral health care products (OTC); oral antiseptic products; tentative final monograph, 6084–6124
NOTICES
Grants and cooperative agreements; availability, etc.:
Children's nutrition label literacy project, 6032–6034
Meetings:
Investigational new drugs; procedure to monitor clinical hold process, 6034–6035

General Services Administration
RULES
Federal property management:
Motor equipment management and use and replacement standards, 5962–5963

Health and Human Services Department
See Food and Drug Administration

Housing and Urban Development Department
NOTICES
Agency information collection activities under OMB review, 6037–6039
Grants and cooperative agreements; availability, etc.:
Low income housing—
Drug elimination program, 6039–6040
Privacy Act:
Systems of records, 6035–6037

Interior Department
See Land Management Bureau

International Trade Administration
NOTICES
Antidumping:
Carbon and alloy steel wire rod from—
Brazil, 5984–5987
Japan, 5987–5990
Forged stainless steel flanges from—
India, 5994–5995
Taiwan, 5995–5996
Grain-oriented electrical steel from—
Italy, 5991–5994
Japan, 5990–5991
Trade Promotion Coordinating Committee; recommendation to reduce barriers to exports related to product standards and certification, 5996
United States-Canada free-trade agreement; binational panel reviews:
Machine tufted carpeting from—
United States, 5997
Magnesium from—
Canada, 5997
Preformed fiberglass pipe insulation with vapor barrier from—
United States, 5996–5997

International Trade Commission
NOTICES
Import investigations:
Anisotropically etched one megabit and greater DRAMS, components, and products containing such DRAMS, 6042–6043
Fresh garlic from—
China, 6043–6044
Sebacic acid from—
China, 6044
Stainless steel flanges from—
India et al., 6044–6045
Vehicle security systems and components, 6045

Interstate Commerce Commission
NOTICES
Railroad operation, acquisition, construction, etc.:
Gateway Eastern Railway Co., 60456046
Peninsula Corridor Joint Powers Board, 6046
San Bernardino Associated Governments, 6046

Labor Department
See Occupational Safety and Health Administration
See Pension and Welfare Benefits Administration
NOTICES
Meetings:
Future of Worker-Management Relations Commission, 6046–6047

Land Management Bureau
NOTICES
Classification of public lands:
California, 6040
Closure of public lands:
Idaho, 6040–6041
Environmental statements; availability, etc.:
Owyhee County, ID; training range; correction, 6041
Recreation management restrictions, etc.
Utah public lands; explosive materials, destructive devices, and Class A and B fireworks use prohibition, 6041
Resource management plans, etc.:
Jackson District, FL, 6041–6042

National Aeronautics and Space Administration
PROPOSED RULES
Acquisition regulations:
Small disadvantaged businesses (SDBs); Mentor-protege program, 5974–5978

National Archives and Records Administration
See Federal Register Office

National Institute of Standards and Technology
NOTICES
Information processing standards, Federal:
Escrowed encryption standard, 5997–6005

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Gulf of Mexico and South Atlantic coastal migratory pelagic resources, 5962
PROPOSED RULES
Fishery conservation and management:
Atlantic billfishes; scoping meetings, 5978–5979
Limited access management of fisheries off Alaska, 5979–5983

National Science Foundation
NOTICES
Antarctic Conservation Act of 1978; permit applications. etc., 6060–6061
Meetings:
DOE/NSF Nuclear Science Advisory Committee, 6061
Graduate Education and Research Development Special Emphasis Panel, 6061

National Telecommunications and Information Administration
NOTICES
Preliminary spectrum reallocation report; 200 megahertz for public use; availability, 6005

Navy Department
NOTICES
Meetings:
Planning and Steering Advisory Committee, 6008

Nuclear Regulatory Commission
RULES
Operator licenses:
Comprehensive requalification written examination and operating tests, 5934–5939
NOTICES
Meetings:
Medical Uses of Isotopes Advisory Committee, 6061–6062
Applications, hearings, determinations, etc.:
Commonwealth Edison Co., 6062–6064
Entergy Operations, Inc., 6064
Iowa Electric Light & Power Co. et al., 6064–6065

Occupational Safety and Health Administration
RULES
Safety and health standards, etc.:
Hazard communication, 6126–6184

Pacific Northwest Electric Power and Conservation Planning Council
NOTICES
Power plan amendments:
Columbia River Basin fish and wildlife program, 6065

Pension and Welfare Benefits Administration
NOTICES
Employee benefit plans; prohibited transaction exemptions:
Richmond, Fredericksburg & Potomac Railway Co. Employee Thrift and Investment Plan, et al., 6047–6060

Physician Payment Review Commission
NOTICES
Meetings, 6065

Presidential Documents
ADMINISTRATIVE ORDERS
Somalia; assistance for police force reestablishment (Presidential Determination No. 94-14 of February 1, 1994), 5931
Soviet Union, former, Independent States of; reports to Congress on demilitarization, authority delegations to Secretaries of State, Defense, and Director of OMB (Memorandum of January 29, 1994), 5929

Public Health Service
See Food and Drug Administration

Research and Special Programs Administration
NOTICES
Hazardous materials transportation; preemption determinations, 6186–6193

Resolution Trust Corporation
RULES
Service of process, 5939–5940
NOTICES
Coastal Barrier Improvement Act; property availability:
Campobello Island Estates, Canada, 6065–6066

Securities and Exchange Commission
RULES
Organization, functions, and authority delegations:
Regional Directors et al., 5942–5946
NOTICES
Self-regulatory organizations; proposed rule changes:
Cincinnati Stock Exchange, Inc., 6066–6068
Applications, hearings, determinations, etc.:
DLJ LBO Plans Management Corp., 6068–6072
Janus Aspen Series et al., 6072–6077
Templeton Value Fund, Inc., 6077–6078

Small Business Administration
RULES
Business loans:
Defense economic assistance, 5940–5941
NOTICES
Disaster loan areas:
California, 6078
Illinois et al., 6079
Meetings; district and regional advisory councils:
Connecticut, 6079
Hawaii, 6079
Massachusetts, 6079

Textile Agreements Implementation Committee
See Committee for the Implementation of Textile Agreements

Transportation Department
See Coast Guard
See Federal Aviation Administration
See Federal Highway Administration
See Research and Special Programs Administration
NOTICES
Aviation proceedings:
Hearings, etc.—
Grand Airways, Inc., 6079
Virgin Islands Seaplane Shuttle, 6079

Travel and Tourism Administration
NOTICES
Meetings:
Travel and Tourism Advisory Board, 6005

Separate Parts In This Issue

Part II
Department of Health and Human Services, Food and Drug Administration, 6084–6124

Part III
Department of Labor, Occupational Safety and Health Administration, 6126–6184

Part IV
Department of Transportation, Research and Special Programs Administration, 6186–6193

Part V
Corporation for National and Community Service, 6196–6203

Part VI
Corporation for National and Community Service, 6206–6211

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
Free **Electronic Bulletin Board** service for Public Law numbers and **Federal Register** finding aids is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Administrative Orders:
Presidential Determinations:
94–14 of February 1, 1994 5931
Memorandums:
January 29, 1994 5929

7 CFR
58 5933

10 CFR
55 5934

12 CFR
1627 5939

13 CFR
122 5940

14 CFR
Proposed Rules:
39 (4 documents) 5964, 5965, 5966, 5968

17 CFR
200 5942
202 5942
203 5942
230 5942
239 5942
240 5942
249 5942
249b 5942
259 5942
269 5942
274 5942
275 5942
279 5942

18 CFR
157 5946

21 CFR
177 5947
Proposed Rules:
356 6084

29 CFR
1910 6126
1915 6126
1917 6126
1918 6126
1926 6126
1928 6126

32 CFR
228 5948

33 CFR
100 5950
110 5951
117 5953
165 (3 documents) 5950, 5951, 5954
Proposed Rules:
117 5970

40 CFR
52 5955
60 5955
712 5956
716 5956
Proposed Rules:
156 5971
180 5972

41 CFR
101–38 5962

46 CFR
Proposed Rules:
514 5974
580 5974
581 5974

48 CFR
Proposed Rules:
1819 5974
1852 5974

50 CFR
642 5963
Proposed Rules:
644 5978
676 5979

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

Presidential Documents

Title 3—

The President

Memorandum of January 29, 1994

Delegation of Responsibilities Under Sections 1203–1207 of Title XII of Public Law 103–160

Memorandum for the Secretary of State, the Secretary of Defense, [and] the Director of the Office of Management and Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3 of the United States Code, I hereby delegate:

1. to the Secretary of State the authority and duty vested in the President under section 1203(d) of the Cooperative Threat Reduction Act of 1993, Title XII of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103–160);

2. to the Secretary of Defense the authorities and duties vested in the President under sections 1203(a), 1204, 1206, and 1207 of Public Law 103–160.

The Secretary of Defense shall not exercise authority delegated by number 2 hereof with respect to any former Soviet republic unless the Secretary of State has exercised his authority and performed the duty delegated by number 1 hereof, as applicable, with respect to that former Soviet republic. The Secretary of Defense shall not obligate funds in exercise of authority delegated by number 2 hereof unless the Director of the Office of Management and Budget has made the determination that expenditures are to be counted as discretionary spending in the national defense function (050), as applicable to the funds to be transferred.

The Secretary of State is authorized and directed to publish this memorandum in the **Federal Register**.

William J. Clinton

THE WHITE HOUSE,
Washington, January 29, 1994.

[FR Doc. 94–3121
Filed 2–7–94; 1:32 pm]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 94–14 of February 1, 1994

Provision of Assistance To Support the Reestablishment of Police Forces in Somalia

Memorandum for the Secretary of State

Pursuant to the authority vested in me by section 614(a)(1) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2364(a)(1) (the "Act"), I hereby:

(1) determine that it is important to the security interests of the United States to furnish up to $12 million under Chapter 6 of Part II of the Act, from funds appropriated for Peacekeeping Operations (PKO) for fiscal year 1994, for purposes of supporting efforts to reestablish police forces in Somalia, without regard to section 512 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1994 (Public Law 103–87), and sections 620(q) and 660 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151 *et seq.*), or any other provision of law within the scope of section 614(a)(1) of the Act; and

(2) authorize the furnishing of such assistance.

You are hereby authorized and directed to transmit this determination to the Congress and to publish it in the **Federal Register**.

William J. Clinton

THE WHITE HOUSE,
Washington, February 1, 1994.

[FR Doc. 94–3174
Filed 2–7–94; 2:00 pm]
Billing code 4710–10–M

Rules and Regulations

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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 58

[DA-93-24]

RIN 0581-AB04

Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products: Revision of User Fees

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service is increasing the fees charged for services provided under the dairy grading program. This rule will yield an estimated $308,000 of additional user fee revenue in FY 1994. The program is a voluntary, user-fee funded program conducted under the authority of the Agricultural Marketing Act of 1946, as amended.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Lynn G. Boerger, USDA/AMS/Dairy Division, Dairy Grading Branch, room 2750-South Building, P.O. Box 96456, Washington, DC 20090-6456, (202) 720-9381.

SUPPLEMENTARY INFORMATION: The Department is issuing this final rule in conformance with Executive Order 12866.

This final rule has been reviewed in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, and the Administrator, Agricultural Marketing Service, has determined that it will not have a significant economic impact on a substantial number of small entities. The changes will not significantly affect the cost per unit for grading and inspection services. The Agricultural Marketing Service estimates that this rule will yield an additional $308,000 in user fee revenue during FY 1994. The Agency does not believe the increases will affect competition. Furthermore, the dairy grading program is a voluntary program.

In addition, this final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is not intended to have preemptive effect with respect to any State or local laws, regulations, or policies. This rule is not intended to have retroactive effect. There are no administrative procedures which must be exhausted prior to any judicial challenges to this rule or the application of its provisions.

The Agricultural Marketing Act of 1946, as amended, authorizes the Secretary of Agriculture to provide Federal dairy grading and inspection services that facilitate marketing and help consumers obtain the quality of dairy products they desire. The Act provides that reasonable fees be collected from the users of the services to cover the cost of maintaining the program.

Since the costs of the grading program are covered by user fees, it is essential that fees be increased to cover the cost of maintaining a financially self-supporting program. The last fee increase under this program became effective on January 26, 1992. Since that time, Congress increased the salaries of Federal employees by 3.7 percent as of January 10, 1993. Also, there have been normal increases in other operating costs. In addition, recent congressional action will result in additional salary increases of varying amounts in 1994. Although the program's operating reserves were adequate to cover the January 10, 1993, salary increase, this will not be the case for 1994 salary increases, and a fee increase is needed.

The grading program fees also need to be increased to cover the costs related to the development of dairy product standards and other activities now performed by the Dairy Division's Standardization Branch. In the recent FY 1994 appropriations bill, Congress appropriated money for the development of standards by the Agricultural Marketing Service but at the same time stipulated that the program costs be recovered through user fees, with the fees being turned over to the U. S. Treasury. Since the dairy standardization program is an essential part of the dairy grading program, it is appropriate that the standardization program costs be recovered through the fees charged the users of the grading program.

The projected cost of the dairy standardization program for FY 1994 is $435,000. To lessen the initial impact of transferring this cost to the users of the grading program, only about 2/3 of this cost would be recovered, with the remainder being covered by the grading program's operating reserves. Further fee increases about a year later presumably would be needed to cover the remaining portion of the standards costs.

On October 26, 1993, the Agricultural Marketing Service published in the **Federal Register** (58 FR 57567) for public comment a document proposing a $2.60 increase in the hourly fees for both the resident and nonresident programs, except for a $3.00 increase for nonresident services between the hours of 6 p.m. and 6 a.m. The only comments received were from the States of Oklahoma and Idaho, which opposed the fee increases. State officials stated that the inspection and grading program is being run in an inefficient manner and that steps should be taken to reduce program costs.

Program officials are continually seeking ways to operate the program more efficiently and to reduce operating costs. Examples of actions taken in recent years include the closing of 3 of 4 field offices and a reduction in headquarters staff. Also, program officials are currently working with the various States to address their concerns regarding program costs. At the same time, it is essential that the fees be increased now to cover current operating costs.

Pursuant to 5 U.S.C. 553, it is hereby found that good cause exists for not delaying the effective date of this action until 30 days after publication of this final rule in the **Federal Register**. A revenue shortfall warrants putting the higher rates into effect as quickly as possible. The increase in fees is essential for effective management and operation of the program and to satisfy the intent of the Agricultural Marketing Act of 1946. A proposed rule setting forth proposed fee increases was published in the **Federal Register** on October 26, 1993 (58 FR 57567). Therefore, the provisions of this final rule are known to interested parties.

Accordingly, the program fees are being increased as set forth below.

Program Changes Adopted in the Final Rule

This document makes the following changes in the regulations implementing the dairy inspection and grading program:

1. Increases the hourly fee for nonresident services from $44.60 to $47.20 for services performed between 6 a.m. and 6 p.m. and from $49.00 to $52.00 for services performed between 6 p.m. and 6 a.m.

The nonresident hourly rate is charged to users who request an inspector or grader for particular dates and amounts of time to perform specific grading and inspection activities. These users of nonresident services are charged for the amount of time required to perform the task and undertake related travel, plus travel costs.

2. Increases the hourly fee for continuous resident services from $39.60 to $42.20.

The resident hourly rate is charged to those who are using grading and inspection services performed by an inspector or grader assigned to a plant on a continuous, year-round, resident basis.

List of Subjects in 7 CFR Part 58

Diary products, Food grades and standards, Food Labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 58 is amended as follows:

PART 58—[AMENDED]

Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products

1. The authority citation for part 58 is revised to read as follows:

Authority: 7 U.S.C. 1621–1627, unless otherwise noted.

2. Section 58.43 is revised to read as follows:

§ 58.43 Fees for inspection, grading, and sampling.

Except as otherwise provided in § 58.43 and §§ 58.38 through 58.46, charges shall be made for inspection, grading, and sampling service at the hourly rate of $47.20 for service performed between 6 a.m. and 6 p.m., and $52.00 for service performed between 6 p.m. and 6 a.m., for the time required to perform the service calculated to the nearest 15-minute period including the time required for preparation of certificates and reports and the travel time of the inspector and grader in connection with the performance of the service. A minimum charge of one-half hour shall be made for service pursuant to each request or certificate issued.

3. Section 58.45 is revised to read as follows:

§ 58.45 Fees for continuous resident service.

Irrespective of the fees and charges provided in §§ 58.39 and 58.43, charges for the inspector(s) and grader(s) assigned to a continuous resident program shall be made at the rate of $42.20 per hour for services performed during the assigned tour of duty. Charges for service performed in excess of the assigned tour of duty shall be made at a rate of 1½ times the rate stated in this section.

Dated: February 2, 1994.

Lon Hatamiya,

Administrator.

[FR Doc. 94–2961 Filed 2–8–94; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 55

RIN 3150–AE39

Renewal of Licenses and Requalification Requirements for Licensed Operators

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to delete the requirement that each licensed operator at power, test, and research reactors pass a comprehensive requalification written examination and an operating test conducted by the NRC during the term of the operator's 6-year license as a prerequisite for license renewal. The final rule requires that facility licensees shall have a requalification program reviewed and approved by the Commission and shall, upon request consistent with the needs of the Commission's inspection program, submit to the Commission a copy of its annual operating tests or comprehensive written examinations used for operator requalification for review by the Commission. In addition, the final rule amends the "Scope" provisions of the regulations pertaining to operators' licenses to include facility licensees. The amendments will improve operational safety at each facility by redirecting NRC resources to administer the requalification program by inspecting and overseeing facility requalification programs rather than conducting requalification examinations. This, in turn, will reduce both licensee and NRC costs related to the program.

EFFECTIVE DATE: March 11, 1994.

FOR FURTHER INFORMATION CONTACT: Anthony DiPalo, Office of Nuclear Regulatory Research, telephone: (301) 492–3784, or Frank Collins, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 504–3173.

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the Nuclear Waste Policy Act (NWPA) of 1982 authorized and directed the NRC "to promulgate regulations, or other appropriate Commission regulatory guidance, for the training and qualifications of civilian nuclear power plant operators, supervisors, technicians and other appropriate operating personnel." The regulations or guidance were to "establish simulator training requirements for applicants for civilian nuclear power plant operator licenses and for operator requalification programs; requirements governing NRC administration of requalification examinations; requirements for operating tests at civilian nuclear power plant simulators, and instructional requirements for civilian nuclear power plant licensee personnel training programs." On March 25, 1987 (52 FR 9453), the Commission accomplished the objectives of the NWPA that were related to licensed operators by publishing a final rule in the **Federal Register** that amended 10 CFR part 55 and became effective May 26, 1987. The amendment revised the licensed operator requalification program by establishing (1) simulator training requirements, (2) requirements for operating tests at simulators, and (3) instructional requirements for the program (formerly appendix A to 10 CFR part 55). The final rule also stipulated that in lieu of the Commission accepting certification by the facility licensee that the licensee has passed written examinations and operating tests given by the facility licensee within its Commission approved program developed by using a systems approach to training (SAT), the Commission may give a comprehensive requalification written examination and

an annual operating test. In addition, the amended regulations required each licensed operator to pass a comprehensive requalification written examination and an operating test conducted by the NRC during the term of the operator's 6-year license as a prerequisite for license renewal.

Following the 1987 amendment to part 55, the NRC began conducting operator requalification examinations for the purpose of license renewal. As a result of conducting these examinations, the NRC determined that the existing regulations have established a high standard of licensee performance and that the NRC examiners were largely duplicating tasks that were already required of, and routinely performed by, the facility licensees.

The NRC revised its requalification examination procedures in 1988 to focus on performance-based evaluation criteria that closely paralleled the training and evaluation process used for a SAT based training program. This revision to the NRC requalification examination process enabled the NRC to conduct comprehensive examinations for the purpose of renewing an individual's license and, at the same time, use the results of the examinations to determine the adequacy of the facility licensee's requalification training program.

Since the NRC began conducting its requalification examination program, the facility program and individual pass rates have improved from 81 to 90 percent and from 83 to 91 percent, respectively, through fiscal year 1991. The NRC has also observed a general improvement in the quality of the facility licensees' testing materials and in the performance of their operating test evaluators. Of the first 79 program evaluations conducted, 10 programs were evaluated as unsatisfactory. The NRC issued Information Notice No. 90–54, "Summary of Requalification Program Deficiencies," dated August 28, 1990, to describe the technical deficiencies that contributed to the first 10 program failures. Since that time only 6 programs, of 120 subsequent program evaluations, have been evaluated as unsatisfactory.

Pilot requalification examinations were conducted during the period August through December 1991. The pilot test procedure directed the NRC examiners to focus on the evaluation of crews, rather than individuals, in the simulator portion of the operating test. In conducting the pilot examinations, the NRC examiners and the facility evaluators independently evaluated the crews and compared their results. The results were found to be in agreement. Furthermore, the NRC examiners noted that the facility evaluators were competent at evaluating crews and individuals and were aggressive in finding deficiencies and recommending remedial training for operators who exhibited weaknesses. The performance of the facilities' evaluators during the pilot examinations further confirmed that the facility licensees can find deficiencies, provide remedial training, and retest their licensed operators appropriately.

In June 1992, the Commission agreed with the staff to proceed with initiation of rulemaking to eliminate the requirement for each licensed operator to pass a comprehensive requalification written examination and operating test administered by the Commission during the term of the operator's 6-year license. On December 28, 1992, proposed amendments to 10 CFR part 55 on renewal of licensees and requalification requirements for licensed operators were submitted to the Commission for approval.

On May 20, 1993 (58 FR 29366), the Commission published a proposed rule in the **Federal Register** to amend 10 CFR part 55. The proposed amendments were to:

1. Delete the requirement that each licensed operator pass an NRC-administered requalification examination during the term of his or her license.

2. Require that facility licensees submit to the NRC their annual requalification operating tests and comprehensive requalification written examinations at least 30 days prior to the conduct of these tests and examinations.

3. Include "Facility Licensees" in the "Scope" of part 55.

The period for public comment on the proposed amendments ended on July 20, 1993.

Summary of Public Comments

The NRC received 42 comments on the proposed rule. Based on analysis of these comments, several changes have been made in the final rule. A summary of the public comments and, where appropriate, a description of the changes that resulted from them is discussed for each of the proposed amendments to 10 CFR part 55.

1. *Proposed Amendment:* Delete the requirement that each licensed operator pass an NRC-administered requalification examination during the term of a licensed operator's 6-year license.

General Statement: Of the 42 comments received, 36 favored this proposed amendment and 6 opposed its adoption. Most of the respondents who favored the proposed change based their support on the expectation that this change would reduce the regulatory burden on licensees and would improve operational safety at nuclear facilities. One respondent indicated that while the NRC's involvement has had a positive impact on the content and conduct of licensee requalification, utilities have proven their ability to develop and administer requalification examinations that meet the requirements of 10 CFR 55.59(a)(2)(iii). Another respondent representing the utility industry stated that, "We believe the performance-based inspection process will be an effective means for ensuring high quality operator requalification programs." This respondent further stated, "The proposed rule change will also afford better operating crew continuity. Because personnel changes occur over time, operating crews may be configured with individuals who have or have not had an NRC administered exam. In the past, it has been a common practice to reconfigure crews to accommodate the NRC-administered requalification examination by putting together individuals whose 6 years is about to end. Use of this practice to facilitate the conduct of requalification exams may not be in the best interest of crew coordination and teamwork."

The six comments in opposition to the proposed amendment to delete the NRC-conducted requalification examination varied in content. For example, two public citizen respondents were against a rule change of any kind on the basis it would give the public the perception that the NRC's authority over the operation of power and non-power reactor plants would be weakened. Two respondents, one representing a State public service department with oversight of a nuclear power plant and a second representing a State nuclear safety department, urged that from a defense-in-depth standpoint to reactor safety the proposed rule should be reconsidered. The State of Vermont, in two separate comments, indicated that it was because of the current regulation that the NRC was able to detect the unsatisfactory requalification program at Vermont Yankee and identify corrective actions to ensure safety of the plant. The State of Illinois contended that the current regulations provided incentive for licensees to maintain quality operator training programs and that the likelihood of further improving or even maintaining that quality without the periodic independent involvement by the NRC is unlikely. The State of Illinois recommended a combination of routine

NRC inspections of crew examinations on a plant simulator and a periodic independent test administered simultaneously to all licensed operators every 6 years. Finally, one respondent was opposed to this amendment, especially its application to test and research reactors and suggested the existing rule be deleted because the regulatory analysis for the 1987 rule stated that the rule would not apply to non-power reactors (NPR). This same respondent believed it important to maintain NRC staff competence in relation to NPR operator licensing and felt this could be accomplished by maintaining a nucleus of specialized qualified personnel, either as part of or in conjunction with the NPR directorate, and through specialized training and administration of initial examinations, which occur rather frequently.

Response: After reviewing the six comments opposing the proposed regulation, the Commission has concluded that the basis for this requirement remains sound and that it should be adopted. This determination is based on the following considerations:

(i) The NRC believes that since the beginning of the requalification program, experience indicates that weaknesses in implementation of facility licensee's programs are generally the root cause of deficiencies in the performance of operators.

(ii) The NRC believes if its resources were directed towards inspection and oversight of facility licensee's requalification programs rather than continuing to conduct individual operator requalification examinations, the operational safety at each facility will continue to be ensured and in fact, will be improved. A routine inspection frequency of once per SALP cycle will ensure consistency between inspection scheduling and licensee performance. A minimum routine inspection frequency of at least once every 2 years will ensure active NRC oversight of facility licensee's requalification programs. For facility licensees with good performance, consideration will be given to not performing an onsite inspection during the SALP period.

(iii) The NRC believes that the facility requalification programs have been demonstrated to be basically sound during the pilot examinations. Given the broad range of possible approaches built into the inspection process, the NRC would only conduct examinations when they are the most effective tool to evaluate and understand the programmatic issues, or if the NRC loses confidence in the facility licensee's ability to conduct its own examinations.

Examples which could result in a regional management decision for a "for cause" requalification examination include:

a. Requalification inspection results which indicate an ineffective licensee requalification program;

b. Operational problems for which operator error is a major contributor;

c. A SALP Category 3 rating in plant operations attributed to operator performance; and

d. Allegations regarding significant training program deficiencies.

When conditions such as these exist, the NRC may initiate planning to conduct requalification examinations during the next annual examination cycle scheduled by the facility.

Regarding the comments from the State of Vermont, the proposed inspection program includes reviews, observations, and parallel grading of selected operating tests and written examinations by NRC examiners, reviews of operational performance, interviews of facility personnel, and a general inspection of the facility licensee's implementation of its requalification training program. Application of the inspection program in the case of Vermont Yankee would have disclosed discrepancies in evaluation of operator performance and also would have allowed insight to other, more programmatic, deficiencies. The requalification inspection program implements routine NRC inspections as recommended by the State of Illinois as well as "for cause" examinations.

The Commission believes the existing regulation should not be deleted in the case of non-power reactors, as recommended in the public comments. A continuing need exists for the regulation to apply to operators of all types of reactors. The proposed amendment will continue to ensure operational safety at non-power reactors by inspecting facility requalification programs rather than conducting requalification examinations. The NRC will maintain examiner proficiency by conducting examinations for initial license applicants.

2. *Proposed Amendment:* Require that facility licensees submit to the NRC their annual requalification operating tests and comprehensive requalification written examinations at least 30 days prior to conducting these tests and examinations.

General Statement: Of the 42 comments received, only 1 respondent favored the amendment as proposed. This response came from a university operated research reactor, stating that submitting requalification examinations by the facility to the NRC for review prior to administering the examination was less burdensome, by comparison, than retaining the existing regulation. On the other hand, most respondents stated that submitting all examinations and tests to the NRC 30 days before their administration would place an undue burden on facility licensees and the NRC with little return on the investment. Several respondents offered alternatives that included shortening the lead time, requiring that the examinations and tests be submitted after they are administered, submitting the question banks from which the examinations are developed, and simply having the examinations available for on-site inspection.

Response: This requirement was included in the proposed regulation so that the NRC could evaluate the proposed examination materials, in conjunction with other information already available to the NRC, to determine the scope of the on-site inspection. However, the pilot inspection program has demonstrated that a facility's proposed examinations are not an absolute necessity in preparing for the on-site activities. In addition, those facility licensees' examination and simulator scenario banks that were evaluated were found to be adequate for an effective requalification program to be managed by the licensees' staffs. Although being able to review the proposed examinations at the NRC did save some on-site inspection effort, the inspectors were still able to complete the Temporary Inspection procedures within the time allowed (i.e., two inspectors on-site for 1 week).

The NRC believes that it will be advantageous to have selected examinations available for review at NRC offices in addition to other documentation customarily provided, consistent with the Commission's inspection program needs. During the on-site inspection, the inspectors will observe the facility evaluators administer written examinations and operating tests to the crews being evaluated. Although the facility examination may last several weeks, the NRC's on-site inspection usually lasts only one week. Normally, the NRC intends to request that the facility licensee submit only those written examinations or operating tests that will be administered during the week of the NRC inspection. Obtaining this examination material in advance of the inspection will allow the inspectors to prepare for their on-site inspection activities by reviewing the examinations or tests before they travel to the facility. This advance preparation will result in

a more effective use of on-site inspection time and reduce the burden on the facility licensee by placing fewer demands on their training staff during the examination week. Therefore, the NRC will delete the amendment to § 55.59(c) as proposed from the final rulemaking and will require instead that comprehensive written examinations or operating tests be submitted upon request consistent with the Commission's inspection program needs and sustained effectiveness of the facility licensee's examination and simulator scenario banks.

3. *Proposed Amendment:* Include facility licensees in the scope of 10 CFR part 55, specifically § 55.2, will be revised to include facility licensees.

General Statement: Only 1 of the 42 respondents to the FRN addressed and endorsed this provision of the proposed rulemaking.

Response: The NRC believes the absence of comments regarding this proposal substantiates the NRC's position that this is simply an administrative correction and does not materially change the intent of the regulation. The NRC considers this amendment as an administrative addition to these regulations. The NRC proposed this change to eliminate the ambiguities between the regulations of parts 50 and 55. Section 50.54 (i) through (m) already imposes part 55 requirements on facility licensees, and part 55 already specifies requirements for facility licensees. On this basis, the NRC has determined that the requirement should be adopted.

Finding of No Significant Environmental Impact: Availability

The Commission has determined that under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule is not a major Federal Action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval number 3150–0101.

The rule will relax existing information collection requirements for the separately cleared, "Reactor Operator and Senior Reactor Operator Licensing Training and Requalification Programs." The public burden for this collection of information is expected to be reduced by 3 hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding the estimated burden reduction or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019, (3150–0101), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the values (benefits) and impacts (costs) of implementing the regulation for licensed operator requalification. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Anthony DiPalo, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3784.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact upon a substantial number of small entities. This rule primarily affects the companies that own and operate light-water nuclear power reactors and non-power research reactors. The companies that own and operate these reactors do not fall within the scope of the definition of "small entity" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration in 13 CFR part 121.

Backfit Analysis

The staff believes that it could ensure and improve operational safety at each facility by directing its resources to inspect and oversee facility requalification programs rather than conducting requalification examinations. The staff's experience since the beginning of the requalification program indicates that weaknesses in the implementation of the facility programs are generally the root cause of significant deficiencies in the performance of licensed operators. The staff could more effectively allocate its resources to perform on-site inspections of facility requalification examination and training programs in accordance with indicated programmatic performance rather than scheduling examiners in accordance with the number of individuals requiring license renewal. By re-directing the examiner resources, the staff expects to find and correct programmatic weaknesses earlier, and thus improve operational safety.

Currently, facility licensees assist in developing and coordinating the NRC-conducted requalification examinations. The assistance includes providing to the NRC the training material used for development of the written examinations and operating tests and providing facility personnel to work with the NRC during the development and conduct of the examinations. The Commission has concluded on the basis of the analysis required by 10 CFR 50.109, that complying with the requirements of this final rule would reduce the regulatory burden on the facility licensees by reducing the effort expended by the facility licensees to assist the NRC in developing and conducting NRC requalification examinations for licensed operators. A smaller increase in regulatory burden is anticipated due to a need for the facility licensee to provide data and support for periodic requalification program inspections.

As part of the final rule, facility licensees shall have a requalification program reviewed and approved by the Commission and shall, upon request consistent with the Commission's inspection program needs, submit a copy of its comprehensive written examinations or annual operating tests to the Commission. The NRC has determined that the pilot inspection program demonstrated that the facility's proposed examinations are not an absolute necessity in preparing for the on-site activities. Therefore, the NRC would request test submittal on a case-by-case basis consistent with the Commission's test inspection program needs and review these examinations for conformance with 10 CFR 55.59(a)(2)(i&ii). The NRC would continue to expect each facility to meet all of the conditions required of a requalification program in accordance with 10 CFR 55.59(c).

Licensed operators would not have to take any additional actions. Each operator would be expected to continue to meet all the conditions of his or her

license described in 10 CFR 55.53, which includes passing the facility requalification examinations for license renewal. Each licensed operator would be expected to continue to meet the requirements of the facility requalification training program. However, the licensed operator would no longer be required to pass a requalification examination conducted by the NRC during the term of his or her license in addition to passing the facility licensee's requalification examinations, as a condition of license renewal.

The "Scope" of part 55, 10 CFR 55.2, would be revised to include facility licensees. This is an administrative addition to these regulations. It eliminates currently existing ambiguities between the regulations of parts 50 and 55. Part 50, in § 50.54(i) through (m), already imposes part 55 requirements on facility licensees, and part 55 already specifies requirements for facility licensees.

The Commission believes that licensed operators are one of the main components and possibly the most critical component of continued safe reactor operation, especially with respect to mitigating the consequences of emergency conditions. Two-thirds of the requalification programs that have been evaluated as "unsatisfactory" had significant problems in the quality or implementation of the plant's emergency operating procedures (EOPs). In some of these cases, the facility licensees did not train their operators on challenging simulator scenarios or did not retrain their operators after the EOPs were revised. The Commission believes that it could have identified these problems sooner by periodic inspection of facility requalification training and examination programs. Facility licensees could have then corrected these problems and improved overall operator job performance sooner.

This final rule will improve operational safety by providing the staff direction to find and correct weaknesses in facility licensee requalification programs. The experience gained from conducting NRC requalification examinations indicates that the NRC is largely duplicating the efforts of the facility licensees to maintain a high standard of operator performance. The NRC could now, by amending the regulations, more effectively use its resources to oversee facility licensee requalification programs rather than conducting individual operator requalification examinations. In FY92, the NRC resources committed to this program for NRC staff and contractor support were approximately 12 FTE and $1.3 million (equivalent to 8 FTE), respectively. The staff projects that a slightly larger average number of examinations, requiring approximately 1.5 additional staff FTE and an additional $200,000 contractual support (equivalent to 1.25 FTE), would be conducted in future years if the NRC continues conducting requalification examinations for all licensed operators. Thus, if it is assumed that without the rule change, this program would continue into the future, the relevant baseline NRC burden would approximate $2.85 (1.35 NRC + 1.5 contractor) million per year in 1992 dollars for FY93 through FY97. The 13.5 (12 + 1.5) NRC staff years (FTE) were converted to $1.35 million ($100,000 per staff year) based on allowances for composite wage rates and direct benefits.[1]

Under the final rule change, NRR's analysis indicates that NRC staff could perform all necessary inspections of requalification exam programs with 11 NRC FTEs and $300,000 in contractor support, equivalent to 1.85 contractor FTEs, per year. At $100,000 per NRC FTE and $162,000 per contractor FTE, this converts to an annual cost in 1992 dollars of $1.4 million. Thus, the annual savings in NRC operating costs is estimated to be on the order of $1.45 million ($2.85 million less $1.4 million). Over an assumed 25-year remaining life, based on a 5% real discount rate, the 1992 present worth savings in NRC resources is estimated at about $20.25 million in 1992 dollars.

Each facility licensee would continue in its present manner of conducting its licensed operator requalification program. However, this final rule reduces the burden on the facility licensees because each facility licensee would have its administrative and technical staff expend fewer hours than are now needed to assist in developing and conducting the NRC requalification examinations. Facility licensees are expected to realize a combined annual operational cost savings of approximately $1.24 million. Over an assumed 25-year remaining life, based on a 5% real discount rate, the 1992 present worth industry savings is estimated at about $17.48 million in 1992 dollars.

In summary, the final rule will result in improved operational safety by providing more timely identification of weaknesses in facility licensees' requalification programs. In addition, the final rule would also reduce the resources expended by both the NRC and the licensees. The Commission has, therefore, concluded that the final rule meets the requirements of 10 CFR 50.109, that there would be a substantial increase in the overall protection of public health and safety and the cost of implementation is justified.

List of Subjects in 10 CFR Part 55

Criminal penalty, Manpower training programs, Nuclear power plants and reactors, Reporting and record-keeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 55.

PART 55—OPERATORS' LICENSES

1. The authority citation for 10 CFR part 55 continues to read as follows:

Authority: Secs. 107, 161, 182, 68 Stat. 939, 948, 953, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2137, 2201, 2232, 2282); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Sections 55.41, 55.43, 55.45, and 55.59 also issued under sec. 306, Pub. L. 97–425, 96 Stat. 2262 (42 U.S.C. 10226). Section 55.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237).

2. In § 55.2, paragraph (c) is added to read as follows:

§ 55.2 Scope.

* * * * *

(c) Any facility licensee.

§ 55.57 [Amended]

3. Section 55.57 is amended by removing paragraph (b)(2)(iv).

4. In § 55.59, the introductory text of paragraph (c) is revised to read as follows:

§ 55.59 Requalification.

* * * * *

(c) *Requalification program requirements.* A facility licensee shall have a requalification program reviewed and approved by the Commission and shall, upon request consistent with the Commission's inspection program

[1] NRC labor costs presented here differ from those developed under the NRC's license fee recovery program. For regulatory analysis purposes, labor costs are developed under strict incremental cost principles wherein only variable costs that are directly related to the development, implementation, and operation and maintenance of the proposed requirement are included. This approach is consistent with guidance set forth in NUREG/CR–3568, "A Handbook for Value Impact Assessment," and general cost benefit methodology. Alternatively, NRC labor costs for fee recovery purposes are appropriately designed for full cost recovery of the services rendered and, as such, include non-incremental costs (e.g. overhead and administrative and logistical support costs).

needs, submit to the Commission a copy of its comprehensive requalification written examinations or annual operating tests. The requalification program must meet the requirements of paragraphs (c) (1) through (7) of this section. In lieu of paragraphs (c) (2), (3), and (4) of this section, the Commission may approve a program developed by using a systems approach to training.

* * * * *

Dated at Rockville, Maryland, this 2nd day of February, 1994.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 94-2927 Filed 2-8-94; 8:45 am]

BILLING CODE 7590-01-P

RESOLUTION TRUST CORPORATION

12 CFR Part 1627

RIN 3205-AA19

Service of Process Upon the Resolution Trust Corporation

AGENCY: Resolution Trust Corporation.

ACTION: Final rule.

SUMMARY: The Resolution Trust Corporation (RTC) hereby issues this final rule designating the officers upon whom service of process may be made when RTC is sued in its receivership, conservatorship, or corporate capacities. In the interest of providing prompt guidance in an area that has caused much confusion, RTC is publishing this final rule.

EFFECTIVE DATE: This final rule is effective February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Gregg H. S. Golden (Counsel), telephone 202-736-3042.

SUPPLEMENTARY INFORMATION:

I. Background

Section 501(a) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) added a new section 21A to the Federal Home Loan Bank Act, 12 U.S.C. 1441a, establishing the RTC. RTC was authorized to sue and be sued in its corporate capacity (12 U.S.C. 1441a(b)(9), as amended by the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991, Public Law No. 102-233, sections 310 and 314(2)(B)(i), 105 Stat. 1761, 1769, 1771 (1991)). The provisions of the Federal Rules of Civil Procedure establishing the method for service of process upon a government corporation contemplate that the corporation will designate an agent for service.

By reference to section 11, 12, and 13 of the Federal Deposit Insurance Act, 12 U.S.C. 1821, 1822, and 1823, FIRREA also granted RTC the same powers as the Federal Deposit Insurance Corporation when acting in its receivership or conservatorship capacity (12 U.S.C. 1441a(b)(4)(A), as amended). Inherent among these is the power to sue and be sued in such capacity, see 12 U.S.C. 1821(d)(2).

Because of the important differences among the capacities in which RTC functions, process is frequently served upon officers, employees, or temporary agents who have little or no connection with or responsibility for the component of RTC involved in the underlying lawsuit. Both RTC and the litigants are inconvenienced by the resulting confusion, delay, and expense. In the interest of reducing these costs to the public, RTC by this rule designates the agents who will accept service of process on behalf of RTC in its conservatorship, receivership, and corporate capacities.

Because RTC acts as conservator or receiver for a large number of savings associations, and because compulsory process (such as a subpoena for production of documents) does not always clearly identify the institution in question, the regulation provides that where process is served upon RTC in its capacity as conservator or receiver for a savings association, the savings association should be clearly identified on the face of the papers. This provision is intended to facilitate a prompt and constructive response to the papers.

On April 8, 1993 (58 FR 18144), RTC issued an Interim Rule with Request for Comments, designating its agents for service of process. A printing error in the original publication was corrected by notice on April 22, 1993 (58 FR 21627). RTC has proceeded under authority of the interim rule in the succeeding months, and thus has obtained useful experience in the practicality of the rule. RTC has received one comment on its interim rule and is now issuing a final rule.

II. Comment and Discussion

In response to the April 8, 1993, interim rule and request for comment, RTC received one comment. That single comment commended RTC's express designation of agents for service of process, and asked that RTC also consider designating specific officers to receive notices under agreements with other parties.

RTC's experience with the interim rule has been generally favorable.

III. Regulatory Flexibility Act Statement

Pursuant to section 605(b) of the Regulatory Flexibility Act, RTC hereby certifies that this proposal is not expected to have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

List of Subjects in 12 CFR Part 1627

Administrative practice and procedure.

For the reasons set out in the preamble, the Resolution Trust Corporation revises part 1627 of title 12, chapter XVI, of the Code of Federal Regulations to read as follows:

PART 1627—SERVICE OF PROCESS UPON THE RESOLUTION TRUST CORPORATION

Sec.
1627.1 Service of process on RTC in its corporate capacity.
1627.2 Service of process on RTC as conservator or receiver.

Authority: 12 U.S.C. 1441a(b)(4)(A), (9)(E), (11)(A), 1821(d)(2).

§ 1627.1 Service of process on RTC in its corporate capacity.

Any summons, complaint, subpoena, or other legal process issued against RTC in its corporate capacity shall be duly issued and served upon:

(a) The Assistant General Counsel (Litigation); and

(b) The Secretary, the address for both of whom is: 801 17th Street, NW., Washington, DC 20434-0001; and

(c) Upon such other persons as may be required by the provisions of the Federal Rules of Civil Procedure governing service of process upon an agency of the United States.

§ 1627.2 Service of process on RTC as conservator or receiver.

(a) Any summons, complaint, subpoena, or other legal process issued against RTC in its capacity as conservator or receiver for a savings association shall be duly issued and served upon RTC's Assistant General Counsel in the field office having jurisdiction over the state, Commonwealth, possession, territory, or district in which such savings association has its principal office. The name and principal office of such savings association should be stated on the face of the summons, complaint, subpoena, or other process. In addition, a copy of such process shall be delivered to the Secretary, Resolution Trust Corporation, 801 17th Street NW., Washington, DC 20434-0001 (telephone: 202-416-7572).

(b) The addresses of RTC's field offices and the states over which each office has jurisdiction shall be published from time to time in the **Federal Register** and maintained by the Secretary, Resolution Trust Corporation, whose address and telephone number are given in paragraph (a) of this section.

By Order of the Chief Executive Officer of the Resolution Trust Corporation.

Dated at Washington, DC, this 3rd day of February, 1994.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Secretary.

[**Note:** This appendix will not appear in the Code of Federal Regulations.

Appendix—Field Offices of the Resolution Trust Corporation Department of Legal Services

Resolution Trust Corporation, 100 Colony Square, suite 2300, Atlanta, GA 30361.
Responsible for: Alabama, the District of Columbia, Florida, Georgia, Maryland, North Carolina, Puerto Rico, South Carolina, Tennessee, the Virgin Islands, Virginia, and West Virginia.

Resolution Trust Corporation, 3500 Maple Avenue, suite 1500, Dallas, TX 75219.
Responsible for: Louisiana, Mississippi, and Texas.

Resolution Trust Corporation, 1225 17th Street, suite 3200, Denver, CO 80202.
Responsible for: Arizona, Colorado, New Mexico, Nevada, and Utah.

Resolution Trust Corporation, 4000 MacArthur Boulevard, 5th floor, P.O. Box 6210, Newport Beach, CA 92658–6210.
Responsible for: California, Guam, and Hawaii.

Resolution Trust Corporation, 7400 West 110th Street, suite 500, Overland Park, KS 66210–2346.
Responsible for: Alaska, Arkansas, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, North Dakota, Nebraska, Ohio, Oklahoma, Oregon, South Dakota, Washington, Wisconsin, and Wyoming.

Resolution Trust Corporation, Valley Forge Corporation Center, 1000 Adams Avenue, P.O. Box 1500, Valley Forge, PA 19482–1500.
Responsible for: Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Alabama (Atlanta)
Alaska (Overland Pk.)
Arizona (Denver)
Arkansas (Overland Pk.)
California (Newport Beach)
Colorado (Denver)
Connecticut (Valley Forge)
Delaware (Valley Forge)
D.C. (Atlanta)
Florida (Atlanta)
Georgia (Atlanta)
Guam (Newport Beach)
Hawaii (Newport Beach)
Idaho (Overland Pk.)
Illinois (Overland Pk.)
Indiana (Overland Pk.)
Iowa (Overland Pk.)
Kansas (Overland Pk.)
Kentucky (Overland Pk.)
Louisiana (Dallas)
Maine (Valley Forge)
Maryland (Atlanta)
Massachusetts (Valley Forge)
Michigan (Overland Pk.)
Minneosta (Overland Pk.)
Mississippi (Dallas)
Missouri (Overland Pk.)
Montana (Overland Pk.)
Nebraska (Overland Pk.)
Nevada (Denver)
New Hampshire (Valley Forge)
New Jersey (Valley Forge)
New Mexico (Denver)
New York (Valley Forge)
N. Carolina (Atlanta)
N. Dakota (Overland Pk.)
Ohio (Overland Pk.)
Oklahoma (Overland Pk.)
Oregon (Overland Pk.)
Pennsylvania (Valley Forge)
Puerto Rico (Atlanta)
Rhode Island (Valley Forge)
S. Carolina (Atlanta)
S. Dakota (Overland Pk.)
Tennessee (Atlanta)
Texas (Dallas)
Utah (Denver)
Vermont (Valley Forge)
Virgin Isls. (Atlanta)
Virginia (Atlanta)
Washington (Overland Pk.)
W. Virginia (Atlanta)
Wisconsin (Overland Pk.)
Wyoming (Overland Pk.)

[FR Doc. 94–2875 Filed 2–8–94; 8:45 am]

BILLING CODE 6714–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 122

Business Loans—Defense Economic Assistance

AGENCY: Small Business Administration (SBA).

ACTION: Final rule.

SUMMARY: This final regulation implements Section 7(a)(21) of the Small Business Act ("Act"), enacted on September 4, 1992. Under this final rule, SBA could make or guarantee loans to small business concerns which have been detrimentally affected by the closure or substantial reduction of a Department of Defense installation.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Charles R. Hertzberg, Assistant Administrator for Financial Assistance, Small Business Administration, 409 3rd Street SW., Washington, DC 20416 Telephone 202/205–6490.

SUPPLEMENTARY INFORMATION: Section 7(a)(21) of the Act (Pub. L. 102–366, 106 Stat. 997–968 15 U.S.C. 636(a)(21)) was enacted on September 4, 1992. On August 26, 1993, SBA published in the **Federal Register** (58 FR 45078) a proposed regulation which would implement Section 7(a)(21) of the Act. The Agency received no comments. Accordingly, the final regulation is being promulgated without change from the proposed rule.

Under this final regulation SBA is authorized to make direct or guaranteed loans to assist a small business concern that has been, or can reasonably be expected to be, detrimentally affected by the closure or substantial reduction of a Department of Defense (DOD) installation. SBA is also authorized under this final rule to assist a small business concern which has been detrimentally affected by the termination, or substantial reduction, of a DOD program on which such small business was a prime contractor or subcontractor (or supplier) at any tier.

Under this final regulation, the Agency is also authorized to make or guarantee loans to a qualified individual who seeks to establish, or acquire, and operate a small business concern in an area that has been or can reasonably be expected to be detrimentally affected by such closure or substantial reduction. For purposes of Section 7(a)(21) of the Act, "qualified individual" is defined to be: (1) A member of the Armed Forces of the United States, honorably discharged from active duty involuntarily or pursuant to a program providing bonuses or other inducements to encourage voluntary separation or early retirement; or (2) a civilian DOD employee involuntarily separated from Federal service or retired pursuant to a program offering inducements to encourage early retirement; or (3) an employee of a prime contractor, subcontractor, or supplier at any tier of a DOD program whose employment is involuntarily terminated (or voluntarily terminated pursuant to a program offering inducements to encourage

voluntary separation or early retirement) due to the termination (or substantial reduction) of a DOD program.

In recognition that greater risk may be associated with a loan to an applicant under this program, the final rule resolves any reasonable doubts concerning the small business concern's proposed business loan for transition to nondefense-related markets in favor of the loan applicant when SBA makes any determination regarding the sound value of the proposed loan. In order to determine "sound value", SBA will consider such factors as quality of the product or service, technical qualifications of the applicant's management and employees, sales projections and the applicant's financial status.

Because the Act requires SBA to resolve any credit doubts in favor of the loan applicant under this program, the final rule does not authorize any loan under section 7(a)(21) of the Act to be made under the certified lenders program (where the lender is entitled to a three day review by SBA) or the preferred lenders program (where the lender has authority to commit the Agency's guaranty without submitting any paperwork to SBA for review).

Compliance With Executive Orders 12612, 12778 and 12866, the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., and the Paperwork Reduction Act, 44 U.S.C. ch. 35

Executive Order 12866 and Regulatory Flexibility Act

SBA certifies that this final rule would not be a significant regulatory action for purposes of E.O. 12866 and, for purposes of the Regulatory, Flexibility Act, 5 U.S.C. 601 *et seq.*, would not have a significant economic impact on a substantial number of small entities, for the following reasons:

1. It would not result in an annual economic effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

2. It would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. It would not materially alter the budgetary impact of entitlements grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. It would not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Executive Order 12612

SBA certifies that this final rule would have no Federalism implications warranting the preparation of a Federalism Assessment in accordance with Executive Order 12612.

Paperwork Reduction Act

For purposes of the Paperwork Reduction Act, 44 U.S.C., ch 35, SBA hereby certifies that this final rule imposes no new reporting or recordkeeping requirements.

Executive Order 12778

SBA certifies that this final rule is drafted, to the extent practicable, in accordance with the standards set forth in Section 2 of E.O. 12778.

[Catalog of Federal Domestic Assistance Programs, No. 59–012, Small Business Loans]

List of Subjects in 13 CFR Part 122

Loan programs—business.

Pursuant to the authority contained in section 5(b)(6) of the Small Business Act (15 U.S.C. 634(b)(6)), SBA is amending Part 122, Chapter I, Title 13, Code of Federal Regulations, as follows:

PART 122—BUSINESS LOANS

1. The authority citation for part 122 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(a), 636(m).

2. Sections 122.62 through 122.62–4 are added to read as follows:

§ 122.62 Defense Economic Transition Assistance under Section 7(a)(21) of the Act.

§ 122.62–1 General rule.

(a) *Business.* The Act authorizes SBA, subject to the availability of funds appropriated for this purpose, to make direct or guaranteed loans to assist a small business concern that has been (or can reasonably be expected to be) detrimentally affected by:

(1) *Closure.* The closure (or substantial reduction) of a Department of Defense installation; or

(2) *Termination.* The termination (or substantial reduction) of a Department of Defense program on which such small business was a prime contractor or subcontractor (or supplier) at any tier.

(b) *Qualified Individual.* Under this program, SBA is authorized to make direct or guaranteed loans to a qualified individual who seeks to establish (or acquire) and operate a small business concern.

§ 122.62–2 Qualified individual.

Qualified individual, for purposes of this program, is:

(a) *Military status.* A member of the Armed Forces of the United States, honorably discharged from active duty involuntarily or pursuant to a program providing bonuses or other inducements to encourage voluntary separation or early retirement; or

(b) *Civilian status.* A civilian employee of the Department of Defense involuntarily separated from Federal service or retired pursuant to a program offering inducements to encourage early retirement; or

(c) *Contractor or supplier.* An employee of a prime contractor, subcontractor, or supplier at any tier of a Department of Defense program whose employment is involuntarily terminated (or voluntarily terminated pursuant to a program offering inducements to encourage voluntary separation or early retirement) due to the termination (or substantial reduction) of a Department of Defense program.

§ 122.62–3 Repayment ability.

Any reasonable doubts concerning the small business concern's proposed business plan for transition to nondefense-related markets shall be resolved in favor of the loan applicant when making any determination regarding the sound value of the proposed loan. In order to determine "sound value", SBA will consider such factors as quality of the product or service, technical qualifications of the applicant's management and employees, sales projections and the applicant's financial status.

§ 122.62–4 Loan making authority.

Since greater risk may be associated with a loan to an applicant under this program, any defense economic assistance loan made by a participating lender cannot be made under the Certified Lenders Program pursuant to part 120, subpart E of this chapter, or under the Preferred Lenders Program pursuant to part 120, subpart D of this chapter.

Dated: November 15, 1993.

Erskine B. Bowles,

Administrator.

[FR Doc. 94–2934 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR PARTS 200, 202, 203, 230, 239, 240, 249, 249b, 259, 269, 274, 275, and 279

[Release No. 34–33573]

Regional Office Reorganization

ACTION: Final rule amendments.

SUMMARY: The Securities and Exchange Commission is amending its rules to reflect the reorganization of its regional offices into five regional and six district offices. The Director of the Division of Enforcement will have overall responsibility for the five regional offices, but other Division Directors will continue to be responsible for managing their respective programs in each regional and district office. This reorganization is designed to create a more efficient reporting structure and to improve program accountability. The Commission is also correcting addresses appearing in its rules and eliminating certain redundant rules of organization.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: James Clarkson, Director, Regional Office Operations, (202) 272–3090; Anne Sullivan, Office of General Counsel, (202) 272–7525.

SUPPLEMENTARY INFORMATION: On August 27, 1993, the Chairman of the Securities and Exchange Commission announced a new structure for regional offices and changed the designations of the offices and of their chief supervisory personnel. This change is intended to improve program services and streamline the operation of regional and district offices.

As a result of the reorganization, the former structure in which there were nine regional offices and three branch offices has now been replaced by a new structure comprised of five regional offices and six district offices. The heads of regional offices, located in New York, Miami, Chicago, Denver, and Los Angeles, are now designated Regional Directors. The chief supervisory personnel for the district offices, located in Boston, Philadelphia, Atlanta, Fort Worth, Salt Lake City, and San Francisco, are designated District Administrators.[1] The District Offices and their Administrators will operate under the supervision of the Regional Directors. The Director of the Division of Enforcement has overall responsibility for the five regional offices; other Commission Division Directors are responsible for managing their respective programs in each office.[2]

In order to reflect this reorganization, the Commission is amending certain of its rules to substitute the terms "regional director" or "district administrator" for "regional administrator" where appropriate, and to add the term "district" where appropriate in rules which refer to "regional offices." In addition, the Commission is updating the addresses which appear in its rules for all its field offices. It is also adding rules which describe the duties of district administrators and delegate authority to these persons.[3] Finally, the Commission is removing Subpart E of its Rules of Organization, Conduct and Ethics, and Information, relating to Deputy Employment Officers, which is superseded by regulations covering agency equal employment opportunity programs in 29 CFR Part 1614, and therefore is no longer necessary.[4]

The Commission has determined that these amendments and additions to its rules relate solely to the agency's organization, procedure or practice. Therefore, the provisions of the Administrative Procedure Act ("APA") regarding notice of proposed rulemaking and opportunities for public participation,[5] are not applicable. Similarly, the provisions of the Regulatory Flexibility Act,[6] which apply only when notice and comment are required by the APA or other law, are not applicable.

Effects on Competition

Section 23(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act")[7] requires the Commission, in adopting rules under the Exchange Act, to consider the anti-competitive effects of such rules, if any, and to balance any impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission has considered the regional office reorganization, editing, and nomenclature changes adopted in this release in light of the standards cited in section 23(a)(2) and believes that their adoption would not impose any burden on competition not necessary or appropriate in furtherance of the Exchange Act.

Statutory Basis or Rule

The amendments to the Commission's rules are adopted pursuant to the authorities set forth therein.

List of Subjects

17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies), Equal employment opportunity, Freedom of information, government employees, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

17 CFR Part 202

Administrative practice and procedure.

17 CFR Part 203

Administrative practice and procedure, Investigations.

17 CFR Parts 230, 239, 240, 249, 249b, 259, 269, 274, 275, and 279

Reporting and recordkeeping requirements.

In accordance with the foregoing, 17 CFR, chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

1. The authority citation for part 200, subpart A, is amended by adding the following citation:

Authority: 15 U.S.C. 77s, 78d–1, 78d–2, 78w, 78*ll*(d), 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

---

[1] The Commission will close its Seattle District Office in July 1994 and transfer the functions of that office to the two other Pacific Region offices. Registrants currently filing with the Seattle District Office should continue to do so until June 30, 1994; thereafter, all registrants in the Pacific Region should make required filings in the Commission's Pacific Regional Office, located at 5670 Wilshire Boulevard, 11th Floor, Los Angeles, California 90036. Until July, the Seattle District Office will be located at 915 Second Avenue, Seattle, Washington, 98174, and will be open from 8 a.m. until 4:30 p.m. Pacific Standard Time.

[2] The Commission will continue to conduct regulatory functions in regional and district offices. Thus, both types of offices will perform regulatory functions with respect to registered brokers, dealers, transfer agents, investment companies, investment advisers, and others, and will receive filings from those registered entities as well as from other designated reporting entities, such as government securities brokers and dealers.

[3] By separate action, certain functions previously carried on in most field offices have been consolidated. In Securities Act Release No. 7034 (Dec. 8, 1993), the Commission reduced the offices in which small business filings may be made to four regional offices and one district office. Consistent with this change, authority under the Securities Act of 1933 will not be extended by rule to District Administrators, but will be separately delegated by the Chairman only to the Atlanta District Office.

[4] The Commission is not changing references to regional offices in any rule relating to member or employee conduct because it anticipates that the entire conduct rules will be revised in the near future.

[5] 5 U.S.C. 553.

[6] 5 U.S.C. 603(a).

[7] 15 U.S.C. 78w(a)(2).

Sections 200.27, 200.27a, 200.30–6, and 200.30–6a are also issued under 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77q, 77u, 78e, 78g, 78h, 78i, 78k, 78m, 78o, 78o–4, 78q, 78q–1, 78t–1, 78u, 77hhh, 77uuu, 80a–41, 80b–5, and 80b–9.

* * * * *

2. Section 200.11 is amended by revising the section heading and paragraphs (a)(2) and (b) and adding paragraph (c) to read as follows:

§ 200.11 Headquarters Office—Regional and District Office relationships.

(a) * * *

(2) Each Regional Director is responsible, subject to the supervision of the Director of the Division of Enforcement, for the direction and supervision of his or her work force and for the execution of all programs in his or her region as shown in paragraph (b) of this section, in accordance with established policy. Each District Administrator is responsible, subject to the supervision of the relevant Regional Director, for the direction and supervision of his or her work force and for the execution of all programs through his or her office, in accordance with established policy.

(b) Regional Directors and District Administrators of the Commission.

Region 1: Northeast Region. Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia—Regional Director, 7 World Trade Center, suite 1300, New York, NY 10048.

Boston District—District Administrator, 73 Tremont Street, Sixth Floor, suite 600, Boston, MA 02108.

Philadelphia District—District Administrator, The Curtis Center, suite 1005 E., 601 Walnut Street, Philadelphia, PA 19106.

Region 2: Southeast Region. Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virgin Islands—Regional Director, 1401 Brickell Avenue, suite 200, Miami, FL 33131.

Atlanta District—District Administrator, 3475 Lenox Road, NE., suite 1000, Atlanta, GA 30326.

Region 3: Midwest Region. Illinois, Indiana, Iowa, Kentucky, Michigan, Missouri, Ohio, Wisconsin—Regional Administrator, Northwestern Atrium Center, 500 West Madison Street, suite 1400, Chicago, IL 60611.

Region 4: Central Region. Arkansas, Colorado, Kansas, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, Wyoming—Regional Administrator, 1801 California Street, suite 4800, Denver, CO 80202.

Fort Worth District—District Administrator, 801 Cherry Street, 19th Floor, Fort Worth, TX 76102. Salt Lake District—District Administrator, 500 Key Bank Tower, 50 S. Main Street, suite 500, Box 79, Salt Lake City, UT 84144.

Region 5: Pacific Region. Alaska, Arizona, California, Guam, Hawaii, Idaho, Montana, Nevada, Oregon, Washington—Regional Director, 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036.

San Francisco District—District Administrator, 44 Montgomery Street, San Francisco, CA 94104.

(c) The following geographic allocation determines where registered brokers, dealers, transfer agents, clearing agents, registered securities associations, investment advisers, and others as designated in this chapter must file reports required to be filed in regional or district offices:

Northeast Regional Office: New Jersey, New York.

Boston District Office: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Philadelphia District Office: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia.

Southeast Regional Office: Florida, Puerto Rico, Virgin Islands.

Atlanta District Office: Alabama, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee.

Midwest Regional Office: Illinois, Indiana, Iowa, Kentucky, Ohio, Michigan, Minnesota, Missouri, Wisconsin.

Central Regional Office: Colorado, Nebraska, New Mexico, North Dakota, South Dakota, Utah, Wyoming.

Fort Worth District Office: Arkansas, Kansas, Oklahoma, Texas.

Pacific Regional Office: Alaska, Arizona, California, Guam, Hawaii, Idaho, Montana, Nevada, Oregon, Washington.

§ 200.12 [Amended]

3. In § 200.12, remove the words "Regional Administrators" and add, in their place, the words "Regional Directors and District Administrators".

4. Section 200.27 is amended by revising the section heading, removing the words "Regional Administrator" and "Regional Administrators'" and adding in their place "Regional Director" and "Regional Directors'" and revising the last sentence to read as follows:

§ 200.27 The Regional Directors.

* * * In addition, the Northeast Regional Director is responsible for the Commission's participation in cases under chapters 9 and 11 of the Bankruptcy Code in the Northeast Region, excepting Delaware, District of Columbia, Maryland, Virginia, and West Virginia; the Southeast Regional Director is responsible for such participation in the Southeast Region, as well as Delaware, District of Columbia, Maryland, Virginia, and West Virginia; the Midwest Regional Director is responsible for such participation in the Midwest and Central Regions, excepting Utah; and the Pacific Regional Director is responsible for such participation in the Pacific Region and Utah.

5. Section 200.27a is added to read as follows:

§ 200.27a The District Administrators.

Each District Administrator is responsible for executing the Commission's programs as set forth below, subject to review by the appropriate Regional Director and policy direction and review by the relevant Division Directors, the General Counsel, and the Chief Accountant in Washington, DC. The District Administrators' responsibilities include particularly the investigation of transactions in securities on national securities exchanges, in the over-the-counter market, and in distribution to the public; the examination of members of national securities exchanges and registered brokers and dealers, transfer agents, investment advisers and investment companies including the examination of reports filed under § 240.17a–5 of this chapter; the prosecution of injunctive actions in U.S. District Courts and administrative proceedings before Administrative Law Judges; the rendering of assistance to U.S. Attorneys in criminal cases; and the making of the Commission's facilities more readily available to the public in that district.

§ 200.30–1 [Amended]

6. In § 200.30–1(g)(2), remove the word "Administrator" and add, in its place, the word "Director".

§ 200.30–5 [Amended]

7. In § 200.30–5(i)(1), remove the word "Administrator" and add, in its place, the word "Director".

§ 200.30–6 [Amended]

8. In § 200.30–6, amend the section heading by removing the word "Administrators" and adding, in its place, the word "Directors" and remove the word "Administrator" each time it appears and add, in its place, the word "Director".

9. In the introductory text of paragraph (a) of § 200.30–6, remove the words "Form S–18 (§ 239.28 of this chapter)" and add, in their place, the words "Forms SB–1 and SB–2 (§§ 239.9 and 239.10 of this chapter)".

10. Section 200.30–6a is added to read as follows:

§ 200.30–6a Delegation of authority to District Administrators.

Pursuant to the provisions of Pub. L. 87–592, 76 Stat. 394, 15 U.S.C. 78d–1,

the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following functions to each District Administrator, to be performed by him or her or under his or her direction by such person or persons as may be designated from time to time by the Chairman of the Commission:

(a) With respect to the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*):

(1) Pursuant to section 15(b)(2)(C) of the Act (15 U.S.C. 78o(b)(2)(C)):

(i) To delay until the second six-month period from registration with the Commission the inspection of newly registered broker-dealers that have not commenced actual operations within six months of their registration with the Commission; and

(ii) To delay until the second six-month period from registration with the Commission the inspection of newly registered broker-dealers to determine whether they are in compliance with applicable provisions of the Act and rules thereunder, other than financial responsibility rules.

(2) Pursuant to Rule 0–4 (§ 240.0–4 of this chapter), to disclose to the Comptroller of the Currency, the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation and to the state banking authorities, information and documents deemed confidential regarding registered clearing agencies and registered transfer agents, *Provided* That, in matters in which the Commission has entered a formal order of investigation, such disclosure shall be made only with the concurrence of the Director of the Division of Enforcement or his or her delegate and the General Counsel or his or her delegate.

(b) With respect to the Investment Advisers Act of 1940 (15 U.S.C. 80b-1 *et seq.*): Pursuant to Rule 204–2(j)(3)(ii) (§ 275.204–2(j)(3)(ii) of this chapter), to make written demands upon non-resident investment advisers subject to the provisions of such rule to furnish to the Commission true, correct, complete and current copies of any or all books and records which such non-resident investment advisers are required to make, keep current or preserve pursuant to any provisions of any rule or regulation of the Commission adopted under the Investment Advisers Act of 1940, or any part of such books and records which may be specified in such demand.

(c) In nonpublic investigatory proceedings within the responsibility of the District Administrator, to grant requests of persons to procure copies of the transcript of their testimony given pursuant to Rule 6 of the Commission Rules Relating to Investigations (§ 203.6 of this chapter).

(d) To notify the Securities Investor Protection Corporation ("SIPC") of facts concerning the activities and the operational and financial condition of any registered broker or dealer which is or appears to be a member of SIPC and which is in or approaching financial difficulty within the meaning of Section 4 of the Securities Investor Protection Act of 1970 as amended (15 U.S.C. 78aaa *et seq.*).

(e) Notwithstanding anything in the foregoing, in any case in which the District Administrator believes it appropriate, he or she may submit the matter to the Commission.

§ 200.30–11 [Amended]

11. In § 200.30–11(c)(2), add the words "or district" after the word "regional".

Subpart D—Information and Requests

12. The authority citation for part 200, subpart D continues to read in part as follows:

Authority: 80 Stat. 383, as amended, 31 Stat. 54, secs. 19, 23, 48 Stat. 85, 901, as amended, sec. 20, 49 Stat. 85, 833, sec. 319, 53 Stat. 1173, secs. 38, 211, 54 Stat. 841, 855; 5 U.S.C. 552, as amended, 15 U.S.C. 77f(d), 77s, 77ggg(a), 78m(F)(3), 78w, 79t, 79v(a), 77sss, 80a–37, 80a–44(c), 80a–44(b), 80b–10(a), 80b–11.

* * * * *

13. In § 200.80(c)(1)(ii), add the words "and district" after the word "regional" each time it appears, and revise the flush text and the list of addresses appearing in paragraph (c)(1)(iii) as follows:

§ 200.80 Commission records and information.

* * * * *

(c) * * *

(1) * * *

(iii) * * *

The addresses of the Commission's regional and district offices are:

Northeast Regional Office. 7 World Trade Center, suite 1300, New York, NY 10048. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Boston District Office—73 Tremont Street, suite 600, Boston, MA 02108. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Philadelphia District Office—The Curtis Center, suite 1005 E., 601 Walnut Street, Philadelphia, PA 19106. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Southeast Regional Office. 1401 Brickell Avenue, suite 200, Miami, FL 33131. Office hours—8:30 a.m. to 5 p.m. E.S.T.

Atlanta District Office—Lenox Road, NE., suite 1000, Atlanta, GA 30326. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Midwest Regional Office. Northwestern Atrium Center, 500 West Madison Street, suite 1400, Chicago, IL 60611. Office hours—8:45 a.m. to 5:15 p.m. C.S.T.

Central Regional Office. 1801 California Street, suite 4800, Denver, CO 80202. Office hours—8 a.m. to 4:30 p.m. M.S.T.

Fort Worth District Office—801 Cherry Street, 19th Floor, Fort Worth, TX 76102. Office hours—8:30 a.m. to 5 p.m. C.S.T.

Salt Lake District Office—500 Key Bank Tower, 50 S. Main Street, suite 500, Box 79, Salt Lake City, UT 84144. Office hours—8 a.m. to 4:30 p.m. M.S.T.

Pacific Regional Office. 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036. Office hours 8:30 a.m. to 5 p.m. P.S.T.

San Francisco District Office—44 Montgomery Street, San Francisco, CA 94104. Office hours—8:30 a.m. to 5 p.m. P.S.T.

* * * * *

14. In § 200.80(c)(2), remove the words "Branch Offices" and, in their place, add the words "District Offices".

15. In § 200.80 (d)(7)(i) and (e)(7)(iii), remove the word "branch" each time it appears and, in its place, add the word "district".

16. In the introductory text of § 200.80(e), add the words "or district" after the word "regional".

Subpart E—Regulation Regarding Equal Employment Opportunity

17. Subpart E is removed and reserved.

Subpart G—Plan of Organization and Operation Effective During Emergency Conditions

18. The authority citation for part 200, subpart G continues to read in part as follows:

Authority: 15 U.S.C. 77s, 78w, 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

* * * * *

§ 200.202 [Amended]

19. In § 200.202(a), remove the word "Branch", and add, in its place, the word "District", and remove the words "Regional Administrator" and add, in their place, the words "Regional Director or District Administrator".

20. In § 200.203(c)(1)(vi), remove the word "Administrators" and add, in its place, the word "Directors" and add paragraph (c)(1)(vii) to read as follows:

§ 200.203 Organization, and delegations of authority.

* * * * *

(c) * * *

(1) * * *

(vii) The District Administrators in order of seniority.

* * * * *

§ 200.204 [Amended]

21. In § 200.204, remove the words "Regional Administrators" and add, in their place, the words "Regional Directors and District Administrators".

Subpart H—Regulations Pertaining to the Privacy of Individuals and Systems of Records Maintained by the Commission

22. The authority citation for part 200, subpart H continues to read in part as follows:

Authority: Pub. L. 93–579, sec. (f), 5 U.S.C. 552a(f), unless otherwise noted.

* * * * *

23. In § 200.303 (a)(2) and (b)(2), remove the word "Branch" and add, in its place, the word "District" and in paragraph (a)(2) revise the list of offices to read as follows:

§ 200.303 Times, places and requirements for requests pertaining to individual records in a record system and for the identification of individuals making requests for access to the records pertaining to them.

(a) * * *

(2) * * *

Northeast Regional Office. 7 World Trade Center, suite 1300, New York, NY 10048. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Boston District Office—73 Tremont Street, Sixth Floor, suite 600, Boston, MA 02108. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Philadelphia District Office—The Curtis Center, suite 1005 E., 601 Walnut Street, Philadelphia, PA 19106. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Southeast Regional Office. 1401 Brickell Avenue, suite 200, Miami, FL 33131. Office hours—8:30 a.m. to 5 p.m. E.S.T.

Atlanta District Office—Lenox Road, NE., suite 1000, Atlanta, GA 30326. Office hours—9 a.m. to 5:30 p.m. E.S.T.

Midwest Regional Office. Northwestern Atrium Center, 500 West Madison Street, suite 1400, Chicago, IL 60611. Office hours—8:45 a.m. to 5:15 p.m. C.S.T.

Central Regional Office. 1801 California Street, suite 4800, Denver, CO 80202. Office hours—8 a.m. to 4:30 p.m. C.S.T.

Fort Worth District Office—801 Cherry Street, 19th Floor, Fort Worth, TX 76102. Office hours—8:30 a.m. to 5 p.m. C.S.T.

Salt Lake District Office—500 Key Bank Tower, 50 S. Main Street, suite 500, Box 79, Salt Lake City, UT 84144. Office hours—8 a.m. to 4:30 p.m. M.S.T.

Pacific Regional Office. 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036. Office hours 8:30 a.m. to 5 p.m. P.S.T.

San Francisco District Office—44 Montgomery Street, San Francisco, CA 94104. Office hours—8:30 a.m. to 5 p.m. P.S.T.

* * * * *

§ 200.309 [Amended]

24. In § 200.309(a)(1), remove the word "Branch" each time it appears, and in its place, add the word "District."

PART 202—INFORMAL AND OTHER PROCEDURES

25. The authority citation for part 202 continues to read in part as follows:

Authority: 15 U.S.C. 77s, 77t, 78d–1, 78u, 78w, 78*ll*(d), 79r, 79t, 77sss, 77uuu, 80a–37, 80a–41, 80b–9, and 80b–11, unless otherwise noted.

* * * * *

§ 202.2 [Amended]

26. In § 202.2 add the words "or district" between the words "regional" and "offices".

§ 202.3 [Amended]

27. In § 202.3(a), remove the words "Form S–18 (17 CFR 239.28)" and add, in their place, the words "Forms SB–1 and SB–2 (17 CFR 239.9 and 239.10)".

§ 202.5 [Amended]

28. In § 202.5(c) remove the words "or Regional Administrator" and add, in their place, the words ", Regional Director, or District Administrator".

§ 202.7 [Amended]

29. In § 202.7(a), add the words "or district" between the words "regional" and "office."

PART 203—RULES RELATING TO INVESTIGATIONS

30. The authority citation for part 203 continues to read as follows:

Authority: 15 U.S.C. 77s, 78w, 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

§§ 203.2 and 203.7 [Amended]

31. In §§ 203.2 and 203.7(a), add the words "Director or District" between the word "Regional" and the word "Administrator".

32. In § 203.7(a), add the words "or District" between the word "Regional" and the word "Offices".

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

33. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m, 78n, 78o, 78w, 78*ll*(d), 79t, 80a–8, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

§ 230.445 [Amended]

34. In § 230.445(b), remove the word "branch" and add in its place add the word "district".

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

35. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79*l*, 79m, 79n, 79q, 79t, 80a–8, 80a–29, 80a–30 and 80a–37, unless otherwise noted.

* * * * *

§ 239.0–1 [Amended]

36. In § 239.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

Subpart A—Rules and Regulations Under the Securities Exchange Act of 1934

37. The authority citation for part 240, continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

§§ 240.15c3–1, 240.17a–3, 240.17–5 [Amended]

38. In part 240, add the words "or district" after the words "regional" and "region" each time they appear in the following places:

(a) The introductory text of § 240.15c3–1(a)(6)(iv), and § 240.15c3–1 (a)(6)(v), (a)(7)(iv), (c)(2)(x)(B)(*1*)(ii), (c)(2)(x)(F)(3), and (e)(1)(iv);

(b) Section 240.17a–3(b)(2);

(c) Section 240.17a–5(a)(3), (b)(1), the introductory text of § 240.17a–5(c)(1), § 240.17a–5(c)(2)(iii), (c)(2)(iv), (d)(1)(i), (d)(6), (e)(4), (f)(2)(i), the introductory text of § 240.17a–5(f)(4), and § 240.17a–5(m)(1); and

(d) Section 240.17a–11(g).

§§ 240.15c3–1, 240.17a–7 [Amended]

39. In §§ 240.15c3–1(c)(12), 240.17a–7 (b)(1) and (b)(2), add the words "or District" after the word "Regional" each time it appears.

40. In part 240, add the words "or district" after the word "region" and the words "or District" after the word "Regional" each time they appear in the following places:

(a) Section 240.15c3–1d (c)(6)(i) and (c)(6)(ii);

(b) Section 240.17Ad–2(h)(1).

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

41. The authority citation for part 249 continues to read in part as follows:

Authority: 15 U.S.C. 78a, *et seq.*, unless otherwise noted;

* * * * *

§ 249.0–1 [Amended]

42. In § 249.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

PART 249b—FURTHER FORMS, SECURITIES EXCHANGE ACT OF 1934

43. The authority citation for part 249b continues to read in part as follows:

Authority: 15 U.S.C. 78a *et seq.*, unless otherwise noted;

* * * * *

§ 249b.100, 249b.102, and 249b.200 [Amended]

44. In § 249b.100, 249b.102, and 249b.200, add the words "and district" between the words "regional" and "offices" in the appended footnote each time they appear.

PART 259—GENERAL RULES AND REGULATIONS, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935

45. The authority citation for part 259 continues to read as follows:

Authority: 15 U.S.C. 79e, 79f, 79g, 79j, 79*l*, 79m, 79n, 79q, 79t.

§ 259.0–1(b) [Amended]

46. In § 259.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

PART 269—FORMS PRESCRIBED UNDER THE TRUST INDENTURE ACT OF 1939

47. The authority citation for part 269 continues to read as follows:

Authority: 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78*ll*(d), unless otherwise noted.

§ 269.0–1 [Amended]

48. In § 269.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

49. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 80a–1, *et seq.*, unless otherwise noted.

§ 274.0–1 [Amended]

50. In § 274.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

51. The authority citation for part 275 continues to read in part as follows:

Authority: Sec. 203, 54 Stat. 850, as amended, 15 U.S.C. 80b–3; sec. 204, 54 Stat. 852, as amended, 15 U.S.C. 80b–4; sec. 206A, 84 Stat. 1433, as added, 15 U.S.C. 80b–6A; sec. 211, 54 Stat. 855, as amended, 15 U.S.C. 80b–11, unless otherwise noted;

* * * * *

§ 275.204–2 [Amended]

52. In § 275.204–2(j)(3)(i) and (j)(3)(ii), add the words "or District" between the words "Regional" and "Office" each time they appear.

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

53. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b–1, *et seq.*

* * * * *

§ 279.0–1 [Amended]

54. In § 279.0–1(b), add the words "and district" between the words "regional" and "offices" each time they appear.

Dated: February 2, 1994.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–2826 Filed 2–8–94; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Project Cost and Annual Limits

February 3, 1994.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: Pursuant to the authority delegated by 18 CFR 375.307(e)(1), the Director of the Office of Pipeline and Producer Regulation computes and publishes the project cost and annual limits specified in Table I of § 157.208(d) and Table II of § 157.215(a) for each calendar year.

EFFECTIVE DATE: January 1, 1994.

FOR FURTHER INFORMATION, CONTACT: Martin A. Burless, Jr., Chief, Pipeline Certificates and Projects Branch, Division of Pipeline Certificates, OPPR, (202) 208–0581

SUPPLEMENTARY INFORMATION:

Order of the Director, OPPR

February 3, 1994.

Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶61,216). Section 157.215(a) specified the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the "limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GNP implicit price deflator' published by the Department of Commerce for the previous calendar year."

Pursuant to § 375.307(e)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to the Director of the Office of Pipeline and Producer Regulation. The cost limits for calendar years 1982 through 1994, as published in Table I of § 157.208(d) and Table II of § 157.215(a), are hereby issued.

Note that these inflation adjustments are based on the Gross Domestic Product (GDP) Implicit Price Deflator rather than the Gross National Product (GNP) Implicit Price Deflator, which is

not yet available for 1993. The Commerce Department advises that in recent years the annual change has been virtually the same for both indices. Further adjustments will be made, if necessary.

List of Subjects in 18 CFR Part 157

Natural gas.

Robert J. Cupina,

Deputy Director, Office of Pipeline and Producer Regulation.

Accordingly, 18 CFR part 157 is amended as follows:

PART 157—[AMENDED]

1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

§ 157.208 [Amended]

2. Table I in § 157.208(d) is revised to read as follows:

TABLE I

Year	Limit	
	Auto. project cost limit (col. 1)	Prior notice project cost limit (col. 2)
1982	$4,200,000	$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000
1991	6,000,000	16,700,000
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000

§ 157.215 [Amended]

3. Table II in § 157.215(a) is revised to read as follows:

TABLE II

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000

[FR Doc. 94–2895 Filed 2–8–94; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 93F–0058]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers as components of surface primers used in conjunction with regulated silicone polymers in repeat-use, food-contact applications. This action is in response to a petition filed by General Electric Co.

DATES: Effective February 9, 1994; written objections and requests for a hearing by March 11, 1994.

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

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 22, 1993 (58 FR 21583), FDA announced that a food additive petition (FAP 3B4362) had been filed by General Electric Co., c/o 700 13th St. NW., suite 1200, Washington, DC 20005. The petition proposed that the food additive regulations be amended to provide for the safe use of polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers as surface primers with silicone polymers regulated in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) and § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600).

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymer is safe and that the regulations should be amended by adding new § 177.2465 (21 CFR 177.2465) as set forth below.

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

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

Any person who will be adversely affected by this regulation may at any time on or before March 11, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

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

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

2. New § 177.2465 is added to subpart C to read as follows:

§ 177.2465 Polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers.

Polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers (CAS Reg. No. 26936–30–1) may be safely used as components of surface primers used in conjunction with silicone polymers intended for repeated use and complying with § 175.300 of this chapter and § 177.2600, in accordance with the following prescribed conditions.

(a) *Identity.* For the purpose of this section, polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers are produced by the polymerization of methylmethacrylate and trimethoxysilylpropylmethacrylate.

(b) *Conditions of use.* (1) The polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers are used at levels not to exceed 6.0 percent by weight of the primer formulation.

(2) The copolymers may be used in food contact applications with all food types under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter.

Dated: January 31, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–2881 Filed 2–8–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 228

Security Protective Force

AGENCY: National Security Agency, DOD.

ACTION: Final rule.

SUMMARY: The National Security Agency (NSA) has promulgated regulations which protect its foreign intelligence facilities within the United States. The classified and highly sensitive worldwide activities of the Agency are directed and supervised from these various facilities. Furthermore, all intelligence support functions for the conduct of the various foreign intelligence missions of the NSA are managed from these facilities. Pursuant to a Delegation of Authority to the Director, NSA from the Administrator of General Services effective October 1, 1986, the NSA was empowered to promulgate this part, which has the force of law. Pursuant to the Delegation, the NSA has the authority to carry out the protective police functions set forth above with respect to property under its charge and control, and has promulgated this part pursuant thereto.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Peter R. Badger, Office of General Counsel, National Security Agency. (301) 688–5015.

SUPPLEMENTARY INFORMATION: On September 30, 1991, the Administrator of General Services signed a Delegation of Authority, effective October 1, 1991, which delegated to the Director, NSA the authorities vested in the Administrator by, inter alia, the Act of June 1, 1948, 62 Stat. 281, Sections 1 through 4 (40 U.S.C. 318–318c), to perform functions with respect to the protection of the buildings and grounds occupied by the Agency. 40 U.S.C. 318 empowers the Administrator of General Services to appoint special policemen to protect property under his charge and control. In furtherance of this purpose, such special policemen are granted the same powers as sheriffs and constables, and are authorized to enforce laws enacted for the protection of persons and property, to prevent breaches of the peace, to suppress affrays (brawls) or unlawful assemblies, and to enforce with criminal penalties any rules and regulations made and promulgated by the Administrator. Section 318a provides specific authority to promulgate regulations to be enforced by such special policemen.

On July 2, 1991, NSA published this regulation as a proposed rule with comment period. No comments were received, and the rule is now being published in final without substantive changes.

This rule is not a significant regulatory action within the meaning of Executive Order 12866 of September 30, 1993. As required by the Regulatory Flexibility Act, it has been certified that this rule will not have a significant impact on small business entities. This rule is not subject to the Paperwork Reduction Act because it will not impose on the public any reporting or record keeping requirements

List of Subjects in 32 CFR Part 228

Security measures.

Accordingly, Title 32, Chapter I, Subchapter M is amended to add a new Part 228 to read as follows:

PART 228—SECURITY PROTECTIVE FORCE

Sec.
228.1 Applicability.
228.2 Control of activities on protected property.
228.3 Restrictions on admission to protected property.
228.4 Control of vehicles on protected property.
228.5 Enforcement of parking regulations.
228.6 Security inspection.
228.7 Prohibition on weapons and explosives.
228.8 Prohibition on photographic or electronic recording or transmitting equipment.
228.9 Prohibition on narcotics and illegal substances.
228.10 Prohibition on alcohol.
228.11 Restrictions on the taking of photographs.
228.12 Physical protection of facilities.
228.13 Disturbances on protected property
228.14 Prohibition on gambling.
228.15 Restriction regarding animals.
228.16 Soliciting, vending, and debt collection.
228.17 Distribution of unauthorized materials.
228.18 Penalties and the effect on other laws.

Authority: 40 U.S.C. 318–318c.

§ 228.1 Applicability.

This part applies to all property under the charge and control of the Director, NSA, and to all persons entering in or on such property (hereinafter referred to as "protected property"). Employees of the NSA and any other persons entering upon protected property shall be subject to these regulations.

§ 228.2 Control of activities on protected property.

Persons in and on protected property shall at all times comply with official signs of a prohibitory, regulatory, or directory nature and with the direction of Security Protective Officers and any other duly authorized personnel.

§ 228.3 Restrictions on admission to protected property.

Access to protected property shall be restricted to ensure the orderly and secure conduct of Agency business. Admission to protected property will be restricted to employees and other persons with proper authorization who shall, when requested, display government or other identifying credentials to the Security Protective Officers or other duly authorized

personnel when entering, leaving, or while on the property.

§ 228.4 Control of vehicles on protected property.

Drivers of all vehicles entering or while on protected property shall comply with the signals and directions of Security Protective Officers or other duly authorized personnel and any posted traffic instructions. All vehicles shall be driven in a safe and careful manner at all times, in compliance with applicable motor vehicle laws.

§ 228.5 Enforcement of parking regulations.

For reasons of security, parking regulations shall be strictly enforced. Except with proper authorization, parking on protected property is not allowed without a permit. Parking without a permit or other authorization, parking in unauthorized locations or in locations reserved for other persons, or parking contrary to the direction of posted signs or applicable state or federal laws and regulations is prohibited. Vehicles parked in violation, where warning signs are posted, shall be subject to removal at the owner's risk, which shall be in addition to any penalties assessed pursuant to § 228.18. The Agency assumes no responsibility for the payment of any fees or costs related to such removal which may be charged to the owner of the vehicle by the towing organization. This paragraph may be supplemented from time to time with the approval of the NSA Director of Security or his designee by the issuance and posting of such specific traffic directives as may be required, and when so issued and posted such directives shall have the same force and effect as if made a part hereof. Proof that a vehicle was parked in violation of these regulations or directives may be taken as *prima facie* evidence that the registered owner was responsible for the violation.

§ 228.6 Security inspection.

Any personal property, including but not limited to any packages, briefcases, containers or vehicles brought into, while on, or being removed from protected property are subject to inspection. A search of a person may accompany an investigative stop or an arrest.

§ 228.7 Prohibition on weapons and explosives.

No persons entering or while on protected property shall carry or possess, either openly or concealed, firearms, any illegal or legally controlled weapon (e.g., throwing stars, switchblades), explosives, or items intended to be used to fabricate an explosive or incendiary device, except as authorized by the NSA Director of Security or his designee at each Agency facility. The use of chemical agents (Mace, tear gas, etc.) on protected property in circumstances that do not include an immediate and unlawful threat of physical harm to any person or persons is prohibited; however, this prohibition does not apply to use by law enforcement personnel in the performance of their duties.

§ 228.8 Prohibition on photographic or electronic recording or transmitting equipment.

No person entering or while on protected property shall bring or possess any kind of photographic, recording or transmitting equipment (including but not limited to cameras, cellular telephones, or recorders), except as specially authorized by the NSA Director of Security or his designee at each Agency facility.

§ 228.9 Prohibition on narcotics and illegal substances.

Entering or being on protected property under the influence of, or while using or possessing, any narcotic drug, hallucinogen, marijuana, barbiturate or amphetamine is prohibited. Operation of a motor vehicle entering or while on protected property by a person under the influence of narcotic drugs, hallucinogens, marijuana, barbiturates or amphetamines is also prohibited. These prohibitions shall not apply in cases where the drug is being used as prescribed for a patient by a licensed physician.

§ 228.10 Prohibition on alcohol.

Entering or being on protected property under the influence of alcoholic beverages is prohibited. Operation of a motor vehicle entering or while on protected property by a person under the influence of alcoholic beverages is prohibited. The use of alcoholic beverages on protected property is also prohibited, except on occasions and on protected property for which the NSA Deputy Director for Support Services or his designee has granted approval for such use.

§ 228.11 Restrictions on the taking of photographs.

In order to protect the security of the Agency's facilities, photographs may be taken on protected property only with the consent of the NSA Director of Security or his designee. The taking of photographs includes the use of television cameras, video taping equipment, and still or motion picture cameras.

§ 228.12 Physical protection of facilities.

The willful destruction of, or damage to any protected property, or any buildings or personal property thereon, is prohibited. The theft of any personal property, the creation of any hazard on protected property to persons or things, and the throwing of articles of any kind at buildings or persons on protected property is prohibited. The improper disposal of trash or rubbish, or any unauthorized or hazardous materials on protected property is also prohibited.

§ 228.13 Disturbances on protected property.

Any conduct which impedes or threatens the security of protected property, or any buildings or persons thereon, or which disrupts the performance of official duties by Agency employees, or which interferes with ingress to or egress from protected property is prohibited. Also prohibited is any disorderly conduct, any failure to obey an order to depart the premises, any unwarranted loitering, any behavior which creates loud or unusual noise or nuisance, or any conduct which obstructs the usual use of entrances, foyers, lobbies, corridors, offices, elevators, stairways or parking lots.

§ 228.14 Prohibition on gambling.

Participating in games for money or other personal property, or the operating of gambling devices, the conduct of a lottery, or the selling or purchasing of numbers tickets, in or on protected property is prohibited. This prohibition shall not apply to the vending or exchange of chances by licensed blind operators of vending facilities for any lottery set forth in a State law and conducted by an agency of a State as authorized by section 2(a)(5) of the Randolph-Sheppard Act, as amended [20 U.S.C. 107(a)(5)].

§ 228.15 Restriction regarding animals.

No animals except guide dogs for the blind or hearing impaired, or guard or search dogs used by authorized state or federal officials, shall be brought upon protected property, except as authorized by the NSA Director of Security or his designee at each Agency facility.

§ 228.16 Soliciting, vending, and debt collection.

Commercial or political soliciting, vending of all kinds, displaying or distributing commercial advertising, collecting private debts or soliciting alms on protected property is prohibited. This does not apply to:

(a) National or local drives for welfare, health, or other purposes as authorized by the "Manual on Fund Raising Within the Federal Service," issued by the U.S. Office of Personnel Management under Executive Order 12353, 47 FR 12785, 3 CFR, 1982 Comp., p. 139, or by other federal laws or regulations; and

(b) Authorized employee notices posted on Agency bulletin boards.

§ 228.17 Distribution of unauthorized materials.

Distributing, posting or affixing materials, such as pamphlets, handbills, or flyers, on protected property is prohibited, except as provided by § 228.16, as authorized by the NSA Director of Security or his designee at each Agency facility, or when conducted as part of authorized Government activities.

§ 228.18 Penalties and the effect on other laws.

Whoever shall be found guilty of violating any provision of these regulations is subject to a fine of not more than $50 or imprisonment of not more than 30 days, or both. In the case of traffic and parking violations, fines assessed shall be in accordance with the schedule(s) of fines adopted by the United States District Court for the District where the offense occurred. Nothing in these regulations shall be construed to abrogate or supersede any other Federal laws or any State or local laws or regulations applicable to any area in which the protected property is situated.

Dated: February 3, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–2884 Filed 2–8–94; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 100 and 165

[CGD 94–007]

Safety, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary rules issued.

SUMMARY: This document provides required notice of substantive rules adopted by the Coast Guard and temporarily effective between October 1, 1993 and December 31, 1993, which were not published in the **Federal Register**. This quarterly notice lists temporary local regulations, security zones, and safety zones, which were of limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This notice lists temporary Coast Guard district regulations that were established and terminated between October 1, 1993 and December 31, 1993, as well as several regulations which were not included in the previous quarterly list.

ADDRESSES: The complete text of these temporary regulations may be examined at, and is available on request, from Executive Secretary, Marine Safety Council (G–LRA), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001.

FOR FURTHER INFORMATION CONTACT: Sheri de Grom, Executive Secretary, Marine Safety Council at (202) 267–1477 between the hours of 8 a.m. and 3 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety needs of the waters within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. Safety zones may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. Security zones limit access to vessels, ports, or waterfront facilities to prevent injury or damage. Special local regulations are issued to assure the safety of participants and spectators at regattas and other marine events. Timely publication of these regulations in the **Federal Register** is often precluded when a regulation responds to an emergency, or when an event occurs without advance notice. However, the affected public is informed of these regulations through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is frequently provided by Coast Guard patrol vessels enforcing the restrictions imposed by the regulation.

Because mariners are notified by Coast Guard officials on-scene prior to enforcement action, **Federal Register** notice is not required to place the special local regulation, security zone, or safety zone in effect. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To discharge this legal obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary special local regulations, security zones, and safety zones. Permanent regulations are not included in this list because they are published in their entirety in the **Federal Register**. Temporary regulations may also be published in their entirety if sufficient time is available to do so before they are placed in effect or terminated. These safety zones, special local regulations and security zones have been exempted from review under E.O. 12866 because of their emergency nature, or limited scope and temporary effectiveness.

The following regulations were placed in effect temporarily during the period October 1, 1993 and December 31, 1993, unless otherwise indicated.

Dated: February 4, 1994.

Sheri de Grom,

Executive Secretary, Marine Safety Council.

QUARTERLY REPORT

Docket No.	Location	Type	Effective date
Baltimore 93–05–027	Annapolis, MD	Safety Zone	12/31/93
Charleston 93–106	Cooper River, SC	Safety Zone	10/13/93
Charleston 93–121	Cooper River, SC	Safety Zone	11/23/93
Charleston 93–128	Cooper River, SC	Safety Zone	12/23/93
Corpus Christi 93–024	Corpus Christi Ship Channel	Safety Zone	12/1/93
Corpus Christi 93–026	Brownsville, TX	Safety Zone	12/20/93
Hampton Roads 93–05–004	Hampton Roads, VA	Safety Zone	11/22/93
Hampton Roads 93–05–005	Hampton Roads, VA	Safety Zone	11/26/93

QUARTERLY REPORT—Continued

Docket No.	Location	Type	Effective date
Hampton Roads 93–05–006	Hampton Roads, VA	Safety Zone	11/30/93
Hampton Roads 93–05–007	Hampton Roads, VA	Safety Zone	12/2/93
Hampton Roads 93–05–008	Hampton Roads, VA	Safety Zone	12/2/93
Houston 93–009	Houston, TX	Safety Zone	9/1/93
Houston 93–010	Houston, TX	Safety Zone	9/30/93
Houston 93–013	Houston Ship Channel	Safety Zone	12/8/94
Jacksonville 93–102	Jacksonville, FL	Safety Zone	10/2/93
Jacksonville 93–117	Jacksonville, FL	Safety Zone	11/26/93
Jacksonville 93–118	Jacksonville, FL	Safety Zone	11/27/93
Jacksonville 93–123	Jacksonville, FL	Safety Zone	12/4/93
Jacksonville 93–126	Jacksonville, FL	Safety Zone	12/31/93
Miami 93–113	Port Everglades, FL	Safety Zone	10/29/93
Mobile 93–004	Big Bayou Canot, AL	Safety Zone	9/22/93
Morgan City 93–004	Atchafalaya River, LA	Safety Zone	9/23/93
New Orleans 93–016	Lower Mississippi River	Safety Zone	9/19/93
New Orleans 93–017	Lower Mississippi River	Safety Zone	9/15/93
New Orleans 93–018	Lower Mississippi River	Security Zone	9/28/93
New Orleans 93–019	Lower Mississippi River	Safety Zone	10/29/93
New Orleans 93–020	New Orleans, LA	Safety Zone	10/24/93
New Orleans 93–021	Lower Mississippi River	Safety Zone	10/15/93
New Orleans 93–022	Lower Mississippi River	Safety Zone	11/7/93
San Francisco Bay 93–13	San Francisco Bay, CA	Safety Zone	10/7/93
San Francisco Bay 93–14	San Francisco Bay, CA	Safety Zone	10/8/93
San Francisco Bay 93–15	San Francisco Bay, CA	Safety Zone	10/9/93
San Francisco Bay 93–16	San Francisco Bay, CA	Safety Zone	10/10/93
San Francisco Bay 93–17	San Francisco Bay, CA	Safety Zone	10/9/93
San Francisco Bay 93–18	San Francisco Bay, CA	Safety Zone	10/13/93
San Francisco Bay 93–19	San Francisco Bay, CA	Safety Zone	10/9/93
San Juan 93–109	St. Croix, U.S. Virgin Islands	Security Zone	11/14/93
San Juan 93–112	Fajardo, P.R.	Safety Zone	11/20/93
San Juan 93–122	San Juan, P.R.	Safety Zone	11/21/93
St. Louis 93–032	Upper Mississippi River	Safety Zone	10/8/93
St. Louis 93–033	Illinois River	Safety Zone	10/8/93
St. Louis 93–034	Upper Mississippi River	Safety Zone	10/8/93
St. Louis 93–035	Upper Mississippi River	Safety Zone	11/26/93
Wilmington 93–006	Atlantic Intracoastal Waterway, NC	Safety Zone	10/12/93
01–93–140	Keyport, New Jerey	Safety Zone	10/23/93
01–93–155	East River, New York	Security Zone	12/13/93
01–93–400	Boston, MA	Security Zone	10/28/93
01–93–501	Greenwich Harbor, CT	Safety Zone	11/11/93
02–93–032	Ohio River	Special Local	10/31/93
05–93–071	Wilmington, NC	Special Local	10/2/93
07–93–092	Islamorada, FL	Special Local	10/2/93
07–93–098	Miami, FL	Special Local	10/9/93
07–93–105	Jacksonville, FL	Special Local	11/27/93
07–93–107	Ft. Lauderdale, FL	Special Local	11/10/93
07–93–108	Pompano Beach, FL	Special Local	12/12/93
07–93–116	Charleston, SC	Special Local	12/11/93
07–93–120	AVATAR World Cup Championships	Special Local	11/26/93
13–93–032	Queets, WA to Port of Benton, WA	Safety Zone	10/13/93
13–93–033	Port of Benton, WA	Safety Zone	10/21/93

[FR Doc. 94–3001 Filed 2–8–94; 8:45 am]
BILLING CODE 4910–14–M

33 CFR Part 110 and 165

[CCGD11–93–007]

RIN 2115–AE62

Regulated Navigation Area; San Pedro Bay, CA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This rule restricts vessel movement in Commercial Anchorage G and expands the Regulated Navigation Area at the approach to Los Angeles/Long Beach Harbor, California and prescribes certain vessel operating requirements for vessels operating in that area. The rule is a proactive prevention measure to enhance navigation safety in the approach to and departure from this heavily transited area. This rule does not change existing regulations associated with the pilot areas.

EFFECTIVE DATE: March 11, 1994.

FOR FURTHER INFORMATION CONTACT: Lieutenant Scott Pisel, Eleventh Coast Guard District, Aids to Navigation and Waterways Management Branch, 501 West Ocean Blvd., Long Beach, CA 90822–5399, telephone (310) 980–4300 ext. 501.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Commander Michael Haucke, Project Manager, and Lieutenant Commander Craig Juckniess, Project Counsel.

Regulatory History

On November 26, 1993, the Coast Guard published a notice of proposed rulemaking entitled Regulated Navigation Area; San Pedro Bay, CA in the **Federal Register** (58 FR 62300–02). The Coast Guard received one letter commenting on the proposal. A public hearing was not requested and one was not held.

Background and Purpose

The combined harbor of Los Angeles and Long Beach is the largest shipping complex in the United States. Since 1980, over 7,000 vessels have called on the port annually, equalling over 14,000 transits of the regulated navigation area. During times of heavy traffic, incoming traffic in the morning and outgoing traffic in the evening, large ships may be closer than one minute apart when moving through the bottleneck of the two breakwater harbor entrances or gates. To prevent maritime accidents, this rule will restrict vessel movement in Commercial Anchorage G and expand the regulated navigation area to ensure maritime safety through better regulation of vessel movements in the prescribed area.

This regulated navigation area contains two pilot areas, a restricted navigation area and a precautionary area. All are marked on navigational charts.

The now disbanded Los Angeles/Long Beach Port and Navigational Safety Committee, consisting of Long Beach, Los Angeles and Navy Pilots; Ports of Los Angeles and Long Beach; dry cargo vessel operators; the tanker industry; the towing industry; and the U.S. Navy and Coast Guard, worked to minimize risk, reduce close calls, and prevent collisions in San Pedro Bay. After the EXXON VALDEZ grounding in 1989, the Committee accelerated its work to improve navigational safety and focused specifically on San Pedro Bay. The Committee concluded that a larger regulated navigation area, better organization, and stricter regulation of incoming and outgoing vessel traffic was needed to prevent accidents.

Pursuant to the State of California Oil Spill Prevention, Abatement, and Removal Act of 1990, the Long Beach/Los Angeles Harbor Safety Committee was created. This new committee, with representatives from the Ports of Los Angeles and Long Beach, local pilots, tank vessel operators, dry cargo vessel operators, towing industry, a local environmental representative, Los Angeles Fisherman's Association, a maritime labor representative, and the State of California, agreed that better regulation of vessel movements in the prescribed area would increase navigation safety.

Discussion of Comments and Changes

One letter was received commenting on the proposed rule, which addressed two different areas of concern. The commenter first suggested altering the description of vessel categories subject to the operating requirements of Anchorage G and the San Pedro Bay Regulated Navigation Area to include towing vessels only while engaged in towing. This clarification is appropriate and is reflected in the final rule.

The commenter's second concern was the prohibition on vessels transiting the pilot areas, Anchorage G, and the waters between Commercial Anchorage G and the Middle Breakwater. A primary purpose of this rule is to reduce the volume of vessel traffic, and to regulate operating conditions, within the Regulated Navigation Area in order to facilitate the safe navigation of large vessels entering and departing the Los Angeles and Long Beach Harbors. The category of towing vessels excepted from the prohibition against entering the waters between Anchorage G and the Middle Breakwater has been expanded to include vessels "engaged in towing vessels to or from Commercial Anchorage G, or to or from the waters between Commercial Anchorage G and the Middle Breakwater." The remaining restrictions on vessel movement within these areas are retained as proposed.

Regulatory Evaluation

This rule is not a significant regulatory action under Executive Order 12866 and is not significant under the Department of Transportation regulatory policies and procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a Regulatory Evaluation is unnecessary.

Small Entities

The impact of this rule is minimal, therefore, the Coast Guard Certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

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

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this rule and concluded that, under section 2.B.2 of Commandant Instruction M16475.1B, it will have no environmental impact and it is categorically excluded from further environmental documentation.

List of Subjects

33 CFR Part 110

Anchorage grounds.

33 CFR Part 165

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

For the reasons set out in the preamble, the Coast Guard amends 33 CFR parts 110 and 165 as follows:

PART 110—[AMENDED]

1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 2030, 2035 and 2071; 49 CFR 1.46 and 33 CFR 1.05–1(g). Section 110.1a and each section listed in 110.1a is also issued under 33 U.S.C. 1223 and 1231.

2. Section 110.214 is amended by adding paragraph (a)(7)(iii) to read as follows:

§ 110.214 Los Angeles and Long Beach Harbors, California.

(a) * * *

(7) * * *

(iii) Vessels 30 meters or over in length, towing vessels of 8 meters or over in length engaged in towing, every vessel of 100 gross tons and upward carrying one or more passengers for hire while navigating, and each dredge and floating plant engaged in operations shall not enter anchorage G unless:

(A) In an emergency;

(B) Proceeding to anchor in or departing from Commercial Anchorage G;

(C) Standing by with confirmed pilot boarding arrangements; or,

(D) Engaged in towing vessels to or from Commercial Anchorage G.

* * * * *

PART 165—[AMENDED]

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5, 49 CFR 1.46.

4. Section 165.1109 is revised to read as follows:

§ 165.1109 San Pedro Bay, California—Regulated navigation area.

(a) *Location.* The following is a regulated navigation area: The water area of San Pedro Bay encompassed by the following geographic coordinates:

From Point Fermin Light (33°42′18″ N, 118°17′36″ W) thence along the shoreline to the San Pedro Breakwater, thence along the San Pedro Breakwater and the Middle Breakwater (following the COLREGS Demarcation Lines) to Long Beach Channel Entrance Light "2" (33°42′42″ N, 118°14′42″ W), thence south southeast to 33°40′31″ N, 118°08′42″ W; thence west to 33°40′31″ N, 118°12′03″ W; thence west southwest to 33°39′17″ N, 118°16′00″ W; thence northeast to 33°40′06″ N, 118°17′38″ W; thence north to the point of origin.

[Datum: NAD 1983]

(b) *Pilot areas.* There are two pilot areas within the regulated navigation area described in paragraph (a). They are defined as follows:

(1) The Los Angeles Pilot Area is enclosed by a line beginning at Los Angeles Light (33°42′30″ N, 118°15′06″ W); thence easterly to Los Angeles Main Channel Entrance Light 2 (33°42′42″ N, 118°14′42″ W); thence southeasterly to 33°41′36.2″ (N, 118°13′46.2″ W; thence southwest to 33°41′13.9″ N, 118°14′55.4″ W; thence north to the point of origin.

[Datum: NAD 1983]

(2) The Long Beach Pilot Area is enclosed by a line beginning at Long Beach Light (33°43′24″ N, 118°11′12″ W); thence easterly to Long Beach Channel Entrance Light 2 (33°43′24″ N, 118°10′48″ W); thence southerly to 33°42′09.1″ N, 118°10′26.2″ W; thence west to 33°42′09.1″ N, 118°11′35.5″ W; thence northeasterly to the point of origin.

[Datum: NAD 1983]

(c) *Definitions.* For the purposes of this section:

(1) *Floating plant*—means any vessel, other than a vessel underway and making way, engaged in any construction, manufacturing, or exploration operation.

(2) *Vessel*—means every description of watercraft, used or capable of being used as a means of transportation on water.

(d) The following regulations apply to all vessels while operating within the regulated navigation area:

(1) *Los Angeles Pilot Area:*

(i) No vessel may enter the Los Angeles Pilot Area unless it is entering or departing the Los Angeles Main Channel via the Los Angeles Harbor Entrance (Angel's Gate).

(ii) Vessels entering the Los Angeles Pilot Area shall pass directly through without stopping or loitering unless stopping is necessary to embark or disembark a pilot.

(iii) Vessels shall leave Los Angeles Approach Lighted Bell Buoy "LA" to port when entering and departing Los Angeles Main Channel;

(2) *Long Beach Pilot Area:*

(i) No vessel may enter the Long Beach Pilot Area unless it is entering or departing Long Beach Harbor Entrance (Queen's Gate).

(ii) Every vessel entering the Long Beach Pilot Area shall pass directly thorugh without stopping or loitering unless stopping is necessary to embark or disembark a pilot.

(iii) Every vessel shall leave Long Beach Approach Lighted Whistle Buoy "LB" to port when entering and departing Long Beach Channel and departing vessels shall pass across the southern boundary of the Long Beach Pilot Area.

(e) The following regulations contained in paragraphs (e)(1) through (e)(4) apply to vessels 30 meters (approximately 98 feet) or over in length, towing vessels of 8 meters (approximately 26 feet) or over in length engaged in towing, vessels of 100 gross tons and upward carrying one or more passengers for hire while navigating, and each dredge and floating plant engaged in operations in the regulated navigation area:

(1) Such vessel's speed shall not exceed 12 knots;

(2) All verbal contact between such vessels shall be communicated in the English language. No such vessel may enter or transit within the regulated navigation area unless there is at least one person on the bridge immediately available to communicate with other vessels in the English language;

(3) When such vessels in the regulated navigation area encounter meeting, crossing, or overtaking situations as defined by the International Regulations for Prevention of Collisions at Sea, 1972 (72 COLREGS) the master, pilot or person in charge of each such vessel shall make verbal passing arrangements with the other over radiotelephone in addition to sound signal requirements of the 72 COLREGS;

(4) No such vessel may enter the waters between Commercial Anchorage G and the Middle Breakwater as defined by an area enclosed by a line beginning at Los Angeles Main Channel Entrance Light 2 (33°42′42″ N, 118°14′42″ W); thence eastward along the middle breakwater to Long Beach Light (33°43′24″ N, 118°11′12″ W); thence south to 33°43′05.3″ N, 118°11′15.3″ W; thence westerly to 33°43′05.3″ N, 118°12′15.7″ W; thence southwesterly parallel to the breakwater to 33°42′29.9″ N, 118°14′16.0″ W; thence to the point of origin, unless such vessel is:

(i) In an emergency;

(ii) Proceeding to anchor in or departing Commercial Anchorage G;

(iii) Standing by with confirmed pilot boarding arrangements; or,

(iv) Engaged in towing vessels to or from Commercial Anchorage G, or to or from the waters between Commercial Anchorage G and the Middle Breakwater.

Dated: January 24, 1994.

R.D. Herr,

Rear Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 94–3000 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–14–M

---

33 CFR Part 117

[CGD05–93–054]

Drawbridge Operation Regulations; York River, Yorktown, VA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations governing the operation of the George P. Coleman Memorial drawbridge across the York River, mile 7.0, at Yorktown, Virginia, by restricting bridge openings during the morning and evening rush hours to all vessel traffic. This is intended to provide for the regularly scheduled drawbridge openings to help reduce motor vehicle traffic delays and congestion on the roads and highways linked by this drawbridge.

EFFECTIVE DATE: This rule is effective on March 11, 1994.

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

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Linda G. Gilliam, Project Manager, Bridge Section, and LT Monica L. Lombardi, Project Counsel, Legal Office.

Regulatory History

On August 19, 1993, the Coast Guard published a notice of proposed rulemaking entitled York River, Yorktown, Virginia, in the **Federal Register** (58 FR 44155). The comment

period ended October 4, 1993. The Coast Guard received eight letters commenting on the proposal. The Commander, Fifth Coast Guard District, also published the proposed rule as a public notice on August 27, 1993, with the comment period ending October 4, 1993. A public hearing was not requested and one was not held.

Background and Purpose

The Virginia Department of Transportation requested that peak morning and evening vehicular traffic period openings of the George P. Coleman Memorial drawbridge across the York River, mile 7.0, at Yorktown, Virginia, be restricted to help reduce rush hour highway traffic congestion, but remain open on signal during the rest of the time.

Currently, the Coleman Bridge opens for vessel traffic on demand. This rule will restrict the passage of vessels during rush hours by eliminating bridge openings between the hours of 6 a.m. to 8 a.m. and 3 p.m. to 6 p.m., Monday through Friday, except Federal holidays, year round. Vessels in an emergency shall pass at any time. The draw shall open on signal at all other times.

In developing this final rule, the Coast Guard considered all views and believes this final rule will not unduly restrict commercial/military vessels passage through the bridge since they can plan their vessel transits around the restricted hours of operation.

Discussion of Comments and Changes

The eight comments received as a result of the public notice issued by the District Commander are all in favor of the new restrictions for the Coleman Bridge. No new or additional changes are being made to the regulatory language of this final rule.

Regulatory Evaluation

This action is not considered a significant regulatory action under Executive Order 12866 and is not significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. This opinion is based on the fact that the regulations will not unduly cause a hardship on commercial/military vessels who will be able to plan their vessel transits around the hours of restriction.

Small Entities

No comments were received concerning small entities or on the economic impact this rule would have on small entities. Since the impact on these regulations is expected to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*), that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

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

Federalism

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

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2.g.(5) of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, the Coast Guard amends part 117 of title 33, Code of Federal Regulations to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g)

2. Section 117.1025 is added to read as follows:

§ 117.1025 York River.

(a) The Coleman Memorial Bridge, mile 7.0, at Yorktown, shall open on signal; except from 6 a.m. to 8 a.m. and 3 p.m. to 6 p.m., Monday through Friday, except Federal holidays, the bridge shall remain closed to navigation.

(b) The bridge shall be opened at any-time for vessels in an emergency which presents danger to life or property.

Dated: January 14, 1994.

W.T. Leland,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 94–2999 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–14–M

---

33 CFR Part 165

[CG COTP BALTIMORE, MD Regulation 94–001]

Regulated Navigation Area; Ice Operations In Chesapeake Bay

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This document implements 33 CFR 165.503 the Ice Navigation Season on the northern portion of the Chesapeake Bay and its tributaries, including the Chesapeake and Delaware Canal. This regulated navigation area will be placed in effect on January 3, 1994. The purpose of these Regulations is to enhance the safety of navigation in the affected waters. It requires operators of certain vessels, during their vessel's transit of the Regulated Navigation Area, to be aware of currently effective Ice Navigation Season Captain of the Port Orders issued by the Captain of the Port Baltimore.

EFFECTIVE DATES: This document is effective from January 3, 1994, until such time as necessary for the safe transit of vessels in the area and this notice is canceled by the Captain of the Port. Cancellation Notice will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

LT Mark Williams, USCG Marine Safety Office, Custom House, 40 South Gay Street, Baltimore, Maryland 21202–4022, (410) 962–5105.

DRAFTING INFORMATION: Drafted by LT Mark Williams project officer, MSO Baltimore, and LT John Gately, project attorney, Fifth Coast Guard District Legal Office.

Dated: December 29, 1993.

G.S. Cope,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. 94–3002 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL88-1-6187; FRL-4835-9]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: Environmental Protection Agency.

ACTION: Technical amendments.

SUMMARY: This document contains corrections to final rules which were published on September 29, 1982 and August 8, 1984. These revisions related to items incorporated by reference in to the Illinois State Implementation Plan which is designated as § 52.720 Identification of plan, subpart O—Illinois, part 52, chapter I, title 40 of the Code of Federal Regulations.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Randolph O. Cano at (312) 886-6036.

SUPPLEMENTARY INFORMATION: On September 29, 1982, (47 FR 42733) when the United States Environmental Protection Agency (U.S. EPA) approved a revision to the Illinois State Implementation Plan (SIP) in the form of a May 28, 1981 Illinois Pollution Control Board (IPCB) Final Opinion and Order of the Board in proceeding R78-17 U.S. EPA erroneously codified its approval at 40 CFR 52.720(c)(37). Paragraph (c)(37) had already been utilized to codify U.S. EPA's November 27, 1981, (46 FR 57893) approval of a revision to the Illinois SIP in the form of an April 3, 1980, IPCB Opinion and Order of the Board.

On August 8, 1984 (49 FR 31685), when U.S. EPA approved a revision to the Illinois SIP in the form of the satisfaction of the conditional approval of a revised part D sulfur dioxide control strategy for Cincinnati Pekin and Elm Grove Townships in Tazewell County and for Logan and Limestone Townships in Peoria County, U.S. EPA erroneously codified its approval at 40 CFR 52.720(c)(46). Paragraph (c)(46) had already been utilized to codify U.S. EPA's February 22, 1984 (49 FR 6490) approval of a revision to the Illinois SIP in the form of a May 19, 1983 Opinion and Order of the IPCB in proceeding PCB 82-147 which granted Del Monte Corporation's Can Manufacturing Plant No. 115 which is located in Rochelle, Ogle County, Illinois a variance from the requirements of IPCB Rule 205(n)(1)(B)(i) and Rule 205(n)(1)(B)(iv) until December 31, 1994.

Need for Correction

These duplicate uses of paragraphs 52.720 (c)(37) and (c)(46) make citations to these paragraphs confusing and unclear as well as imprecise. For this reason U.S. EPA is publishing these technical amendments to avoid further confusion.

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Ozone, Particulate matter, Sulfur oxides.

Dated: January 26, 1994.

Valdas V. Adamkus,

Regional Administrator.

Accordingly, part 52, chapter I, title 40 of the Code of Federal Regulations is corrected by making the following technical amendments:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart O—Illinois

§ 52.720 [Amended]

2. Section 52.720 is amended by redesignating the second paragraph (c)(37) as paragraph (c)(43).

3. Section 52.720 is amended by redesignating the second paragraph (c)(46) as (c)(47).

[FR Doc. 94-2910 Filed 2-8-94; 8:45 am]

BILLING CODE 6560-50-P

---

40 CFR Part 60

[FRL-4836-3]

Standards of Performance for New Stationary Sources, Supplemental Delegation of Authority to the Commonwealth of Kentucky

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation of authority.

SUMMARY: On October 18, 1993, the Commonwealth of Kentucky Department for Environmental Protection requested that EPA delegate authority for implementation and enforcement of additional and revised categories of New Source Performance Standards (NSPS). Since EPA's review of Kentucky's pertinent laws, rules, and regulations showed them to be adequate for the implementation and enforcement of these federal standards, the Agency has made the delegations as requested.

EFFECTIVE DATE: The effective date of the delegation of authority is December 14, 1993.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection during normal business hours at the following locations:

Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street, Atlanta, Georgia 30365.

Natural Resources and Environmental Protection Cabinet, Department for Environmental Protection, Division for Air Quality, 316 St. Clair Mall, Frankfort, Kentucky 40601.

Effective immediately, all requests, applications, reports and other correspondence required pursuant to the newly delegated standards should not be submitted to the Region IV office, but should instead be submitted to the following address:

Natural Resources and Environmental Protection Cabinet, Department for Environmental Protection, Division for Air Quality, 316 St. Clair Mall, Frankfort, Kentucky 40601.

FOR FURTHER INFORMATION CONTACT: Scott Southwick, Regulatory Planning and Development Section, Air Programs Branch, United States Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Georgia, 30365, (404) 347-2864.

SUPPLEMENTARY INFORMATION: Section 301, in conjunction with Sections 110 and 111(c)(1) of the Clean Air Act as amended November 15, 1990, authorizes EPA to delegate authority to implement and enforce the standards set out in 40 CFR part 60, NSPS.

On April 12, 1977, EPA initially delegated the authority for implementation and enforcement of the NSPS programs to the Commonwealth of Kentucky. On October 18, 1993, Kentucky requested a delegation of authority for implementation and enforcement of the following NSPS categories found in 40 CFR part 60.

New Categories for NSPS

1. Subpart Dc 401 KAR 59:435 Small Industrial-Commercial-Institutional Steam Generating Units (except § 60.48c(a)).

2. Subpart Kb 401 KAR 59:485 Storage Vessels for Petroleum Liquids (after 7/23/84) (except §§ 60.111b(f)(4), 60.114b, 60.116b(e)(3) (iii) and (iv), and 60.116b(f)(2)(iii)).

Revised Categories for NSPS

1. Subpart F 401 KAR 59:450 Portland Cement Plants.

2. Subpart G 401 KAR 59:455 Nitric Acid Plants.

3. Subpart I 401 KAR 59:465 Hot Mix Asphalt Facilities.

4. Subpart L 401 KAR 59:490 Secondary Lead Smelters.

5. Subpart M 401 KAR 59:495 Secondary Brass and Bronze Ingot Production Plants.

6. Subpart N 401 KAR 59:500 Iron and Steel Plants.

7. Subpart Na 401 KAR 59:505 Secondary Emissions from BOP Steel Facilities (after 1/10/83).

8. Subpart T 401 KAR 59:535 Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants.

9. Subpart U 401 KAR 59:540 Phosphate Fertilizer Industry: Superphosphoric Acid Plants.

10. Subpart V 401 KAR 59:545 Phosphate Fertilizer Industry: Diammonium Phosphate Plants.

11. Subpart W 401 KAR 59:550 Phosphate Fertilizer Industry: Triple Super Plants.

12. Subpart X 401 KAR 59:555 Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities.

13. Subpart AA 401 KAR 59:570 Steel Plants: Electric Arc Furnaces (After 12/21/74 and on or before 8/17/83).

14. Subpart AAa 401 KAR 59:575 Steel Plants: Electric Arc Furnaces and Argon-Oxy Decarbon (after 10/7/83).

15. Subpart BB 401 KAR 59:580 Kraft Pulp Mills.

16. Subpart CC 401 KAR 59:585 Glass Manufacturing Plants.

17. Subpart DD 401 KAR 59:590 Grain Elevators.

18. Subpart EE 401 KAR 59:595 Surface Coating of Metal Furniture (except § 60.316(d)).

After a thorough review of the request, the Regional Administrator determined that such a delegation was appropriate for these source categories with the conditions set forth in the original delegation letter of April 12, 1977. Kentucky sources subject to the requirements of these subparts will now be under the jurisdiction of the Commonwealth of Kentucky. On December 14, 1993, EPA delegated the authority for the above mentioned source categories in a letter from Winston A. Smith, Director, Air Pesticides, and Toxics Management Division to John E. Hornback, Director, Kentucky Division for Air Quality.

Action

Since review of the pertinent Kentucky laws, rules, and regulations showed them to be adequate for the implementation and enforcement of the aforementioned categories of NSPS, the Commonwealth's request for delegation was granted. The EPA hereby notifies the public that it has delegated the authority for the source categories listed above (except those sections, as noted, that may not be delegated).

The Office of Management and Budget has exempted this rule from the requirements of section 6 of Executive Order 12866.

Authority: This notice is issued under the authority of sections 101, 110, 111, and 301 of the Clean Air Act, as amended (42 U.S.C. 7401, 7410, 7411, 7412, and 7601).

Dated: January 24, 1994.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 94–2966 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–P

---

40 CFR Parts 712 and 716

[OPPTS–82042; FRL–4745–5]

Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Interagency Testing Committee (ITC) in its 32nd Report to EPA revised the Toxic Substances Control Act (TSCA) Section 4(e) Priority List by designating for testing 34 chemical substances. The ITC recommendations must be given priority consideration by EPA in promulgating test rules. EPA is adding certain of these chemical substances to two model information-gathering rules: the TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) and the TSCA Section 8(d) Health and Safety Data Reporting Rule. These model rules will require: Manufacturers and importers of the substances identified herein to report certain production, use, and exposure-related information, and manufacturers, importers, and processors of the listed substances to report unpublished health and safety data to EPA. This document also makes certain modifications to a final rule published in the **Federal Register** of May 14, 1993, and a technical amendment to that rule published in the **Federal Register** of September 10, 1993.

EFFECTIVE DATE: This rule will become effective on March 11, 1994.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, TSCA Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. E–543, Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: This rule adds 34 chemical substances to the PAIR and 28 chemical substances to the section 8(d) Health and Safety Data Reporting Rule. Manufacturers, importers, and processors of these chemicals will be required to report unpublished health and safety data, and manufacturers and importers will be required to report end use, exposure, and production volume data to EPA. Because the ITC has expressed no need for ecological effects information for the substances being added to the section 8(d) rule via this action, EPA is not requiring the reporting of these data for the subject substances under the section 8(d) rule.

This rule also provides CAS Registry Numbers for seven chemicals listed under the siloxanes category in a final rule published in the **Federal Register** of May 14, 1993 (58 FR 28511). These CAS numbers did not exist at the time of publication of that rule, but they have since been assigned and are now included for both the PAIR and section 8(d) rule. The seven chemicals are: Octacosamethylcyclotetradecasiloxane (CAS No. 149050-40-8); dotriacontamethylcyclohexadecasiloxane (CAS No. 150026-95-2); tetratriacontamethylcycloheptadecasiloxane (CAS No. 150026-96-3); octatriacontamethylcyclononadecasiloxane (CAS No. 150026-97-4); tetracontamethylcycloeicosasiloxane (CAS No. 150026-98-5); tetracontamethylnonadecasiloxane (CAS No. 150026-99-6); and dotetracontamethyleicosasiloxane (CAS No. 150027-00-2). Finally, in a technical amendment published in the **Federal Register** of September 10, 1993 (58 FR 47647), the chemical polydimethylsiloxane (CAS No. 9016-00-6), was inadvertently left in the regulatory text portion of 712.30(x); this document removes the chemical from 712.30(x).

Additionally, this notice corrects two chemical names added to 40 CFR parts 712 and 716 in the **Federal Register** of May 14, 1993. In 712.30(x) and 716.120(d), non-endblocked siloxanes (CAS No. 70131-67-8), is being revised to read siloxanes and silicones, di-Me, hydroxy-terminated, and dimethylmethyl 3,3,3-trifluoropropyl (CAS No. 115361-68-7), is being revised to read dimethylmethyl 3,3,3-trifluoropropyl siloxane.

I. Background

Section 4(e) of TSCA established the ITC and authorized it to recommend to EPA chemical substances and mixtures

(chemicals) to be given priority consideration in proposing test rules under section 4. For some of these chemicals, the ITC may designate that EPA must respond to its recommendations within 12 months. In this time, EPA must either initiate a rulemaking to test the chemical or publish in the **Federal Register** its reasons for not doing so.

On June 2, 1993, EPA announced the receipt of the 32nd Report of the ITC, and it was then published in the **Federal Register** of July 16, 1993 (58 FR 38490). The 32nd Report revises the Committee's priority list of chemicals by designating 34 chemical substances to the section 4(e) priority list.

At the request of the Occupational Safety and Health Agency (OSHA), the ITC designated, via its 32nd Report, a group of 34 chemical substances which may cause harm to exposed workers by absorption through the skin. OSHA nominated these substances (and 24 previously via the ITC's 31st Report (58 FR 26898, May 5, 1993)) for testing to support the assignment of Permissible Exposure Limits (PELS) "skin designations."

This rule adds 34 chemical substances to the PAIR and 28 substances to the section 8(d) Health and Safety Data Reporting Rule (6 substances are currently listed on the 8(d) rule, as described in Unit II of this preamble). These two rules are model information gathering rules which assist ITC in making testing recommendations and aid EPA in responding to the ITC recommendations.

EPA issued the PAIR under section 8(a) of TSCA (15 U.S.C. 2607(a)), and it is codified at 40 CFR part 712. This model section 8(a) rule establishes standard reporting requirements for manufacturers and importers of the chemicals listed in the rule at 40 CFR 712.30. These manufacturers and importers are required to submit a one-time report on general volume, end use, and exposure-related information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710–35).

EPA uses this model section 8(a) rule to gather current information on chemicals of concern quickly. EPA issued the model Health and Safety Data Reporting Rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. The section 8(d) model rule requires past, current, and prospective manufacturers, importers, and processors of listed chemicals to submit to EPA copies and lists of unpublished health and safety studies on the listed chemicals that they manufacture, import, or process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

These model rules provide for the automatic addition of ITC priority list chemicals. Whenever EPA announces the receipt of an ITC report, EPA may, at the same time without further notice and comment, amend the two model information-gathering rules by adding the recommended chemicals. The amendment adding these chemicals to the PAIR and the Health and Safety Data Reporting Rule becomes effective 30 days after publication in the **Federal Register**.

For the chemicals listed under § 716.120(d) of the section 8(d) rule which are being added under the category "OSHA Chemicals in Need of Dermal Absorption Testing," the reporting of ecological effects data will not be required. Because no member of the ITC has expressed a need for these data, EPA believes there is no need to collect this information at this time.

II. Chemicals To Be Added

In its 32nd Report to EPA, the ITC designated 34 chemical substances for dermal absorption testing. EPA is adding 34 chemical substances to the PAIR and 28 substances to the section 8(d) Health and Safety Data Reporting Rule; these substances are listed in the regulatory text section of this document. EPA is not adding to the section 8(d) six of the substances listed in the ITC report because the substances were previously listed on the section 8(d) rule and are currently subject to reporting. These six substances are: Bromoform (CAS No. 75-25-2), (52 FR 16022, May 1, 1987); 1,1-dichloroethane (CAS No. 75-34-3), (52 FR 16022, May 1, 1987); methyl methacrylate (CAS No. 80-62-6), (54 FR 8484, February 28, 1989); p-toluidine (CAS No. 106-49-0), (51 FR 2890, January 22, 1986); beta-chloroprene (CAS No. 126-99-8), (49 FR 46741, November 28, 1984); and m-phthalodinitrile (CAS No. 626-17-5), (56 FR 42688, August 30, 1991).

Manufacturers, importers, and processors of the 28 substances being listed on the 8(d) rule by this action will not be required to report ecological effects data under the 8(d) rule for those substances.

For a complete listing of the substances being added to the section 8(d) rule and the PAIR, see the regulatory text section of this document.

III. Reporting Requirements

A. Preliminary Assessment Information Rule

All persons who manufactured or imported the chemical substances named in this rule during their latest complete corporate fiscal year must submit a Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710-35) for each manufacturing or importing site at which they manufactured or imported a named substance. A separate form must be completed for each substance and submitted to the Agency no later than May 10, 1994. Persons who have previously and voluntarily submitted a Manufacturer's Report to the ITC or EPA may be able to submit a copy of the original Report to EPA or to notify EPA by letter of their desire to have this voluntary submission accepted in lieu of a current data submission. See § 712.30(a)(3).

Details of the reporting requirements, the basis for exemptions, and a facsimile of the reporting form, are provided in 40 CFR part 712. Copies of the form are available from the TSCA Environmental Assistance Division at the address listed under FOR FURTHER INFORMATION CONTACT.

B. Health and Safety Data Reporting Rule

Listed below are the general reporting requirements of the section 8(d) model rule.

1. Persons who, in the 10 years preceding the date a substance is listed, either have proposed to manufacture, import, or process, or have manufactured, imported, or processed, the listed substance must submit to EPA: A copy of each health and safety study which is in their possession at the time the substance is listed.

2. Persons who, at the time the substance is listed, propose to manufacture, import, or process; or are manufacturing, importing, or processing the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the substance is listed.

b. A list of health and safety studies known to them but not in their possession at the time the substance is listed.

c. A list of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the date the substance is listed and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture, import, or process the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture, import, or process the listed substance.

b. A list of health and safety studies known to them but not in their possession at the time they propose to manufacture, import, or process the listed substance.

c. A list of health and safety studies that are ongoing at the time they propose to manufacture, import, or process the listed substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the time they propose to manufacture, import, or process the listed substance, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of the completion date.

The bulk of reporting is required at the time the substance is listed. Persons described in categories 1 and 2 do all or most of their health and safety data reporting at the start of the reporting period. The remaining reporting requirements, specifically categories 2(d), 2(e), and 3, continue prospectively.

Detailed guidance for reporting unpublished health and safety data is provided in the **Federal Register** of September 15, 1986 (51 FR 32720). Also found there are explanations of the reporting exemptions.

C. Submission of PAIR Reports and Section 8(d) Studies

PAIR reports and section 8(d) health and safety studies must be sent to:

TSCA Document Processing Center (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, ATTN: (insert either PAIR or 8(d) Reporting).

D. Removal of Chemical Substances from the Rules

Any person who believes that section 8(a) or 8(d) reporting required by this rule is unwarranted, should promptly submit to EPA in detail the reasons for that belief. EPA, in its discretion, may remove the substance from this rule for good cause (40 CFR 712.30 and 716.105). When withdrawing a substance from the rule, EPA will issue a rule amendment for publication in the **Federal Register**.

IV. Release of Aggregate Data

EPA will follow procedures for the release of aggregate statistics as prescribed in the **Federal Register** notice of June 13, 1983 (48 FR 27041). Included in the notice are procedures for requesting exemptions from the release of aggregate data. Exemption requests concerning the release of aggregate data on any chemical substance must be received by EPA no later than May 10, 1994.

V. Economic Analysis

A. Preliminary Assessment Information Rule

EPA estimates the PAIR reporting cost of this rule is $258,405. To calculate this figure, EPA used information from a variety of published sources as well as information from OPPTS's Risk Management 1 (RM1) reports on similar chemicals to generate a list of 107 firms that manufacture and/or import the 34 chemicals at a total of 161 sites. The published sources used include: SRI International's *Directory of Chemical Producers, Chemical Economics Handbook*, and *Specialty Chemicals*; other multi-client studies; the U.S. International Trade Commission's *Synthetic Organic Chemicals*; and company product literature. An unknown number of the businesses affected by the addition of the chemicals to the Priority List may qualify as a small business as defined in 40 CFR 712.25(c). However, for this analysis it is assumed that all firms identified will report. Therefore, EPA expects 107 firms to generate a total of 161 reports (some sites produce more than 1 of the 34 chemicals).

Reporting Costs (dollars)

(a) 161 reports estimated at $843 per report = $135,723
(b) 234 sites at $762 per site = $122,682
Total Cost = $258,405
Mean cost per site = $258,405/161 sites = $1,605
Mean cost per firm = $258,405/107 firms = $2,415

Reporting Burden (hours)

(a) Rule familiarization: 18 hrs/site x 161 sites = 2,898
(b) Reporting: 16 hrs/report x 161 reports = 2,576
Total burden hours = 5,474
Average burden per site = 5,474 hours/161 sites = 34
Average burden per firm = 5,474 hours/107 firms = 51

EPA Costs (dollars)

Processing cost = 161 reports x $95/report = $15,295

B. Health and Safety Data Reporting Rule

EPA estimates the total reporting costs for establishing section 8(d) reporting requirements for 28 chemicals will be $111,939. This cost estimate is high because the Agency is uncertain about the likely number of respondents to the rule. Although EPA has used the best available data to make its economic projections, much of the information is based upon the 1986 TSCA Inventory Update and secondary information from industry sources. Therefore, EPA tends to overestimate rather than underestimate reporting burden.

The estimated reporting costs are broken down as follows:

Initial corporate review	$ 26,811
Site identification	13,250
File searches at site	27,242
Photocopying existing studies	4,585
Title listing	1,380
Managerial review for CBI	26,707
Reporting on newly-initiated studies	580
Submission of newly-initiated studies	1,035
Submissions after initial reporting period	10,349
Total	$ 111,939

Reporting Burden (hours)

(a) Initial review: 2 hours/firm x 258 firms = 516 hrs
(b) Reporting: 6.2 hours/firm x 258 firms = 2,174 hrs
Total reporting burden hours = 2,690 hrs

VI. Rulemaking Record

The following documents constitute the record for this rule (docket control number OPPTS–82042). All of these documents are available to the public in the TSCA Nonconfidential Information Center (NCIC), formerly the TSCA Public Docket Office, from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The NCIC is located at EPA Headquarters, Rm. E–G102, 401 M St., SW., Washington, DC 20460.

1. This final rule.
2. The economic analysis for this rule.
3. The Thirty-second Report of the ITC.

VII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency

must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a"significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments of communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, it has been determined that this rule is not "significant" and is therefore not subject to OMB review.

B. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and have been assigned OMB control numbers 2070–0054 for PAIR reporting and 2070–0004 for TSCA section 8(d) reporting.

Public reporting burden for this collection of information is estimated to average 34 hours for PAIR per response and 8.2 hours for section 8(d), including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Parts 712 and 716

Environmental protection, Chemicals, Hazardous substances, Health and safety data, Recordkeeping and reporting requirements.

Dated: January 24, 1994.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR Chapter I is amended as follows:

Part 712—[AMENDED]

1. In part 712:

a. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

b. Section 712.30(x) is amended by adding 34 chemicals in CAS number sequence, to the category "OSHA Chemicals in Need of Dermal Absorption Testing," and under the category "siloxanes," by deleting the entire CAS number entry for 9016–00–6, revising the CAS number entries for 70131-67-8 and 115361-68-7, and repositioning and adding CAS numbers to the following substances: Octacosamethylcyclotetradecasiloxane, dotriacontamethylcyclohexadecasiloxane, tetratriacontamethylcycloheptadecasiloxane, octatriacontamethylcyclononadecasiloxane, tetracontamethylcycloeicosasiloxane, tetracontamethylnonadecasiloxane, and dotetracontamethyleicosasiloxane to read as follows:

§ 712.30 Chemicals lists and reporting periods.

* * * * *

(x) * * *

CAS No.	Substance	Effective date	Reporting date
*	*	*	*
OSHA Chemicals in Need of Dermal Absorption Testing			
*	*	*	*
61-82-5	Amitrole	3/11/94	5/10/94
*	*	*	*
74-96-4	Ethyl bromide	3/11/94	5/10/94
75-15-0	Carbon disulfide	3/11/94	5/10/94
75-25-2	Bromoform	3/11/94	5/10/94
75-34-3	1,1-Dichloroethane	3/11/94	5/10/94
*	*	*	*
77-78-1	Dimethyl sulfate	3/11/94	5/10/94
*	*	*	*
79-46-9	2-Nitropropane	3/11/94	5/10/94
*	*	*	*
80-62-6	Methyl methacrylate	3/11/94	5/10/94
84-66-2	Diethyl phthalate	3/11/94	5/10/94
88-72-2	o-Nitrotoluene	3/11/94	5/10/94
89-72-5	o-sec-Butylphenol	3/11/94	5/10/94
90-04-0	o-Anisidine	3/11/94	5/10/94
95-13-6	Indene	3/11/94	5/10/94
95-49-8	o-Chlorotoluene	3/11/94	5/10/94
*	*	*	*
99-65-0	m-Dinitrobenzene	3/11/94	5/10/94

CAS No.	Substance	Effective date	Reporting date
100-00-5	p-Nitrochlorobenzene	3/11/94	5/10/94
100-01-6	p-Nitroaniline	3/11/94	5/10/94
100-44-7	Benzyl chloride	3/11/94	5/10/94
100-63-0	Phenylhydrazine	3/11/94	5/10/94
* * *	* * *	*	*
106-49-0	p-Toluidine	3/11/94	5/10/94
* * *	* * *	*	*
108-44-1	m-Toluidine	3/11/94	5/10/94
* * *	* * *	*	*
108-90-7	Chlorobenzene	3/11/94	5/10/94
* * *	* * *	*	*
109-99-9	Tetrahydrofuran	3/11/94	5/10/94
* * *	* * *	*	*
121-14-2	2,4-Dinitrotoluene	3/11/94	5/10/94
122-39-4	Diphenylamine	3/11/94	5/10/94
* * *	* * *	*	*
126-99-8	beta-Chloroprene	3/11/94	5/10/94
* * *	* * *	*	*
150-76-5	p-Methoxyphenol	3/11/94	5/10/94
* * *	* * *	*	*
528-29-0	o-Dinitrobenzene	3/11/94	5/10/94
* * *	* * *	*	*
540-59-0	1,2-Dichloroethylene	3/11/94	5/10/94
* * *	* * *	*	*
626-17-5	m-Phthalodinitrile	3/11/94	5/10/94
* * *	* * *	*	*
768-52-5	N-Isopropylaniline	3/11/94	5/10/94
1300-73-8	Xylidine	3/11/94	5/10/94
6423-43-4	Propylene glycol dinitrate	3/11/94	5/10/94
* * *	* * *	*	*
25013-15-4	Vinyl toluene	3/11/94	5/10/94
* * *	* * *	*	*
Siloxanes			
* * *	* * *	*	*
70131-67-8	Siloxanes and silicones, di-Me, hydroxy-terminated	10/12/93	2/28/94
* * *	* * *	*	*
115361-68-7	Dimethylmethyl 3,3,3-trifluoropropyl siloxane	10/12/93	2/28/94
149050-40-8	Octacosamethylcyclotetradecasiloxane	* * *	* * *
150026-95-2	Dotriacontamethylcyclohexadecasiloxane	* * *	* * *
150026-96-3	Tetratriacontamethylcycloheptadecasiloxane	* * *	* * *
150026-97-4	Octatriacontamethylcyclononadecasiloxane	* * *	* * *
150026-98-5	Tetracontamethylcycloeicosasiloxane	* * *	* * *
150026-99-6	Tetracontamethylnonadecasiloxane	* * *	* * *
150027-00-2	Dotetracontamethyleicosasiloxane	* * *	* * *
* * *	* * *	*	*

PART 716—[AMENDED]

2. In part 716:

a. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

b. Section 716.120(d) is amended by adding 28 chemicals in CAS number sequence, to the category "OSHA Chemicals in Need of Dermal Absorption Testing," and under the category "siloxanes," revising the entry for "non-endblocked siloxanes" to read siloxanes and silicones, di-Me, hydroxy-terminated, revising the entry for "dimethylmethyl 3,3,3-trifluoropropyl" to read dimethylmethyl 3,3,3-trifluoropropyl siloxane, and adding CAS numbers to the following substances: Dotetracontamethyleicosasiloxane, dotriacontamethylcyclohexadecasiloxane, octacosamethylcyclotetradecasiloxane, octatriacontamethylcyclononadecasiloxane, tetracontamethylcycloeicosasiloxane, tetracontamethylnonadecasiloxane, and tetratriacontamethylcycloheptadecasiloxane to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(d) * * *

Category	CAS No.	Special exemptions	Effective date	Sunset date
* * *	* * *	* * *		
OSHA Chemicals in Need of Dermal Absorption Testing				
Amitrole	61-82-5	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
o-Anisidine	90-04-0	§716.20(b)(3) applies	3/11/94	3/11/04
Benzyl chloride	100-44-7	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
o-sec-Butylphenol	89-72-5	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Carbon disulfide	75-15-0	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Chlorobenzene	108-90-7	§716.20(b)(3) applies	3/11/94	3/11/04
o-Chlorotoluene	95-49-8	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
1,2-Dichloroethylene	540-59-0	§716.20(b)(3) applies	3/11/94	3/11/04
Diethyl phthalate	84-66-2	§716.20(b)(3) applies	3/11/94	3/11/04
Dimethyl sulfate	77-78-1	§716.20(b)(3) applies	3/11/94	3/11/04
m-Dinitrobenzene	99-65-0	§716.20(b)(3) applies	3/11/94	3/11/04
o-Dinitrobenzene	528-29-0	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
2,4-Dinitrotoluene	121-14-2	§716.20(b)(3) applies	3/11/94	3/11/04
Diphenylamine	122-39-4	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Ethyl bromide	74-96-4	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Indene	95-13-6	§716.20(b)(3) applies	3/11/94	3/11/04
N-Isopropylaniline	768-52-5	§716.20(b)(3) applies	3/11/94	3/11/04
p-Methoxyphenol	150-76-5	§716.20(b)(3) applies	3/11/94	3/11/04
p-Nitroaniline	100-01-6	§716.20(b)(3) applies	3/11/94	3/11/04
p-Nitrochlorobenzene	100-00-5	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
2-Nitropropane	79-46-9	§716.20(b)(3) applies	3/11/94	3/11/04
o-Nitrotoluene	88-72-2	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Phenylhydrazine	100-63-0	§716.20(b)(3) applies	3/11/94	3/11/04
Propylene glycol dinitrate	6423-43-4	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Tetrahydrofuran	109-99-9	§716.20(b)(3) applies	3/11/94	3/11/04
m-Toluidine	108-44-1	§716.20(b)(3) applies	3/11/94	3/11/04
Vinyl toluene	25013-15-4	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Xylidine	1300-73-8	§716.20(b)(3) applies	3/11/94	3/11/04
* * *	* * *	* * *		
Siloxanes				
Dimethylmethyl 3,3,3-trifluoropropyl siloxane	115361-68-7		* * *	* * *
* * *	* * *	* * *		
Dotetracontamethyleicosasiloxane	150027-00-2		* * *	* * *
Dotriacontamethylcyclohexadecasiloxane	150026-95-2		* * *	* * *
* * *	* * *	* * *		
Octacosamethylcyclotetradecasiloxane	149050-40-8		* * *	* * *
* * *	* * *	* * *		
Octatriacontamethylcyclononadecasiloxane	150026-97-4		* * *	* * *
* * *	* * *	* * *		
Siloxanes and silicones, di-Me, hydroxy-terminated	70131-67-8	* * *	* * *	* * *
Tetracontamethylcycloeicosasiloxane	150026-98-5		* * *	
* * *	* * *	* * *		
Tetracontamethylnonadecasiloxane	150026-99-6		* * *	* * *
* * *	* * *	* * *		
Tetratriacontamethylcycloheptadecasiloxane	150026-96-3		* * *	* * *

[FR Doc. 94–2970 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101–38

[FPMR Amendment G–106]

Passenger Sedan/Station Wagon Replacement Standards

AGENCY: Federal Supply Service, GSA.

ACTION: Final rule.

SUMMARY: This regulation updates minimum replacement standards for sedans and station wagons for executive agencies. These standards were initially published in Federal Property Management Regulations Temporary Regulation G–55 on January 28, 1992. GSA has decided to make these minimum replacement standards permanent. This amendment will codify replacement standards of 3 years and 60,000 miles for sedans and station wagons for executive agencies.

EFFECTIVE DATE: July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Michael W. Moses, Fleet Management Division, 703–305–6272.

SUPPLEMENTARY INFORMATION: The General Services Administration (GSA) has determined that this is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for and consequences of this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

FPMR Temporary Regulation G–55 established a minimum replacement standard of 3 years or 60,000 miles for passenger sedans and station wagons instead of the 6 years or 60,000 miles replacement standard contained in 41 CFR 101–38.402(a) for such vehicles. The regulation allowed all executive agencies the option to replace their passenger sedans and station wagons on a more timely basis if they deemed it to be in their best interest and cost beneficial.

GSA originally intended to publish a supplement to FPMR Temp. Reg. G–55 extending the expiration date until June 30, 1994. GSA has reconsidered its earlier decision and decided to codify the regulation, making the replacement standards in G–55 permanent.

Regulatory Flexibility Act

This amendment is not required to be published in the **Federal Register** for notice and comment. Therefore, the Regulatory Flexibility Act does not apply.

List of Subjects in 41 CFR Part 101–38

Government property management, Motor vehicles.

For the reasons set forth in the preamble, 41 CFR Part 101–38 is amended as follows:

PART 101–38—MOTOR EQUIPMENT MANAGEMENT

1. The authority citation for Part 101–38 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c)).

Subpart 101–38.4—Use and Replacement Standards

2. Section 101–38.402 is amended by revising paragraph (a) to read as follows:

§ 101–38.402 Replacement standards.

(a) Table of minimum replacement standards.

TABLE OF MINIMUM REPLACEMENT STANDARDS

Vehicle description	Life expectancy	
	Years	Miles
Passenger vehicles:		
Sedans/station wagons	3	60,000
Ambulances	7	60,000
Buses:		
Intercity-type	N/A	280,000
City-type	N/A	150,000
School-type	N/A	80,000
Trucks:		
Less than 12,500 pounds GVWR	6	50,000
12,500–23,999 GVWR	7	60,000
24,000 pounds and over	9	80,000
4- or 6-wheel drive vehicles	6	40,000

* * * * *

Dated: November 9, 1993.

Roger W. Johnson,

Administrator of General Services.

[FR Doc. 94–2951 Filed 2–8–94; 8:45 am]

BILLING CODE 6820–24–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 642

[Docket No. 930791–3191; I.D. 123093E]

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Trip limit reduction.

SUMMARY: NMFS reduces the commercial trip limit in the Florida east coast zone to 25 king mackerel per day in or from the exclusive economic zone (EEZ). This trip limit reduction is necessary to protect the overfished Gulf king mackerel resource.

EFFECTIVE DATES: The 25-fish commercial trip limit is effective 12:01 a.m., local time, February 7, 1994, and remains in effect through March 31, 1994, unless the commercial fishery for king mackerel in the Florida east coast zone is closed before March 31 by publication of a notice in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Mark F. Godcharles, 813–893–3161.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented by regulations at 50 CFR part 642, under the authority of the Magnuson Fishery Conversation and Management Act.

Catch limits recommended by the Councils and implemented by NMFS for the Gulf of Mexico migratory group of king mackerel for the current fishing year (July 1, 1993, through June 30, 1994, 58 FR 58509, November 2, 1993) set the commercial quota of king mackerel in the Florida east coast zone at 865,000 pounds (392,361 kg). In accordance with 50 CFR 642.31(a)(1), from the date that 50 percent of the zone's commercial quota has been harvested until a closure of the Florida east coast zone has been effected, king mackerel in or from the EEZ may be possessed aboard or landed from a

permitted vessel in amounts not exceeding 25 per day. The 25-fish trip limit remains in effect through March 31, 1994, when the boundary of the Gulf migratory group of king mackerel shifts from the east coast to the west coast of Florida, unless 100 percent of the commercial quota is reached before March 31, in which case the commercial fishery for king mackerel in the Florida east coast zone is closed by publication of a notice in the **Federal Register**.

NMFS has determined that 50 percent of the commercial quota for Gulf group king mackerel from the Florida east coast zone was reached on February 6, 1994. Accordingly, a 25-fish trip limit applies to king mackerel in or from the EEZ in the Florida east coast zone effective 12:01 a.m., local time, February 7, 1994. The Florida east coast zone extends from the Dade/Monroe County, Florida (25°20.4′ N. latitude) to the Volusia/Flagler County, Florida boundary (29°25′ N. latitude) from November 1 through March 31.

Classification

This action is required by 50 CFR 642.31(a)(1) and (b).

Authority: 16 U.S.C. 1801 *et seq.*

List of Subjects in 50 CFR Part 642

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: February 4, 1994.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–2968 Filed 2–4–94; 3:21 pm]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93–NM–226–AD]

Airworthiness Directives; Airbus Industrie Model A300 Series Airplanes Equipped With BFGoodrich Evacuation Door Slides

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 Airbus Model A300 series airplanes. This proposal would require modification of certain evacuation door slides. This proposal is prompted by a report that, during flight crew training, the toe end of the slide lane tore. The actions specified by the proposed AD are intended to prevent damage to the slide, which could render the slide unusable, contribute to injury of passengers on the slide, and delay or impede the evacuation of passengers during an emergency.

DATES: Comments must be received by April 5, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–226–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 BFGoodrich Company, Aircraft Evacuation Systems, Sustaining Engineering, Department 7916, Phoenix, AZ 85040. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806–2425.

FOR FURTHER INFORMATION CONTACT: Andrew Gfrerer, Aerospace Engineer, Systems and Equipment Branch, ANM–131L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806–2425; telephone (310) 988–5338; fax (310) 988–5210.

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 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 93–NM–226–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. 93–NM–226–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has recieved a report that on three occasions, during flight crew training, the toe end of the slide lane tore on certain BFGoodrich evacuation door slides installed on Airbus Model A300 series airplanes. Subsequent testing, conducted by BFGoodrich (the manufacturer of the evacuation door slides), repeated such a failure mode. Investigation of the testing results has revealed that installation of an additional splice panel on the back side of the slide surfaces will eliminate tearing at the toe end. Tearing at the toe end of the slide lane, if not corrected, could render the slide unusable, which could contribute to injury of passengers on the slide, and could delay or impede the evacuation of passengers during an emergency.

The FAA has reviewed and approved BFGoodrich Alert Service Bulletin 7A1299–25A274, dated December 15, 1993, that describes procedures for modification of BFGoodrich evacuation door slides having part numbers (P/N) 7A1299–001 and 7A1299–002. This modification involves applying a splice panel to the back side of the main and toe end sliding surface. Accomplishment of this modification will prevent tearing at the toe end of the slide lane.

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design equipped with the subject BFGoodrich evacuation door slides, the proposed AD would require modification those slides by applying a splice panel to the back side of the main and toe end sliding surface. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Currently, there are no Airbus Model A300 series airplanes equipped with BFGoodrich evacuation door slides on the U.S. Register that would be affected by this proposed AD. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would take approximately 6.2 work hours per slide to accomplish the proposed actions, at an average labor

rate of $55 per work hour. Required parts would be provided by BFGoodrich at no cost to the operators. Based on these figures, the total cost impact of the proposed AD is estimated to be $341 per slide.

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 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 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

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

Airbus Industrie: Docket 93–NM–226–AD.

Applicability: All Model A300 series airplanes, equipped with BFGoodrich evacuation slides having part numbers (P/N) 7A1299–001 and 7A1299–002, certificated in any category.

Note 1: The requirements of this AD are not applicable to Airbus Model A310, A300–600, and A320 series airplanes.

Compliance: Required as indicated, unless accomplished previously.

To prevent tearing of the toe end of the slide, which could render the slide unusable, contribute to injury of passengers on the slide, and could delay or impede the evacuation of passengers during an emergency, accomplish the following:

(a) Within 3 months after the effective date of this AD, modify the evacuation door slides having P/N's 7A1299–001 and 7A1299–002, in accordance with BFGoodrich Alert Service Bulletin 7A1299–25A274, dated December 15, 1993.

(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, Los Angeles Aircraft Certification Office (ACO), ANM–100S, 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, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(c) Special flight permits may be issued in accordance with FAR 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 February 3, 1994.

N.B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–2915 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 93–NM–202–AD]

Airworthiness Directives; Beech Aircraft Corp. Model 400A and 400T 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 Beech Model 400A and 400T airplanes. This proposal would require inspection to detect damage of the wire harness in the wheel well of the main landing gear (MLG), and modification, if necessary. This proposal is prompted by reports of damage to wire harnesses due to abrasion. The actions specified by the proposed AD are intended to prevent loss of control of the fuel supply to the engine or loss of control of the retraction/extension system for the MLG and MLG door.

DATES: Comments must be received by April 5, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–202–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 Beech Aircraft Corporation, Commercial Service Department, P.O. Box 85, Wichita, Kansas 67201–0085. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas.

FOR FURTHER INFORMATION CONTACT: Larry Engler, Aerospace Engineer, Airframe Branch, ACE–115W, FAA, Small Airplane Directorate, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4122; fax (316) 946–4407.

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 93–NM–202–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. 93–NM–202–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Recently, the FAA has received reports of damaged wire harnesses in the wheel well of the main landing gear (MLG) on certain Beech Model 400A and 400T airplanes. These harnesses became abraded when they came in contact with tires spinning in the wheel well following retraction of the MLG. Investigation revealed that these wire harnesses were routed and clamped incorrectly during production. The wire harness in the wheel well of the MLG operates the boost pump, low fuel switch, up-lock switch, gear door switch, and left-hand low fuel pressure switch on these airplanes. Damaged wire harnesses, if not corrected, could result in loss of control of the fuel supply to the engine or loss of control of the retraction/extension system for the MLG and MLG door.

The FAA has reviewed and approved Beechcraft Service Bulletin 2479, Revision 1, dated November1993, that describes procedures for inspection to detect damage of the wire harness in the wheel well of the MLG, and modification, if necessary. This modification entails removing the damaged wiring, splicing in new wiring, and installing additional clamps to ensure that tires spinning the wheel well of the MLG do not come in contact with the wire harness. This service bulletin references Chapter 20–00 of the Aircraft Maintenance Manual and Air Force Technical Order P/N T.O. 1–1A–14 for further service information.

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 require a general visual inspection to detect damage of the wire harness in the wheel well of the MLG, and modification of the damaged harness. The actions would be required to be accomplished in accordance with the service bulletin described previously.

There are approximately 59 Model 400A and 400T airplanes of the affected design in the worldwide fleet. The FAA estimates that 46 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $5,060, or $110 per airplane.

The total 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 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 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

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

Beech: Docket 93–NM–202–AD.

Applicability: Model 400A airplanes having serial numbers RK–1 through RK–41 inclusive, and Model 400T airplanes having serial numbers TT–2 through TT–19 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of control of the fuel supply to the engine or loss of control of the retraction/extension system for the main landing gear (MLG) and MLG door, accomplish the following:

(a) Within 200 hours time-in-service after the effective date of this AD, perform a general visual inspection to detect damage of the wire harness in the wheel well of the MLG in accordance with Beechcraft Service Bulletin 2479, Revision 1, dated November 1993.

(1) If no damage is if found, no further action is required by this AD.

(2) If damage is found, prior to further flight, modify the wiring in accordance with the service bulletin.

Note 1: This service bulletin references Chapter 20–00 of the Aircraft Maintenance Manual and Air Force Technical Order P/N T.O. 1–1A–14 for further service information regarding procedures for modification (removal and splicing) of the wiring.

(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, Wichita Aircraft Certification Office (ACO), FAA, Small 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, Wichita ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(c) Special flight permits may be issued in accordance with Federal Aviation Regulations (FAR) 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 February 3, 1994.

N.B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–2916 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 93–NM–207–AD]

Airworthiness Directives; Canadair Model CL–600–1A11, –2A12, and –2B16 Series 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 Canadair Model CL–600–1A11, –2A12, and –2B16 series airplanes. This proposal would require a test of the engine throttle quadrant to determine if the throttle lever bypasses the idle stop into the shut-off position, and modification of the throttle quadrant or replacement of the throttle quadrant with a modified unit. This proposal is prompted by reports of unintentional engine shutdown on Model CL–600–2A12 and –2B16 series airplanes. The actions specified by the proposed AD are intended to prevent inadvertent shutdown of an engine while the airplane is taxiing or in flight.

DATES: Comments must be received by April 5, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–207–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 Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station A, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 181 South Franklin Avenue, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Raymond J. O'Neill, Aerospace Engineer, Propulsion Branch, ANE–174, FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 181 South Franklin Avenue, room 202, Valley Stream, New York 11581; telephone (516) 791–7421; fax (516) 791–9024.

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 93–NM–207–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. 93–NM–207–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Transport Canada Aviation, which is the airworthiness authority for Canada, recently notified the FAA that an unsafe condition may exist on certain Canadair Model CL–600–1A11, –2A12, and –2B16 series airplanes. Transport Canada Aviation advises that it has received two reports of unintentional engine shutdown: One incident occurred during flight on a Model CL–600–2A12, the other occurred on a Model CL–600–2B16 while the airplane was on the ground. In both cases, engine shutdown occurred when the throttle lever over-rode the idle stop during throttle retardation. The throttle lever then moved directly to the shut-off position.

Tests results performed on throttle quadrants that were both installed and not installed revealed that, in some cases, the idle stop spring-loaded pawl can be lifted sufficiently for it to pass over the idle stop without pressure being applied to the release latch. This condition becomes more apparent when the friction device on the quadrant is loaded and a side load is applied to the throttle lever. This condition, if not corrected, could result in inadvertent shutdown of an engine while the airplane is taxiing or in flight.

Model CL–600–1A11 series airplanes are similar in type design to the airplane models on which the reported incidents occurred. Therefore, all three models are subject to the addressed unsafe condition.

Bombardier has issued Canadair Alert Service Bulletin A600–0615, dated June 10, 1992 (for Model CL–600–1A11 series airplanes), and Canadair Alert Service Bulletin A601–0374 (for Model CL–600–2A12 and –2B16 series airplanes), Revision 1, dated September 30, 1992. These service bulletins describe procedures for a test of the engine throttle quadrant to determine if the throttle lever bypasses the idle stop into the shut-off position, and modification of the throttle quadrant or replacement of the throttle quadrant with a modified unit. The modification involves removing material from the small triangular area on the outboard sides of both idle stop pawls to obtain specified protrusion dimensions or foot widths, testing each throttle lever to ensure it does not pass the idle stop into the shut-off position, and permanently reidentifying the unit. Transport Canada Aviation classified these service bulletins as mandatory and issued Canadian Airworthiness Directive CF–92–23, dated November 17, 1992, in order to assure the continued airworthiness of these airplanes in Canada.

The Canadair alert service bulletins discussed previously reference two service bulletins as additional sources of service information: Sargent Aerospace Service Bulletins 43058–76–03 (for Model CL–600–1A11 series airplanes) and 43068–76–05 (for Model CL–600–2A12 and –2B16 series airplanes), both dated April 13, 1992.

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada Aviation has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada Aviation, 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 or develop on other airplanes of the same type design registered in the United States, the proposed AD would require a test of the engine throttle quadrant to determine if the throttle lever bypasses the idle stop into the shut-off position,

and modification of the throttle quadrant or replacement of the throttle quadrant with a modified unit. The actions would be required to be accomplished in accordance with the Canadair alert service bulletins described previously.

The FAA estimates that 150 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 17 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $140,250, or $935 per airplane. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

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 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

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

Canadair Limited: Docket 93–NM–207–AD.

Applicability: Model CL–600–1A11 series airplanes, serial numbers 1004 through 1085 inclusive, equipped with Sargent throttle quadrants, part numbers 600–90601–69, –71, and –73; Model CL–600–2A12 series airplanes, serial numbers 3001 through 3066 inclusive, equipped with Sargent throttle quadrants, part numbers 600–90601–983, –1013, –1015, –1017, and –1019; and Model CL–600–2B16 series airplanes, serial numbers 5001 through 5114 inclusive, equipped with Sargent throttle quadrants, part numbers 600–90601–983, –1013, –1015, –1017, and –1019; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent inadvertent shutdown of an engine while the airplane is taxiing or in flight, accomplish the following:

(a) Within 50 hours time-in-service after the effective date of this AD, perform a test of the engine throttle quadrant to determine if the throttle lever bypasses the idle stop into the shut-off position, in accordance with Canadair Alert Service Bulletins A600–0615, dated June 10, 1992 (for Model CL–600–1A11 series airplanes), or A601–0374, Revision 1, dated September 30, 1992 (for Model CL–600–2A12 and –2B16 series airplanes), as applicable.

Note 1: Canadair Alert Service Bulletins A600–0615 and A601–0374 reference Sargent Aerospace Service Bulletins 43058–76–03 (for Model CL–600–1A11 series airplanes) and 43058–76–05 (for Model CL–600–2A12 and –2B16 series airplanes), both dated April 13, 1992, for additional service information.

(1) If the throttle lever bypasses the idle stop into the shut-off position, prior to further flight, modify the throttle quadrant or replace the throttle quadrant with a modified unit, in accordance with the applicable service bulletin.

(2) If the throttle lever does not bypass the idle stop into the shut-off position, within 600 landings after the effective date of this AD, modify the throttle quadrant or replace the throttle quadrant with a modified unit, in accordance with the applicable 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, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with Federal Aviation Regulations (FAR) 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 February 3, 1994.

N.B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–2914 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 93–NM–201–AD]

Airworthiness Directives; Fokker Model F27 Series 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 Fokker Model F27 series airplanes. This proposal would require replacement of certain bolts that are currently installed in various flight critical components of the airplane. This proposal is prompted by reports of incidents involving corrosion and fatigue cracking in transport category airplanes that are approaching or have exceeded their economic design goal; these incidents have jeopardized the airworthiness of the affected airplanes. The actions specified by the proposed AD are intended to prevent reduced structural integrity of various flight critical components of the airplane.

DATES: Comments must be received by April 5, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–201–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 Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Mark Quam, Aerospace Engineer, Standardization Branch, ANM–113,

FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2145; fax (206) 227–1320.

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 93–NM–201–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. 93–NM–201–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

In April 1988, a high-cycle transport category airplane (specifically, a Boeing Model 737) was involved in an accident in which the airplane suffered major structural damage during flight. Investigation of this accident revealed that the airplane had numerous fatigue cracks and a great deal of corrosion. Subsequent inspections conducted by the operator on other high-cycle transport category airplanes in its fleet revealed that other airplanes had extensive fatigue cracking and corrosion.

Prompted by the data gained from this accident, the FAA sponsored a conference on aging airplanes in June 1988, which was attended by representatives from the aviation industry and airworthiness authorities from around the world. Because of the tremendous increase in air travel, the relatively slow pace of new airplane production, and the apparent economic feasibility of operating older technology airplanes rather than retiring them, increased attention needs to be focused on the aging airplane fleet to maintain its continued operational safety.

The Air Transport Association (ATA) of America and the Aerospace Industries Association (AIA) of America agreed to undertake the task of identifying and implementing procedures to ensure the continued structural airworthiness of aging transport category airplanes. An Airworthiness Assurance Task Force (AATF) was established in August 1988, with members representing aircraft manufacturers, operators, regulatory authorities, and other aviation industry representatives worldwide. The objective of the AATF was to sponsor "Working Groups" to:

1. Select service bulletins, applicable to each airplane model in the transport fleet, to be recommended for mandatory modification of aging airplanes;
2. Develop corrosion-directed inspections and prevention programs;
3. Review the adequacy of each operator's structural maintenance program;
4. Review and update the Supplemental Inspection Program (SIP); and
5. Assess repair quality.

The Working Group assigned to review the Fokker Model F27 series airplanes has completed its work on Item (1), above. The Working Group has identified certain service difficulties that warrant mandatory modification of these airplanes. The Working Group considers that these service difficulties warrant mandatory modification of the airplane to assure continued operational safety of Model F27 airplanes that have exceeded their economic design goal.

The "economic design goal" of an airplane is typically considered to be the period of service after which a substantial increase in the maintenance costs is expected to take place in order to assure continued operational safety. The economic design goal for Fokker Model F27 series airplanes is 20 years for structural problems associated with environmental deterioration, and 60,000 flight cycles for structural problems associated with fatigue damage.

The Working Group has recommended Fokker Service Bulletin F27/51–10, Revision 2, dated June 12, 1993, for mandatory modification. This service bulletin describes procedures for replacement of AN bolts that are currently installed in the following flight critical components of the airplane with NAS bolts. The manufacturing process used to produce NAS bolts yields superior quality bolts that are anticipated to preclude cracking in these areas:

1. Flight controls (including the push-pull rods of the trim drive mechanism; aileron, rudder, elevator, and elevator trim tab controls; and elevator hinge support assemblies).
2. Control surfaces (including elevator, rudder, aileron, and tab hinge bolts).
3. Fuel control installations.
4. Engine mount and nacelle brace installations.
5. Engine control installations.

This service bulletin has been amended by Service Bulletin Change Notification F27/51 - 10REV2/01, dated October 1, 1993, to correct an error in a part number referenced in the service bulletin.

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, classified the original release of the service bulletin as mandatory and issued Netherlands Airworthiness Directive (BLA) 91–111, dated September 13, 1991, in order to assure the continued airworthiness of these airplanes in the Netherlands.

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, 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 or develop on other airplanes of the same type design registered in the United States, the proposed AD would require replacement of AN bolts that are currently installed in various flight critical components of the airplane with NAS bolts. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The proposed compliance time for implementation of this modification program is within 3 years after the effective date of the AD. This time interval was based upon the ability of

the manufacturer to provide the parts necessary for the modification, and the time necessary to incorporate the modification.

In the interim, safety will be provided by various means currently in place that are considered satisfactory to detect damage prior to the occurrence of an unsafe condition. These include operators' ongoing basic maintenance programs; continuing inspections required by numerous AD's issued previously; the SIP mandated by AD 92-19-07, Amendment 39-8365 (57 FR 42693, September 16, 1992); the FAA's increased emphasis on surveillance of operators' maintenance programs and procedures; and the FAA's participation in programs to physically inspect high-time airplanes during scheduled heavy maintenance.

The FAA estimates that 39 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 250 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Required parts would cost approximately $690 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $563,160, or $14,440 per airplane. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

The FAA recognizes that the proposed modification would require a large number of work hours to accomplish. However, the 3-year compliance time specified in paragraph (a) of this proposed AD should allow ample time for the replacement of AN bolts to be accomplished coincidentally with scheduled major airplane inspection and maintenance activities, thereby minimizing the costs associated with special airplane scheduling.

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 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 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14a CFR 11.89.

§ 39.13 [Amended]

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

Fokker: Docket 93-NM-201-AD.

Applicability: Model F27 series airplanes, having serial numbers 10102 through 10612 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of various flight critical components of the airplane, accomplish the following:

(a) Within 3 years after the effective date of this AD, remove AN bolts that are currently installed in the flight controls, control surfaces, fuel control installations, engine mount and nacelle brace installations, and engine control installations, and replace them with NAS 1303/1320 bolts, in accordance with Fokker Service Bulletin F27/51-10, Revision 2, dated June 12, 1993, as amended by Service Bulletin Change Notification F27/51 - 10REV2/01, dated October 1, 1993.

(b) As of the effective date of this AD, no person shall install on any airplane any AN bolt having a part number that is listed in Fokker Service Bulletin F27/51-10, Revision 2, dated June 12, 1993, as amended by Service Bulletin Change Notification F27/51 - 10REV2/01, dated October 1, 1993, in any of the flight critical components identified in the service bulletin.

(c) 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: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(d) Special flight permits may be issued in accordance with Federal Aviation Regulations (FAR) 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 February 3, 1994.

N. B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94-2917 Filed 2-8-94; 8:45 am]

BILLING CODE 4910-13-U

Coast Guard

33 CFR Part 117

[CGD13-93-036]

Drawbridge Operation Regulations; South Fork of the Willapa River, WA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: At the request of the Washington State Parks and Recreation Commission, the Coast Guard is considering an amendment to the regulations governing the operation of the swing span bridge near the mouth of the South Fork of the Willapa River, mile 0.3, at Raymond, Washington. The proposed regulations would enable the owners to maintain the bridge in the closed position for trail use with the provision that they restore the drawbridge machinery to operating condition upon a six month notice from the District Commander. This structure was formerly owned by the Burlington Northern Railroad Company, which is abandoning the rail corridor of which this bridge is a part. The Parks and Recreation Commission has acquired ownership of this structure as part of the trail system plan which incorporates the abandoned line. Presently, the operating regulations require 24 hours notice for opening the bridge for the passage of a vessel. In recent years the swing span has been maintained in the open position, except for train passage.

DATES: Comments must be received on or before April 11, 1994.

ADDRESSES: Comments should be mailed to Commander (oan), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174-1067. The comments and other

materials referenced in this notice will be available for inspection and copying at 915 Second Avenue, room 3410, Seattle, Washington. Normal office hours are between 7:45 a.m. and 4:15 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: John E. Mikesell, Chief, Plans and Programs Section, Aids to Navigation and Waterways Management Branch, (206) 220–7270.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data, or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with, or any recommended changes in, the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, Thirteenth Coast Guard District, will evaluate all communications received and determine a course of final action on this proposal. The proposed regulations may be changed in light of comments received.

Drafting Information

The drafters of this notice are Austin Pratt, project officer, and Lieutenant Laticia Argenti, project attorney.

Discussion of the Proposed Regulations

The purpose of the proposed regulations is to maintain the bridge as part of a planned recreational trail, while still accommodating the reasonable needs of navigation. The trail plan is based on an abandoned rail line. The Coast Guard must consider the impact to navigation, if any, in its evaluation of the proposal. If the impact of this is minimal then it would allow the Coast Guard to absolve the new owner of the responsibility for keeping bridge operators in regular attendance at the bridge. Essentially, this proposed regulation would authorize the conversion of the swing span to a fixed bridge until evidence is demonstrated to the District Commander that the reasonable needs of navigation require the drawbridge to open. Following notice from the District Commander, the owner will be granted six months in which to restore the drawbridge to full operating condition to provide for navigation. At that time the operating regulations will also be evaluated.

Federalism Assessment and Certification

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

Economic Assessment and Certification

This proposal is not considered a significant regulatory action under Executive Order 12866 and is not significant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979).

The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), the Coast Guard certifies that the proposed regulations, if adopted, will not have a significant impact on a substantial number of small entities.

Environmental Assessment and Certification

This action has been reviewed by the Coast Guard and has been determined to be categorically excluded from further environmental documentation under the authority of 40 CFR 1507.3 and in accordance with paragraph 2.B.2.g.(5) of the NEPA Implementing Procedures, COMDTINST M16475.1B. A copy of the Categorical Exclusion Certification is available for review in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 117 of title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. Section 117.1063 is amended by revising paragraph (b) to read as follows:

§ 117.1063 Willapa River.

(a) * * *

(b) The draw of the Washington State Parks and Recreation Commission's bridge across the South Fork Willapa River, mile 0.3, at Raymond, need not open for the passage of vessels. The draw shall be returned to operable condition within six months after notification by the District Commander to do so.

Dated: January 27, 1994.

John A. Pierson,

Captain, U.S. Coast Guard, Acting Commander, 13th Coast Guard District.

[FR Doc. 94–3003 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 156

[OPP–250090; FRL–4572–2]

Flammability Labeling Requirements for Total Release Foggers; Notification to Secretary of Agriculture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification to Secretary of Agriculture.

SUMMARY: Notice is given that the Administrator of EPA has forwarded to the Secretary of Agriculture a proposed regulation pursuant to section 25(a)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The proposed rule proposes additional precautionary labeling relating to the flammability of total release fogger pesticides.

FOR FURTHER INFORMATION CONTACT: By mail: Tina E. Levine, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North, 6th Floor, 2800 Crystal Drive, Arlington, VA, (703–308–8393).

SUPPLEMENTARY INFORMATION: Section 25(a)(2)(A) of FIFRA requires that the Administrator provide the Secretary of Agriculture with a copy of any proposed regulation at least 60 days prior to signing it for publication in the **Federal Register**. If the Secretary comments in writing regarding the proposed regulation within 30 days after receiving it, and if requested by the Secretary, the Administrator shall issue for publication in the **Federal Register** with the proposed regulation, the comments of the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing within 30 days after receiving the proposed regulation, the Administrator may sign the proposed regulation for publication in the **Federal Register** anytime after the 30–day period.

As required by FIFRA section 25(a)(2), a copy of this proposed regulation has been forwarded to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

As required by FIFRA section 25(d), a copy of this proposed regulation has also been forwarded to the Scientific Advisory Panel.

List of Subjects in 40 CFR Part 156

Environmental protection, Labeling.

Authority: 7 U.S.C. 136 et seq.

Dated: January 31, 1994.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 94-2701 Filed 2-8-94; 8:45 am]

BILLING CODE 6560-50-F

---

40 CFR Part 180

[PP-5F3251/P577; FRL-4757-5]

RIN No. 2070-AC18

Pesticide Tolerances for Aluminum Tris(O-Ethylphosphonate)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish a tolerance for residues of the fungicide fosetyl-Al, aluminum tris(*O*-ethylphosphonate) in or on dried hops at 45 ppm. This regulation to establish the maximum permissible level of residue of the fungicide in or on the commodity was requested in a petition submitted by Rhone-Poulenc Ag Co.

DATES: Comments, identified by the document control number [PP-5F3251/P577], must be received on or before March 11, 1994.

ADDRESSES: By mail, submit written comments to: Public Docket and Freedom of Information Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5540.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of May 24, 1985 (50 FR 21503), which announced that Rhone-Poulenc Ag Co., P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, had submitted a pesticide tolerance petition (PP 5F3251) and a food/feed additive petition (FAP 5H5468) to EPA requesting that the Administrator, pursuant to sections 408(d) and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish a tolerance for the fungicide fosetyl-Al, aluminum tris(*O*-ethylphosphonate) in or on fresh hops at 10 parts per million (ppm) and dried hops at 20 ppm, respectively. Subsequently, Rhone-Poulenc petitioned the Agency to amend the proposed tolerance for dried hops to increase the tolerance from 20 ppm to 45 ppm. Rhone-Poulenc amended the proposed tolerance a second time, notice of which appeared in the **Federal Register** of January 7, 1994 (59 FR 1017), requesting a section 408 tolerance for fosetyl-Al of 45 ppm in hops instead of separate tolerances for fresh and dried hops under sections 408 and 409. There were no comments received in response to the initial notice of filing.

Prior to this action, EPA had not proposed to establish a tolerance for fosetyl-Al on hops because dried hops have been considered a processed food requiring a section 409 tolerance and EPA was concerned that a section 409 tolerance for fosetyl-Al might be prohibited by section 409's Delaney anti-cancer clause. Recently, EPA reclassified dried hops as a raw agricultural commodity. Tolerances for raw agricultural commodities are set under section 408 of the FFDCA, which contains no Delaney Clause.

EPA has been considering for some time whether dried hops are properly classified as a processed food. The FFDCA defines a RAC as "food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." Elsewhere, the FFDCA lists canning, cooking, freezing, dehydration, and milling as examples of processing activities for RACs.

Congress indicated in its most recent appropriations bill for EPA that it believes that EPA's treatment of dried hops as a processed food was a misinterpretation of the statute. That bill, Public Law 103-124, which was signed by President Clinton on October 28, 1993, prohibits EPA from using funds for any regulatory activity under FFDCA or FIFRA resulting from the classification of hops as a processed food. In the Congressional report that accompanied the bill, the Appropriations Committee explained that this limitation on spending was directed at barring EPA from acting on what Congress believes is an erroneous interpretation of the term RAC as it applies to dried hops, S. Rep. 103-137, 103d Cong., 1st Sess. 121 (1993). In consideration of these factors, EPA revised its guidelines to change the classification of dried hops from a processed commodity to a RAC. EPA requests comments on this change. To be consistent, EPA is proposing this tolerance as on dried hops rather than on hops as requested by Rhone-Poulenc.

The data submitted in the petitions and all other relevant material have been evaluated. The toxciology data considered in support of the tolerances include:

1. A rat acute oral study with an LD_{50} of 5.4 grams (g)/kilogram (kg).
2. A mouse acute oral study with an LD_{50} of 3.4 gm/kg.
3. A 90-day rat feeding study with a no-observed-effect level (NOEL) of 5,000 ppm (500 milligrams (mg)/kg/day).
4. A 90-day dog feeding study with a NOEL of 10,000 ppm (250 mg/kg/day).
5. A 21-day rabbit dermal study with a NOEL of 1.5 g/kg/day (the highest dose tested (HDT)).
6. A carcinogenicity study in mice with no carcinogenic effects observed at any dose level under the conditions of the study (the highest dose tested was 2,857/4,286 mg/kg body weight (bwt)/day).
7. A rat chronic feeding/carcinogenicity study with a NOEL of 8,000 ppm (400 mg/kg/ bwt/day) for systemic effects (carcinogenic effects observed are discussed below).
8. A 2-year dog feeding study with a NOEL of 10,000 ppm (250 mg/kg bwt/day) and a lowest-effect-level (LEL) of 20,000 ppm (500 mg/kg bwt/day) based on slight degenerative effects on the testes.

9. A reproduction study in rats with a NOEL of 300 mg/kg/bwt/day and an LEL of 600 mg/kg/ bwt/day based on effects on animal weights in some groups and urinary tract changes in some groups.

10. Teratology studies in rabbits and rats with teratogenic NOELs of 500 mg/kg/day and 1,000 mg/kg/day, respectively.

11. Ames mutagenicity assays, *E. coli* phage induction tests, micronucleus tests in mice, DNA repair tests using *E. coli*, and *Saccharomyces cervisiae* yeast assay that were negative.

As stated in a notice published in the **Federal Register** of November 2, 1983 (48 FR 50532), carcinogenic effects were noted in the rat chronic feeding/carcinogenicity study. In this study, Charles River CD rats were dosed with aluminum tris(*O*-ethylphosphonate) at levels of 0, 2,000, 8,000, and 40,000/30,000 ppm (0, 100, 400, and 2,000/1,500 mg/kg bwt/day). The 40,000 ppm dose was reduced to 30,000 ppm after 2 weeks following observations of staining of the abdominal fur and red coloration of the urine at 40,000 ppm (2,000 mg/kg bwt/day).

The highest dose level of the chemical tested in the male Charles River CD-1 rats (2,000/1,500 mg/kg bwt/day) in this study appears to approximate a maximum tolerated dose (MTD) based on the finding of urinary bladder hyperplasia at this dose. Similarly, an MTD level appeared to be satisfied in the female Charles River CD-1 rats at the high-dose level of 2,000 mg/kg/ bwt/day, during the first 2 weeks of the carcinogenicity/chronic feeding study, before the dose level was reduced to 1,500 mg/kg bwt/day.

The study demonstrated a significantly elevated incidence of urinary bladder tumors (adenomas and carcinomas combined) at the highest dose level tested (2,000/1,500 mg/kg) in male Charles River CD-1 rats. The tumors were mainly seen in surviving males at the time of terminal sacrifice. The original pathological diagnosis of these tumors was independently confirmed by another consulting pathologist, who also reported an elevated incidence of urinary bladder hyperplasia in high-dose male rats. No increase in incidence of urinary bladder tumors was observed in female rats.

In 1986, the Health Effects Division Peer Review Committee for Carcinogenicity of the Office of Pesticide Programs concluded that the available data provided limited evidence of the carcinogenicity of fosetyl-Al in male rats and classified the pesticide as a Category C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with proposed Agency guidelines, published in the **Federal Register** of November 23, 1984 (49 FR 46294). The Health Effects Division Peer Review Committee for Carcinogenicity determined that a quantitative risk assessment was not appropriate for the following reasons:

1. The carcinogenic response observed with this chemical was confined solely to the high-dose males at one site (urinary bladder) in rats.

2. The tumor response was primarily due to an increase in benign tumors.

3. The tumors were seen only in surviving animals at the time of terminal sacrifice.

4. The carcinogenic effects were observed only at unusually high doses which exceed the commonly used limit dose of 1,000 mg/kg/day recommended as an upper-limiting dose for bioassays.

5. The chemical was not carcinogenic when administered in the diet to Charles River CD-1 mice at dose levels ranging from 2,500 to 30,000 ppm (357 to 4,286 mg/kg bwt/day).

6. Fosetyl-Al was not mutagenic in eight well conducted genotoxic assays.

In 1993, the Health Effects Division Peer Review Committee (PRC) for Carcinogenicity revisited the carcinogenicity classification of fosetyl-Al owing to a recent 90-day feeding study of fosetyl-Al in rats that showed a strong association between the presence of uroliths in the urinary bladder and the incidence of urinary bladder tumors in treated rats. The PRC concluded that fosetyl-Al is not amenable to classification using the current Agency cancer guidelines. Based on a mechanistic evaluation of the only tumors seen, those that occurred at exceptionally high doses in the bladder of male rats, it appears that humans are not likely to be exposed to doses of fosetyl-Al that produce the urinary tract toxicity that precedes and seems to lead to the tumor response in rats. In particular, anticipated human dietary and occupational exposures to fosetyl-Al are far below the NOEL in rats for the apparent urinary tract tumor precursors (stone formation and attendant epithelial irritation). These effects are produced in rats at extremely high doses, under conditions not anticipated to occur outside of the experimental laboratory. The PRC concludes that pesticidal use of fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, the standard risk assessment approach of using the Reference Dose (RfD) based on systemic toxicity was applied to fosetyl-Al.

Using a 100-fold safety factor and the NOEL of 250 mg/kg bwt/day determined by the most sensitive species from the 2-year dog feeding study, the RfD is 3.0 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.0453 mg/kg bwt/day and utilizes 1.5 percent of the RfD for the overall U.S. population. The exposure of the most highly exposed subgroup in the population did not utilize a significantly greater amount of the RfD. Previous tolerances have been established for fosetyl-Al, aluminum tris(*O*-ethylphosphonate), in asparagus, avocadoes, brassica vegetable crop group, caneberries, citrus, cucurbit vegetables group, dry bulb onions, fresh ginseng root, leafy vegetables crop group, pineapples, pineapple forage and fodder, and strawberries.

The metabolism of aluminum tris(*O*-ethylphosphonate) in plants is adequately understood. There is no reasonable expectation of secondary residues occurring in milk, eggs, and meat of livestock or poultry as a result of this use on hops.

An adequate analytical method, gas-liquid chromatography, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 242, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-4432.

The pesticide is considered useful for the purposes for which the tolerances are sought. Based on the above information considered by the Agency, the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under FIFRA, as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with FFDCA section 408(e).

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document

control number, [PP 5F3251/P577]. All written comments filed in response to this petition will be available in the Public Docket and Freedom of Information Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 26, 1994.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. In § 180.415, by amending paragraph (a) by alphabetically inserting the raw agricultural commodity dried hops, to read as follows:

§ 180.415 Aluminum tris(O-ethylphosphonate); tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hops, dried	45
* * * * *	

* * * * *

[FR Doc. 94-2699 Filed 2-8-94; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL MARITIME COMMISSION

46 CFR Parts 514, 580 and 581

[Docket No. 93-22]

Coloading Practices by Non-Vessel-Operating Common Carriers; Shipper Affiliate Access to Service Contracts

AGENCY: Federal Maritime Commission.

ACTION: Proposed rule; extension of time.

SUMMARY: The Commission by notice of Proposed Rulemaking published November 24, 1993 (58 FR 62077) proposed amendments to its non-vessel-operating common carrier ("NVOCC") coloading rules to clarify ambiguities and to address current practices resulting in increased application of untariffed NVOCC charges. Sixty days was allowed for comment. Requests for additional time to comment ranging from 30 to 90 days subsequently were filed by various interests. Upon consideration of these requests, the Commission determined to grant a 30-day extension. Upon further consideration of this matter the Commission now has determined to grant an additional 15 day extension.

DATES: Comments due on or before March 11, 1994.

ADDRESSES: Send comments (original and 20 copies) to: Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol St., NW., Washington, DC 20573-0001, (202) 523-5725.

FOR FURTHER INFORMATION CONTACT: Wm. Jarrel Smith, Jr., Director, Bureau of Investigations, Federal Maritime Commission, 800 North Capitol St., NW., Washington, DC 20573-0001, (202) 523-5860.

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 94-2909 Filed 2-8-94; 8:45 am]

BILLING CODE 6730-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1819 and 1852

Mentor-Protege Program

AGENCY: Office of Small and Disadvantaged Business Utilization (OSDBU), National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: This proposed rule establishes NASA policy for the Mentor-Protege Program which is designed to increase the overall participation of Small Disadvantaged Businesses (SDBs) in NASA contracts and subcontracts. The resultant increased participation of SDBs in NASA contracts and subcontracts will enhance NASA's efforts to meet and sustain the annual minimum eight (8) percent goal prescribed in Public Law 101-144 and its amended version Public Law 101-507.

DATES: Comments are due no later than April 11, 1994.

ADDRESSES: Comments should be addressed to Ms. Rae C. Martel, NASA Headquarters, NASA Office of Small and Disadvantaged Business Utilization, (Code K), Washington, DC 20546. Comments should also be addressed to the Office of Information and Regulatory Affairs of OMB, ATTN: Desk Officer for NASA, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Ms. Rae C. Martel, Telephone: (202) 358-2088 or 1800-2NASA-95.

SUPPLEMENTARY INFORMATION:

Background

The rule proposes NASA's policy on its Mentor-Protege Program. With respect to prime contractors, it defines eligibility for participation, allowable developmental assistance measures that will enhance the capabilities of SDBs to perform NASA contracts and subcontracts, and incentives for program participation. Further, it defines the transportability of subcontracting goal credit features from the Department of Defense (DOD) Mentor-Protege Program to NASA Contractors. However, the effectiveness of a mentor under the NASA Program will be evaluated by the measurable amount of developmental assistance provided under NASA contracts. Participation in the program is voluntary.

With regard to SDBs, "Socially And Economically Disadvantaged Businesses" include the eligible participants set forth in NASA's Eight (8) percent legislation, Public Law 101-144 and the amended provision in Public Law 101-507.

Availability of NASA FAR Supplement

The NASA FAR Supplement, of which this proposed coverage will become a part, is codified in 48 CFR, chapter 18, and is available in its entirety on a subscription basis from the Superintendent of Documents, Government Printing Office, Washington, DC 20402. Cite GPO Subscription Stock Number 933-003-00000-1. It is not distributed to the

public, whether in whole or in part, directly by NASA.

Impact

NASA certifies that this regulation will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This proposed rule imposes reporting or recordkeeping requirements subject to OMB approval under the Paperwork Reduction Act, which will be requested separately.

List of Subjects in 48 CFR Parts 1819 and 1852

Government procurement.

Deidre A. Lee,

Associate Administrator for Procurement.

Accordingly, 48 CFR parts 1819 and 1852 are proposed to be amended as follows:

1. The authority citation for 48 CFR parts 1819 and 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

PART 1819—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

2. Subpart 1819.72 is added to read as follows:

Subpart 1819.72 [Added]

Subpart 1819.72—The NASA Mentor-Protege Program

1819.7201 Scope of subpart.
1819.7202 Definitions.
1819.7203 Non-affiliation.
1819.7204 Transportability of features from the Department of Defense (DOD) mentor-protege program to NASA contractors.
1819.7205 General policy.
1819.7206 Incentives for prime contractor participation.
1819.7207 Measurement of program success.
1819.7208 Mentor firms.
1819.7209 Protege firms.
1819.7210 Selection of protege firms.
1819.7211 Application process for mentor firms to participate in the program.
1819.7212 OSDBU review and approval process of agreement.
1819.7213 Agreement contents.
1819.7214 Developmental assistance.
1819.7215 Obligation.
1819.7216 Internal controls.
1819.7217 Reports.
1819.7218 Program review.
1819.7219 Contract and solicitation clauses.

Subpart 1819.72—The NASA Mentor-Protege Program

1819.7201 Scope of subpart.

The NASA Mentor-Protege Program is designed to incentivize NASA prime contractors to assist High Tech small disadvantaged businesses (SDB)s in enhancing their capabilities to perform NASA contracts and subcontracts, foster the establishment of long term business relationships between SDBs and NASA prime contractors, and increase the overall number of SDBs that receive NASA contract and subcontract awards.

1819.7202 Definitions.

Historically Black Colleges and Universities, as used in this subpart, means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2 and listed therein.

Minority Educational Institutions, as used in this subpart, means institutions meeting the criteria established in 34 CFR 607.2 by the Secretary of Education.

Small Disadvantaged Business concern, as used in this subpart, means a small business concern owned or controlled by individuals who are both socially and economically disadvantaged (within the meaning of section 8(a) (5) and (6) of the Small Business Act (15 U.S.C. 637(a) (5) and (6))).

1819.7203 Non-affiliation.

For purposes of the Small Business Act, a protege firm may not be considered an affiliate of a mentor firm solely on the basis that the protege firm is receiving developmental assistance referred to in 1819.7214 from such mentor firm under the program.

1819.7204 Transportability of features from the Department of Defense (DOD) mentor-protege program to NASA contractors.

(a) In accordance with the benefits authorized by the DOD Mentor-Protege Program (Pub. L. 101–510, section 831, as amended by Pub. L. 102–190, section 814) a NASA contractor who is also an approved DOD Mentor can transfer credit features to their NASA contracts.

(b) NASA prime contractors, who are approved DOD mentors, can award subcontracts non-competitively under their NASA contracts to the proteges which they are assisting under the DOD program (Pub. L. 101–510, section 831(f)(2)).

(c) NASA prime contractors may count the costs of developmental assistance provided to proteges being assisted under the DOD program toward meeting the goals in their subcontracting plans under their NASA prime contracts (Pub. L. 102–190, section 814). Limitations which may reduce the value of this benefit include:

(1) Credit toward attaining subcontracting goals is available only to the extent that the developmental assistance costs have not been reimbursed to the contractor by DOD as direct or indirect costs; or

(2) The credit is available to meet the goals of a NASA subcontracting plan only to the extent that it has not been applied to a DOD subcontracting plan. The same unreimbursed developmental assistance costs cannot be counted toward meeting the subcontracting goals of more than one prime contract. These costs would accrue from credit for the multiples attributed to assistance provided by Small Business Development Centers, Historically Black Colleges and Universities and minority educational institutions.

(d) The features identified in paragraphs (a), (b), and (c) of this section point out the portability of features from the DOD Mentor-Protege Program to NASA prime contractors. NASA mentors will be held to show "good faith" by providing actual developmental assistance beyond transferring credit from activity in the DOD activity to NASA subcontracting plans.

1819.7205 General policy.

(a) Eligible large business prime contractors, not included on the "Parties Excluded from Procurement Programs" list, who have at least one active subcontracting plan, and who are approved as mentor firms will enter into agreements with eligible (SDBs) as protege firms to provide appropriate developmental assistance to enhance the capabilities of SDBs to perform as subcontractors and suppliers. Eligible small business prime contractors, not included on the "Parties Excluded from Procurement Programs" list and that are capable of providing developmental assistance to SDBs, may be approved as mentors.

(b) The pilot program has a duration of three years commencing from [the date of the published final rule]. During this period, eligible mentor firms, which have received approval by NASA to participate in the program pursuant to subpart 1819.9212, may enter into agreements with protege firms.

(c) The award fee evaluation plans contained in all NASA cost-plus-award-fee contracts may include a factor for evaluation of a contractor's performance associated with Mentor-Protege Program participation.

(d) Other contract types, including cost-plus-fixed-fee, with subcontracting opportunities may include the clause at 52.219–10, Incentive Subcontracting Program for Small and Small Disadvantaged Business Concerns, for use in evaluating a contractor's performance associated with Mentor-

Protege Program participation when a subcontracting plan is required.

(e) Costs incurred by a mentor to negotiate an agreement with a protege and to implement the agreement are incurred by both parties at their own risk. NASA will not reimburse these costs.

1819.7206 Incentives for prime contractor participation.

(a) Under cost-plus-award fee contracts, mentor firms may be eligible to earn award fee associated with their performance as a mentor by performance evaluation period. This performance may be evaluated to determine the degree to which the participation went beyond (exceeded) the negotiated SDB goals commitment.

(b) Under other contract types with subcontracting opportunities, including cost-plus-fixed-fee, mentor firms may be eligible to earn fee associated with their performance as a mentor. This performance may be evaluated to determine the degree to which the participation went beyond (exceeded) the negotiated SDB goals commitment.

(c) The overall developmental assistance performance of NASA contractors, in promoting the use of SDBs as subcontractors, may be an evaluation factor in award fee plans of all cost-plus-award-fee contracts. Criteria under the factor could include:

(1) Active participation in the NASA Mentor Protege Program;

(2) Actions taken by the contractor to develop working relationships with SDBs and others;

(3) The amount and quality of developmental assistance provided;

(4) Subcontracts awarded to SDBs and others;

(5) Success of the protege firms in increasing their business as a result of receiving developmental assistance; and

(6) Accomplishment of any other activity as related to the Mentor-Protege relationship.

1819.7207 Measurement of program success.

The overall success of the program will be measured by the extent to which it results in:

(a) An increase in the number, dollar value and percentage of subcontracts awarded to SDBs by mentor firms under NASA contracts since the date of entry into the program;

(b) An increase in the number and dollar value of contract and subcontract awards to protege firms since the time of their entry into the program (under NASA contracts, contracts awarded by other Federal agencies and under commercial contracts);

(c) An increase in the number and dollar value of subcontracts awarded to a protege firm by its mentor firm; and

(d) An increase in subcontracting with SDB firms in industry categories where SDBs have not traditionally participated within the mentor firm's activity.

1819.7208 Mentor firms.

(a) Eligibility:

(1) Contractors eligible for receipt of government contracts;

(2) Large prime contractors performing under contracts with at least one negotiated subcontracting plan as required by FAR 19.7; and

(3) Small Business prime contractors that can provide developmental assistance to enhance the capabilities of SDBs to perform as subcontractors and suppliers. A small business prime contractor performing under a NASA contract that does not contain a negotiated subcontracting plan may apply.

(b) Mentors will be encouraged to identify and select:

(1) A broad base of firms including those defined as emerging SDB firms (e.g., an SDB whose size is no greater than 50% of the size standard applicable to the SIC code assigned to a contracting opportunity); and

(2) SDBs in addition to firms with whom they have established business relationships.

§ 1819.7209 Protege firms.

(a) For selection as a protege, a firm must be:

(1) A small disadvantaged business concern as defined by FAR 19.001;

(2) Certified as small in the SIC code for the services or supplies to be provided by the protege to the mentor; and

(3) Eligible for receipt of government contracts.

(b) A protege firm may self-certify to a mentor firm that it meets each of the eligibility requirements in paragraphs (a) (1), (2) and (3) of this section. Mentor firms may rely in good faith on a written representation of a business concern that such business meets the requirements in paragraphs (a) (1) and (2).

(c) Historically Black Colleges and Universities, minority educational institutions, and small women-owned businesses are eligible as proteges under this program.

(d) Proteges may have multiple mentors. Proteges should maintain a system for developing reports of mentoring activity by federal agency.

§ 1819.7210 Selection of protege firms.

(a) Mentor firms will be solely responsible for selecting protege firms. The mentor is encouraged to identify and select protege firms that represent a balance in company size, e.g., start-up, emerging, etc.

(b) Mentor firms may have more than one protege.

(c) The selection of protege firms by mentor firms may not be protested, except as in paragraph (d) of this section.

(d) In the event of a protest regarding the size or disadvantaged status of a business concern eligible to be a protege firm, the mentor firm shall refer the protest to the Associate Administrator, NASA Office of Small and Disadvantaged Business Utilization (OSDBU) for resolution. When appropriate, NASA will seek an advisory option from the SBA.

§ 1819.7211 Application process for mentor firms to participate in the program

(a) Prime contractors interested in becoming a mentor firm must submit a request to the NASA OSDBU to be approved under the program. The application will be evaluated on the extent to which the company plans to provide developmental assistance and that a balance is represented among the size and SDB status of such potential proteges. The information required in paragraph (b) of this section must be submitted to be considered for approval as a mentor firm.

(b) A proposed mentor must submit the following information to the NASA OSDBU:

(1) Certification that the mentor firm is currently performing under at least one active approved subcontracting plan (small business exempted) and that they are currently eligible for the award of federal contracts;

(2) The cognizant NASA contract number(s), type of contract, performance (including options), title of technical program effort, name of NASA Program Manager (including contact information) and name of NASA field center where support is provided;

(3) The number of proposed Mentor-Protege arrangements;

(4) Data on all current NASA contracts and subcontracts to include the contract/subcontract number(s), period of performance, awarding NASA installation or contractor and contract/subcontract value(s) including options;

(5) Data on total (NASA) subcontracts awarded and SDB awards.

(6) Information on the proposed types of developmental assistance. For each proposed Mentor-Protege relationship include information on the company's ability to provide developmental assistance to the identified protege firm and how that assistance will potentially

increase subcontracting opportunities for the protege firm, including subcontracting opportunities in industry categories where SDBs are not dominant in the company's current subcontractor base; and

(7) A Letter of Intent signed by both the mentor and protege(s).

§ 1819.7212 OSDBU review and approval process of agreement.

(a) Information and Letter of Intent is reviewed by NASA OSDBU. NASA OSDBU will provide a copy of the submitted information to the cognizant NASA technical program manager and contracting officer for a parallel review and concurrence.

(b) If OSDBU approves the application, then the mentor

(1) Negotiates agreement with the protege; and

(2) Submits an original and two (2) copies of the agreement to NASA OSDBU for approval by the NASA Mentor-Protege program manager, the NASA technical program manager and the contracting officer.

(c) Upon agreement approval, the mentor may implement development assistance program.

(d) An approved agreement will become a part of the official subcontracting plan, where applicable. Other agreements will be incorporated into the contract.

(e) If OSDBU disapproves the application, then the mentor may provide additional information for reconsideration.

§ 1819.7213 Agreement contents.

The contents of the agreement must contain:

(a) Names and addresses of mentor and protege firms and a point of contact within both firms who will oversee the agreement;

(b) Procedures for the mentor firm to notify the protege firm, OSDBU, and the contracting officer, in writing, at least 30 days in advance of the mentor firm's intent to voluntarily withdraw from the program;

(c) Procedures for a protege firm to notify the mentor firm in writing at least 30 days in advance of the protege firm's intent to voluntarily terminate the mentor-protege agreement. The mentor shall notify the OSDBU and the contracting officer immediately upon receipt of such notice from the protege;

(d) A description of the developmental program for the protege, including the type of developmental assistance that will be provided by the mentor firm to the protege firm, and a schedule for providing assistance and criteria for evaluation of the protege's developmental success;

(e) A listing of the number and types of subcontracts to be awarded to the protege firm;

(f) Program participation term;

(g) Termination procedures;

(h) Plan for accomplishing work should the agreement be terminated; and

(i) Other terms and conditions, as appropriate.

1819.7214 Developmental assistance.

The forms of developmental assistance a mentor can provide to a protege include:

(a) Management guidance relating to

(1) Financial management,

(2) Organizational management,

(3) Overall business management/planning, and

(4) Business development;

(b) Engineering and other technical assistance;

(c) Noncompetitive award of subcontracts under NASA contractors;

(d) Progress payments based on costs. The customary progress payment rate for all NASA contracts with small disadvantaged businesses is 95 percent. This customary progress payment rate for SDBs may be used by prime contractors;

(e) Advance payments. While a mentor can make advance payments to its proteges who are performing as subcontractors, the mentor will only be reimbursed by NASA for these costs if advance payments have been authorized in accordance with statute and regulation; and

(f) Loans.

1819.7215 Obligation.

(a) Mentor or protege may voluntarily withdraw from the program as mutually agreed by both mentor and protege.

(b) Mentor and protege firms will submit a "lessons learned" evaluation to the NASA OSDBU at the conclusion of the pilot program period or the conclusion of their effort whichever comes first.

1819.7216 Internal controls.

The NASA OSDBU will manage the program. Internal controls will be established by NASA OSDBU to achieve the stated program objectives (by serving as checks and balances against undesired actions or consequences) such as:

(a) Reviewing and evaluating mentor applications for realism, validity and accuracy of provided information; and

(b) Reviewing quarterly progress reports submitted by mentors and proteges on protege development to measure protege progress against the master plan contained in the approved agreement.

1819.7217 Reports.

(a) Quarterly reports shall be submitted by the mentor to the NASA mentor-protege program manager, NASA Headquarters OSDBU to include information as outlined in 1819.7206(b).

(b) Proteges are encouraged to submit quarterly reports, to the NASA mentor-protege program manager, on program progress as pertains to their mentor-protege agreement.

(c) The NASA technical program manager shall submit quarterly reports, for the purposes of award fee determination, assessing the prime contractor's performance in the mentor-protege program as pertains to the technical effort and protege development.

(d) The NASA mentor-protege program manager will submit quarterly reports to the cognizant contracting officer regarding participating prime contractor's performance in the program for use in the award fee determination process.

1819.7218 Program review.

At the conclusion of each year in the mentor-protege program, the prime contractor and protege will formally brief the NASA mentor-protege program manager, the technical program manager, and the contracting officer during a formal program review regarding program accomplishments as pertains to the approved agreement.

1819.7219 Solication provisions and contract clause.

(a) The contracting officer shall insert the provision at 1852.219–77, NASA Mentor-Protege Program, in all solicitations and contracts with subcontracting plans or that offer subcontracting opportunities, regardless of the dollar value of the prime contract.

(b) The contracting officer shall insert the provision at 1852.219–78, Evaluation of Prime Contractor Participation in the Mentor-Protege Program, in all solicitations containing the provisions at 1852.219–77, NASA Mentor-Protege Program or FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan.

(c) The contracting officer shall insert the clause at 1852.219–79, Mentor Responsibility and Evaluation, in contracts where the prime contractor is a participant in the NASA Mentor-Protege Program.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

a. Sections 1852.219–77, 1852.219–78, and 1852.219–79 are added to read as follows:

1852.219–77 NASA Mentor-Protege Program.

As prescribed in 1819.7219(a), insert the following provision:

NASA Mentor-Protege Program (Jan 1994)

(a) Prime contractors, including certain small businesses, are encouraged to participate in the NASA pilot mentor-protege program for the purpose of providing developmental assistance to eligible small disadvantaged businesses to enhance their capabilities and increase their participation in NASA contracts.

(b) The pilot program consists of:

(1) Mentor firms, which are prime contractors with at least one active subcontracting plan;

(2) Protege firms, which are small disadvantaged business (SDB) concerns, include the eligible participants as set forth in Public Law 101–144, as amended by Public Law 101–507, as follows:

"Small Business concerns or other organizations owned or controlled by socially and economically disadvantaged individuals (within the meaning of section 8(a) (5) and (6) of the Small Business Act (15 U.S.C. 637(a) (5) and (6)), including Historically Black Colleges and Universities and Minority Educational Institutions". For the purpose of this section economically and socially disadvantaged individuals shall be deemed to include women;"

(3) Mentor-Protege agreements, approved by the NASA Office of Small and Disadvantaged Business Utilization;

(4) Potential of payment of additional award fee for voluntary participation and successful performance in the mentor-protege program.

(c) Mentor participation in the program, described in 48 CFR 1819.72, means providing technical, managerial and financial assistance to aid SDBs in developing requisite high-tech expertise and business systems to compete successfully for NASA contracts and subcontracts.

(d) Contractors interested in participating in the pilot program are encouraged to contact the NASA OSDBU, Washington, DC 20546, (202) 358–2088, for further information.

(End of clause)

1852.219–78 Evaluation of Prime Contractor Participation in the NASA Mentor-Protege Program.

As prescribed in 1819.7219(b), insert the following provision:

Evaluation of Prime Contractor Participation in the NASA Mentor-Protege Program (Jan 1994)

This subfactor will consider the proposed participation and extent of developmental assistance to be provided by a prime contractor to small disadvantaged businesses.

1852–219–79 Mentor Requirements and Evaluation.

As prescribed in 1819–7219(c), insert the following provision:

Mentor Requirements and Evaluation (Jan 1994)

(a) The purpose of the NASA Mentor-Protege Program (Program) is for a NASA prime contractor to provide developmental assistance to a small disadvantaged business (SDB). The Mentor's active participation in the Program, in compliance with the terms of the negotiated Mentor-Protege Agreement, demonstrates both a commitment to achieve the goal of its contractual subcontracting plan and a commitment to increase the participation of SDBs in NASA contracts and subcontracts. This commitment will be recognized in determining the Mentor's performance fee.

(b) The OSDBU will evaluate the contractor's performance through the Performance Evaluation process. The evaluation will consider the following:

(1) Specific actions taken by the contractor, during the evaluation period, to increase the participation of SDBs as subcontractors and suppliers;

(2) Specific actions taken by the contractor during this evaluation period to develop the technical and corporate administrative expertise of the SDBs as defined in the agreement;

(3) To what extent the Protege has met the developmental objectives in the agreement; and

(4) To what extent the firm's participation in the Mentor-Protege Program resulted in the Protege receiving competitive contract(s) and subcontract(s) from private firms and agencies other than the Mentor.

(c) Quarterly reports shall be submitted by the mentor to the NASA mentor-protege program manager, NASA Headquarters OSDBU to include information as outlined in 1819.7206(b).

(d) The Mentor will notify the OSDBU and the contracting officer, in writing, at least 30 days in advance of the mentor firm's intent to voluntarily withdraw from the program or upon receipt of a Protege's notice to withdraw from the Program;

(e) Mentor and protege firms will submit a "lessons learned" evaluation to the NASA OSDBU at the conclusion of the pilot program period or the conclusion of their effort whichever comes first. At the conclusion of each year in the mentor-protege program, the prime contractor and protege will formally brief the NASA mentor-protege program manager, the technical program manager, and the contracting officer during a formal program review regarding program accomplishments as pertains to the approved agreement.

(End of clause)

[FR Doc. 94–2876 Filed 2–8–94; 8:45 am]

BILLING CODE 7510–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 644

[I.D. 011194F]

Atlantic Billfish Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Atlantic billfishes; notice of scoping meetings and request for comments.

SUMMARY: NMFS will hold scoping meetings to receive comments concerning the Atlantic billfish fishery from fishery participants and other members of the public regarding: A definition of overfishing; reducing fishing mortality; reporting requirements; and other issues. NMFS is also soliciting written comments on issues of concern in this fishery. NMFS requests input at any time during the scoping process, by mail or by fax. An issues/options statement will be prepared for the initial hearing and revised, based on written and oral comments, for subsequent hearings.

DATES: Written scoping comments must be received on or before April 11, 1994. The Scoping meetings will be held on February 21, March 3, and March 24, 1994. See **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Written scoping comments should be sent to Richard B. Stone, Chief, Highly Migratory Species Management Division (F/CM4), Office of Fisheries Conservation and Management, National Marine Fisheries Service, 1315 East-West Highway, room 14853, Silver Spring, MD 20910. Clearly mark the outside of the envelope "Atlantic Billfish Scoping Comments." Input for the issues/options statement may also be provided to the same address, or by sending a fax to C. Michael Bailey at 301–713–1035.

The Scoping meetings will be held in Miami, FL; Rockport, ME; and Linthicum, MD. See **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: C. Michael Bailey at telephone 301–713–2347 or fax 301–713–1035.

SUPPLEMENTARY INFORMATION: The Atlantic, Caribbean and Gulf of Mexico billfish fisheries are managed under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act) (16 U.S.C. 1801 *et seq.*). Fishing by U.S. vessels is governed by regulations implementing the fishery

management plan (FMP) at 50 CFR part 644.

Atlantic Billfishes

Final regulations implementing the FMP for Billfishes of the Atlantic Ocean became effective on September 28, 1988. Billfish means sailfish, *Istiophorus platypterus;* white marlin, *Tetrapturus albidus;* blue marlin, *Makaira nigricans;* and longbill spearfish, *Tetrapturus pfluegeri.*

To reduce fishing mortality, and as part of the rebuilding program, the FMP established minimum sizes, prohibited fishing with certain gear types and prohibited sale of billfish. NMFS wishes to obtain public comment on any problems that might have developed in this fishery and options for dealing with these problems. Issues to be scoped include: A definition of overfishing; reducing fishing mortality; reporting requirements; and any other issues of concern.

Scoping Meetings

Depending upon the interest of the audience, the Meeting Officer may increase the length of the meetings, and additional meetings may be announced at a later date. The meeting schedule is as follows:

February 21, 1994, Miami, Florida 1 to 4 p.m.

RSMAS Auditorium, University of Miami, 4600 Rickenbacker Causeway, Miami, Florida 33149–1098

March 3, 1994, Rockport, Maine 7 to 8 p.m.

Samoset Resort, Warrington Street, Rockport, Maine 04856

March 24, 1994, Linthicum, Maryland 6 to 9 p.m.

At site of ICCAT Advisory Committee meeting: Guest Quarters Hotel, Baltimore-Washington International Airport, 1300 Concourse Drive, Linthicum, MD 21090

Dated: February 3, 1994.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management.

[FR Doc. 94–2943 Filed 2–4–94; 3:21 pm]

BILLING CODE 3510–22–P

50 CFR Part 676

[Docket No. 940103–4003; I.D. 122893B]

RIN 0648–AD19

Limited Access Management of Fisheries off Alaska, Determinations and Appeals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This document proposes procedures to govern appeals of initial administrative determinations under the Alaska fixed gear Pacific halibut and sablefish Individual Fishing Quota (IFQ) limited access program. This proposed rule sets forth: Who may appeal initial administrative determinations; the time period for submitting appeals; what must be included in appeals; procedures regarding acceptance of appeals; the authority of appellate officers; the process for disqualifying appellate officers; evidentiary procedures; the hearing process, including discretionary pre-hearing conferences; post-hearing decisions; and general procedures for appeals. The intended effect of this action is to set forth proposed procedures for appeals from initial administrative determinations made by NMFS management staff and decisions issued by appellate officers under the IFQ program.

DATES: Comments must be received at the following address no later than March 28, 1994.

ADDRESSES: Comments may be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, 709 W. 9th, room 453, Juneau, AK 99801 or P.O. Box 21668, Juneau, AK 99802, Attention: Lori J. Gravel. Copies of this proposed rule, and the final environmental impact statement/supplementary environmental impact statement (FEIS/SEIS) for the halibut and sablefish IFQ programs, respectively, may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510.

FOR FURTHER INFORMATION CONTACT: John Lepore, Fisheries Regulations Specialist, Alaska Region, NMFS, at 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

The IFQ program is a regulatory regime intended by the North Pacific Fishery Management Council (Council) to promote the conservation and management of halibut and sablefish resources, and to further the objectives of the Magnuson Fishery Conservation and Management Act (Magnuson Act) and the Northern Pacific Halibut Act (Halibut Act).

The Alaskan fisheries using fixed gear for Pacific halibut (*Hippoglossus stenolepis*) and sablefish (*Anoplopoma fimbria*) in the areas defined in 50 CFR 676.10 (b) and (c) will be managed through the IFQ program beginning in 1995. Further information on the program is contained in the preamble to the final regulations implementing the program (50 CFR part 676) (58 FR 59375, November 9, 1993).

This action proposes procedures for appeals under 50 CFR part 676. Appeals would be available from initial administrative determinations made by NMFS management staff and appellate officers' decisions. Final action on this proposed rule will be taken by NMFS after review and consideration of public comments.

Initial Administrative Determinations

Initial administrative determinations are the findings of NMFS staff on eligibility for initial allocation, transfer and use of quota share (QS) and IFQ under the IFQ program. Initial administrative determinations become the final agency action within 90 days of its issuance unless appealed under the procedure described below.

Examples of initial administrative determinations that would be made by NMFS staff are: (1) Whether applicants have submitted sufficient documentation to demonstrate that they are qualified persons, or their successors-in-interest, as defined in 50 CFR 676.20(a)(1); (2) whether to grant initial QS allocations to applicants based on the documentation provided in applications; (3) whether documentation submitted with applications, or documentation requested by NMFS staff, supports the claims made on applications for initial QS allocations; (4) whether to grant initial QS allocations based on specific vessel categories and fishery statistical areas; and (5) other issues that might arise under 50 CFR part 676.

Prior to making initial administrative determinations, NMFS staff would be able to request additional information from applicants to support their applications. Applicants would be provided 90 days to respond to these requests. Requests for additional information would provide an opportunity for applicants to submit additional documentation for claims not consistent with data contained in NMFS files. Requests for additional

information could not in themselves be the subject of an administrative appeal. Appealable determinations would not be made until: (1) An applicant has responded to the request by providing additional information within the time period; (2) an applicant has waived the right to respond to the request for additional information, and instead has requested that a determination be made on the application in its current form; or (3) an applicant has not responded within the applicable time period.

Appeals

Persons, as defined in 50 CFR 676.11, whose interests are directly and adversely affected by initial administrative determinations made by NMFS staff or by decisions issued by appellate officers would be able to appeal those determinations or decisions. The proposed rule would establish a 2-tier appeals process (*i.e.*, appeal of an initial administrative determination to the appellate officer and appeal of an appellate officer's decision to the Regional Director). This process would provide applicants with a reasonable opportunity to be heard concerning agency actions.

Appeals would have to be in writing; appeals made orally, either in person at NMFS, or over the telephone, would not be accepted. The writing requirement protects the applicant (now appellant) by providing a written record of the issues appealed and ensuring that the appeal becomes part of the record. Appeals would also have to be in original form. This means that NMFS would not accept appeals sent by electronic transmission (telefacsimile). Appeals could be either mailed or personally delivered to NMFS. Appeals submitted by mail may be sent certified, return receipt requested, to provide the appellant with evidence of mailing the appeal in case it becomes lost or destroyed.

Addresses of record would be established from the addresses used by persons on their first correspondence to NMFS, Restricted Access Management, Juneau, AK. For most persons, this first correspondence would be their request for an application for QS allocation. Any changes to the address of record should be promptly provided to NMFS in writing. The burden to notify NMFS of address changes would be on the IFQ program applicant because the applicant is in the best position to have knowledge of such changes. Supplying address changes ensures that NMFS would have an accurate and current address for correspondence.

Eligibility to appeal would begin on either the date initial determinations were made by NMFS staff or on the date decisions were issued by appellate officers. Appeals would have to be filed with NMFS within 90 days of the date an initial administrative determination was made, or within 45 days of the date an appellate officer's decision was issued.

Appellants would be required to submit a full written statement in support of the appeal, including a concise statement of the reasons why the initial administrative determination has a direct and adverse effect on the appellant and should be reversed or modified. The appellate officer may request additional information from the appellant to resolve the appeal. Appeals merely challenging the IFQ regulations would not be accepted.

In addition to the written statement of appeal, an appellant may request, in writing, a hearing on one or more issues material to the appeal. A request for a hearing would have to be accompanied by a concise statement: (1) Raising a genuine and substantial issue of adjudicative fact for resolution; and (2) listing available and specifically identified reliable evidence upon which the factual issue can be resolved. A hearing would not be held on issues of policy or law, or upon the basis of mere allegations, denials, or general descriptions of positions and contentions.

The appellant could, and would be encouraged to, supply evidence supporting the statement of appeal and request for a hearing. By timely submitting a complete appeal, and by providing sufficient supporting evidence, the appellate officer could make a decision in the appellant's favor without further proceedings. Alternatively, the appellate officer could deny the appeal as unfounded, a decision that would be appealable to the Regional Director. Finally, the appellate officer could decide to order a hearing to aid in the disposition of one or more of the issues presented on appeal.

Hearings

Written or oral hearings would be held at the appellate officer's discretion to resolve genuine and substantial issues of adjudicative fact, if such hearings would be useful to resolve those issues. The decision of whether to hold a written or oral hearing would be solely within the appellate officer's discretion and could not be appealed to the Regional Director.

The appellate officer could order a written hearing on a determination that the issues presented in an appeal could be resolved by allowing the appellant an opportunity to respond through written submissions. The written hearing process would be the preferred method of resolving issues unless the appellate officer determined that an oral hearing is necessary. The appellate officer might decide to order an oral hearing on one or more issues after beginning the written hearing process.

On ordering a written hearing, the appellate officer would provide the appellant with notice that a written hearing has been ordered, provide the appellant with a statement of issues to be determined, and provide the appellant with 30 days to file a written response, which might include affidavits from the appellant or other witnesses. The statement of issues would provide the appellant with information concerning the issues to be determined at hearing by the appellate officer. This statement would help to focus the appellant on pertinent, rather than extraneous, issues. The appellate officer might, at his/her sole discretion, extend the 30-day filing period for the written response if the appellant shows good cause for failing to meet the deadline. This extension would be provided only in cases in which the appellant could not respond within the time period. The success of the IFQ program depends on the timely disposition of all appeals. Extensions for an unjustified failure to meet filing deadlines would not be allowed.

The appellate officer would order an oral hearing on a determination that an oral hearing is necessary to resolve one or more issues presented in the appeal. As explained above, the decision to order either an oral or written hearing lies solely within the appellate officer's discretion. On ordering an oral hearing, the appellate officer would provide the appellant with notice that an oral hearing has been ordered, provide the appellant with a statement of issues to be determined by the hearing process, and provide the appellant with notice, at least 30 days in advance, of the place, date, and time of the oral hearing. Hearings would be held in Juneau at the prescribed date and time, unless the appellate officer determines, based upon good cause shown, that a different place, date, or time would better serve the interests of justice. As explained above, routine delays would not be allowed, and the ordering of continuances, like extensions, would be solely within the appellate officer's discretion.

The proposed rule would allow appellate officers to order pre-hearing conferences. The pre-hearing conference could be used to simplify the issues, obtain stipulations and admissions of facts, and discuss the possibility of

settlement without further proceedings. Simplifying the issues would increase the efficiency of the hearing process by ensuring that the appellant's time and effort are not wasted on extraneous issues. Stipulations, which are conditions that are specified and agreed on in advance, and admissions of fact, which are admissions that certain facts are not in dispute and do not need to be proved, would assist in streamlining the hearing process. Settlements could be beneficial to all parties concerned, allowing for the resolution of some issues without the time and cost that would be associated with using the entire hearing process. The formal rules of evidence would not apply.

The appellate officer would have authority to conduct hearings in an orderly manner, including the powers specifically listed in proposed § 676.25(i). In addition, NMFS is considering whether the appellate officers have the legal authority to (1) issue subpoenas to compel testimony and the production of documentary evidence, and (2) take depositions and cause depositions to be taken. Although these additional powers are not specifically enumerated in proposed § 676.25(i), NMFS nevertheless requests public comment on the authority for, and advisability of, granting appellate officers these powers.

To provide for the integrity of the process, appellate officers would withdraw from an appeal at any time they deem themselves disqualified. This could occur because of financial connection to the case, *ex parte* communications, or some other personal bias. In addition, appellants would be able to request withdrawal of the appellate officer. An appellate officer might withdraw upon the appellant's motion if it was entered prior to the issuance of a decision and the appellant demonstrated personal bias or other basis for disqualification. If the appellate officer denies the motion to withdraw, he/she would have to do so on the record.

At the conclusion of the hearing, whether oral or written, the appellate officer would close the record and issue a decision. The proposed rule would require that the appellate officer's decision be based solely on the record of the proceedings, ensuring that the appellant would have the opportunity to review all information that was used in the decision-making process. This requirement would also establish a record for review on appeal.

Appeal to the Regional Director

An appellant whose interests are directly and adversely affected by an appellate officer's decision would have an opportunity to appeal that decision to the Regional Director. A written appeal to the Regional Director would have to be filed within 45 days of the issuance of the appellate officer's decision. If the appellate officer's decision was not appealed within this 45-day period, that decision would become effective upon the expiration of the time period and would be considered a final agency action. A 45-day period is proposed because it is long enough to provide the appellant with reasonable time to prepare an adequate appeal to the Regional Director, but not be too long as to unduly delay the appeals process. An appeal to the Regional Director would have to clearly and concisely state the reasons why the appellate officer's decision has a direct and adverse effect on the appellant, or other party, and should be modified, reversed, or remanded.

The Regional Director would resolve the appeal based solely on the record as developed by the appellate officer and would not hold another hearing. Another hearing at this stage of the process is unnecessary because all evidence and testimony for the proper disposition of issues should have been presented to the appellate officer and would be in the record. The appellate officer's decision would be affirmed by either the Regional Director denying the appeal or issuing an order affirming the appellate officer's decision. The Regional Director could deny appeals that are submitted after the 45-day period or appeals that did not articulate a sufficient basis to modify, remand, or reverse the appellate officer's decision. The Regional Director could also order that an appellate officer's decision be modified or reversed, or remanded to an appellate officer for further proceedings consistent with the Regional Director's decision. In all cases, the Regional Director would issue a written decision explaining the reasons for the determination. Unless a remand was ordered, a decision by the Regional Director would be a final agency action subject to judicial review. In the case of a remand, the appellate officer would need to conduct further proceedings consistent with the Regional Director's decision.

Classification

This proposed rule is designed to implement the appeals portion of the IFQ program, a program intended by the Council to promote the conservation and management of the halibut and sablefish resources, and to further the objectives of the Magnuson Act and the Halibut Act. This proposed rule is consistent with the national standards, other provisions of the Magnuson Act, the Halibut Act, and other applicable laws.

A regulatory flexibility analysis was prepared for the IFQ program, describing the effects of this program on small entities. This analysis was contained in the FEIS for the IFQ program. The Secretary of Commerce concluded that the IFQ program would have a significant economic impact on a substantial number of small entities based on this analysis. Any effect of this proposed rule, which implements the appeals process for the IFQ program, was included in this prior analysis.

This proposed rule contains a collection of information requirement subject to the Paperwork Reduction Act of 1980. The estimated response time for the collection of information required to file an appeal to a QS application is 4 hours. The collection of information has been approved by the Office of Management and Budget, OMB control numbers 0648–0272 (IFQs for Pacific Halibut and Sablefish in the Alaska Fisheries) and 0648–0269 (Western Alaska CDQ Program).

This rule is not subject to review under E.O. 12866.

List of Subjects in 50 CFR Part 676

Fisheries; Reporting and recordkeeping requirements.

Dated: February 3, 1994.

Nancy Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 676 is proposed to be amended as follows:

PART 676—LIMITED ACCESS MANAGEMENT OF FEDERAL FISHERIES IN AND OFF ALASKA

1. The authority citation for 50 CFR part 676 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.* and 16 U.S.C. 1801 *et seq.*

2. In § 676.25, the text is added to read as follows:

§ 676.25 Determinations and appeals.

(a) *General.* The following section describes the procedure for appealing initial administrative determinations and appellate officers' decisions made under 50 CFR part 676.

(b) *Who May Appeal.* Any person whose interest is directly and adversely affected by either an initial administrative determination or an appellate officer's decision may file a written appeal. For purposes of this

section, such a person will be referred to as "applicant" or "appellant".

(c) *Submission of Appeals.* Appeals must be in writing and must be submitted in original form to NMFS, P.O. Box 21668, Juneau, AK 99802; or to NMFS, 709 W 9th, room 413, Juneau, AK 99801. Appeals transmitted by electronic means will not be accepted.

(d) *Time Periods for Appeals and Date of Filing.* (1) Appeals must be filed within the following time periods:

(i) Appeals from initial administrative determinations must be filed within 90 days of the date the determination was made; and

(ii) Appeals from appellate officers' decisions must be filed within 45 days of the date the decision was issued.

(2) The time periods within which appeals must be filed begin to run on the date of issuance of the initial administrative determination or appellate officer's decision that gives rise to the appeal. Saturdays, Sundays, and Federal holidays will not be included in computing such time periods, which conclude at the close of business of the final enumerated day, except that when such time periods conclude on a Saturday, Sunday, or Federal holiday, such periods will be extended to the close of business on the next business day.

(3) For purposes of this section, the date of filing is the date the appeal is received by NMFS.

(4) All other time periods established under this section will be computed in a manner consistent with the provisions of paragraphs (d)(2) and (3) of this section.

(e) *Address of Record.* NMFS will establish as the address of record the address used by the applicant in initial correspondence to NMFS, Restricted Access Management, after the application period has begun. Notices of all actions affecting the applicant after establishing an address of record will be mailed to that address unless the applicant provides NMFS, in writing, with any changes to that address. NMFS bears no responsibility if a notice is sent to the address of record and is not received because the applicant's actual address has changed without notification to NMFS.

(f) *Statement of Reasons for Appeals from Initial Determinations.* Applicants must timely submit a full written statement in support of the appeal, including a concise statement of the reasons why the initial administrative determination has a direct and adverse effect on the applicant and should be reversed or modified. If the applicant requests a hearing on any issue presented in the appeal, such request for hearing must be accompanied by a concise written statement raising genuine and substantial issues of adjudicative fact for resolution and a list of available and specifically identified reliable evidence upon which the factual issues can be resolved. The appellate officer will limit his/her review to the issues stated in the appeal; all issues not set out in the appeal will be waived.

(g) *Decision Whether to Order a Hearing.* The appellate officer will review the applicant's appeal and request for hearing and, at his/her sole discretion, proceed as follows:

(1) Deny the appeal. A decision to deny the appeal may be appealed to the Regional Director as provided in paragraph (o) of this section;

(2) Issue a decision on the merits of the appeal if the record contains sufficient information on which to reach final judgment. A decision on the merits of the appeal may be appealed to the Regional Director as provided in paragraph (o) of this section; or

(3) Order that a hearing be conducted. The appellate officer may so order only if the appeal demonstrates the following:

(i) There is a genuine and substantial issue of adjudicative fact for resolution at a hearing. A hearing will not be ordered on issues of policy or law;

(ii) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be ordered on the basis of mere allegations or denials or general descriptions of positions and contentions;

(iii) The evidence described in the request for hearing, if established at hearing, would be adequate to justify resolution of the factual issue in the way sought by the applicant. A hearing will not be ordered if the evidence described is insufficient to justify the factual determination sought, even if accurate; and

(iv) Resolution of the factual issue in the way sought by the applicant is adequate to justify the action requested. A hearing will not be ordered on factual issues that are not determinative with respect to the action requested.

(h) *Types of Hearings.* If the appellate officer determines that a hearing should be held to resolve one or more genuine and substantial issues of adjudicative fact, he/she may order:

(1) A written hearing, as provided in paragraph (m) of this section; or

(2) An oral hearing, as provided in paragraph (n) of this section.

(i) *Authority of the Appellate Officer.* The appellate officer is vested with general authority to conduct all hearings in an orderly manner, including the authority to:

(1) Administer oaths;

(2) Call and question witnesses; and

(3) Issue a written decision based on the record.

(j) *Evidence.* All evidence that is relevant, material, reliable, and probative may be included in the record. Formal rules of evidence do not apply to hearings conducted under this section.

(k) *Appellate Officer Decisions.* The appellate officer will close the record and issue a decision after he/she determines that there is sufficient information on the record of the proceedings and all procedural requirements have been met. The decision must be based solely on the record of the proceedings. Appellate officers' decisions will become effective 45 days after the date the decision is issued, unless appellant files a timely appeal to the Regional Director in accordance with paragraph (o) (1) and (2) of this section, or the Regional Director orders review of the appellate officer's decision in accordance with paragraph (o)(4) of this section.

(l) *Disqualification of an Appellate Officer.* (1) The appellate officer will withdraw from an appeal at any time he/she deems himself/herself disqualified.

(2) The appellate officer may withdraw from an appeal on an appellant's motion if:

(i) The motion is entered prior to the appellate officer's issuance of a decision; and

(ii) The appellant demonstrates that the appellate officer has a personal bias or any other basis for disqualification.

(3) If the appellate officer denies a motion to withdraw, he/she will so rule on the record.

(m) *Written Hearing.* (1) An appellate officer may order a written hearing under paragraph (h)(1) of this section if he/she:

(i) Orders a hearing as provided in paragraph (g)(3) of this section; and

(ii) Determines that the issues to be resolved at hearing can be resolved by allowing the appellant to present written materials to support his/her position.

(2) After ordering a written hearing, the appellate officer will:

(i) Provide the appellant with notice that a written hearing has been ordered;

(ii) Provide the appellant with a statement of issues to be determined at hearing; and

(iii) Provide the appellant with 30 days to file a written response. The appellant may also provide documentary evidence to support his/

her position. The period to file a written response may be extended at the sole discretion of the appellate officer if the appellant shows good cause for the extension.

(3) The appellate officer may, after reviewing the appellant's written response and documentary evidence:

(i) Order that an oral hearing be held, as provided in paragraph (h)(2) of this section, to resolve issues that cannot be resolved through the written hearing process;

(ii) Request supplementary evidence from the appellant before closing the record; or

(iii) Close the record.

(4) The appellate officer will close the record and issue a decision after he/she determines there is sufficient information on the record. This decision will be considered final for purposes of appeal to the Regional Director as provided in paragraph (o) of this section.

(n) *Oral Hearing.* (1) The appellate officer may order an oral hearing under paragraphs (h)(2) and (m)(3)(i) of this section if he/she:

(i) Orders a hearing as provided in paragraph (g)(3) of this section; and

(ii) Determines that the issues to be resolved at hearing can best be resolved through the oral hearing process.

(2) After ordering an oral hearing, the appellate officer will:

(i) Provide the appellant with notice that an oral hearing has been ordered;

(ii) Provide the appellant with a statement of issues to be determined at hearing; and

(iii) Provide the appellant with notice, at least 30 days in advance, of the place, date, and time of the oral hearing. Oral hearings will be held in Juneau at the prescribed date and time, unless the appellate officer determines, based upon good cause shown, that a different place, date, or time will better serve the interests of justice. A continuance of the oral hearing may be ordered at the sole discretion of the appellate officer if the appellant shows good cause for the continuance.

(3) The appellate officer may, either at his/her own discretion or on the motion of the appellant, order a pre-hearing conference, either in person or telephonically, to consider:

(i) The simplification of issues;

(ii) The possibility of obtaining stipulations, admissions of facts, and agreements to the introduction of documents;

(iii) The possibility of settlement or other means to facilitate resolution of the case; and

(iv) Such other matters as may aid in the disposition of the proceedings.

(4) The appellate officer must provide the appellant with notice of a pre-hearing conference, if one is ordered, at least 30 days in advance of the conference. All action taken at the pre-hearing conference will be made part of the record.

(5) At the beginning of the oral hearing, the appellate officer may first seek to obtain stipulations as to material facts and the issues involved and may state any other issues on which he/she may wish to have evidence presented. Issues to be resolved at the hearing will be limited to those identified by the appellate officer as provided in paragraph (g)(3) of this section. The appellant will then be given an opportunity to present his/her case.

(6) During the oral hearing, the appellant has the right to present reliable and material oral or documentary evidence and to conduct such cross-examination as may be required in the interests of justice.

(7) After the conclusion of the oral hearing the appellant may be given time by the appellate officer to submit any supplementary information that may assist in the resolution of the case.

(8) The appellate officer will close the record and issue a decision on the appeal after he/she determines there is sufficient information on the record. This decision will be considered final for purposes of appeal to the Regional Director as provided in paragraph (o) of this section.

(o) *Appeals to the Regional Director.* An appellant may appeal an appellate officer's decision to the Regional Director. All such appeals must be filed with the Regional Director within the time period established in paragraph (d)(1)(ii) of this section.

(1) An appeal to the Regional Director of an appellate officer's decision must be accompanied by a full written statement in support of the appeal, including a concise statement of the reasons why the appellate officer's decision has a direct and adverse effect on the appellant and should be modified, reversed, or remanded.

(2) The Regional Director may order a review of the appellate officer's decision and may issue a decision on review that modifies or reverses the appellate officer's decision, or remands that decision to the appellate officer for further proceedings consistent with the decision on review. The Regional Director's decision will be based solely on the record as developed by the appellate officer.

(3) If the Regional Director denies the appeal, the appellate officer's decision is affirmed, and the action is a final agency action subject to judicial review under 5 U.S.C. 704.

(4) Within 45 days of the date the appellate officer's decision is issued, the Regional Director may, at his/her own discretion, order review of any appellate officer's decision. If the Regional Director orders review of an appellate officer's decision, the Regional Director must notify the appellant and prepare an order that affirms, modifies, reverses, or remands the decision to the appellate officer for further proceedings consistent with the decision on review. If the appellate officer's decision is modified or reversed, the Regional Director must issue a written decision explaining the reasons for his/her determination. Unless a remand is ordered, the Regional Director's decision is a final agency action subject to judicial review under 5 U.S.C. 704.

[FR Doc. 94–2871 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

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.

U.S. COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Arizona Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Arizona Advisory Committee to the Commission will convene at 10 a.m. and adjourn 1 p.m. on Saturday, February 26, 1994, at the Hilton-Tucson, 7600 East Broadway, Tucson, Arizona 85710. The purpose of the meeting is to discuss the border violence project and plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Manuel Pena or Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–0508). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, February 3, 1994.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 94–2941 Filed 2–8–94; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the South Carolina Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the South Carolina Advisory Committee to the Commission will convene at 1 p.m. and adjourn at 4 p.m. on Thursday, March 10, 1994, at the Embassy Suites Hotel, Boardroom, 200 Stoneridge Drive in Columbia, South Carolina. The purpose of the meeting is to: (1) To discuss the status of the Commission and SACs; (2) to discuss civil rights progress and/or problems in the State; and (3) to review and discuss the draft report on Racial Tensions in South Carolina.

Persons desiring additional information, or planning a presentation to the Committee, should contact Bobby D. Doctor, Director of the Southern Regional Office, 404–730–2476 (TDD 404–730–2481). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, February 4, 1994.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 94–2942 Filed 2–8–94; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–821]

Final Determination of Sales at Less Than Fair Value: Certain Carbon and Alloy Steel Wire Rod from Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Ellen Grebasch or Erik Warga, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3773 or 482–0922, respectively.

FINAL DETERMINATION: We determine that imports of certain carbon and alloy steel wire rod ("steel wire rod") from Brazil are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since our November 19, 1993, preliminary determination (58 FR 62636, November 29, 1993), the following events have occurred:

On December 8, 1993, interested party Michelin Tire Corporation requested a public hearing.

Petitioners (Connecticut Steel Corporation, Georgetown Steel Corporation, Keystone Steel & Wire Company, and North Star Steel Texas, Inc.), respondent Siderurgica Mendes Junior ("SMJ"), and other interested parties ("the Barnes Group"—comprised of Barnes Group Inc., Associated Spring, and NHK-Associated Spring Suspension Components Inc.—and Amercord Inc.) filed case briefs on January 5, and rebuttal briefs on January 10, 1994. The other mandatory respondent, Cia Siderurgica de Guanabara ("Cosigua"), did not file a brief or a rebuttal.

A public hearing took place on January 12, 1994. At our request, interested parties in the companion investigation of wire rod from Canada also submitted case and rebuttal briefs and attended the hearing to discuss the scope of the three ongoing investigations of certain carbon and alloy steel wire rod.

Scope of Investigation

The products covered by this investigation are hot-rolled carbon steel and alloy steel wire rod, in coils, of approximately round cross section, between 0.20 and 0.75 inches in solid cross-sectional diameter. The following products are excluded from the scope of this investigation:

- Steel; wore rod 5.5 mm or less in diameter, with tensile strength greater than or equal to 1040 MPa, and the following chemical content, by weight: carbon greater than or equal to 0.79%, aluminum less than or equal to 0.005%, phosphorous plus sulfur less than or equal to 0.040%, and nitrogen less than or equal to 0.006%;
- Free-machining steel containing 0.03% or more of lead, 0.05% or more of bismuth, 0.08% or more of sulfur, more than 0.4% of phosphorus, more than 0.05% of selenium, and/or more than 0.01% of tellurium;
- Stainless steel rods, tool steel rods, free-cutting steel rods, sulfurized steel rods, ball bearing steel rods, high-nickel steel rods, and concrete reinforcing bars and rods; and
- Wire rod 7.9 to 18 mm in diameter, containing 0.43 to 0.73% carbon by weight,

and having partial decarburization and seams no more than 0.75 mm in depth.

The products under investigation are currently classifiable under subheadings 7213.31.3000, 7213.31.6000, 7213.39.0030, 7213.39.0090, 7213.41.3000, 7213.41.6000, 7213.49.0030, 7213.49.0090, 7213.50.0020, 7213.50.0040, 7213.50.0040, 7213.50.0080, 7227.20.0000, 7227.90.6000, and 7227.90.6050 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Period of Investigation

The period of investigation is October 1, 1992, through March 31, 1993.

Such or Similar Comparisons

We have determined that the merchandise covered by this investigation constitutes a single category of "such or similar" merchandise.

Best Information Available

Because both mandatory respondents failed to respond to our questionnaire, we based our determination on best information available (BIA) pursuant to section 776(c) of the Act.

In determining what rate to use as BIA, the Department of Commerce ("the Department") follows a two-tiered methodology, whereby the Department normally assigns lower margins to those respondents who cooperated in an investigation and margins based on more adverse assumptions for those respondents who did not cooperate in an investigation. According to the Department's two-tiered BIA methodology outlined in the Final Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products, Certain Cold-Rolled Carbon Steel Flat Products, and Certain Cut-to-Length Carbon Steel Plate From Belgium, 58 FR 37083, (July 9, 1993), when a company refuses to provide the information requested in the form required, or otherwise significantly impedes the Department's investigation, it is appropriate for the Department to assign to that company the higher of (1) the margin alleged in the petition, or (2) the highest calculated rate of any respondent in the investigation. Because there were no cooperative respondents in this investigation, we are assigning to all exporters, as BIA, a margin of 36.02 percent, the highest margin calculated based on information in the petition on merchandise that is within the scope of this investigation (as amended).

Fair Value Comparisons

To determine whether respondents made sales of steel wire rod from Brazil in the United States at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We calculated USP using the methodology described in the preliminary determination, except that we calculated taxes on U.S. sales in accordance with our revised tax methodology. Our revised methodology consisted of applying the home market tax rate to USP. See, *e.g.*, Stainless Steel Wire Rod from France (58 FR 68865, December 29, 1993) (Final Determination) ("French Wire Rod").

Foreign Market Value

We calculated FMV using the methodology described in the preliminary determination, except that the ICMs value-added tax was not deducted from FMV. In addition, we calculated a readjustment of the amount of tax on the U.S. credit expenses added to FMV by applying the tax rate to those expenses. This readjustment amount was also added to FMV (See French Wire Rod).

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Interested Party Comments

Comment 1. Michelin contends that the Department must exclude from the scope of the investigation tire cord quality 1070 steel wire rod ("TCQ 1070"), which Michelin imports, because Michelin has been unable to obtain that product in commercial quantities from any U.S. manufacturer. Additionally, Michelin suggests that the *Flat Panel Displays* case [1] ("*FPDs*") established that the Department is required to determine, within a class or kind of merchandise, whether "there are any distinct products for which U.S. manufactures do not manufacture a like product." Michelin contends that TCQ 1070 is a distinct product, and that the portion of the petition pertaining to TCQ 1070 should be dismissed for lack of standing on the part of petitioners. If TCQ 1070 is not found to be a distinct product Michelin suggests that TCQ 1070 is essentially the same as tire cord quality 1080 steel wire rod ("TCQ 1080"), which is already excluded from the scope of the investigation pursuant to petitioners' October 19, 1993, petition amendment. Accordingly, Michelin argues, TCQ 1070 and TCQ 1080 should be evaluated jointly. Based on this premise, Michelin contends that the Department should determine that the two subsets of all steel wire rod—tire cord quality and non-tire cord quality—constitute two distinct classes or kinds of merchandise based on the *Diversified Products* criteria,[2] and class-or-kind-specific dumping margins should be calculated.

Stelco Inc., commenting on scope in the context of the companion investigation of wire rod from Canada,[3] argues that the antidumping law does not permit the Department to accept without explanation or analysis petitioners' October 18, 1993, amendment to the petition (excluding TCQ 1080) over the objection of an interested party. To grant a contested exclusion request, Stelco suggests, requires an explicit finding that the product in question be "* * * co-extensive with a rational class or kind of wire rod product subcategory." A reasonable analysis, according to Stelco, can lead only to the joint consideration and disposition of petitioners' amendment (excluding TCQ 1080) and Michelin's request (to exclude TCQ 1070).

Petitioners object to the request to exclude TCQ 1070 because the precedent of other antidumping investigations of wire rod, as well as the *Diversified Products* criteria and the criteria used to determine like products, demonstrate no "bright line" upon which to base a decision to treat TCQ 1070 as a distinct product or to find that wire rod products comprise multiple classes or kinds. Petitioners also contend that the request is untimely.

Petitioners claim that there is substitutability between the products that Michelin would exclude on the one hand and products that would remain within the scope on the other hand (*e.g.*, tire bead quality wire rod). Petitioners

[1] Final Determination and Partial Rescission: Flat Panel Displays from Japan (56 FR 32376, July 16, 1991).

[2] The *Diversified Products Corp.* v. *United States* (572 F. Supp. 883 (CIT 1983)) case upheld a class-or-kind decision which considered the following criteria: (1) The product's general physical characteristics; (2) its ultimate use; (3) the expectations of the ultimate purchaser; (4) the channels of trade; and (5) cost.

[3] Stelco, a Canadian wire rod producer, is not an interested party in this proceeding. However, the scope issues in the three concurrent wire rod investigations are essentially the same and thus best disposed of together. Therefore, we have placed Stelco's scope comments on the record in this proceeding.

further claim that the description of the product that Michelin proposes to exclude encompasses products that petitioners produce. Finally, petitioners suggest that, even if the Department determines tire cord quality wire rod to be a distinct product or a separate class or kind, petitioners' standing must be accepted unless challenged by a domestic producer.

With respect to Stelco's argument that the Department's acceptance of petitioners' amendment was unlawful, petitioners contend that Department precedent requires only that scope amendments "be timely and consistent with the intent of the petitioner."

DOC Position. We agree with petitioners. Accordingly, we have not excluded TCQ 1070 from the scope of this investigation but will continue to exclude TCQ 1080.

The Act and our regulations do not provide for consideration of domestic availability in determining whether a product should or should not fall within the scope of an investigation. See, *e.g.*, Appendix to Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Argentina (58 FR 37062, July 9, 1993) ("*Flat-Rolled Steel*"). Additionally, our acceptance of petitioners' amendment excluding TCQ 1080 from the scope of the petition was lawful and appropriate. Under our regulations, section 353.12(b)(4) requires a petitioner to describe the scope in filing a petition and section 353.12(e) provides that a petitioner may amend the petition.

We agree that we must evaluate scope amendments. Generally, when a petitioner asks to amend the scope of a petition, our chief concern is the administrative feasibility of granting the request (*see, e.g., Flat-Rolled Steel* cases, where petitioners' late plate scope amendment was rejected)—including such factors as whether time permits soliciting any required new information and practicality for customs purposes. In addition, we will evaluate on its merits any opposition to an exclusion request. However, the act on the part of a petitioner of making such a request is generally sufficient justification for granting such an exclusion, because it is a statement by petitioner that it does not need relief from a product's competition. Further, this view of a petitioner's important role in determining the scope is supported by Department practice in past cases (*e.g.*, *Flat-Rolled Steel* cases).

In this case, Stelco opposes the exclusion of TCQ 1080 on the grounds that this product should not be considered separately from TCQ 1070. While we agree that TCQ 1070 and TCQ 1080 are similar in many respects, these similarities do not require that the two products' fates be inextricably intertwined. The two products have different minimum carbon contents, and the matching criteria in the three companion wire rod cases (upon which all interested parties were afforded an opportunity to comment) rank grade/carbon content highest among relevant characteristics of wire rod. Thus, the two are meaningfully distinct products, only one of which (TCQ 1070) petitioners have chosen to include in the scope of their petition.

Notwithstanding Stelco's unsupported allegations concerning petitioners' exclusion request, neither the statute nor the regulations requires the Department to determine that products whose exclusion is contested represent a distinct class or kind of merchandise or a distinct like product, nor did the *FPDs* case establish a requirement for a like product analysis. In *FPDs*, a like product analysis was conducted in order to evaluate the petitioner's standing with respect to one class or kind of merchandise.

With respect to whether TCQ 1070 can be excluded over petitioners' opposition, such exclusions are possible only if the product is determined to be part of a separate class or kind of merchandise which petitioners do not produce. TCQ and non-TCQ wire rod do not constitute separate classes or kinds of merchandise—even applying the *Diversified Products* criteria (which, we note, are guidelines, not mandatory criteria for defining class or kind).[4] In short, there is no bright line among the product groups at issue in this case. Further, there is no precedent for separate classes or kind in other investigations or wire rod, and no party broached this issue when asked to comment on matching criteria. In any case, since petitioners claim that they produce TCQ 1070, a separate class or kind finding would not result in a finding that petitioners lack standing.

In conclusion, petitioners have requested a scope amendment that can be administered. Petitioners oppose the exclusion of TCQ 1070, and TCQ 1070 is neither a distinct product for which petitioners lack standing nor part of a separate tire cord quality class or kind of merchandise. While similar to TCQ 1080, TCQ 1070 differs in terms of a characteristic recognized as significant: Carbon content. Challenges to like product or class-or-kind determinations are subject to very high standards and are difficult for the Department to sustain. Petitioners' scope definition is afforded great weight because petitioners can best determine from what products they require relief. Moreover, in administering the law the Department may not take into account potential shortages in domestic supply.

Comment 2. Petitioners and the Barnes Group request the exclusion of valve spring quality wire rod from the scope of this investigation, in accordance with petitioners' November 1993 petition amendment.

DOC Position. We agree that valve spring quality wire rod should, in accordance with petitioners' amendment, be excluded from the scope. This amendment has not been contested, and nothing on the record in this proceeding gives rise to concern over feasibility.

Comment 3. SMJ alleges that, in the petition margin calculations on which the preliminary LTFV margin calculations were based, the adjustment to USP for foreign inland freight charges was overstated as a result of an erroneous inflation adjustment. SMJ also alleges that the margin calculations do not properly account for the 12-percent ICMS tax that is assessed on home market sales of the subject merchandise.

Petitioners counter that SMJ has misinterpreted information on the record and arrived at an unsubstantiated conclusion. The only appropriate change to the preliminary LTFV margin calculations is that, in calculating the LTFV margin, the Department should revise its treatment of Brazilian indirect taxes to be consistent with the Court of International Trade's holding in *Federal-Mogul Corporation* v. *United States*, Court Nos. 91–07–00530 and 91–08–00569, Slip. Op 93–194 (CIT October 7, 1993). (The Court ordered that, to calculate the addition to United States price, the home market tax rate be applied to United States price at the same point in the stream of commerce where the tax is applied to home market sales.)

DOC Position. We agree with petitioners. The information upon which the petition margin calculations were based was accepted for purposes of initiating this investigation. When a

[4] Wire rod has in past cases been broadly defined in terms of the same general physical characteristics and range of ultimate users. Customers expect to draw or stamp the product into various other downstream products. While different technical specifications and uses exist, it would be prohibitively difficult to identify each unique combination as defining a separate class or kind of merchandise. No differences in channels of trade, such as sale to end users versus sales to resellers, distinguish groups of wire rod. Although tire cord quality wire rod has a relatively high cost, it is not the only type of wire rod included in the scope that has a high cost.

respondent has chosen not to cooperate with our investigation, the BIA margins calculated are not open to cross-examination unless a plain clerical error or methodological inconsistency is involved. SMJ has drawn conclusions based on their own speculation, but not explicitly supported by the information on the record. With respect to taxes, petitioners have pointed out a methodological inconsistency (inasmuch as the Department's treatment of taxes changed after the preliminary determination). Therefore, we have adjusted USP and FMV according to the *Federal-Mogul* CIT decision in order to be consistent with current practice (see "United States Price" section of this notice, above).

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to continue to suspend liquidation of all entries of steel wire rod from Brazil that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated dumping margins, as shown below. The suspension of liquidation will remain in effect until further notice. The weighted-average margins are as follows:

Manufacturer/producer/exporter	Margin percentage
All companies	36.02

ITC Notification

In accordance with section 735(d) of the Act, we have notified the ITC of our determination. The ITC will now determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry within 45 days. If the ITC determines that material injury, or threat of material injury, does not exist with respect to the subject merchandise, the proceeding will be terminated and all securities posted will be refunded or cancelled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on all imports of the subject merchandise from Brazil entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notice to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility, pursuant to 19 CFR 353.34(d), concerning the return or destruction of proprietary information disclosed under APO. Failure to comply is a violation of the APO.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673(d)) and 19 CFR 353.20(a)(4).

Dated: February 2, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2995 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–M

[A–588–830]

Final Determination of Sales at Less Than Fair Value: Certain Carbon and Alloy Steel Wire Rod From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Ellen Grebasch or Erik Warga, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3773 or 482–0922, respectively.

FINAL DETERMINATION: We determine that imports of certain carbon and alloy steel wire rod ("steel wire rod") from Japan are being, or are likely to be, sold in the United States at less than fair value, as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since our November 19, 1993, preliminary determination (58 FR 62638, November 29, 1993), the following events have occurred.

On December 8, 1993, interested party Michelin Tire Corporation requested a public hearing.

Petitioners (Connecticut Steel Corporation, Co-Steel Raritan, and Keystone Steel & Wire Co.), and interested parties ("the Barnes Group"—comprised of Barnes Group Inc., Associated Spring, and NHK-Associated Spring Suspension Components Inc.—and Amercord Inc.) filed case briefs on January 5, and rebuttal briefs on January 10, 1994. Another interested party Goodyear Tire & Rubber Company, also filed a rebuttal brief on January 10.

A public hearing took place on January 12, 1994. At our request, interested parties in the companion investigation of wire rod from Canada also submitted case and rebuttal briefs and attended the hearing to discuss the scope of the three ongoing investigations of certain carbon and alloy steel wire rod.

On January 18, 1994, Keystone Steel & Wire Co. withdrew as a petitioner. On January 24, 1994, respondents, Nippon Steel Corporation and Kobe Steel Inc., and Sumitomo Metal Industries (another Japanese wire rod exporter) requested termination of the investigation.

Scope of Investigation

The products covered by this investigation are hot-rolled carbon steel and alloy steel wire rod, in coils, of approximately round cross section, between 0.20 and 0.75 inches in solid cross-sectional diameter. The following products are excluded from the scope of this investigation:

- Steel wire rod 5.5 mm or less in diameter, with tensile strength greater than or equal to 1040 MPa, and the following chemical content, by weight: carbon greater than or equal to 0.79%, aluminum less than or equal to 0.005%, phosphorous plus sulfur less than or equal to 0.040%, and nitrogen less than or equal to 0.006%;
- Free-machining steel containing 0.03% or more of lead, 0.05% or more of bismuth, 0.08% or more of sulfur, more than 0.4% of phosphorus, more than 0.05% of selenium, and/or more than 0.01% of tellurium;
- Stainless steel rods, tool steel rods, free-cutting steel rods, resulfurized steel rods, ball bearing steel rods, high-nickel steel rods, and concrete reinforcing bars and rods; and
- Wire rod 7.9 to 18 mm in diameter, containing 0.43 to 0.73% carbon by weight, and having partial decarburization and seams no more than 0.75 mm in depth.

The products under investigation are currently classifiable under subheadings 7213.31.3000, 7213.31.6000, 7213.39.0030, 7213.39.0090, 7213.41.3000, 7213.41.600, 7213.49.0030, 7213.49.0090, 7213.50.0020, 7213.50.0040, 7213.50.0080, 7227.20.0000, 7227.90.6000, and 7227.90.6050 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Period of Investigation

The period of investigation is October 1, 1992, through March 31, 1993.

Such or Similar Comparisons

We have determined that the merchandise covered by this investigation constitutes a single category of "such or similar" merchandise.

Best Information Available

Because both mandatory respondents failed to respond to our questionnaire, we based our determination on best information available (BIA) pursuant to section 776(c) of the Act.

In determining what rate to use as BIA, the Department of Commerce ("the Department") follows a two-tiered methodology, whereby the Department normally assigns lower margins to those respondents who cooperated in an investigation and margins based on more adverse assumptions for those respondents who did not cooperate in an investigation. According to the Department's two-tiered BIA methodology outlined in the Final Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products, Certain Cold-Rolled Carbon Steel Flat Products, and Certain Cut-to-Length Carbon Steel Plate From Belgium, (58 FR 37083, July 9, 1993), when a company refuses to provide the information requested in the form required, or otherwise significantly impedes the Department's investigation, it is appropriate for the Department to assign to that company the higher of (1) the margin alleged in the petition, or (2) the highest calculated rate of any respondent in the investigation. Because there were no cooperative respondents in this investigation, we are assigning to all exporters, as BIA, a margin of 47.71 percent, the highest margin calculated based on information in the petition on merchandise that is within the scope of this investigation (as amended).

Fair Value Comparisons

To determine whether respondents made sales of steel wire rod from Japan in the United States at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We calculated USP using the methodology described in the preliminary determination.

Foreign Market Value

We calculated FMV using the methodology described in the preliminary determination

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Interested Party Comments

Comment 1. Michelin contends that the Department must exclude from the scope of the investigation tire cord quality 1070 steel wire rod ("TCQ 1070"), which Michelin imports, because Michelin has been unable to obtain that product in commercial quantities from any U.S. manufacturer. Additionally, Michelin suggests that the Flat Panel Displays case [1] ("FPDs") established that the Department is required to determine, within a class or kind of merchandise, whether "there are any distinct products for which U.S. manufacturers do not manufacture a like product." Michelin contends that TCQ 1070 is a distinct product, and that the portion of the petition pertaining to TCQ 1070 should be dismissed for lack of standing on the part of petitioners. If TCQ 1070 is not found to be a distinct product Michelin suggests that TCQ 1070 is essentially the same as tire cord quality 1080 steel wire rod ("TCQ 1080"), which is already excluded from the scope of the investigation pursuant to petitioners' October 19, 1993, petition amendment. Accordingly, Michelin argues, TCQ 1070 and TCQ 1080 should be evaluated jointly. Based on this premise, Michelin contends that the Department should determine that the two subsets of all steel wire rod—tire cord quality and non-tire cord quality—constitute two distinct classes or kinds of merchandise based on the *Diversified Products* criteria,[2] and class-or-kind-specific dumping margins should be calculated.

Stelco Inc., commenting on scope in the context of the companion investigation of wire rod from Canada,[3] argues that the antidumping law does not permit the Department to accept without explanation or analysis petitioners' October 18, 1993, amendment to the petition (excluding TCQ 1080) over the objection of an interested party. To grant a contested exclusion request, Stelco suggests, requires an explicit finding that the product in question be "* * * co-extensive with a rational class or kind of wire rod product subcategory." A reasonable analysis, according to Stelco, can lead only to the joint consideration and disposition of petitioners' amendment (excluding TCQ 1080) and Michelin's request (to exclude TCQ 1070).

Petitioners object to the request to exclude TCQ 1070 because the precedent of other antidumping investigations of wire rod, as well as the *Diversified Products* criteria and the criteria used to determine like products, demonstrate no "bright line" upon which to base a decision to treat TCQ 1070 as a distinct product or to find that wire rod products comprise multiple classes or kinds. Petitioners also contend that the request is untimely.

Petitioners claim that there is substitutability between the products that Michelin would exclude on the one hand and products that would remain within the scope on the other hand (*e.g.*, tire bead quality wire rod). Petitioners further claim that the description of the product that Michelin proposes to exclude encompasses products that petitioners produce. Finally, petitioners suggest that, even if the Department determines tire cord quality wire rod to be a distinct product or a separate class or kind, petitioners' standing must be accepted unless challenged by a domestic producer.

With respect to Stelco's argument that the Department's acceptance of petitioners' amendment was unlawful, petitioners contend that Department precedent requires only that scope amendments "be timely and consistent with the intent of the petitioner."

DOC Position. We agree with petitioners. Accordingly, we have not excluded TCQ 1070 from the scope of this investigation but will continue to exclude TCQ 1080.

The Act and our regulations do not provide for consideration of domestic availability in determining whether a product should or should not fall within the scope of an investigation. *See, e.g.*, Appendix to Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Argentina (58 FR 37062, July 9, 1993) ("Flat-Rolled Steel"). Additionally, our acceptance of petitioners' amendment excluding TCQ 1080 from the scope of the petition was lawful and appropriate. Under our regulations, section 353.12(b)(4)

[1] Final Determination and Partial Rescission: Flat Panel Displays from Japan (56 FR 32376, July 16, 1991)

[2] The *Diversified Products Corp.* v. *United States* (572 F. Supp. 883 (CIT 1983)) case upheld a class-or-kind decision which considered the following criteria: (1) The product's general physical characteristics; (2) its ultimate use; (3) the expectations of the ultimate purchaser; (4) the channels of trade; and (5) cost.

[3] Stelco, a Canadian wire rod producer, is not an interested party in this proceeding. However, the scope issues in the three concurrent wire rod investigations are essentially the same and thus best disposed of together. Therefore, we have placed Stelco's scope comments on the record in this proceeding.

requires a petitioner to describe the scope in filing a petition and section 353.12(e) provides that a petitioner may amend the petition.

We agree that we must evaluate scope amendments. Generally, when a petitioner asks to amend the scope of a petition, our chief concern is the administrative feasibility of granting the request (see, e.g., Flat-Rolled Steel cases, where petitioners' late plate scope amendment was rejected)—including such factors as whether time permits soliciting any required new information and practicality for customs purposes. In addition, we will evaluate on its merits any opposition to an exclusion request. However, the act on the part of a petitioner of making such a request is generally sufficient justification for granting such an exclusion, because it is a statement by petitioner that it does not need relief from a product's competition. Further, this view of a petitioner's important role in determining the scope is supported by Department practice in past cases (e.g., Flat-Rolled Steel cases).

In this case, Stelco opposes the exclusion of TCQ 1080 on the grounds that this product should not be considered separately from TCQ 1070. While we agree that TCQ 1070 and TCQ 1080 are similar in many respects, these similarities do not require that the two products' fates be inextricably intertwined. The two products have different minimum carbon contents, and the matching criteria in the three companion wire rod cases (upon which all interested parties were afforded an opportunity to comment) rank grade/carbon content highest among relevant characteristics of wire rod. Thus, the two are meaningfully distinct products, only one of which (TCQ 1070) petitioners have chosen to include in the scope of their petition.

Notwithstanding Stelco's unsupported allegations concerning petitioners' exclusion request, neither the statute nor the regulations requires the Department to determine that products whose exclusion is contested represent a distinct class or kind of merchandise or a distinct like product, nor did the *FPDs* case establish a requirement for a like product analysis. In *FPDs*, a like product analysis was conducted in order to evaluate the petitioner's standing with respect to one class or kind of merchandise.

With respect to whether TCQ 1070 can be excluded over petitioners' opposition, such exclusions are possible only if the product is determined to be part of a separate class or kind of merchandise which petitioners do not produce. TCQ and non-TCQ wire rod do not constitute separate classes or kinds of merchandise—even applying the *Diversified Products* criteria (which, we note, are guidelines, not mandatory criteria for defining class or kind).[4] In short, there is no bright line among the product groups at issue in this case. Further, there is no precedent for separate classes or kind in other investigations of wire rod, and no party broached this issue when asked to comment on matching criteria. In any case, since petitioners claim that they produce TCQ 1070, a separate class or kind finding would not result in a finding that petitioners lack standing.

In conclusion, petitioners have requested a scope amendment that can be administered. Petitioners oppose the exclusion of TCQ 1070, and TCQ 1070 is neither a distinct product for which petitioners lack standing nor part of a separate tire cord quality class or kind of merchandise. While similar to TCQ 1080, TCQ 1070 differs in terms of a characteristic recognized as significant: carbon content. Challenges to like product or class-or-kind determinations are subject to very high standards and are difficult for the Department to sustain. Petitioners' scope definition is afforded great weight because petitioners can best determine from what products they require relief. Moreover, in administering the law the Department may not take into account potential shortages in domestic supply.

Comment 2. Petitioners and the Barnes Group request the exclusion of valve spring quality wire rod from the scope of this investigation, in accordance with petitioners' November 1993 petition amendment.

DOC Position. We agree that valve spring quality wire rod should, in accordance with petitioners' amendment, be excluded from the scope. This amendment has not been contested, and nothing on the record in this proceeding gives rise to concern over feasibility.

Comment 3. Respondents contend that the Department should terminate this investigation because of the January 18, 1994, withdrawal by three of the five original petitioners. Respondents reason that these three companies' withdrawal as petitioners constitutes a withdrawal of support, which, in turn, should be considered opposition to the petition. Alternatively, respondents request that the domestic industry be polled to determine whether a majority supports the petition.

DOC Position. We disagree. The Department's policy has been to accept the representation of petitioners that the petition has been filed on behalf of the domestic industry. In this case, the withdrawal of certain producers as petitioners was not accompanied by a statement that they oppose the petition. Because there has been no showing of opposition by domestic producers, we conclude that the petition was filed on behalf of the U.S. industry. See *Suramerica de Aleaciones Laminadas* v. *United States*, 966 F.2d 660 (Fed. Cir. 1992). In addition, neither the statute nor our regulations require a petitioner to establish affirmatively that it had or continues to have the support of a majority of domestic producers. See *Trent Tube* v. *Avesta Sandvik Tube*, 975 F.2d 807, 812–813 (Fed. Cir. 1992). Finally, the Department only considers polling the domestic industry when members of that industry have submitted for the record statements of opposition to the petition. See Final Determination of Sales at Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Japan (56 FR 16300, April 22, 1991).

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to continue to suspend liquidation of all entries of the subject merchandise from Japan that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated dumping margins, as shown below. The suspension of liquidation will remain in effect until further notice. The weighted-average margins are as follows:

Manufacturer/producer/exporter	Margin percentage
All companies	47.71

ITC Notification

In accordance with section 735(d) of the Act, we have notified the ITC of our determination. The ITC will now determine whether these imports are materially injuring, or threaten material

[4] Wire rod has in past cases been broadly defined in terms of the same general physical characteristics and range of ultimate uses. Customers expect to draw or stamp the product into various other downstream products. While different technical specifications and uses exist, it would be prohibitively difficult to identify each unique combination as defining a separate class or kind of merchandise. No differences in channels of trade, such as sale to end users versus sales to resellers, distinguish groups of wire rod. Although tire cord quality wire rod has a relatively high cost, it is not the only type of wire rod included in the scope that has a high cost.

injury to, the U.S. industry within 45 days. If the ITC determines that material injury, or threat of material injury, does not exist with respect to the subject merchandise, the proceeding will be terminated and all securities posted will be refunded or cancelled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on all imports of the subject merchandise from Japan entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notice to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility, pursuant to 19 CFR 353.34(d), concerning the return or destruction of proprietary information disclosed under APO. Failure to comply is a violation of the APO.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673(d)) and 19 CFR 353.20(a)(4).

Dated: February 2, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2996 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–M

[A–588–831]

Preliminary Determination of Sales at Less Than Fair Value: Grain-Oriented Electrical Steel From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: February 7, 1994.

FOR FURTHER INFORMATION CONTACT: Jeffery B. Denning or Michael Ready, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4194 or (202) 482–2613, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that imports of grain-oriented electrical steel from Japan are being, or are likely to be, sold in the United States at less than fair value ("LTFV"), as provided in section 733 of the Tariff Act of 1930, as amended (the "Act"). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on September 15, 1993, (58 FR 49017, September 21, 1993), the following events have occurred:

On October 20, 1993, the International Trade Commission ("ITC") issued an affirmative preliminary injury determination in this case (see Investigation No. 731–TA–660).

In October 1993, the Department of Commerce (the "Department") requested and received comments, and rebuttal comments, from petitioners and all interested parties (including the sole respondent in the concurrent investigation involving Italian producers) on the model matching hierarchy to be used in this investigation.

In October 1993, the Department contacted Nippon Steel Corporation ("Nippon"), and Kawasaki Steel Corporation ("Kawasaki"), (producers who accounted for at least 60 percent of the exports of the subject merchandise to the United States during the period of investigation ("POI")), to communicate our intention to have officials from the Department travel to their production facilities and headquarters for the purpose of presenting the antidumping questionnaire, and answering any questions regarding the ensuing investigation. Nippon and Kawasaki declined to participate in that presentation.

On November 4, 1993, the Department published a revision of the scope of this investigation to correct an error published in the notice of initiation. See Revision of Scope of Investigations: Grain-Oriented Electrical Steel from Japan, 58 FR 58838. The scope stated below conforms to that revision.

On November 2, 1993, the Department transmitted the antidumping duty questionnaires to Nippon and Kawasaki, and on November 12 and 15, 1993, Nippon and Kawasaki, respectively, advised the Department that they would not be responding to the Department's questionnaire.

Scope of the Investigation

The product covered by this investigation is grain-oriented silicon electrical steel, which is a flat-rolled alloy steel product containing by weight at least 0.6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, of a thickness of no more than 0.56 millimeters, in coils of any width, or in straight lengths which are of a width measuring at least 10 times the thickness, as currently classifiable in the Harmonized Tariff Schedule of the United States ("HTS") under item subheadings 7225.10.0030, 7226.10.1030, 7226.10.5015 and 7226.10.5065. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

The HTS subheadings listed above reflect a revision from those identified in our Notice of Initiation, and in our published Revision of Scope of Investigations (58 FR 58838, November 4, 1993). This revision is due to the fact that the HTS has been amended so that there are now specific subheadings for grain-oriented electrical steel. This revision of identified HTS subheadings pertains to this investigation, as well as the concurrent antidumping and countervailing duty investigations of grain-oriented electrical steel from Italy (case nos. A–475–811, C–473–812, respectively).

Period of Investigation

The period of investigation is March 1 through August 31, 1993.

Such or Similar Comparisons

We have determined that the merchandise covered by this investigation constitutes a single category of such or similar merchandise.

Fair Value Comparisons

To determine whether sales of grain-oriented electrical steel from Japan to the United States were made at less than fair value, we compared the United States price ("USP") to the foreign market value ("FMV"), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

Because both Nippon and Kawasaki failed to respond to our questionnaire, we based our determination on best information available ("BIA"), pursuant to section 776(c) of the Act.

In determining what to use as BIA, the Department follows a two-tiered methodology, whereby the Department normally assigns lower margins to those respondents who cooperated in an investigation and margins based on more adverse assumptions for those respondents who refused to cooperate. A full description of the Department's BIA methodology is included in Appendix II to the Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from the United Kingdom (58 FR 37215, July 9, 1993). Because Nippon and Kawasaki have refused to respond in any way to our antidumping questionnaire, we have

determined each to be a non-cooperative respondent. As a result, we have based our preliminary determination on the comparison in the petition between U.S. price and home market price which yielded the highest antidumping margin. Petitioner's bases for these prices are fully described in our notice of initiation of this investigation (see, Initiation of Antidumping Duty Investigations: Grain-Oriented Electrical Steel From Italy and Japan, 58 FR 49017, September 21, 1993). For this determination, we also made adjustments to petitioner's calculations to account for Japanese consumption taxes. (See Memorandum to Lou Apple, dated January 28, 1994.)

Currency Conversion

Petitioners made currency conversions based on the average of the official exchange rates in effect during the month of the U.S. sale, as certified by the Federal Reserve Bank of New York.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of grain-oriented electrical steel from Japan that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Margin percentage
Kawasaki Steel Corporation	31.08
Nippon Steel Corporation	31.08
All others	31.08

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry before the later of 120 days after the date of this preliminary determination or 45 days after our final determination.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary no later than March 2, 1994, and rebuttal briefs no later than March 7, 1994. A hearing, if requested, will be held on March 9, 1994, at 10 am at the U.S. Department of Commerce in room 3708. Parties should confirm by telephone the time, date, and place of the hearing 48 hours prior to the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

If this investigation proceeds normally, we will make our final determination not later than 75 days after the date of this preliminary determination.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: February 2, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2997 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–475–811]

Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Grain-Oriented Electrical Steel From Italy

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Jeffery B. Denning or Jennifer L. Katt, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4194 and 482–0498, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that grain-oriented electrical steel ("GOES") from Italy is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the "Act"). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on September 15, 1993, (58 FR 49017, September 21, 1993), the following events have occurred:

On October 20, 1993, the United States International Trade Commission ("ITC") issued an affirmative preliminary injury determination (see Investigation No. 701–TA–355, 58 FR 54168).

On November 4, 1993, the Department of Commerce ("Department") published a revision to the scope of this investigation (see 58 FR 58838, November 4, 1993). That scope revision is reflected below in the "Scope of the Investigation" section of this notice.

In November 1993, the Department issued its antidumping duty questionnaire to ILVA S.p.A. and Acciai Speciali Terni ("Terni"), the sole Italian producer of subject merchandise during the period of investigation. After formal transmittal of the questionnaire, officials from the Department traveled to Terni's production facilities in Italy in order to outline the Department's antidumping procedures, answer questions Terni might have concerning the proceeding and discuss any difficulties Terni may encounter in meeting the Department's reporting requirements.

In November and December, respectively, Terni submitted its responses to Sections A and B through D of our questionnaire.

In December 1993, the Department issued a supplemental questionnaire, and in January 1994, Terni submitted its response to that supplement.

On January 26, 1994, Terni requested a postponement of the final determination in this investigation.

Postponement of Final Determination

Pursuant to section 735(a)(2)(A) of the Act, on January 26, 1994, Terni requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until not more than 135 days after the date of publication of the affirmative preliminary determinations. Pursuant to 19 CFR 353.20(b), if our preliminary determination is affirmative, and the Department receives a request from producers or resellers who account for a significant portion of the exports under investigation, we will, absent compelling reasons to the contrary, grant the request.

Because no such compelling reasons exist, we are postponing the final determination until the 135th day after the date of publication of this notice in the **Federal Register**.

Scope of the Investigation

The product covered by this investigation is grain-oriented silicon electrical steel, which is a flat-rolled alloy steel product containing by weight at least 0.6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, of a thickness of no more than 0.56 millimeters, in coils of any width, or in straight lengths which are of a width measuring at least 10 times the thickness, as currently classifiable in the Harmonized Tariff Schedule of the United States ("HTS") under item numbers 7225.10.0030, 7226.10.1030, 7226.10.5015 and 7226.10.5065. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

The HTS subheadings listed here reflect a revision from those identified in our Notice of Initiation, and in our published Revision of Scope of Investigations (58 FR 58838, November 4, 1993). This revision is due to the fact that the Harmonized Tariff Schedule has been amended so that there are now specific HTS subheadings for grain-oriented silicon electrical steel. This revision of identified HTS numbers pertains to this investigation, as well as the concurrent antidumping investigation from Japan (A–588–831) and countervailing duty investigation from Italy (C–475–812).

Period of Investigation

The period of investigation ("POI") is March 1, 1993, through August 31, 1993.

Such or Similar Comparisons

We have determined that the class or kind of merchandise subject to this investigation constitutes a single such or similar category. In making our fair value comparisons, in accordance with the Department's standard methodology, we first compared identical merchandise, as determined by the model-matching criteria contained in Appendix V of the questionnaire ("Appendix V"), on file in Room B–099 of the main building of the Department of Commerce ("Public File"). Since there were sales of identical merchandise in the home market to compare to U.S. sales, all of our price-to-price comparisons involved identical merchandise.

Because Terni reported a single level of trade for both the home and United States markets, in accordance with 19 CFR 353.58, all comparisons were made at the same level of trade.

Fair Value Comparisons

To determine whether Terni's sales of GOES from Italy to the United States were made at less than fair value, we compared the United States price ("USP") to the foreign market value ("FMV"), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

All of Terni's U.S. sales to the first unrelated purchaser took place prior to importation into the United States. Therefore, in accordance with section 772(b) of the Act, our calculation of USP was based on the purchase price ("PP") methodology.

We calculated Terni's PP sales based on packed and delivered prices to unrelated customers in the United States. We made deductions, where appropriate, for U.S. brokerage and handling, U.S. duty and customs fees and freight expenses. We have also made adjustments for the value-added tax paid on comparison sales in Italy. These adjustments are made pursuant to *Federal-Mogul Corp. and The Torrington Co.* v. *United States*, 834 F. Supp. 1391 (CIT, 1993). For discussion of this adjustment *see*, Final Results of Administrative Review: Certain Industrial Forklifts from Japan, (59 FR 1374, January 10, 1994) and Final Determination of Sales at Less Than Fair Value: Certain Stainless Steel Wire Rods from France, (58 FR 68865, December 29, 1993).

Foreign Market Value

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of subject merchandise to the volume of third country sales of subject merchandise, in accordance with section 773(a)(1)(B) of the Act. As a result we determined that the home market was viable, and therefore, we have based FMV on home market sales.

We used the Department's related party test to determine whether sales to related customers were made on an arm's length basis. See Appendix II to Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Argentina, (58 FR 37077, July 9, 1993), for a discussion of this test. We excluded from our price-to-price comparisons any sales to related customers we determined were not at arm's length. Additionally, after issuance of the questionnaire, Terni stated in a submission that it sold only one type of GOES in the United States (conventional permeability GOES), but sold this as well as other types of GOES in its home market (high permeability GOES and "downgraded" GOES). Terni claimed that during the POI it had home market sales of identical merchandise, as determined by the Department's model-matching criteria, for all "models" of GOES sold in the United States, and requested that it be allowed to limit its reporting of home market sales on that basis. We agreed to Terni's request. Consequently, Terni was required to provide full reporting of all home market sales of conventional permeability GOES, as well as the following information for all remaining home market sales of subject merchandise:

(1) All the Appendix V product characteristics for each unique product, as determined by that criteria, for all home market POI sales of subject merchandise;

(2) The total POI volume and value of sales, broken down for each month of the POI, for each unique home market product, as determined by Appendix V and;

(3) Sample sales invoices and order confirmations for POI sales of each unique product, as determined by Appendix V.

(See Memorandum from Team to Richard W. Moreland, dated December 10, 1993, in the Public File)

Cost of Production

Based on allegations contained in the petition, and in accordance with section 773(b) of the Act, we initiated an investigation to determine whether Terni's home market POI sales were made at prices below its cost of production ("COP"), and over an extended period of time.

A. Calculation of COP

We calculated COP based on the sum of Terni's cost of materials, fabrication, general expenses and home market packing reported on its sales database, in accordance with section 773(b) of the Act. We relied on the submitted COP, except in the following instances where the costs were not appropriately quantified or valued:

1. We disallowed G&A expenses reported on a divisional basis for the POI. We were unable to determine ILVA S.p.A.'s annual G&A costs based on the information submitted. As BIA, pursuant to section 776(c) of the Act, we used the average 1992 SG&A percentage for the domestic industry as reported in petitioner's cost allegation dated August 26, 1993. Since we could not breakout the selling expenses from this percentage, we disregarded all

submitted selling and G&A expenses, and used the domestic average SG&A rate.

2. Terni's submitted financial expense was calculated based exclusively on interest expense incurred on a divisional basis during the period March 1 to August 31, 1993. The Department's policy is to compute a company's interest expense percentage using its audited consolidated annual financial statements for the year that most closely represents the POI. As BIA, we recalculated interest expense based on 1992 ILVA Group consolidated financial statements.

(See Concurrence Memorandum, dated January 28, 1994, for discussion of these adjustments)

B. Test of Home Market Sale Prices

After calculating COP, we tested whether, as required by section 773(b) of the Act, Terni's home market sales of subject merchandise were made at prices below COP, in substantial quantities, and over an extended period of time, according to the following methodology:

On a model-specific basis, (as determined by Appendix V) we compared COP to reported prices, minus movement charges and rebates. If over 90 percent of the sales of a model were at prices equal to or greater than the COP, we did not disregard any below-cost sales of that model because we determined that the below-cost sales were not made in "substantial quantities". If between ten and 90 percent of the sales of a given model were at prices equal to or greater than the COP, we discarded only the below-cost sales, provided sales of that model were also found to be made over an extended period of time. Where we found that more than 90 percent of the sales of a model were at prices below the COP and sold over an extended period of time, in accordance with section 773(b) of the Act, we disregarded all sales of that model, and calculated FMV based on constructed value ("CV").

In order to determine whether sales were made over an extended period of time, we performed the following analysis on a model-specific basis: (1) if a respondent sold a product in only one month of the POI and there were sales in that month below the COP, or (2) if a respondent sold a product during two months or more of the POI and there were sales below the COP during two or more of those months, then below-cost sales were considered to have been made over an extended period of time. Otherwise the below-cost sales were not considered as having been made over an extended period of time.

C. Results of COP Test

We found that for certain models of GOES more than 90 percent of home market sales were at below-COP prices and were made over an extended period of time. Since Terni provided no indication that these sales were at prices that would permit recovery of all costs within a reasonable period of time and in the normal course of trade, we based FMV on CV for all U.S. sales left without an identical match to home market sales as a result of our application of the COP test.

D. Calculation of CV

We calculated CV based on the sum of Terni's cost of materials, fabrication, general expenses and U.S. packing costs as reported in the U.S. sales database. We made the adjustments described above for COP. In accordance with section 773(e)(1)(B)(i) and (ii) of the Act we included: (1) the greater of Terni's reported general expenses, adjusted as detailed above, or the statutory minimum of ten percent of the cost of manufacture ("COM") and; (2) for profit, we used the statutory minimum, eight percent of COM and general expenses (because actual profit on home market sales was less than eight percent).

Price-to-Price Comparisons

For those products for which there were an adequate number of sales at prices above the COP, we based FMV on home market prices. We calculated FMV based on delivered prices, inclusive of packing and VAT to customers in the home market. Based upon application of our related party test, we made comparisons only to home market sales to unrelated parties. Since all comparisons of U.S. and home market sales involved identical merchandise, we made no adjustments, pursuant to 19 CFR 353.57, for physical differences in merchandise. We deducted credit and warranty expenses. In addition we made deductions, where appropriate, for rebates and inland freight. We subtracted home market packing and added U.S. packing costs. Pursuant to section 773(a)(4)(B) of the Act and 19 CFR 353.56(a)(2), we made circumstance-of-sale-adjustments for imputed credit and, where appropriate, certain U.S. warehousing expenses. We recalculated credit for those sales that had missing payment and or shipment dates. For sales with unreported shipment and payment dates, we used a weighted-average credit days for our imputed credit calculations. For sales with only unreported payment dates, we used the date of the preliminary determination as the paydate (see Concurrence Memorandum).

We included in FMV the amount of the VAT collected in the home market (19 percent). We also calculated the amount of tax that was due solely to the inclusion of price deductions in the original tax base (i.e., 19 percent of the sum of any adjustments, expenses and charges that were deducted from the tax base). We deducted this amount from the FMV after all other additions and deductions had been made. By making this additional tax adjustment, we avoid a distortion that would cause the creation of a dumping margin even when pre-tax dumping is zero (see Concurrence Memorandum).

Price to CV Comparisons

Where we compared Terni's U.S. prices to CV, we deducted from FMV the weighted-average home market direct selling expenses and added the U.S. model specific direct selling expenses.

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank of New York.

Verification

As provided in section 776(b) of the Act, we will verify information that we determine is acceptable for use in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of GOES from Italy that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice. The estimated preliminary less than fair value dumping margins are as follows:

Producer/manufacturer/exporter	Weighted-average margin percentage
ILVA S.p.A. and Acciai Speciali Terni	5.62
All others	5.62

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry before the later of 120 days after the date of this preliminary determination or 45 days after our final determination.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B–099, within ten days of the publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary no later than May 6, 1994, and rebuttal briefs no later than May 12, 1994. A hearing, if requested, will be held on May 17, 1994, at 1 pm at the U.S. Department of Commerce in room 1815. Parties should confirm by telephone the time, date, and place of the hearing 48 hours prior to the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

We will make our final determination not later than 135 days after publication of this determination in the **Federal Register**.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: February 2, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2998 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–533–809]

Amended Final Determination and Antidumping Duty Order; Certain Forged Stainless Steel Flanges From India

AGENCY: Import Administration, International Trade Administration, Commerce.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Mary Jenkins or Brian Smith, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1756 or (202) 482–1766, respectively.

Scope of Order

The products covered by this order are certain forged stainless steel flanges both finished and not-finished, generally manufactured to specification ASTM A–182, and made in alloys such as 304, 304L, 316, and 316L. The scope includes five general types of flanges. They are weld neck, used for butt-weld line connections, threaded, used for threaded line connections, slip-on and lap joint, used with stub ends/butt-weld line connections, socket weld, used to fit pipe into a machined recession, and blind, used to seal off a line. The sizes of the flanges within the scope range generally from one to six inches; however, all sizes of the above described merchandise are included in the scope. Specifically excluded from the scope of this order are cast stainless steel flanges. Cast stainless steel flanges generally are manufactured to specification ASTM A–351. The flanges subject to this order are currently classifiable under subheading 7307.21.1000 and 7307.21.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this order remains dispositive.

Amendment of Final Determination

In accordance with section 735(d) of the Tariff Act of 1930, as amended (the Act), on December 29, 1993, the Department of Commerce (the Department) published its final determination that certain forged stainless steel flanges from India were being sold at less than fair value (58 FR 68853).

On January 18, 1994, Akai Impex Ltd. (Akai), the respondent, alleged that the Department made clerical errors with respect to the product code of one U.S. sale and the price of two additional U.S. sales used in the calculation of the margin for the final determination. First, respondent alleged that the Department incorrectly identified the product code for one of the U.S. sales transactions. Because respondent did not report a constructed value (CV) for the incorrect product code, but did provide CV for the product code in question, respondent alleges that the Department improperly based the margin for sales of this product on best information available (BIA). Regarding the errors in price, respondent alleged that the unit prices for two of Akai's U.S. sales transactions were incorrectly stated on the Department's disclosure documents.

We agree that these are clerical errors. We examined Akai's latest submission to the Department as well as the data on Akai's most recent diskette submission. Both the hard copy of Akai's submission and the sales transactions as shown on Akai's diskette show that the product code and the prices for the three referenced transactions are as stated by Akai. Therefore, we corrected the data in question, and we have recalculated the margin in our final determination to reflect these corrections. The corrected margins appear in the suspension of liquidation section of this notice.

On January 18, 1994, Akai also alleged that clerical errors were made in the cost information submitted for nine products. Akai alleged that the Department erroneously calculated CV for six of these products. In addition, Akai stated that the Department did not use CV data it submitted for three of the nine products.

We examined Akai's verified submission and determined that we used in the calculations the data reported by Akai for six of the products in question. Moreover, we find that Akai did not submit CV data for two products for which it has alleged clerical errors. Finally, for the remaining product, Akai reported duplicate data. As discussed in our final determination, the Department selected the highest reported value as BIA.

We do not agree that these are clerical errors that should be corrected by the Department. In all cases we used the data submitted by Akai. Therefore, we have made no changes to the cost data used in calculating the margin in our final determination. (See memorandum to Barbara R. Stafford from Richard W. Moreland, February 1, 1994, for a detailed explanation of our decision.)

Antidumping Duty Order

In accordance with section 735(a) of the Tariff Act of 1930, as amended (the Act), on December 20, 1993, the Department of Commerce (the Department) made its final determination that certain forged stainless steel flanges from India are being sold at less than fair value (58 FR 68859, December 29, 1993). However, on February 2, 1994, in accordance with section 735(d) of the Act, the U.S. International Trade Commission (ITC) notified the Department that an industry in the United States is threatened with material injury by reason of such imports. The ITC did not determine, pursuant to section 735(b)(4)(B) of the Act, that, but for the suspension of liquidation of entries of certain forged

stainless steel flanges from India, the domestic industry would have been materially injured.

When the ITC finds threat of material injury, and makes a negative "but for" finding, the "Special Rule" provision of section 736(b)(2) applies. Therefore, all unliquidated entries of certain forged stainless steel flanges from India, entered or withdrawn from warehouse, for consumption made on or after the date on which the ITC publishes its notice of final determination of threat of material injury in the **Federal Register** (which is currently scheduled for February 9, 1994) will be liable for the assessment of antidumping duties.

The Department will direct U.S. Customs officers to terminate the suspension of liquidation for entries of certain forged stainless steel flanges imported from India and entered, or withdrawn from warehouse, for consumption before the date on which the ITC publishes its notice of final determination of threat of material injury in the **Federal Register** and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

In accordance with section 736(a)(1) of the Act, the Department will direct U.S. Customs officers to assess, upon further advice by the administering authority, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all relevant entries of certain forged stainless steel flanges from India. U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the estimated weighted-average antidumping duty margin as noted below:

Manufacturer/producer/exporter	Weighted-average margin percentage
Mukand Ltd	210.00
Sunstar Metals Ltd	210.00
Bombay Forgings Pvt. Ltd	210.00
Dynaforge	210.00
Akai Impex Pvt. Ltd	18.56
All Others	162.14

This notice constitutes the antidumping duty order with respect to certain forged stainless steel flanges from India, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: February 4, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–3063 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–583–821]

Antidumping Duty Order: Certain Forged Stainless Steel Flanges From Taiwan

AGENCY: Import Administration, International Trade Administration, Commerce.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Pamela Ward, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1174.

Scope of Order

The products covered by this order are certain forged stainless steel flanges both finished and not-finished, generally manufactured to specification ASTM A–182, and made in alloys such as 304, 304L, 316, and 316L. The scope includes five general types of flanges. They are weld neck, used for butt-weld line connections, threaded, used for threaded line connections, slip-on & lap joint, used with stub ends/butt-weld line connections, socket weld, used to fit pipe into a machined recession, and blind, used to seal off a line. The sizes of the flanges within the scope range generally from one to six inches; however, all sizes of the above described merchandise are included in the scope. Specifically excluded from the scope of this order are cast stainless steel flanges. Cast stainless steel flanges generally are manufactured to specification ASTM A–351. The flanges subject to this order are currently classifiable under subheading 7307.21.1000 and 7307.21.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this order remains dispositive.

Antidumping Duty Order

In accordance with section 735(a) of the Tariff Act of 1930, as amended (the Act), on December 20, 1993, the Department of Commerce (the Department) made its final determination that certain forged stainless steel flanges from Taiwan are being sold at less than fair value (58 FR 68859, December 29, 1993). On February 2, 1994, in connection with section 735(d) of the Act, the U.S. International Trade Commission (ITC) notified the Department that an industry in the United States is threatened with material injury by reason of such imports. The ITC did not determine, pursuant to section 735(b)(4)(B) of the Act, that, but for the suspension of liquidation of entries of certain forged stainless steel flanges from Taiwan, the domestic industry would have been materially injured.

When the ITC finds threat of material injury, and makes a negative "but for" finding, the "Special Rule" provision of section 736(b)(2) applies. Therefore, all unliquidated entries of certain forged stainless steel flanges from Taiwan, entered or withdrawn from warehouse, for consumption made on or after the date on which the ITC publishes its notice of final determination of threat of material injury in the **Federal Register** (which is currently scheduled for February 9, 1994) will be liable for the assessment of antidumping duties.

The Department will direct U.S. Customs officers to terminate the suspension of liquidation for entries of certain forged stainless steel flanges imported from Taiwan and entered, or withdrawn from warehouse, for consumption before the date on which the ITC publishes its notice of final determination of threat of material injury in the **Federal Register** and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

In accordance with section 736(a)(1) of the Act, the Department will direct U.S. Customs officers to assess, upon further advice by the administering authority, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all relevant entries of certain forged stainless steel flanges from Taiwan. U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the estimated weighted-average antidumping duty margin as noted below:

Manufacturer/producer/exporter	Weighted-average margin percentage
Enlin Steel Corporation	48.00
Ta Chen Stainless Pipe Co., Ltd	48.00

Manufacturer/producer/exporter	Weighted-average margin percentage
Tay Precision Industries Co., Ltd	48.00
All Others	48.00

This notice constitutes the antidumping duty order with respect to certain forged stainless steel flanges from Taiwan, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: February 4, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–3064 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DS–P

Trade Promotion Coordinating Committee; Working Group on Product Standards and Certification; Request for Public Comment on Recommendation to Reduce Barriers to Exports Related to Product Standards and Certification

AGENCY: Trade Promotion Coordinating Committee, Working Group on Product Standards and Certification.

ACTION: Request for public comment on recommendation to review programs in order to reduce regulatory barriers to exports related to product standards and certification.

SUMMARY: The Interagency Trade Promotion Coordinating Committee's Working Group on Product Standards and Certification invites written comments from the public on a recommendation to review regulatory and procurement programs to identify outdated or unnecessary restrictions to exports related to product standards and certification.

DATES: Written comments from the public are due on or before May 10, 1994.

FOR FURTHER INFORMATION CONTACT: Charles M. Ludolph, Director, Office of European Community Affairs, room 3036, U.S. Department of Commerce, Washington, DC 20230, (202)482–5276.

SUPPLEMENTARY INFORMATION: The U.S. Government's Trade Promotion Coordinating Committee (TPCC) established a working group to implement recommendations which would promote U.S. exports and reduce barriers to exporting related to product standards and certification. These recommendations were included in the TPCC's first report to Congress, entitled "Toward a National Export Strategy" and dated September 30, 1993. The working group has determined that public views on the implementation of Recommendation Number 8 would be useful. This recommendation charges the TPCC member departments and agencies to: Review regulatory programs to identify outdated or unnecessary restrictions to exports and implement appropriate modifications.

The TPCC Report explains the purpose of this recommendation as follows:

This review is designed to reduce the impact of regulations on exports, while maintaining the domestic level of health and safety protection. For example, prior to 1986, the Federal Food, Drug and Cosmetic Act did not allow U.S. firms to export pharmaceuticals that had not received approval for marketing from the FDA. However, the Drug Export Act amendments of 1986 established provisions that permit such exports, subject to certain restrictions, including notification by the government of the importing country that the products meet its requirements.

Comments from the public should identify any regulatory programs dealing with safety, consumer information, environment, and procurement which are outdated or are unnecessary restrictions to exports related to product standards and certification.

The TPCC was established pursuant to section 201 of the Export Enhancement Act of 1992 (19 U.S.C. para 4727). The TPCC Working Group on Product Standards and Certification is an informal working group of the TPCC charged with identifying means to implement the recommendations embodied in the TPCC report and has no regulatory authority. Therefore, any comments received from the public will not be construed as a petition for change. No commenter is required to provide specific information other than that necessary for self-identification. Copies of the TPCC Report can be reviewed in room 3314, Office of European Community Affairs, U.S. Department of Commerce, Washington DC 20230.

Comments must be filed by May 10, 1994 with Charles Ludolph, Director, Office of European Community Affairs, room 3036, U.S. Department of Commerce, International Trade Administration, Washington, D.C. 20230.

Dated: February 3, 1994.

Charles M. Ludolph,

Director, Office of European Community Affairs.

[FR Doc. 94–3004 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–OA–P

United States-Canada Free-Trade Agreement, Article 1904 Binational Panel Reviews: Notice of Completion of Panel Review

AGENCY: United States-Canada Free-Trade Agreement, Binational Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of Completion of Panel Review of the final determination made by the Deputy Minister for National Revenue, Customs, Excise and Taxation respecting Preformed Fiberglass Pipe Insulation with a Vapor Barrier, Originating in or Exported from the United States of America is terminated. (Secretariat File No. CDA–93–1904–12)

SUMMARY: This notice is effective February 7, 1994, the 31st day following the filing of a consent motion to terminate the binational panel review of this matter.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, United States Secretary, Binational Secretariat, suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the United States-Canada Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from the other country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1989, the Government of the United States and the Government of Canada established Rules of Procedure for Article 1904 Binational Panel Reviews ("Rules"). These Rules were published in the **Federal Register** on December 30, 1988 (53 FR 53212). The Rules were amended by Amendments to the Rules of Procedure for Article 1904 Binational Panel Reviews, published in the **Federal Register** on December 27, 1989 (54 FR 53165). The Rules were further

amended and a consolidated version of the amended Rules was published in the **Federal Register** on June 15, 1992 (57 FR 26698). The panel review in this matter was conducted in accordance with these Rules, as amended.

Background

Rule 73(2) of the Article 1904 Panel Rules provides, in pertinent part, that, "where all participants file Notices of Motion requesting termination, the panel review is terminated." A Consent Motion requesting termination was received from all participants on January 5, 1994. Pursuant to Rule 80(c) of the Article 1904 Panel Rules, the panel review in this matter will be completed on the 31st day following the day on which the panel review was terminated (February 7, 1994).

Dated: February 3, 1994.

James R. Holbein,

United States Secretary, FTA Binational Secretariat.

[FR Doc. 94–2992 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–GJ–M

United States-Canada Free-Trade Agreement, Article 1904 Binational Panel Reviews: Notice of Decision of Panel

AGENCY: United States-Canada Free-Trade Agreement, Binational Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of decision of panel.

SUMMARY: Pursuant to Rule 72 of the Rules of Procedure for Article 1904 Binational Panel Reviews, the Panel established to review the finding made by the Canadian International Trade Tribunal, respecting Machine Tufted Carpeting Originating in or Exported from the United States of America (Injury) issued its decision on remand on January 21, 1994. (Secretariat file No. CDA–92–1904–02)

FOR FURTHER INFORMATION CONTACT: James R. Holbein, United States Secretary, Binational Secretariat, suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTAL INFORMATION: The Binational Panel affirmed in part and remanded in part the investigating authority's determination on remand concerning Machine Tufted Carpeting Originating in or Exported from the United States of America, which was filed on May 25, 1993.

The Binational Panel instructed the investigating authority to provide its determination on remand within 21 days of the panel decision (by February 11, 1994).

Dated: February 3, 1994.

James R. Holbein,

United States Secretary, FTA Binational Secretariat.

[FR Doc. 94–2991 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–GT–M

United States-Canada Free-Trade Agreement, Article 1904 Binational Panel Reviews; Decision of Panel

AGENCY: United States-Canada Free-Trade Agreement, Binational Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of decision of panel.

SUMMARY: On January 27, 1994, a Binational Panel issued its decision in the consolidated reviews of the remand of the Final Affirmative Material Injury Determination in both the Antidumping Duty Investigation and the Countervailing Duty Investigation respecting Magnesium from Canada made by the U.S. International Trade Commission. These determinations were reviewed by the same panel under Secretariat File No. USA–92–1904–05/06 and the decision affected both determinations. The Binational Panel affirmed the redetermination in all respects. A copy of the complete panel decision is available from the Binational Secretariat.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, United States Secretary, Binational Secretariat, suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the United States-Canada Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from the other country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1989, the Government of the United States and the Government of Canada established Rules of Procedure for Article 1904 Binational Panel Reviews ("Rules"). These Rules were published in the **Federal Register** on December 30, 1988 (53 FR 53212). The Rules were amended by Amendments to the Rules of Procedure for Article 1904 Binational Panel Reviews, published in the **Federal Register** on December 27, 1989 (54 FR 53165). The Rules were further amended and a consolidated version of the amended Rules was published in the **Federal Register** on June 15, 1992 (57 FR 26698). The panel review in this matter was conducted in accordance with these Rules.

Background

On August 26, 1992 the U.S. International Trade Commission published the Final Affirmative Material Injury Determinations in the Antidumping Duty and Countervailing Duty Investigations respecting Magnesium from Canada.

On September 25, 1992, Norsk Hydro Canada, Inc. filed Requests for Panel Review with the United States Section of the Binational Secretariat pursuant to Article 1904 of the United States-Canada Free-Trade Agreement. Separate Requests for Panel Review were filed for both the antidumping and countervailing duty injury determinations. In addition, the Government of Quebec filed Requests for Panel Review in this matter.

Panel Decision

On August 27, 1993, the Binational Panel remanded the final determinations to the U.S. International Trade Commission for a detailed explanation on certain aspects of the determination.

The Commission filed a determination on remand on October 27, 1993.

The Binational Panel affirmed the Commission's determination on remand in all requests on January 27, 1994.

Dated: February 3, 1994.

James R. Holbein,

U.S. Secretary, FTA Binational Secretariat.

[FR Doc. 94–2990 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DT

National Institute of Standards and Technology

[Docket No. 930659–4017]

RIN 0693–AB19

Approval of Federal Information Processing Standards Publication 185, Escrowed Encryption Standard (EES)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: The purpose of this notice is to announce that the Secretary of

Commerce has approved a new standard, which will be published as FIPS Publication 185, Escrowed Encryption Standard.

SUMMARY: On July 30, 1993, notice was published in the **Federal Register** (58 FR 40791) that a Federal Information Processing Standard for EES was being proposed for Federal use. The written comments submitted by interested parties and other material available to the Department relevant to this standard were reviewed by NIST. On the basis of this review, NIST recommended that the Secretary approve the standard as a Federal Information Processing Standards Publication and prepared a detailed justification document for the Secretary's review in support of that recommendation. The detailed justification document which was presented to the Secretary is part of the public record and is available for inspection and copying in the Department's Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington DC 20230.

This FIPS contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard. Both sections of the standard are provided in this notice.

EFFECTIVE DATE: This standard is effective March 11, 1994.

ADDRESSES: Interested parties may purchase copies of this standard, including the technical specifications section, from the National Technical Information Service (NTIS). Specific ordering information from NTIS for this standard is set out in the "Where to Obtain Copies" section of the announcement section of the standards.

FOR FURTHER INFORMATION CONTACT: Michael R. Rubin, Deputy Chief Counsel for the National Institute of Standards and Technology, (301) 975–2803, room A1111, Administration Building, National Institute of Standards and Technology, Gaithersburg, MD 20899.

SUPPLEMENTARY INFORMATION: This standard specifies a technology developed by the Federal government to provide strong encryption protection for unclassified information and to provide that the keys used in the encryption and decryption processes are escrowed. This latter feature will assist law enforcement and other government agencies, under the proper legal authority, in the collection and decryption of electronically transmitted information. The encryption technology will be implemented in electronic devices.

The purpose of this standard is to facilitate the acquisition of devices that implement escrowed encryption techniques by Federal government agencies. This standard does not mandate the use of escrowed encryption devices by Federal government agencies, the private sector or other levels of government. The use of such devices is totally voluntary. The standard provides a mechanism for Federal government agencies to use when they wish to specify key escrowed encryption as a requirement in their acquisition documents. Otherwise agencies would have to formally waive the requirements of the recently reaffirmed encryption standard, FIPS 46–2, Data Encryption Standard, if they wanted to use escrowed encryption techniques.

Key escrow technology was developed to address the concern that widespread use of encryption makes lawfully authorized electronic surveillance difficult. In the past, law enforcement authorities have encountered very little encryption because of the expense and difficulty in using this technology. More recently, however, lower cost, commercial encryption technology has become available for use by U.S. industry and private citizens. The key escrow technology provided by this standard addresses the needs of the private sector for top notch communications security, and of U.S. law enforcement to conduct lawfully authorized electronic surveillance.

Analysis of Comments

This FIPS was announced in the **Federal Register** (58 FR 40791 dated July 30, 1993) and was also sent to Federal agencies for review. Comments were received from 22 government organizations in the United States, 22 industry organizations and 276 individuals. Of the 298 comments received from industry organizations and from individuals, 225 were forwarded to NIST by the Electronic Frontier Foundation which had collected them as electronic mail messages.

The Federal government organizations submitting comments included 11 Cabinet departments and 11 other Federal organizations. The 22 industry organizations included several large computer industry organizations, 4 trade associations, 2 professional societies, and several smaller computer industry organizations. The individuals submitting comments included computer systems, networks and software professionals; consultants; professionals affiliated with universities and colleges; students; and many individuals who did not identify their professions.

Comments were grouped for the purpose of this analysis in the following major categories:

A. General comments concerning key escrow encryption;

B. Other general comments;

C. Patent infringement allegations;

D. Economic comments on the standard, including its potential cost to Federal agencies and private organizations that adopt it, and the effect that the standard may have upon the competitiveness of U.S. firms in domestic and world markets; and,

E. Comments on the technical operation of the standard.

Each of these matters is discussed in turn below.

A. General Comments Concerning Key Escrow

Nearly all of the comments received from industry and individuals opposed the adoption of the standard, raising concerns about a variety of issues including privacy; the use of a secret algorithm; the security of the technology; restrictions on software implementation; impact on competitiveness; and lack of procedures for escrowing keys. Over 80 percent of the industry and individual responses repeated the following points which were also made by the Electronic Frontier Foundation:

(1) Five industry organizations and 200 individuals said that guarantees are needed to assure that this standard is not a first step toward prohibition against other forms of encryption. In response, NIST notes that the standard is a specification for voluntary use by the Federal government in the acquisition of devices for escrowed encryption. There is no requirement that the public use this standard. Further, the Administration has announced that it will not propose new legislation to limit the use of encryption technology.

(2) Three industry organizations and 164 individuals said that there had been insufficient technical and operational information available to allow full public comment. Also, seven Federal government organizations, 19 industry organizations, and 213 individuals expressed concern that the details of the escrowed encryption system had not been announced when the FIPS was proposed. Other related concerns included: the escrow agents have not been identified; the operating procedures are unclear; the system will

not be secure if the keys are not protected; the system must allow for enforcement of expiration of wiretap authority. One member of the NIST Computer Privacy and Security Advisory Board stated that the notice was "content-free".

In response, NIST notes that the standard is a technical one, for implementation in electronic devices and use in protection of certain unclassified government communications when such protection is required. It adopts encryption technology developed by the Federal government to provide strong protection for unclassified information and to enable the keys used in the encryption and decryption processes to be escrowed. The technical aspects of the Escrowed Encryption Standard have been set forth in detail, and the classified algorithm has been examined by independent experts.

The responsibility for designation of the key component escrow agents lies with the Attorney General, rather than the Secretary of Commerce. In addition, the Attorney General is charged with reviewing for legal sufficiency the procedures by which an agency establishes its authority to acquire the content of communications encrypted with electronic devices using the Escrowed Encryption Standard. Designation of the key component escrow agents, and approval of procedures for acquisition of key components to facilitate decryption of communications, are separate from the establishment of the technical parameters of this standard. Necessarily, protection of the information encrypted by use of the Escrowed Encryption Standard requires that the key components and other aspects of the system be accorded strict security. Procedures to provide strict security in the programming, storage, and transmission of key components have been developed; however, the security procedures for the key components are beyond the scope of this rule.

Even were the identity of the key component escrow agents, or the procedures under which escrowed key components will be maintained and released for use in conjunction with lawfully authorized interceptions relevant to the technical standards established in the instant rule, the Department of Commerce has found, consistent with 5 U.S.C. 553(b)(B), that notice and public procedure thereon is unnecessary. The technical aspects of the Escrowed Encryption Standard themselves, coupled with the strength of the algorithm and the privacy protections afforded by the Constitution and relevant statutes, afford adequate assurance of the efficacy of the standard for the protection of sensitive unclassified Federal government information, without the need for specifying the identities of key component escrow agents or detailing the procedures respecting maintenance or release of key components.

(3) One Federal government organization, 10 industry organizations, and 199 individuals were concerned that the escrowed encryption system may infringe on individual rights. Some said that the government cannot act as an independent escrow agent. One industry organization and 6 individuals said that the government cannot be trusted to run the escrow system.

The technical capabilities afforded by the Escrowed Encryption Standard permit protection of certain sensitive, but unclassified Federal government information at a level far stronger than that of the Data Encryption Standard, while at the same time permitting decryption of communications in conjunction with electronic surveillance when authorized by law. These comments address policy issues separate from the technical aspects of the Escrowed Encryption Standard established herein. The technical benefits accruing to a Federal government system using the Escrowed Encryption Standard are independent of the identity of the entities serving as key component escrow agents.

With respect to the suggestions that the system may infringe individual rights, the purpose of the escrowing of key components is to permit decryption only in those circumstances in which interception of communications is lawfully authorized, consistent with the Constitution and relevant statutes. To this end, the Attorney General is to review for legal sufficiency the procedures by which an agency establishes its authority to acquire the contents of such communications. The Department of Justice has assured NIST, therefore, that the Escrowed Encryption Standard is fully consistent with protection of individual privacy rights.

(4) Fifteen industry organizations and 193 individuals were concerned that the standard uses a secret algorithm. Some said that since the algorithm is secret, it is not possible to evaluate it. Some said that the algorithm is flawed and is subject to compromise. Two individuals said that the algorithm has severe technical problems, and that the algorithm for generating the unit keys is too predictable. One individual said that in addition to possible decryption via escrowed keys, the algorithm has a back door. Others said that people will not use encryption that they cannot trust, and that the risks of using the EES have not been assessed. One government organization, two industry organizations and 7 individuals said that the technology will not be accepted internationally if the algorithm is not known.

The algorithm was developed originally as a classified algorithm for the U.S. Government to provide highly effective communications security. It is still used for that purpose. There are no trap doors or any known weaknesses in it. A classified algorithm is essential to the effectiveness of the key escrow solution. The use of a classified algorithm assures that no one can produce devices that use the algorithm without the key escrow feature and thereby frustrate the ability of government agencies to acquire the content of communications encrypted with the algorithm, in conjunction with lawfully authorized interception. NIST finds that, because the algorithm needs to remain secret in order to preserve the utility of the key escrow feature, it would be neither practicable nor in the public interest to publish the algorithm.

(5) Eight industry organizations and 181 individuals said that it was premature to adopt the EES as a standard until policy decisions on encryption are made.

The Federal government is committed to protection of sensitive information of all kinds, particularly sensitive, but unclassified information outside the scope of the Warner Amendment. The Escrowed Encryption Standard gives Federal managers the ability to afford their agencies' sensitive but unclassified information protection substantially stronger than possible with the Data Encryption Standard. This standard permits, but does not mandate, the use of the Escrowed Encryption Standard by Federal managers; it in no way mandates use of the standard outside the Federal government. Issuance of the standard at this time is fully consistent with the President's Directive on encryption management.

B. Other General Comments

Twelve individuals questioned the role of the National Security Agency in the development of the standard. In response, NIST notes that NSA, because of its expertise in the field of cryptography and its statutory role as a technical advisor to U.S. government agencies concerning the use of secure communications, developed the technical basis for the standard which allows for the widespread use of encryption technology while affording law enforcement the capability to access

encrypted communications under lawfully authorized conditions. NSA worked in cooperation with the Department of Justice, the FBI and NIST to develop the escrowed encryption standard.

Seven individuals said that there is other technology available for protecting information that is more cost effective and that the EES is not the best solution for the problems identified. NIST notes that use of the standard is voluntary. The standard states that a risk analysis should be performed to determine potential threats and risk and that the costs of providing encryption using this standard as well as alternative methods and their respective costs should be projected. A decision to use this standard should be based on the risk and cost analyses.

One individual said that the government should not broaden its access to private communications. NIST notes that the standard does not broaden access to private communications, Access must be legally authorized.

One government organization, 4 industry organizations and 28 individuals said that the standard hinders security of information and will not help law enforcement activities. NIST responds that, as noted in the President's directive on "Public Encryption Management," new communications technology can frustrate lawful government electronic surveillance and, when exported abroad, thwart foreign intelligence activities critical to our national interests. The Escrowed Encryption Standard provides substantially stronger encryption protection than is currently available under the Data Encryption Standard, and its implementation in hardware is expected to permit ease and transparency of use. It is anticipated that security will be enhanced by the combination of robust encryption with technology easily usable even in circumstances that have not, in the past, readily lent themselves to encryption. The Escrowed Encryption Standard permits the protection of sensitive information with strong encryption, while at the same time permitting protection of the public safety by decryption in conjunction with lawfully authorized electronic surveillance. The key escrowing technique in this standard will allow the government to gain access to encrypted information only with appropriate legal authorization.

Four industry organizations and 17 individuals said that the standard does not respond to any user requirement. NIST responds that the standard provides substantially stronger protection for sensitive, but unclassified Federal government information than is currently available under the DATA Encryption Standard. Moreover, the standard permit law enforcement entities to protect the public safety by gaining access to encrypted information in conjunction with lawfully authorized electronic surveillance.

One industry organization and 20 individuals said that it is unlikely that people engaged in illegal activities will use the standard. NIST notes that the Administration has chosen to encourage the widespread use of key escrow devices to make strong encryption broadly available and affordable.

One individual said that the key escrow program will be funded by asset forfeiture and therefore will not be subject to Congressional review. The Federal government will acquire a number of key escrow-equipped devices, for some of which funds from the Department of Justice Asset Forfeiture Super Surplus Fund will be utilized. NIST notes that the asset forfeiture program is subject to Congressional review and oversight, and to General Accounting Office reviews and audits, if requested by the Congress. There are, however, no plans to use asset forfeiture funds for other aspects of the key-escrow encryption system.

One industry organization stated that the applicability of the standard should be limited to telephony. NIST notes that the standard is applicable to voice, facsimile, and computer information communicated in a telephone system.

One industry organization said that the recommended FIPS deviates from the FIPS process. In response, NIST notes that it uses a variety of methods to develop needed standards, including working closely with other Federal agencies as mandated by the Computer Security Act of 1987. NIST followed its usual procedures in announcing the proposed standard and soliciting comments from government and private sector organizations, as well as from interested members of the public. All comments received to the Federal Register notice announcing the proposed standard have been made part of the public record and are available for inspection and copying at the Central Reference and Records Inspection Facility in the Department of Commerce. The justification document which was presented to the Secretary of Commerce is part of the public record as well.

C. Patent Infringement Allegations

In addition to the above comments, NIST has received two allegations of patent infringement for the key escrow technology adopted by the EES. The first allegation was from the older of an issued patent, the second was from an inventor who had recently filed a patent application with the Patent and Trademark Office. Also, one government organization observed that the patent status of the EES is not clear and may result in cost impacts due to payment of royalties, should EES be found to infringe upon any privately held patent. Based upon information received to date, NIST has not been persuaded that any patent of which it is aware will lead to a successful claim against any use of the EES, including U.S. Government users, for payment of royalties. An infringement study was conducted upon the first infringement allegation, with the result that no infringement was found. When the patent relevant to the second allegation was issued in January of this year, an infringement study was begun on that patent.

D. Economic Effects of the Standard

Public comments were received on three economic aspects of the proposed standard, including concerns about the cost to the government and the private sector of implementing the standard; the effect of the standard upon the competitiveness of U.S. software firms in world markets; and suggestions that the government has bestowed an unfair economic benefit upon the contractor that has been selected to manufacture the escrow encryption semiconductor chips that are called for in the standard. Each of these matters is addressed in turn below.

1. Costs

A number of comments were received concerning the possible cost of implementing the Escrowed Encryption Standard. Thus, one government agency, two industry organizations and nine individuals expressed concern about the cost of administration of the escrow database, or about the cost, availability, implementation and maintenance of the equipment needed to support the standard. Indeed, one Federal organization said that it did not support the standard because there would be an adverse impact if the organization had to replace or modify its current equipment. An industry organization suggested that the standard would impose costs on the private sector if private parties need to use the standard to communicate with the government.

NIST estimates the cost of establishing the escrow system to be approximately $14 million. The cost of operating the key escrow facility is estimated to be $16 million annually.

These costs figures are based upon a number of factors. NIST notes that use of the standard is voluntary for Federal agencies, and that agencies are not required to implement it. Agencies will determine whether to use this standard based on their analyses of the risk of unauthorized disclosure of their sensitive data and the cost of using this standard to protect the data. NIST does not expect the wholesale replacement of the current base of equipment that conforms to FIPS 46–2, Data Encryption Standard. Rather, the implementation of this standard appears most likely to occur as the Federal government replaces old and obsolete equipment. NIST believes that as the Federal government replaces old and obsolete equipment, the additional costs of implementing this standard in electronic devices will prove to be negligible compared to the costs of equivalent encryption protection which would be implemented in encryption devices which do not comply with this standard.

NIST also notes that the standard has no direct applicability to entities that do not operate Federal computer systems. Thus, businesses, universities and other nonprofit organizations and individual citizens are free to use products that conform to the standard, or to ignore the standard if they see fit.

2. Competitiveness

Eight industry organizations and 28 individuals said that the standard will reduce the competitiveness of U.S. computer hardware and software companies in foreign markets. NIST notes that approval of the Escrowed Encryption Standard will not prevent U.S. manufacturers from making other encryption products for the private sector. While export controls may affect the sales of U.S. encryption products abroad, key escrow products are already exportable to U.S. industry and individuals operating abroad in accordance with proper export licensing through the Department of State. Further, a comprehensive policy review on commercial encryption is now underway by the Administration. This review will consider, among other topics, broader export options for key escrow products. Again, approval of the Escrowed Encryption Standard for broader export will not restrict exports of other encryption products. The overseas market for these products will depend on a variety of factors including any restrictions other countries place on imports of encryption technology.

3. Unfair Competitive Advantage

One industry organization and two individuals said that the standard gives an economic advantage to the one company that has been selected by the Government to date to manufacture semiconductor chips which conform to this standard. NIST notes that the company that designed the microcircuit was selected because of its expertise in design of custom cryptographic chips, its secure facilities, and employment of cleared personnel. The company that developed the microcircuit was selected for its technological capabilities to fabricate microcircuits resistant to reverse engineering. Other manufacturers that wish to enter the market and can satisfy the technology and security requirements will be approved to manufacture the microcircuits.

E. Technical Recommendations and Editorial Changes

A wide range of technical issues were raised in the public comment process. Each issue, and a NIST response follows below.

Four industry organizations and 7 individuals said that the required hardware implementation of the escrowed encryption standard was not optimum. Software implementation would be more useful and cost effective. NIST notes that because software is easy to change, secure software implementations of the key escrow technique have been difficult to devise. On August 24, 1993 (58 FR 44662) NIST invited the participation of the software industry in cooperative efforts to meet this challenge. Several organizations have indicated that they wish to collaborate with NIST in this area. NIST will try to establish cooperative partnerships to investigate the implementation of the EES in software.

Three Federal government organizations and one individual said that applicability of the standard should not be restrictive, and that it should allow for other applications and data rates. NIST notes that the scope of applicability was established to address the immediate need for improved telephone security while preserving the law enforcement capability of decrypting intercepted telecommunications that have been lawfully authorized. Use of the standard is voluntary. Use of the standard for other purposes is not prohibited in the standard.

One individual stated that the standard should require two or more escrow agents and that the standard should state that all the components of the device unique key are independent and all are needed to form the key. A change was made to state that the Device Unique Key shall be composed of two components (each 80 bits long) and each component shall be independently generated and stored by an escrow agent. This change provides for the two escrow agents envisioned by the Department of Justice, and two key components, each 80 bits long.

One individual said that the name of Device Identifier (DID) should be device Unique Identifier (UID). Since DID is used elsewhere for another purpose, NIST changed the name of Device Identifier (DID) to device Unique Identifier (UID).

One individual said that the standard should provide for access to both sides of a real-time conversation. NIST notes that if the two keys are different, either a law enforcement official must obtain a court order for both parties of a two-day communication or it can only decrypt one part of a conversation. Therefore, the standard was changed to state that the session key used to encrypt transmitted information shall be the same as the session key used to decrypt received information in a two-way simultaneous communication.

One industry organization said that the standard should specify a register for Leaf Creation Methods. NIST changed the standard to state that the Leaf Creation Method (LCM) shall be registered in the NIST Computer Security Object Register (e.g., LCM–1). Additional LCM's may be created in the future.

One industry organization said that the Cryptographic Protocol Field (CPF) has not been defined and should be removed from the standard since it is an incomplete specification. NIST changed the standard to state that the Cryptographic Protocol Field (CPF) shall be registered in the NIST Computer Security Object Register. This will enable the details on the CPF to be formalized later.

Four Federal government organizations and two individuals said that the standard is not an interoperability standard, that it does not specify parameter lengths and formats and placement in communications, and that the standard provides insufficient technical information for implementation. NIST added information to the standard to explain that it is not an interoperability standard. It does not provide sufficient information to design and implement a security device or equipment. Other specifications and standards will be required to assure interoperability of EES devices in various applications.

Specifications of a particular EES device must be obtained from the manufacturer in order to use it in an application.

One industry commenter said that the standard should specify a register of family keys, such as "FBI Family Key 1," to provide some assurance of interoperability. NIST changed the standard to state that the family key shall have an identifier (KF–ID). The identifier of a family key shall be registered in the NIST Computer Security Object Register. As a result, if more than one family key exists (reasonable assumption), it should be identified so that law enforcement agencies can decrypt the LEAF.

One industry organization and one individual stated that the standard should reference technical specifications explicity (even if they are classified). NIST changed the standard to provide specific information on how to obtain the technical specifications for the SKIPJACK algorithm and the LEAF Creation Method 1.

One industry organization said that parameters (input, output, status, errors) are not specified in the standard, and that diversity of sources of implementations cannot be established. NIST notes that various devices meeting this standard are anticipated. Therefore, the implementations will depend on a number of factors, including physical, electrical and application requirements.

One industry organization said that the standard should state that DID is transmitted in the LEAF. NIST notes that the standard does state this.

One individual said that the reverse engineering protection for the algorithm is not prefect. NIST notes that the standard specifies that the encryption algorithm and the LEAF creation method shall be implemented in electronic devices highly resistant to reverse engineering. It does not specify how the reverse engineering is to be prevented (or deterred). It also does not specify a metric for measuring the prevention (or deterrence). These are difficult to quantify and to specify and depend greatly on the implementation. A study is being performed to evaluate the protection provided by one of the current implementations of the standard (MYK–78). Estimates of the protection provided are 1–4 years of protection against attacks by specialized laboratories investing $1M to $4M.

One industry organization stated that 2**80 keys is sufficient for session key, but it is not sufficient for lifetime keys (family and unique keys). NIST notes that the length of the family key and the device unique key are presently 80 bits for the SKIPJACK algorithm. The session key is also 80 bits. While the security lifetime of a session key is normally much shorter than the security lifetime of a master key (also called Key Encrypting Key), it is convenient to use keys of the same length for all purposes. Present implementations of the EES use one length key for all three types of keys (i.e., 80 bits). This is expected to be sufficiently long for unclassified data encryption for many years. However, the length of the family key and device unique key can be increased in future implementations and future LEAF creation methods. Some provisions for these have been made in the standard.

One industry organization was concerned that disclosure of the Device Unique Key could allow decryption of ALL information ever encrypted with that device (all past and all future), and that this condition could technically be prevented. NIST believes that key escrow procedures intended to administratively control the use of the device Unique Key are outside the scope of standard. Technical controls were not included in the initial design of the MYK–78 but could be added in future designs.

One individual was concerned that two party control is not truly implemented in the "chip." NIST acknowledges that two party control was not in the original design criteria of the chip. Administrative controls are to be used to assure two party control for present design. This two party control feature could be added to future designs.

One individual said that one "tamperproofing session" is supported by the Mykotronics implementation of the EES. However, the second escrow agent entering a key could read first escrow agent's key and hence have both keys. NIST notes that the present method of reverse engineering protection provides for one "programming session" in which device unique parameters are put into the device. The parameters are "locked" after being entered and verified. The present technology allows this to be done only once. Other technologies may be developed which allow two or more independed "program sessions" which prevent reading of previously entered parameters while other parameters are being entered. Future implementations may be have this feature but such requirements at the present time are outside the scope of this standard.

One industry organization recommended that the following should be put into the standard: "The Session Key (80 bits) shall be encrypted with the device Unique Key. The encrypted Session Key is concatenated with the Device Identifier (DID) (xx bits) and the Escrow Authenticator (EA) (yy bits). This result is then encrypted with the Family Key to generate a 128 bit LEAF. The 128 bit LEAF along with a 64 bit Initialization Vector shall be transmitted with the cipher text." NIST acknowledges that this is a general description of the LEAF creation method specified in this standard. The complete specifications are classified. Classified specifications must be obtained in order to implement the standards. Users of devices meeting this standard do not need to know the specifics of the LEAF creation method in order to use security devices meeting this standard. There is, therefore, no purpose in providing this general specification in the standard.

One industry organization recommended that Modes of Operation be developed for the EES, including Counter Addressing or Long Cycle Mode, and that the LFSR should be included. NIST notes that four modes of operation are specified in FIPS–81. Subsets of these four modes are specified in the EES. Other subsets are implemented in various devices implementing this standard. For example, the Output Feedback (OFB) mode is implemented in the MYK–78T while all subsets specified in the standard are implemented in the MYK–80. The Linear Feedback Shift Register (LFSR) mode has been used in some devices but was not included in the Modes of Operation for DES. OFB can be used in the same applications. National security interests were considered when selecting the modes of operation.

One industry organization said that the standard should state length of Family Key. NIST notes that the length of the family key (80 bits) may increase in future implementations, and therefore flexibility is needed in the standard.

Dated: February 4, 1994.

Samuel Kramer,

Associate Director.

Federal Information Processing Standards Publication 185

Announcing the Escrowed Encryption Standard (EES)

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.

Name of Standard: Escrowed Encryption Standard (EES).

Category of Standard: Telecommunications Security.

Explanation: This Standard specifies use of a symmetric-key encryption (and decryption) algorithm (SKIPJACK) and a Law Enforcement Access Field (LEAF) creation method (one part of a key escrow system) which provides for decryption of encrypted telecommunications when interception of the telecommunications is lawfully authorized. Both the SKIPJACK algorithm and the LEAF creation method are to be implemented in electronic devices (e.g., very large scale integration chips). The devices may be incorporated in security equipment used to encrypt (and decrypt) sensitive unclassified telecommunications data. Decryption of lawfully intercepted telecommunications may be achieved through the acquisition and use of the LEAF, the decryption algorithm and the two escrowed key components.

One definition of "escrow" means that something (e.g., a document, an encryption key) is "delivered to a third person to be given to the grantee only upon the fulfillment of a condition" (Webster's Seventh New Collegiate Dictionary). The term, "escrow", for purposes of this standard, is restricted to this dictionary definition.

A key escrow system, for purposes of this standard, is one that entrusts the two components comprising a cryptographic key (e.g., a device unique key) to two key component holders (also called "escrow agents"). In accordance with the above definition of "escrow", the key component holders provide the components of a key to a "grantee" (e.g., a law enforcement official) only upon fulfillment of the condition that the grantee has properly demonstrated legal authorization to conduct electronic surveillance of telecommunications which are encrypted using the specific device whose device unique key is being requested. The key components obtained through this process are then used by the grantee to reconstruct the device unique key and obtain the session key which is then used to decrypt the telecommunications that are encrypted with that session key.

The SKIPJACK encryption/decryption algorithm has been approved for government applications requiring encryption of sensitive but unclassified data telecommunications as defined herein. The specific operations of the SKIPJACK algorithm and the LEAF creation method are classified and hence are referenced, but not specified, in this standard.

Data for purposes of this standard includes voice, facsimile and computer information communicated in a telephone system. A telephone system for purposes of this standard is limited to a system which is circuit switched and operating at data rates of standard commercial modems over analog voice circuits or which uses basic-rate ISDN or a similar grade wireless service.

Data that is considered sensitive by a responsible authority should be encrypted if it is vulnerable to unauthorized disclosure during telecommunications. A risk analysis should be performed under the direction of a responsible authority to determine potential threats and risks. The costs of providing encryption using this standard as well as alternative methods and their respective costs should be projected. A responsible authority should then make a decision, based on the risk and cost analyses, whether or not to use encryption and then whether or not to use this standard.

Approving Authority: Secretary of Commerce.

Maintenance Agency: Department of Commerce, National Institute of Standards and Technology.

Applicability: This standard is applicable to all Federal departments and agencies and their contractors under the conditions specified below. This standard may be used in designing and implementing security products and systems, which Federal departments and agencies use or operate or which are operated for them under contract. These products may be used when replacing Type II and Type III (DES) encryption devices and products owned by the government and government contractors.

This standard may be used when the following conditions apply:

1. An authorized official or manager responsible for data security or the security of a computer system decides that encryption is required and cost justified as per OMB Circular A–130; and

2. The data is not classified according to Executive Order 12356, entitled "National Security Information," or to its successor orders, or to the Atomic Energy Act of 1954, as amended.

However, Federal departments or agencies which use encryption devices for protecting data that is classified according to either of these acts may use those devices also for protecting unclassified data in lieu of this standard.

In addition, this standard may be adopted and used by non-Federal Government organizations. Such use is encouraged when it provides the desired security.

Applications: This standard may be used in any unclassified government and commercial communications. Use of devices conforming to this standard is voluntary for unclassified government applications and for commercial security applications.

Implementations: The encryption/decryption algorithm and the LEAF creation method shall be implemented in electronic devices (e.g., electronic chip packages) which are protected against unauthorized entry, modification and reverse engineering. Implementations which are tested and validated by NIST will be considered as complying with this standard. An electronic device shall be incorporated into a cryptographic module in accordance with FIPS 140–1. NIST will test for conformance with FIPS 140–1. Conforming cryptographic modules can then be integrated into security equipment for sale and use in a security application. Information about devices that have been validated, procedures for testing equipment for conformance with NIST standards, and information about approved security equipment are available from the Computer Systems Laboratory, NIST, Gaithersburg, MD 20899.

Export Control: Implementations of this standard are subject to Federal Government export controls as specified in Title 22, Code of Federal Regulations, Parts 120 through 131 (International Traffic of Arms Regulations—ITAR). Exporters of encryption devices, equipment and technical data are advised to contact the U.S. Department of State, Office of Defense Trade Controls for more information.

Patents: Implementations of this standard may be covered by U.S. and foreign patents.

Implementation Schedule: This standard becomes effective thirty days following publication of this FIPS PUB.

Specifications: Federal Information Processing Standard (FIPS 185), Escrowed Encryption Standard (EES) (affixed).

Cross Index

a. FIPS PUB 46–2, Data Encryption Standard.

b. FIPS PUB 81, Modes of Operation of the DES.

c. FIPS PUB 140–1, Security Requirements for Cryptographic Modules.

Glossary

The following terms are used as defined below for purposes of this standard:

Data—Unclassified voice, facsimile and computer information communicated over a telephone system.

Decryption—Conversion of ciphertext to plaintext through the use of a cryptographic algorithm.

Device (cryptographic)—An electronic implementation of the encryption/decryption algorithm and the LEAF creation method as specified in this standard.

Digital data—Data that have been converted to a binary representation.

Encryption—Conversion of plaintext to ciphertext through the use of a cryptographic algorithm.

Key components—The two values from which a key can be derived (e.g., $KU_1 \oplus KU_2$).

Key escrow—The processes of managing (e.g., generating, storing, transferring, auditing) the two components of a cryptographic key by two key component holders.

LEAF Creation Method—A part of a key escrow system that is implemented in a cryptographic device and creates a Law Enforcement Access Field.

Type I cryptography—A cryptographic algorithm or device approved by the National Security Agency for protecting classified information.

Type II cryptography—A cryptographic algorithm or device approved by the National Security Agency for protecting sensitive unclassified information in systems as specified in section 2315 of Title 10 United States Code, or section 3502(2) of title 44, United States Code.

Type III cryptography—A cryptographic algorithm or device approved as a Federal Information Processing Standard.

Type III(E) cryptography—A Type III algorithm or device that is approved for export from the United States.

Qualifications: The protection provided by a security product or system is dependent on several factors. The protection provided by the SKIPJACK algorithm against key search attacks is greater than that provided by the DES algorithm (e.g., the cryptographic key is longer). However, provisions of this standard are intended to ensure that information encrypted through use of devices implementing this standard can be decrypted by a legally authorized entity.

Where to Obtain Copies of the Standard: Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. When ordering, refer to Federal Information Processing Standards Publication 185 (FIPS PUB 185), and identify the title. When microfiche is desired, this should be specified. Prices are published by NTIS in current catalogs and other issuances. Payment may be made by check, money order, deposit account or charged to a credit card accepted by NTIS.

Federal Information Processing Standards Publication 185

Specifications for the Escrowed Encryption Standard

1. Introduction

This publication specifies Escrowed Encryption Standard (EES) functions and parameters.

2. General

This standards specifies use of the SKIPJACK cryptographic algorithm and a LEAF Creation Method to be implemented in an approved electronic device (e.g., a very large scale integration electronic chip). The device is contained in a logical cryptographic module which is then integrated in a security product for encrypting and decrypting telecommunications.

Approved implementations may be procured by authorized organizations for integration into security equipment. Devices must be tested and validated by NIST for conformance to this standard. Cryptographic modules must be tested and validated by NIST for conformance to FIPS 140–1.

3. Algorithm Specifications

The specifications of the encryption/decryption algorithm (SKIPJACK) and LEAF Creation Method 1 (LCM–1) are classified. The National Security Agency maintains these classified specifications and approves the manufacture of devices which implement the specifications. NIST tests for conformance of the devices implementing this standard in cryptographic modules to FIPS 140–1 and FIPS 81.

4. Functions and Parameters

4.1. Functions

The following functions, at a minimum, shall be implemented:

1. Data Encryption: A session key (80 bits) shall be used to encrypt plaintext information in one or more of the following modes of operation as specified in FIPS 81: ECB, CBC, OFB (64), CFB (1, 8, 16, 32, 64).

2. Data Decryption: The session key (80 bits) used to encrypt the data shall be used to decrypt resulting ciphertext to obtain the data.

3. LEAF Creation: A Family Key (e.g., KF–1) shall be used to create a Law Enforcement Access Field (LEAF) in accordance with a LEAF Creation Method (e.g., LCM–1). the security equipment shall ensure that the LEAF is transmitted in such a manner that the LEAF and ciphertext may be decrypted with legal authorization. No additional encryption or modification of the LEAF is permitted.

4.2 Parameters

The following parameters shall be used in performing the prescribed functions:

1. Device Unique Identifier (UID): The identifier unique to a particular device and used by the Key Escrow System.

2. Device Unique Key (KU): The cryptographic key unique to a particular device and used by the Key Escrow System.

3. Cryptographic Protocol Field (CPF): The field identifying the registered cryptographic protocol used by a particular application and used by the Key Escrow System (reserved for future specification and use).

4. Escrow Authenticator (EA): A binary pattern that is inserted in the LEAF to ensure that the LEAF is transmitted and received properly and has not been modified, deleted or replaced in an unauthorized manner.

5. Initialization Vector (IV): A mode and application dependent vector of bytes used to initialize, synchronize and verify the encryption, decryption and key escrow functions.

6. Family Key (KF): The cryptographic key stored in all devices designated as a family that is used to create a LEAF.

7. Session Key (KS): The cryptographic key used by a device to encrypt and decrypt data during a session.

8. Law Enforcement Access Field (LEAF): The field containing the encrypted session key and the device identifier and the escrow authenticator.

5. Implementation

The Cryptographic Algorithm (i.e. SKIPJACK) and a LEAF Creation Method (e.g., LCM–1) shall be implemented in an electronic device (e.g., VLSI chip) which is highly resistant to reverse engineering (destructive or non-destructive) to obtain or modify the cryptographic algorithm, the UID, the KF, the KU, the EA, the CPF, the operational KS, and any other security or Key Escrow System relevant information. The device shall be able to be programmed/personalized (i.e., made unique) after mass production in such a manner that the UID, KU (or its components), KF (or its components) and EA fixed pattern can be entered once (and only once) and

maintained without external electrical power.

The LEAF and the IV shall be transmitted with the ciphertext. The specifics of the protocols used to create and transmit the LEAF, IV, and encrypted data shall be registered and a CPF assigned. The CPF (and the KF-ID, LCM-ID) shall then be transmitted in accordance with the registered specifications.

Various devices implementing this standard are anticipated. The implementation may vary with the application. The specific electric, physical and logical interface will vary with the implementation. Each approved, registered implementation shall have an unclassified electrical, physical and logical interface specification sufficient for an equipment manufacturer to understand the general requirements for using the device. Some of the requirements may be classified and therefore would not be specified in the underclassified interface specification.

The device Unique Key shall be composed of two components (each a minimum of 80 bits long) and each component shall be independently generated and stored by an escrow agent. The session key used to encrypt transmitted information shall be the same as the session key used to decrypt received information in a two-way simultaneous communication. The Lead Creation Method (LCM), the Cryptographic Protocol Field (CPF), and the Family Key Identifier (KF-ID) shall be registered in the NIST Computer Security Object Register.

This standard is not an interoperability standard. It does not provide sufficient information to design and implement a security device or equipment. Other specifications standards will be required to assure interoperability of EES devices in various applications. Specifications of a particular EES device must be obtained from the manufacturer.

The specification for the SKIPJACK algorithm are contained in the R21 Informal Technical Report entitled "SKIPJACK" (S), R21-TECH-044-91, May 21, 1991. The specifications for LEAF Creation Method 1 are contained in the R21 Informal Technical Report entitled "Law Enforcement Access Field for the Key Escrow Miscrocircuit" (S). Organizations holding an appropriate security clearance and entering into a Memorandum of Agreement with the National Security Agency regarding implementation of the standard will be provided access to the classified specifications. Inquiries may be made regarding the Technical Reports and this program to Director, National Security Agency, Fort George G. Meade, MD 20755–6000, Attn: R21.

[FR Doc. 94–2919 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–CN–M

National Telecommunications and Information Administration

[Docket No. 940231–4031]

Preliminary Spectrum Reallocation Report

ACTION: Notice of release of the Preliminary Spectrum Reallocation Report Identifying 200 Megahertz for Public Use, a request for public comments, and a meeting to introduce the report.

SUMMARY: In accordance with the provisions of the Omnibus Budget Reconciliation Act of 1993, title VI, Communications Licensing and Spectrum Allocation Improvement, the Secretary of Commerce will release the Preliminary Spectrum Reallocation Report to the public and submit it to the President, the Congress and the Federal Communications Commission on February 10, 1994. Interested parties are invited to submit written comments (10 copies) by May 11, 1994. The report will be available on February 10, 1994, at NTIA in hard copy form and on NTIA's Bulletin Board at (202) 482–1199. Comments can be provided in written form or via the NTIA bulletin board.

A meeting will be held at the Department of Commerce at which the report will be introduced and the press and interested parties will have an opportunity to ask questions. The meeting will be on February 10, 1994, from 9:30 to 11:30 in room 4830 at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: The person to contact to obtain copies of the report and provide written comments is: Norbert Schroeder, Program Manager, Spectrum Openness, National Telecommunications and Information Administration, room 4092, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, Telephone: (202) 482–3999, Fax: (202) 482–4396.

Dated: February 4, 1994.

Norbert Schroeder,

Program Manager, Spectrum Openness, NTIA.

[FR Doc. 94–3012 Filed 2–4–94; 3:47 pm]

BILLING CODE 3510–60–P

Travel and Tourism Administration

Travel and Tourism Advisory Board; Board Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5, U.S.C. (App. 1976) notice is hereby given that the Travel and Tourism Advisory Board of the U.S. Department of Commerce will hold its Winter Meeting on February 16 and 17, 1994, 9 a.m. to 5 p.m., in Chicago, Illinois. The meeting will be held at the Hyatt Regency Chicago, 151 E. Wacker Drive.

On February 16, the Board will conduct a public forum to assist the Tourism Policy Council in its effort to create a comprehensive tourism development strategy for the Federal government. Members advise the Secretary of Commerce on matters pertinent to the Department's responsibilities to accomplish the purpose of the National Tourism Policy Act (Pub. L. 97–63), and provide guidance to the Under Secretary for Travel and Tourism.

Agenda items are as follows:

Public Forum—February 16, 1994

Welcome—Darryl Hartley Leonard, Chairman
Presentations By Elected Officials
Panel 1: Tourism Research and Training
Panel 2: Product Development and Promotion
Panel 3: Tourism Infrastructure Development

Winter Meeting—February 17, 1994

I. Call to Order
II. Roll Call
III. Review of Tourism Policy Council
IV. Presentation of USTTA Strategic Plan
V. USTTA Program Update
VI. Briefing on Defense Conversion of Empowerment Zones
VII. Miscellaneous
VIII. Adjournment

A number of seats will be available to observers form the public and press. To assure adequate seating, individuals intending to attend should notify the Committee Control Officer in advance. The public will be permitted to file written statements with the Committee before or after the meeting.

Dana V. Shelley, Committee Control Officer, United States Travel and Tourism Administration, room 1863, U.S. Department of Commerce, Washington, DC 20230 (telephone: 202–482–0137), will respond to public requests for information about the information.

Leslie R. Doggett,

Acting Under Secretary of Commerce for Travel and Tourism.

[FR Doc. 94–3016 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–11–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Import Restraint Limits and Amendment of Export Visa Requirements for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in India

February 3, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits for the new agreement year and amending visa requirements.

EFFECTIVE DATE: February 11, 1994.

FOR FURTHER INFORMATION CONTACT: Jennifer Tallarico, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6705. For information on embargoes and quota re-openings, call (202) 482–3715.

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).

In a Memorandum of Understanding (MOU) dated January 22, 1994 between the Governments of the United States and India, agreement was reached to amend and extend further the Bilateral Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textile Agreement of February 6, 1987, for two consecutive one-year periods beginning on January 1, 1994 and extending through December 31, 1995.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits for the period beginning on January 1, 1994 and extending through December 31, 1994 and to amend the visa requirements to include coverage of merged Categories 338/339.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 58 FR 62645, published on November 29, 1993).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

Rita D. Hayes,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

February 3, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on December 9, 1993; pursuant to the Memorandum of Understanding dated January 22, 1994 between the Governments of the United States and India; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on February 11, 1994, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products in the following categories, produced or manufactured in India and exported during the twelve-month period beginning on January 1, 1994 and extending through December 31, 1994, in excess of the following levels of restraint:

Category	Twelve-month restraint limit [1]
Levels in Group I	
218	9,787,453 square meters.
219	47,442,506 square meters.
313	26,187,602 square meters.
314	5,930,313 square meters.
315	9,960,550 square meters.
317	33,000,000 square meters.
326	7,500,000 square meters.
334/634	106,000 dozen.
335/635	471,912 dozen.
336/636	646,508 dozen.
338/339	3,250,000 dozen.
340/640	1,571,063 dozen.
341	3,488,332 dozen of which not more than 2,092,999 dozen shall be in Category 341–Y [2].
342/642	910,116 dozen.
345	137,388 dozen.
347/348	420,972 dozen.
351/651	202,000 dozen.
363	32,115,628 numbers.
369–D [3]	988,768 kilograms.
369–S [4]	539,328 kilograms.
369–O [5]	11,870,000 kilograms.
641	1,112,589 dozen.
647/648	646,070 dozen.
Group II	
200, 201, 220–229, 237, 239, 300, 301, 330–333, 349, 350, 352, 359–362, 600–607, 611–629, 630–633, 638, 639, 643–646, 649, 650, 652, 659, 665–O [6], 666, 669, 670, and 831–859, as a group.	80,000,000 square meters equivalent.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1993.

[2] Category 341–Y: only HTS numbers 6204.22.3060, 6206.30.3010, 6206.30.3030 and 6211.42.0054.

[3] Category 369–D: only HTS numbers 6302.60.0010, 6302.91.0005 and 6302.91.0045.

[4] Category 369–S: only HTS number 6307.10.2005.

[5] Category 369–O: all HTS numbers except 5702.10.9020, 5702.49.1020, 5702.99.1010 (rugs exempt from the bilateral agreement); 6302.60.0010, 6302.91.0005, 6302.91.0045 (Category 369–D); and 6307.10.2005 (Category 369–S).

[6] Category 665–O: all HTS numbers except 5702.10.9030, 5702.42.2020, 5702.92.0010 and 5703.20.1000 (rugs exempt from the bilateral agreement).

Imports charged to these category limits for the period January 1, 1993 through December 31, 1993 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future pursuant to the provisions of the MOU dated January 22, 1994 between the Governments of the United States and India.

For visa purposes, you are directed, effective on February 11, 1994, to amend further the directive dated November 26, 1979, to include merged Categories 338/339 for goods produced or manufactured in India and exported from India on and after February 11, 1994.

Merchandise in Categories 338/339 may be accompanied by either the appropriate merged category visa or the correct category visa corresponding to the actual shipment.

Shipments entered or withdrawn from warehouse according to this directive which are not accompanied by an appropriate export visa shall be denied entry and a new visa must be obtained.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs

exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Rita D. Hayes,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–2988 Filed 2–8–94; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, applicable form, and OMB control number: Signature and Tally Record, DD Form 1907, OMB Control Number 0702–0027

Type of request: Reinstatement

Number of respondents: 200

Responses per respondent: 225

Annual responses: 45,000

Average burden per response: 3 minutes

Annual burden hours: 1,485

Needs and uses: Signature and Tally Record is a integral part of the Defense Transportation System to provide continuous accountability and custody of classified and sensitive material when using commercial carriers. The form records the shipment transfer from one carrier to another from pickup point to the consignee.

Affected public: Businesses or other for-profit, small businesses or organization

Frequency: On occasion

Respondent's obligation: Mandatory

OMB desk officer: Mr. Edward C. Springer. Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, room 3235, New Executive Office Building, Washington, DC 20503.

DOD clearance officer: Mr. William P. Pearce. Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, suite 1204, Arlington, Virginia 22202–4302.

Dated: February 4, 1994.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–2920 Filed 2–8–94; 8:45 am]

BILLING CODE 5000–04–M

Department of the Air Force

USAF Scientific Advisory Board; Meeting

The Mobility Panel of the USAF Scientific Advisory Board's 1994 Summer Study on "Mission Support & Enhancement for Foreseeable Aircraft Force Structure" will meet on 28 February through 1 March 1994 at HQ AMC, Scott AFB, Illinois and The Federal Express Corporation on 2 March 1994 at Memphis, Tennessee from 8 a.m. to 5 p.m.

The purpose of this meeting will be to receive briefings and gather information related to extending the service life of current inventory aircraft.

The meeting will be closed to the public in accordance with section 552b of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–8845.

Grace T. Rowe,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 94–2954 Filed 2–8–94; 8:45 am]

BILLING CODE 3910–01–M

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board (SAB) 1994 Summer Study Committee of the Special Mission Panel will meet from 8 a.m. to 5 p.m. on 22–23 February 1994 at Hurlburt Field, FL.

The purpose of this meeting is to receive briefings and to have discussions concerning the Special Mission Panel. The meeting will be closed to the public in accordance with section 552b of title 5, United States Code, specifically subparagraphs (1) and (4).

For further information, contact the SAB Secretariat at (703) 697–8404.

Grace T. Rowe,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 94–2955 Filed 2–8–94; 8:45 am]

BILLING CODE 3910–01–M

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board (SAB) 1994 Summer Study Committee Panel on Material Degradation will meet from 8 a.m. to 5 p.m. on 22–25 February 1994 at Wright-Patterson AFB, OH.

The purpose of these meetings are to receive briefings and to have discussions concerning material degradation. These meetings will be closed to the public in accordance with section 552b of title 5, United States Code, specifically subparagraph (1) and (4).

For further information, contact the SAB Secretariat at (703) 697–4648.

Grace T. Rowe,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 94–2956 Filed 2–8–94; 8:45 am]

BILLING CODE 3910–01–M

Office of the Secretary of the Army

Intent To Prepare an Environmental Impact Statement (EIS) for the Disposal and Reuse of Pueblo Depot Activity (PUDA), Pueblo, CO

AGENCY: Department of the Army, DOD.

ACTION: Notice of Intent.

SUMMARY: The Defense Base Closure and Realignment Commission was mandated by Public Law 100–526, the Defense Authorization Amendments and Base Closure and Realignment Act, October 24, 1988. Under this Act, the Secretary of the Army has the authority to dispose of excess and surplus real property and facilities located at a closed or realigned installation. However, the Department of the Army must still prepare environmental analyses to assess the environmental effects of disposal and reuse of the installation. The Army intends to prepare an EIS to assess the environmental and socioeconomic effects of disposal and subsequent rescue of parcels of PUDA. Development of the potential alternative reuses of the disposed property will be made in conjunction with the local community, the Office of Economic Adjustment, and the Army. As required by the National Environmental Policy Act (NEPA), the Army will also analyze the "no action" alternative which identifies impacts of leaving the installation in caretaker status. This analysis will include the direct, indirect, and cumulative effects of disposal and reuse of PUDA.

The public will have an opportunity to comment on the disposal and reuse of PUDA before any action is taken. Comments received as a result of this notice will be used to assist the Army

in identifying potential impacts to the quality of the human environment. Individuals or organizations may participate in the scoping process by written comment or by attending a public hearing.

DATES: A scoping meeting will be held in the vicinity of PUDA on or before March 11, 1994.

ADDRESSES: Written comments or questions regarding this notice may be sent to the following address: Ms. Shirley Barnett, HQ U.S. Army Materiel Command, ATTN: AMCSO, 5001 Eisenhower Avenue, Alexandria, VA 22333–0001.

FOR FURTHER INFORMATION CONTACT: Verbal comments or questions regarding this notice may be directed to Ms. Shirley Barnett at (703) 274–8155.

Dated: January 28, 1994.

Lewis D. Walker,

Deputy Assistant Secretary of the Army (Environmental, Safety & Occupation Health) OASA (IL&E).

[FR Doc. 94–2918 Filed 2–8–94; 8:45 am]

BILLING CODE 3710–08–M

Department of the Navy

Planning and Steering Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), notice is hereby given that the Planning and Steering Advisory Committee will meet on February 23, 1994, from 9:00 a.m. to 3:30 p.m., at the Center for Naval Analyses, 4401 Ford Avenue, Alexandria, Virginia. This session will be closed to the public.

The purpose of this meeting is to discuss topics relevant to SSBN security. The entire agenda will consist of classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that all sessions of the meeting shall be closed to the public because they concern matters listed in 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact; LCDR D.B.DC 20350, Telephone Number: (703) 693–7248.

Dated: January 31, 1994.

Michael P. Rummel,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 94–2950 Filed 2–8–94; 8:45 am]

BILLING CODE 3810–AE–F

DEPARTMENT OF ENERGY

Availability of a Revised Draft Environmental Assessment of the Urgent-Relief Acceptance of Foreign Research Reactor Spent Fuel

AGENCY: United States Department of Energy.

ACTION: Notice.

SUMMARY: In compliance with the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, the Council on Environmental Quality regulations implementing the National Environmental Policy Act, 40 CFR 1500 *et seq.*, and the United States Department of Energy's implementing procedures, 10 CFR part 1021, the Department of Energy has prepared a revised draft Environmental Assessment (DOE/EA–0912) to evaluate the potential environmental impacts of the proposed urgent-relief acceptance of foreign research reactor spent fuel containing uranium enriched in the United States.

DATES: The revised draft Environmental Assessment is available to the general public, and has been distributed to individuals known to be interested in the proposal. Written comments received on or before March 7, 1994, will be considered in the decisionmaking process and, if appropriate, in preparing the final Environmental Assessment. Written comments received after March 7, 1994, will be considered to the extent practicable. Written comments should be sent to Mr. Charles Head at the address listed below.

ADDRESSES AND FURTHER INFORMATION: Persons requesting additional information regarding this proposed action or desiring a copy of the revised draft Environmental Assessment should contact:

Mr. Charles Head, Office of Spent Fuel Management, Office of Environmental Restoration and Waste Management, U.S. Department of Energy (Mail Stop EM–37), 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–0200.

Copies of the revised draft Environmental Assessment are available for public review at the following Department of Energy reading rooms:

U.S. Department of Energy, Freedom of Information Reading Room, Forrestal Building, room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585.

U.S. Department of Energy, Public Reading Room, Gregg Graniteville Library, 171 University Parkway, Aiken, SC 29801.

For general information regarding the Department of Energy National Environmental Policy Act process, please contact:

Ms. Carol M. Borgstrom, Office of National Environmental Policy Act Oversight, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: In October 1993, the Department of Energy distributed for comment a draft Environmental Assessment which evaluated the proposed urgent-relief acceptance of up to 700 elements of foreign research reactor spent fuel containing uranium enriched in the United States. The Department proposed to transport that spent fuel to the United States as part of an effort to minimize the use of highly enriched uranium in civil programs worldwide. This reduces the risk of theft or diversion of this material for use in developing nuclear weapons. The urgency of that proposed action arose from the need to ensure that countries currently possessing this spent fuel continue to support the nonproliferation initiatives of the United States embodied in the Reduced Enrichment for Research and Test Reactors Program until an Environmental Impact Statement could be completed on the proposed policy to accept up to 15,000 spent fuel elements from foreign research reactors for up to fifteen years

It was apparent from the comments that the Department received in response to the October 1993 draft Environmental Assessment that many people did not agree that there is a need for the United States to accept this spent fuel. Others expressed concerns regarding DOE's plans for implementing the proposed action.

Recently completed visits by teams of experts from the United States to foreign research reactors in Europe and Australia, while altering some details of the Department's proposal for urgent-relief acceptance, have confirmed the near-term need for the acceptance of a limited number of foreign research reactor spent fuel elements until the Environmental Impact Statement has been completed. A Notice of Intent announcing the Department's plans for preparation of this Environmental Impact Statement was published in the **Federal Register** on October 21, 1993, and nine public scoping meetings were held during November and December 1993.

A revised draft Environmental Assessment, which includes revisions made in response to comments received on the October 1993 draft, has now been prepared and is available for public review and comment. The proposed

action is to accept a limited number of highly enriched uranium spent fuel elements which would be shipped by sea to any one of seven ports (Newport News, Norfolk, or Portsmouth, Virginia; Charleston, South Carolina; Wilmington, North Carolina; Savannah, Georgia; and Jacksonville, Florida) and then by truck to the Department's Savannah River Site near Aiken, South Carolina, for interim storage.

The revised draft Environmental Assessment notes that failure to accept any spent fuel would have serious negative impacts on the Reduced Enrichment for Research and Test Reactors Program and the attendant United States policy to minimize the civil use of highly enriched uranium. The Reduced Enrichment for Research and Test Reactors Program, initiated in 1978 and still ongoing, is aimed at reducing the demand for highly enriched uranium by developing high density, low enriched uranium fuels which are not directly usable in nuclear weapons, to replace the highly enriched uranium fuels used in both domestic and foreign research reactors. Although the countries from which the Department is considering accepting spent fuel are not themselves countries of nuclear proliferation concern, these countries export research reactors and fuel to developing countries and have participated in the Reduced Enrichment for Research and Test Reactors program. This program has been responsible for gaining worldwide acceptance of low enriched uranium fuels for research reactors, thus promoting important nonproliferation interests.

The Department of Energy invites those interested in the proposed urgent-relief acceptance of a limited number of spent fuel elements from foreign research reactors to review the revised draft Environmental Assessment and to provide comments. Comments postmarked by March 7, 1994, will receive full consideration in the decisionmaking process. Comments postmarked after that date will be considered to the extent practicable.

Issued at Washington, DC, this February 4, 1994.

Tara O'Toole,

Assistant Secretary, Environment, Safety and Health.

[FR Doc. 94-3096 Filed 2-8-94; 8:45 am]

BILLING CODE 6450-01-P

Financial Assistance: State of Idaho, Grant

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice of intent.

SUMMARY: The U.S. Department of Energy, Idaho Operations Office, announces that pursuant to the DOE Financial Assistance Rules 10 CFR 600.7, it intends to award a new start Grant Number DE-FG07-94ID13290 to the State of Idaho. The proposed grant will fund new business development activities by the State of Idaho. The Federal Domestic Catalog Number is 81.104.

FOR FURTHER INFORMATION CONTACT: Ginger L. Sandwina, U.S. Department of Energy, Idaho Operations Office, 785 DOE Place, MS 1221, Idaho Falls, Idaho 83401-1562, (208) 526-8698.

SUPPLEMENTARY INFORMATION: The statutory authorities for the proposed award are 42 U.S.C. 2011 *et seq.*, Atomic Energy Act of 1954 as amended and Public Law 95-91, Department of Energy Organization Act. The proposed award meets the criteria for "non-competitive" financial assistance as set forth in 10 CFR 600.7(b)(2)(i)(c). The applicant represents a unit of government and the activity to be supported is related to performance of a governmental function within the subject jurisdiction, thereby precluding DOE provision of support to another entity. The award of this grant was authorized by the Secretary in the signing of the Settlement Agreement to end the ongoing litigation over the acceptance and storage of spend nuclear fuel at the INEL. The grant provided funding to the State of Idaho to support regional economic development, such as technology transfer, worker training and enhanced training, and local business development. The grant will cover these activities for an indetermined period and will be funded at a level of $500,000 for the initial period and in such amounts as are agreeable to the State and DOE thereafter.

Issued January 26, 1994.

David W. Newnam,

Acting Director, Procurement Services Division.

[FR Doc. 94-2965 Filed 2-8-94; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. ER94-125-000, et al.]

Western Resources, Inc., et al.; Electric Rate and Corporate Regulation Filings

February 1, 1994.

Take notice that the following filings have been made with the Commission:

1. Western Resources, Inc. Kansas Gas and Electric Company

[Docket No. ER94-125-000]

Take notice that on January 25, 1994, Western Resources, Inc. (WRI) tendered for filing an amendment to its November 4, 1993, filing in this docket. The filing provides supporting workpapers for the Interconnection Agreement between WRI and the Kansas City, Kansas, Board of Public Utilities (KCBPU).

Copies of the filing were served on the KCBPU and the Kansas Corporation Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

2. Portland General Electric Company

[Docket No. ER94-138-000]

Take notice that on December 27, 1993, Portland General Electric Company tendered for filing an amendment in the above-referenced docket.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

3. Western Resources, Inc.

[Docket No. ER94-194-000]

Take notice that on January 25, 1994, Western Resources, Inc. (WRI) tendered for filing an amendment to its November 30, 1993, filing in this docket. The filing provides workpapers which define and explain the formulae under which WRI calculates billings to the co-owners of the Jeffrey Energy Center for transmission and dispatch services.

Copies of the filing were served on Missouri Public Service, WestPlains Energy, UtiliCorp United Inc., and the Kansas Corporation Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

4. WestPlains Energy, a division of UtiliCorp United, Inc.

[Docket No. ER94-283-000]

Take notice that on January 13, 1994, WestPlains Energy, a division of UtiliCorp United, Inc. (WestPlains) tendered for filing a Certificate of Concurrence in the Western Systems Coordinating Council Agreement which was filed by PacifiCorp on December 17, 1993 in Docket No. ER94-283.

A copy of the filing was served on PacifiCorp, the Kansas Corporation Commission and the Public Utilities Commission of the State of Colorado.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

5. Oklahoma Gas and Electric Company

[Docket No. ER94-909-000]

Take notice that on January 18, 1994, Oklahoma Gas and Electric Company (OG&E) tendered for filing revised Electric Service Agreements for two of its wholesale municipal customers which are served under OG&E's WM-1 Firm Power Rate Schedule which is part of OG&E's FERC Electric Tariff 1st Revised Volume No. 1.

Copies of this filing have been sent to the affected customers, the Oklahoma Corporation Commission, and the Arkansas Public Service Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

6. Public Service Company of New Mexico

[Docket No. ER94-910-000]

Take notice that on January 18, 1994, Public Service Company of New Mexico (PNM) submitted for filing Modification 9 to the San Juan Project Operating Agreement (Operating Agreement). Under Modification 9 to the Operating Agreement, PNM and Tucson Electric Power Company (TEP) have made certain modifications to the allocation of expenses incurred in operating the San Juan Project to reflect the intended ownership sale of a portion of San Juan Unit 4 to Utah Associated Municipal Power Systems (UAMPS).

PNM requests an effective date for Modification 9 to coincide with the closing of the ownership sale from PNM to UAMPS, presently anticipated to be no later than June 1, 1994.

Copies of the filing have been served upon TEP, UAMPS and the New Mexico Public Utility Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

7. Portland General Electric Company

[Docket No. ER94-924-000]

Take notice that on January 24, 1994, Portland General Electric Company (PGE) tendered for filing an Operation and Maintenance Agreement (Agreement) Between Portland General Electric Company and Eugene Water and Electric Board, Regarding the Stone Creek Hydroelectric Project. PGE respectfully requests that, under the provisions of 18 CFR 35.11, the Commission grant waiver of the notice requirements of 18 CFR 35.3 to allow the Agreement to become effective as of January 24, 1994.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

8. Arizona Public Service Company

[Docket No. ER94-925-000]

Take notice that on January 24, 1994, Arizona Public Service Company (APS) tendered for filing Amendment No. 2 (Amendment) to Service Schedule Q of the Power Coordination Agreement Between APS and the Salt River Project Agricultural Improvement and Power District (SRP) (APS-FPC Rate Schedule No. 3).

The Amendment conforms the liability provisions of Service Schedule Q to the liability provisions of other Service Schedules of the Power Coordination Agreement. The Amendment does not provide for any changes to rates or charges under Service Schedule Q.

Copies of this filing have been served upon SRP and the Arizona Corporation Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

9. Idaho Power Company

[Docket No. ER94-926-000]

Take notice that on January 24, 1994, Idaho Power Company (IPC) tendered for filing a Service Agreement between Cowitz County Public Utility District and Idaho Power Company under Idaho Power's FERC Electric Tariff, Second Revised Volume No. 1 dated January 13, 1994.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

10. Consumers Power Company

[Docket No. ER94-929-000]

Take notice that on January 24, 1994, Consumers Power Company (Consumers) tendered for filing Amendment No. 1 to the Coordinated Operating Agreement between Consumers, the Michigan Public Power Agency and Wolverine Power Supply Cooperative, Inc. which became effective on August 1, 1992 and has been designated as Consumers Rate Schedule FERC No. 67.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

11. Consumers Power Company

[Docket No. ER94-930-000]

Take notice that on January 24, 1994, Consumers Power Company (Consumers) tendered for re-filing the Delhi Interconnection Facilities Agreement with the City of Lansing, and the Redwood, Alba, Hersey, Grand Traverse, Airport, Pere Marquette and Blendon Interconnection Facilities Agreements with Wolverine Power Supply Cooperative, Inc. All such re-filings are made to correct their inadvertent designation as terminated rate schedules in Docket No. ER92-753-000 by the Commission's order issued in September, 1992.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

12. PowerNet G.P.

[Docket No. ER94-931-000]

Take notice that on January 24, 1994, PowerNet G.P. (PowerNet), tendered for filing pursuant to Rule 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.207, a petition for waivers and blanket approvals under various regulations of the Commission, and an order accepting its Rate Schedule No. 1, to be effective on March 24, 1994.

PowerNet intends to engage in electric power and energy transactions as a marketer and a broker. In transactions where PowerNet purchases power, including capacity and related services from electric utilities, qualifying facilities and independent power producers, and resells such power to other purchasers, PowerNet will be functioning as a marketer. In PowerNet's marketing transactions, PowerNet proposes to charge rates mutually agreed upon by the parties. All sales will be at arms-length, and no sales will be to affiliated entities. In transactions where PowerNet does not take title to electric power and/or energy, PowerNet will be limited to the role of a broker and charge a fee for its services. PowerNet is not in the business of producing or transmitting electric power. PowerNet does not currently have or contemplate acquiring title to any electric power transmission facilities.

Rate Schedule No. 1 provides for the sale of energy and capacity at agreed prices. Rate Schedule No. 1 also provides that no sales may be made to affiliates.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

13. Central Maine Power Company

[Docket No. ER94-932-000]

Take notice that on January 25, 1994, Central Maine Power Company (CMP), tendered for filing the Service Agreement entered into with Maine Public Service Company pursuant to CMP's Power Sales Tariff.

CMP has served a copy of the filing on the affected customer and on the Maine Public Utilities Commission.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

14. Appalachian Power Company

[Docket No. ER94-933-000]

Take notice that on January 26, 1994, Appalachian Power Company (APCo), tendered for filing with the Commission a December 13, 1993 Addendum to the existing Electric Service Agreement between APCo and Elk Power Company (Elk Power), which increases APCo's maximum capacity commitment to Elk Power from 3,000 kW to 3,500 kW.

APCo proposes an effective date of April 1, 1994, and states that a copy of its filing was served on the affected customer and the Public Service Commission of West Virginia.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

15. UtiliCorp United Inc.

[Docket No. ES94-13-000]

Take notice that on January 21, 1994, UtiliCorp United Inc. (UtiliCorp) filed an application under § 204 of the Federal Power Act seeking authorization to issue corporate guaranties in support of Secured Debentures in an amount of up to and including $40 million (Canadian) to be issued in one or more series by West Kootenay Power, Lt. (WKP) at some time before December 31, 1995. Also, UtiliCorp requests exemption from the Commission's competitive bidding and negotiated placement regulations. WKP is a wholly-owned subsidiary of UtiliCorp British Columbia Ltd., which in turn is a wholly owned subsidiary of UtiliCorp.

Comment date: February 22, 1994, in accordance with Standard Paragraph E at the end of this notice.

16. New England Power Company

[Docket No. ER94-934-000]

Take notice that on January 26, 1994, New England Power Company (NEP), tendered for filing supplements to its service agreement with Central Vermont Public Service under NEP's FERC Electric Tariff, Original Volume No. 3.

Comment date: February 15, 1994, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94-2929 Filed 2-8-94; 8:45 am]

BILLING CODE 6717-01-P

Alaska Aquaculture, Inc.; Availability of Environmental Assessment

[Project No. 10773-011 Alaska]

February 3, 1994

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 FR 47910), the Office of Hydropower Licensing (OHL) has reviewed an application to amend the licenses for the Burnett River Hatchery Project. The amendment would change project features as follows: (1) Reroute the project's penstock, (2) change the elevation datum, (3) remove the existing powerhouse and build the authorized powerhouse at a different location, and (4) reduce the installed capacity from 330 to 280 kilowatts. This project is located on the Burnett River on Etolin Island along the southeast coast of Alaska. The staff of OHL's Division of Project Compliance and Administration prepared an Environmental Assessment (EA) for the application. In the EA, staff concludes that approval of the proposed amendment application would not constitute a major federal action significantly affecting the equality of the human environment.

Copies of the EA are available for review in the Reference and Information Center, room 3308, of the Commission's offices at 941 North Capitol Street NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 94-2896 Filed 2-8-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM94-2-31-001 and RP94-83-001]

Arkla Energy Resources Co.; Proposed Changes in FERC Gas Tariff

February 3, 1994.

Take notice that on January 27, 1994, Arkla Energy Resources Company (AER) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, with an effective date of January 1, 1994:

Second Revised Sheet No. 4
Second Revised Sheet No. 4.1
Second Revised Sheet No. 4.3

AER states that the revised tariff sheets are being filed in accordance with the conditions set forth in the Commission's letter order issued on January 12, 1994, in Docket Nos. TM94-2-31-000 and RP94-83-000.

AER states that copies of the filing have been mailed to each of AER's customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Commission's public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94-2900 Filed 2-8-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-174-000]

Great Lakes Gas Transmission Limited Partnership; Semi-Annual Transporter's Use Report

February 3, 1994.

Take notice that on January 31, 1994, Great Lakes Gas Transmission Limited Partnership (Great Lakes) filed with the Federal Energy Regulatory Commission its Semi-Annual Transporter's Use Report.

Great Lakes states that the purpose of its filing is to comply with Section 1(f) of Article VIII of Rate Schedule T-4 to its FERC Gas Tariff, Original Volume No. 2 and Section 4.3 of Rate Schedules FT and IT of its FERC Gas Tariff, Second Revised Volume No. 1. Great Lakes

further states that the above-described tariff provisions require Great Lakes to file, each January 31 and July 31, workpapers setting forth the calculations of the monthly Transporter's Use percentages applicable during each month of the immediately preceding six-month period.

Great Lakes states that a copy of its filing was posted and that copies thereof were served on each of its customers, the Public Service Commissions of the States of Minnesota, Wisconsin and Michigan, and on all remaining parties listed on the service list maintained by the Commission's Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Commission's public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94-2901 Filed 2-8-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-143-256]

Great Lakes Gas Transmission Limited Partnership; Revenue Sharing Report

February 3, 1994.

Take notice that on January 26, 1994, Great Lakes Gas Transmission Limited Partnership (Great Lakes) filed with the Federal Energy Regulatory Commission (Commission) its Interruptible/Overrun (I/O) Revenue Sharing Report in accordance with the Stipulation and Agreement (Settlement) filed on September 24, 1992, and approved by the Commission's February 3, 1993 order issued in Docket No. RP91-143-000, et al.

Great Lakes states that this report reflects application of the revenue sharing mechanism and remittances made to firm shippers for I/O revenue collected for the November 1, 1992 through October 31, 1993 period, in accordance with Article IV of the Settlement. Great Lakes further states that such remittances, totalling $2,782,188, were made to Great Lakes' firm shippers on December 28, 1993. The amounts remitted are subject to adjustment at a future date in accordance with Articles III and V of the Settlement because the ratemaking methodology resulting from the implementation of Opinion Nos. 367, 367-A, 368 and 368-A, is subject to judicial review and the outcome of the current proceeding before the Presiding Administrative Law Judge.

Great Lakes states that a copy of its report was sent to the Public Service Commissions of the States of Minnesota, Wisconsin and Michigan, and on all remaining parties listed on the service list maintained by the Commission's Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Commission's public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94-2903 Filed 2-8-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP92-184-007]

Texas Eastern Transmission Corp.; Amendment and Motion to Vacate

February 3, 1994.

Take notice that on January 27, 1994, Texas Eastern Transmission Corporation (Texas Eastern), P.O. Box 1642, Houston, Texas 77056-1642, filed in Docket No. CP92-184-007 pursuant to Section 7(c) to amend and to partially vacate the Commission's order issued July 16, 1993, in Docket Nos. CP92-184-000 *et al.* in order to modify the construction program associated with the Integrated Transportation Project (ITP) and to make corresponding adjustments to the approved initial ITP rates, all as more fully set forth in the application, which is on file and open to public inspection.

It is indicated that on July 16, 1993, the Commission issued an order approving construction and operation of incremental facilities on Texas Eastern's mainline system which would permit Texas Eastern to render part 284 transportation service for specific shippers. Texas Eastern explains that the facilities and associated services were designated as the Integrated Transportation Project (ITP). The order authorized discrete construction programs for 1993 and 1994, consistent with Texas Eastern's plan to implement the underlying transportation service in two stages: 111,000 Dekatherms per day (Dthd) to commence November 1, 1993, and the remaining 90,000 Dthd to commence November 1, 1994, for an aggregate ITP service level of 201,000 Dthd. Reflecting the staged construction approved for ITP facilities, the order also authorized an incremental rate with a built-in step-up, *i.e.*, an initial rate effective November 1, 1993, based on 1993 ITP construction, with a step-up effective November 1, 1994, incorporating 1994 ITP construction costs.

Texas Eastern states that because of the narrow window available for 1993 construction and changes in ITP customer requirements, it has been compelled to reschedule implementation of ITP service. As shown below, the adjustments include deferral to 1994 and 1995 of portions of the service originally scheduled to be initiated in 1993 and deferral until 1995 of some service originally scheduled for implementation in 1994. While there is some reallocation of ITP service among customers, there is no planned change in the ultimate total level of ITP service.

I. Timing of ITP Service Levels Underlying July 16, 1993 Order

ITP shipper	11/01/93 Dthd volumes	11/01/94 Dthd volumes	Total ITP service Dthd volumes
UGI	40,000	0	40,000
PSE&G	25,000	75,000	100,000
Delmarva	40,000	0	40,000
PGW	6,000	0	6,000

ITP shipper	11/01/93 Dthd volumes	11/01/94 Dthd volumes	Total ITP service Dthd volumes
Yankee	0	15,000	15,000
Total	111,000	90,164	201,000

II. Revised Allocations and Timing for ITP Implementation

ITP shipper	11/01/93 Dthd volumes	11/01/94 Dthd volumes	11/01/95 Dthd volumes	Cumulative Dthd volumes
UGI	20,000	10,000	10,000	40,000
PSE&G	13,000	47,000	50,000	110,000
Delmarva	0	20,000	10,000	30,000
PGW	0	6,000	0	6,000
Yankee	0	15,164	0	15,164
Total	33,000	98,164	70,000	201,164

Texas Eastern asserts that the ITP service modifications set forth above necessitate changes in the timing, configuration and extent of facility construction required to support ITP service as well as corresponding adjustments in the initial rates for ITP service. Based on a reevaluation of its ITP facility design analysis, Texas Eastern has determined that it no longer requires approximately 8.92 miles of authorized pipeline along with certain approved compressor modifications. In addition, Texas Eastern states that it will require a total of 11.02 miles of new pipeline which is not already authorized while deferring some of the remaining authorized facilities.,

In order to conform its facility and rate authorizations to the revised ITP service levels and implementation schedule, Texas Eastern requests the following specific authorizations:

(1) To defer construction of a portion of the authorized ITP facilities until 1995;

(2) To vacate certificate authorization as it relates to 8.92 miles of authorized pipeline;

(3) To construct, install, own, and operate an additional 11.02 miles of 36″ pipeline for 1995 ITP service; and

(4) To charge revised section 7(c) initial rates for 1994 ITP service and new initial rates for 1995 ITP service.

Texas Eastern states that it has certificate authority under the July 16, 1993, order to construct the authorized facilities necessary to provide 1994 ITP services. Texas Eastern requests authorization of the proposed additional facilities required for 1995 ITP service by September 1, 1994. Texas Eastern states that it will not install any of the proposed additional facilities or the authorized facilities no longer required until the requested authorizations are granted. Texas Eastern estimates that the capital cost of the proposed additional facilities in $13,966,000 and that the revised cost of all 1994 and 1995 ITP facilities in $100,724,000 and $91,987,000, respectively. Texas Eastern proposes the following revised initial rate for 1994 and new initial rate for 1995 ITP services.

Rate Per Dth	1994	1995
Demand Rate ...	$19.974	$21.078

Texas Eastern states that the subject amended application supersedes other pending ITP applications. Specifically, Texas Eastern states that it will withdraw its applications in Docket Nos. CP92–184–004 and CP94–5–000.

Any person desiring to be heard or to make any protest with reference to said amendment and motion to vacate should on or before February 24, 1994, file with the Federal Energy Regulatory Commission, Washington, DC 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. Any person who has heretofore filed need not file again.

Lois D. Cashell,

Secretary.

[FR Doc. 94–2902 Filed 2–8–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91–54–010]

Trunkline Gas Co.; Annual Reconciliation Report

February 3, 1994.

Take notice that on January 31, 1994, Trunkline Gas Company (Trunkline) tendered for filing working papers reflecting its second annual take-or-pay volumetric surcharge reconciliation.

Trunkline states that the information is submitted pursuant to Article II, Section 8 of the Stipulation and Agreement in the above-captioned proceeding which requires Trunkline to submit, on an annual basis, a report of the take-or-pay volumetric surcharge amounts collected from its customers.

Trunkline states that copies of this filing have been served on all participants in the proceeding and applicable state regulatory agencies.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the

Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–2897 Filed 2–8–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–122–002]

Trunkline LNG Co.; Annual Reconciliation Report

Federal 3, 1994.

Take notice that on January 31, 1994, Trunkline LNG Company (Trunkline LNG) tendered for filing working papers reflecting its first annual reconciliation report.

Trunkline LNG states that the information is submitted pursuant to Article VIII, section 4 of the Stipulation and Agreement in the above-captioned proceeding which requires Trunkline LNG to submit, on an annual basis, a report of the cost and revenues which result from the operation of the PLNG–2 tariff dated June 26, 1987, as amended December 1, 1989.

Trunkline LNG states that copies of this filing have been served on all participants in the proceeding and applicable state regulatory agencies.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–2898 Filed 2–8–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–48–004]

Williston Basin Interstate Pipeline Co.; Compliance Filing

February 3, 1994.

Take notice that on January 27, 1994, Williston Basin Interstate Pipeline Company (Williston Basin), submitted its Compliance Filing pursuant to the Commission's January 12, 1994, "Order Terminating Technical Conference Proceedings, Establishing Hearings, and Consolidating Proceedings."

Williston Basin states that in accordance with Ordering Paragraph (G) of the Commission's Order, a listing of the cash and non-cash payments made to Koch Hydrocarbon Company (Koch) and verification of payment of the settlement amount is contained in the filing. The nature of the non-cash payment is identified in the Appendices to the "Settlement and Release of Claims" dated August 11, 1993, which document was also included in the filing and is to be treated in a confidential manner pursuant to Section 388.112 of the Commission's Regulations. The relief obtained by Williston Basin in exchange for the settlement payment is delineated in the Settlement.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before February 10, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of the filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–2899 Filed 2–8–94; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPP–66188; FRL 4753–5]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn by May 10, 1994, orders will be issued cancelling all of these registrations.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location for commercial courier delivery and telephone number: Room 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5761.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provides that a pesticide registrant may, at any time, request that any of its pesticide registrations be cancelled. The Act further provides that EPA must publish a notice of receipt of any such request in the **Federal Register** before acting on the request.

II. Intent to Cancel

This notice announces receipt by the Agency of requests to cancel some 51 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and 24(c) number) in the following Table 1.

TABLE 1. — REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
000087–00008	Aerosect contains Pyrethrum	Mineral oil - includes paraffin oil from 063503 (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins
000239–00015	Flotox Garden Sulfur	Sulfur
000400–00389	Flowable 75	Aliphatic petroleum hydrocarbons
000400 AL–77–0007	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide

TABLE 1. — REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Product Name	Chemical Name
000400 GA–78–0003	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 GA–81–0021	Vitavax-4G	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 NC–77–0002	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 NM–81–0020	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 SC–77–0004	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 TX–80–0012	Vitavax-4G Granular Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000400 VA–77–0002	Vitavax Flowable Fungicide	5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanalide
000432–00642	Propoxur Transparent Emulsion Spray 0.5%	*o*-Isopropoxyphenyl methylcarbamate
000432–00643	Propoxur Transparent Emulsion Spray 1%	*o*-Isopropoxyphenyl methylcarbamate
000432–00644	Ultratec Insecticide with Propoxur Transparent Emulsion	*o*-Isopropoxyphenyl methylcarbamate
000432–00650	Propoxur Transparent Emulsion Pressurized Spray 1%	*o*-Isopropoxyphenyl methylcarbamate
000432–00696	Ultratec Insecticide with Propoxur	*o*-Isopropoxyphenyl methylcarbamate
000475–00293	Flying Insect Killer Pressurized Spray	2-Methyl-4-oxo-3-(2-propenyl)-2-cyclopenten-1-yl-*d*-trans-2,2-dimethyl- *N*-Octyl bicycloheptene dicarboximide Aliphatic petroleum hydrocarbons (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20%
000475–00319	CAI Dairy Spray	*N*-Octyl bicycloheptene dicarboximide Aliphatic petroleum hydrocarbons (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins
000475–00321	Indoor Fogger VIII	2-Methyl-4-oxo-3-(2-propenyl)-2-cyclopenten-1-yl-*d*-trans-2,2-dimethyl- Aliphatic petroleum hydrocarbons (3-Phenoxyphenyl)methyl *d*-cis and trans*2,2-dimethyl-3-(2-methylpropenyl)cyclopro
000475–00322	CAI Institutional Insect Killer	*N*-Octyl bicycloheptene dicarboximide Aliphatic petroleum hydrocarbons (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins
000538–00059	Quell Lawn Insect Control	*o*-Isopropoxyphenyl methylcarbamate
000707–00102	Dithane M-45 Concentrate Agricultural Fungicide	Zinc ion and manganese ethylenebisdithiocarbamate, coordination product
000802–00377	Lilly/Miller Alphaspra 800	Potassium 1-naphthaleneacetate
000802–00378	Miller's Alphaspra 200	Potassium 1-naphthaleneacetate
000802–00383	Lilly/Miller Holly Dip	Potassium 1-naphthaleneacetate
000875–00094	Wyandotte Multi-Chlor D Highly-Soluble Chlorine Sanitiz	Potassium dichloro-*s*-triazinetrione
000875–00098	Steri-Chlor D Highly-Soluble Chlorinated Sanitizer	Potassium dichloro-*s*-triazinetrione
000875–00149	Oxford 522	Sodium dichloro-*s*-triazinetrione
000875–00152	Oxford Chlor-Avail Powdered Chlorine Sanitizer	Sodium dichloroisocyanurate dihydrate
000875–00172	Oxford 1202	Sodium dichloroisocyanurate dihydrate
002935–00451	Grass & Weed Killer	Aliphatic petroleum hydrocarbons
003487–00022	Eagles-7 Spra-Kill with Baygon	*o*-Isopropoxyphenyl methylcarbamate 2,2-Dichlorovinyl dimethyl phosphate
004758–00045	VAPO Total Release Aerosol	*o*-Isopropoxyphenyl methylcarbamate 2,2-Dichlorovinyl dimethyl phosphate
004758–00087	Holiday Insect Bomb with Baygon	*o*-Isopropoxyphenyl methylcarbamate Aliphatic petroleum hydrocarbons
004758–00116	Holiday Automatic Indoor Fogger	*o*-Isopropoxyphenyl methylcarbamate *N*-Octyl bicycloheptene dicarboximide (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins 2,2-Dichlorovinyl dimethyl phosphate
004758–00139	Holiday Indoor Fogger	*o*-Isopropoxyphenyl methylcarbamate *N*-Octyl bicycloheptene dicarboximide

TABLE 1. — REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Product Name	Chemical Name
		(Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins 2,2-Dichlorovinyl dimethyl phosphate
005481–00349	Alco House and Kennel Fogger	*o*-Isopropoxyphenyl methylcarbamate 2,2-Dichlorovinyl dimethyl phosphate
008590–00184	Agway Malathion ULV Concentrate Insecticide	*O,O*-Dimethyl phosphorodithioate of diethyl mercaptosuccinate
010182–00153	Captan-Sulfur 10–50 Dust	Sulfur cis-*N*-Trichloromethylthio-4-cyclohexene-1,2-dicarboximide
010182–00313	Orthocide Sulfur 10–25 Dust	Sulfur cis-*N*-Trichloromethylthio-4-cyclohexene-1,2-dicarboximide
010182–00314	Orthocide Sulfur 10–50 Dust	Sulfur cis-*N*-Trichloromethylthio-4-cyclohexene-1,2-dicarboximide
010827–00033	Ind-Sol 80 Mosquito Larvacide	Aliphatic petroleum hydrocarbons
010882–00010	Chem-Cide Insect Spray	Aliphatic petroleum hydrocarbons (1-Cyclohexene-1,2-dicarboximido)methyl 2,2-dimethyl-3-(2-methylpropenyl)cycloprop (5-Benzyl-3-furyl)methyl 2,2-dimethyl-3-(2-methylpropenyl)cyclopropanecarboxylate
011715–00103	Better World Automatic Fogger	*o*-Isopropoxyphenyl methylcarbamate 2,2-Dichlorovinyl dimethyl phosphate
011715–00105	Speer Vapona with Baygon One-Shot Fogger	*o*-Isopropoxyphenyl methylcarbamate 2,2-Dichlorovinyl dimethyl phosphate
011715–00140	Fusillade Indoor Fogger (with Propoxur)	*o*-Isopropoxyphenyl methylcarbamate *N*-Octyl bicycloheptene dicarboximide (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins
017816–20003	Sodium Hypochlorite	Sodium hypochlorite
028293–00023	Unicorn Rid RTU	*O,O*-Diethyl *O*-(2-isopropyl-6-methyl-4-pyrimidinyl)phosphorothioate
037425–00005	Adams Anti-Crawl	*o*-Isopropoxyphenyl methylcarbamate *N*-Octyl bicycloheptene dicarboximide (Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20% Pyrethrins
052466–00014	Kennel Spray-TPC	Aromatic petroleum derivative solvent *O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate Aliphatic petroleum hydrocarbons
053719–00002	Bengal Flea Killer	2-Methyl-4-oxo-3-(2-propenyl)-2-cyclopenten-1-yl *d*-trans-2,2-dimethyl- *N*-Octyl bicycloheptene dicarboximide *O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate Aliphatic petroleum hydrocarbons

Unless a request is withdrawn by the registrant within 90 days of publication of this notice, orders will be issued cancelling all of these registrations. Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant directly during this 90–day period. The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA Company Number.

TABLE 2. — REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
000087	Pennsylvania Engineering Co, 1119–21 N. Howard St, Philadelphia, PA 19123.
000239	The Solaris Group, A Div of The Ag Div of Monsanto Co., Box 5008, San Ramon, CA 94583.
000400	Uniroyal Chemical Co Inc., 74 Amity Rd, Bethany, CT 06524.
000432	Roussel UCLAF Corp., 95 Chestnut Ridge Rd, Montvale, NJ 07645.
000475	Reckitt & Coleman Household Products, 1655 Valley Rd, Wayne, NJ 07474.
000538	O.M. Scott & Sons Co, 14111 Scottslawn Rd, Marysville, OH 43041.
000707	Rohm & Haas Co., Agri. Chemicals Registration & Regulator, Independence Mall W., Philadelphia, PA 19105.
000802	Chas H. Lilly Co., 7737 N.E. Killingsworth, Portland, OR 97218.

TABLE 2. — REGISTRANTS REQUESTING VOLUNTARY CANCELLATION—Continued

EPA Company No.	Company Name and Address
000875	Diversey Corp., 12025 Tech Center Dr., Livonia, MI 48150.
002935	Wilbur Ellis Co., 191 W. Shaw Ave., Fresno, CA 93704.
003487	Bacon Products Co. Inc., Box 22187, Chattanooga, TN 37422.
004758	Pet Chemicals, 4242 BF Goodrich Blvd., Box 18993, Memphis, TN 38181.
005481	Amvac Chemical Corp., 4100 E. Washington Blvd, Los Angeles, CA 90023.
008590	Agway Inc., c/o Universal Cooperatives Inc., Box 460, Minneapolis, MN 55440.
010182	Zeneca Inc., Zeneca Ag Products, New Murphy Rd. & Concord Pike, Box 751, Wilmington, DE 19897.
010827	Chemical Specialties Inc., P. O. Box 312, San Marcos, TX 78666.
010882	Chem-Power, 15 Wing Drive, Cedar Knolls, NJ 07927.
011715	Speer Products Inc., Box 18993, Memphis, TN 38181.
017816	Gully Pool Service & Supply Inc., 2757 Fowler St., Ft Myers, FL 33901.
028293	Unicorn Labs & Phaeton Corp., 1000 118th Ave. N, St. Petersburg, FL 33716.
037425	Smithkline Beecham Animal Health, 1600 Paoli Pike, West Chester, PA 19380.
052466	Horse Health Products, Inc., c/o Pitman-Moore Inc., 1201 Douglas Ave., Kansas City, KS 66103.
053719	Bengal Chemical, Inc., P.O. Box 40487, Baton Rouge, LA 70835.

III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before May 10, 1994. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1–year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** No. 123, Vol. 56, dated June 26, 1991. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: January 26, 1994.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 94–2972 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[PF–589; FRL–4753–1]

Nor-Am Chemical Co.; Notice of Filing of Request for a Permanent Tolerance for Clofentezine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received from Nor-Am Chemical Co. a request for permanent tolerances for clofentezine in or on peaches, nectarines, almonds, walnuts, apricots, and cherries.

ADDRESSES: By mail submit written comments, identified by the document control number [PF-589], to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Information submitted and any comment(s) concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed test and any written comments will be available

for public inspection in Rm. 1128 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis Edwards, Jr., Product Manager (PM-19), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 201, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-305-6386.

SUPPLEMENTARY INFORMATION: EPA has received from Nor-Am Chemical Co., Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19808, a request to make the tolerances permanent for residues of clofentezine (3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on peaches, nectarines, walnuts, almonds, apricots, and cherries (reference: 40 CFR 180.446).

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Authority: 21 U.S.C. 346a and 371.

Dated: January 14, 1994.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 94–2443 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPP–30281A]; FRL–4757–2]

Dow Chemical Co.; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications submitted by Dow Chemical Co., to register the pesticide products Antimicrobial DTEA 15% and Antimicrobial DTEA Technical containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Ruth Douglas, Product Manager (PM) 32, Registration Division (7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 278, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703–305–7964).

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of May 27, 1987 (52 FR 19768), which announced that Dow Chemical Company, P.O. 1706, Midland, MI 48674, had submitted applications to register the pesticide products Antimicrobial DTEA 15% and Antimicrobial DTEA Technical (EPA File Symbols 464–ARO and 464–AEN), containing the active ingredients 2-(decylthio)ethaneamine, hydrochloride salt and 2-(decylthio)ethaneamine at 15 and 99.8 percent respectively, active ingredients not included in any previously registered products.

The applications were approved on October 20, 1993, as Antimicrobial DTEA 15% to control bacterial, fungal, and algal slimes in recirculating cooling water systems (EPA Registration Number 464–619) and Antimicrobial DTEA Technical for manufacturing use only (EPA Registration Number 464–620).

The Agency has considered all required data on risks associated with the proposed use of 2-(decylthio)ethaneamine, hydrochloride salt and 2-(decylthio)ethaneamine, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health safety determinations which show that use of 2-(decylthio)ethaneamine, hydrochloride salt and 2-(decylthio)ethaneamine when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on these registrations is contained in a Chemical Fact Sheet on 2-(decylthio)ethaneamine, hydrochloride salt and 2-(decylthio)ethaneamine.

A copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Product Manager. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 401 M St., SW., Washington, D.C. 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: January 26, 1994.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 94–2698 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[PP 2G4038/T655; FRL 4753–8]

Fenbuconazole; Extension of a Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has extended a temporary tolerance for the combined residues of the fungicide fenbuconazole and its metabolites in or on the raw agricultural commodity pecans at 0.1 part per million (ppm).

DATES: This temporary tolerance expires January 4, 1995.

FOR FURTHER INFORMATION CONTACT By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5540.

SUPPLEMENTARY INFORMATION: EPA issued a notice, which was published in the **Federal Register** of February 24, 1993 (58 FR 11233), announcing the establishment of a temporary tolerance for the combined residues of the fungicide fenbuconazole [alpha-(2-[4-chlorophenyl]-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile]; RH-9129 and RH-9130, the diastereomeric lactone metabolites of fenbuconazole [5-(4-chlorophenyl)-

dihydro-3-phenyl-3-(methyl-1*H*-1,2,4-triazole-1-yl)-2-3*H*-furanone]; and RH-6467, the benzylic-ketone metabolite of fenbuconazole [4-(4-chlorophenyl)-2-(methyl -1*H*-1,2,4-triazole)-4-oxo-2-phenyl butanenitrile] in or on the raw agricultural commodity pecans at 0.1 part per million (ppm). This tolerance was issued in response to pesticide petition (PP) 2G4038, submitted by Rohm and Haas Co., Independence Mall West, Philadelphia, PA 19105.

This temporary tolerance has been extended to permit the continued marketing of the raw agricultural commodity named above when treated in accordance with the provisions of experimental use permit 707-EUP-125, which is being extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that the extension of this temporary tolerance will protect the public health. Therefore, the temporary tolerance has been extended on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. Rohm and Haas Co., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This tolerance expires January 4, 1995. Residues not in excess of this amount remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 26, 1994.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 94–2703 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[PF–588; FRL–4749–6]

Pesticide Tolerance Petitions; Amendments and a Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces amendments to pesticide petitions (PP) and to a food and feed additive petition (FAP) proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities. It also announces one withdrawn petition.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, contact the PM named in each petition at the following office location/telephone number:

Product Manager	Office location/telephone number	Address
Cynthia Giles-Parker (PM 22)	Rm. 229, CM #2, 703-305-5540	1921 Jefferson Davis Hwy., Arlington, VA.
Joanne Miller (PM 23)	Rm. 237, CM #2, 703-305-7830	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions and food/feed additive petitions as follows proposing the amendment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities. EPA has also received one notice of withdrawal of a petition without prejudice to future filing.

Amended Petitions

1. *PP 4F3096.* In a notice published in the **Federal Register** of August 8, 1984 (49 FR 31756), it was announced that Janssen Pharmacuetica, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560-0200, had submitted PP 4F3096 proposing that 40 CFR 180.413 be amended to establish a tolerance for imazalil (1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole) and its metabolite 1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol, in or on pome fruits at 7.0 parts per million. Janssen Pharmaceutica has submitted an amendment to the petition, to limit the proposed tolerance to pears at 10.0 ppm.

The proposed analytical method for determining residues is gas chromatography. (PM 22)

2. *PP 8F3622.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189 (formerly Dow Chemical, U.S.A.) has submitted an amendment to PP 8F3622 that proposes amending 40 CFR 180.431 by establishing a regulation permitting residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on the following commodities: corn, filed, grain at 1.0 part per million (ppm); corn, field, forage at 3.0 ppm; and corn, field, fodder at 10.0 ppm. Notice of the petition appeared initially in the **Federal Register** of May 25, 1988 (53 FR 18896), and was amended in the **Federal Register** of April 18, 1990 (55 FR 14466) and the **Federal Register** of May 27, 1992 (57 FR 22232). The proposed analytical method is gas chromatography. (PM 23)

3. *FAP 0H5597.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189 (formerly Dow Chemical, U.S.A.) has submitted an amendment to FAP 0H5597 that proposes amending 40 CFR 185.1100 and 40 CFR 186.1100 by establishing regulations permitting residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on field corn milling fractions at 1.5 parts per million (ppm). Previous notice of this petition appeared in the **Federal Register** of April 18, 1990 (55 FR 14466), proposing to establish a tolerance of 0.6 ppm for the herbicide clopyralid in or on the commodity corn, field, milling fractions, and in the **Federal Register** of May 27, 1992 (57 FR 22232), amending the petition to propose to increase the tolerance from 0.6 ppm to 1.2 ppm. (PM 23).

Withdrawn Petition

4. *FAP 4H5434.* In a notice published in the **Federal Register** of August 8, 1984 (49 FR 31756), it was announced that Janssen Pharmacuetica, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560-0200, had submitted FAP 4H5434 proposing that 21 CFR 561.429 (redesignated as 40 CFR 186.3650 in the **Federal Register** of June 29, 1988 (53 FR 24668)) be amended to establish a tolerance for imazalil (1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole) and its metabolite 1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol, in or on apple pomace (wet/dry) (postharvest) at 30.0 parts per million. Janssen Pharmaceutica has requested that the petition be withdrawn without prejudice to future filing. (PM 22)

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Authority: 7 U.S.C. 136a.

Dated: January 24, 1993.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 94–2444; Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPP–34051; FRL 4753–4]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request for amendment by registrants to delete uses in certain pesticide registrations.

DATES: Unless a request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on May 10, 1994.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery and telephone number: Room 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5761.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

II. Intent to Delete Uses

This notice announces receipt by the Agency of applications from registrants to delete uses in the 14 pesticide registrations listed in the following Table 1. These registrations are listed by registration number, product names and the specific uses deleted. Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before May 10, 1994, to discuss withdrawal of the applications for amendment. This 90–day period will also permit interested members of the public to intercede with registrants prior to the Agency approval of the deletion.

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Registration No.	Product Name	Delete From Label
000239–00739	Ortho Malathion 50 Insect Spray	Dairy barns, chicken houses, stables, dog kennels, asparagus, dogs & cats, animal quarters, beef cattle, chickens, ducks, geese, turkeys, poultry houses, roost paint
000407–00407	6% Malathion Grain Dust	Rice, field and garden seeds, grain sorghum
000407–00434	Malathion Spray	Cotton, soybeans, sugar beets, grain storage, livestock pest control (hogs, sheep, goats, horses, beef, non-milking cattle, poultry, domestic pets), domestic animal housing, dairy barns, loading sheds, lactating young animals, peanuts, safflower, buildings, meat processing plants, homes, food processing plants
000572–00062	Rockland Fruit Tree Spray	Use of wettable powder formulation on peaches and cherries
000572–00186	Rockland General Purpose Spray	Use of wettable powder formulation on peaches and cherries
005905–00443	Malathion 8 Insecticide	Cranberries, carrots, plums, prunes, apples, tobacco, melons pumpkins, soil incorporated treatment for strawberries
011037–00011	Hacienda Malathion 50%	Plums, apples, pears, melons

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

EPA Registration No.	Product Name	Delete From Label
035915–00010	Oxon Italia Simazine Technical	Artichokes, asparagus, sugarcane, swimming pools, farm ponds, cooling towers, aguaria, non-cropland (industrial sites, highways, railroads, rights-of-way)
035915–00011	Sim-Trol 4L	Asparagus, artichokes, sugarcane, non-cropland (industrial sites, highways, rights-of-way)
035915–00012	Sim-Trol 9DF	Asparagus, artichokes, sugarcane, non-cropland (industrial sites, highways, rights-of-way)
035915–00013	Simazine 80WP	Asparagus, artichokes, non-cropland (industrial sites, highways, rights-of-way)
062719–00107	Spike 80W	Use on ditchbanks
062719–00121	Spike 20P	Use on ditchbanks
062719–00122	Spike 40P	Use on ditchbanks

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS.

Company No.	Company Name and Address
000239	Chevron Chemical Company, Ortho Consumer Products Division, 940 Hensley St., Richmond, CA 94804.
000407	Imperial, Inc., P.O. Box 98, Shenandoah, IA 51601.
000572	Rockland Corporation, P.O. Box 809, West Caldwell, NJ 07006.
005905	Helena Chemical Company, 6075 Poplar Ave., Suite 500, Memphis, TN 38119.
011037	Garden Valley Fertilizer Co., Hacienda Enterprises, 565 Charles St., San Jose, CA 95112.
035915	Oxon Italia S.P.A., c/o Pesticide Regulatory Services, 3703 Sedgefield Drive, Valdosta, GA 31602.
062719	DowElanco, 9002 Purdue Road, Indianapolis, IN 46268.

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: January 26, 1994.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 94–2971 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPP–180920; FRL 4757–7]

Receipt of Application for Emergency Exemption to use Oxytetracycline; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Washington State Department of Agriculture (hereafter referred to as the "Applicant") for use of the pesticide oxytetracycline (CAS 79–57–2) to control fire blight on up to 3000 acres of Fuji, Braeburn, Gala and Jonagold apples in Benton, Chelan, Douglas, Grant, Okanogan and Yakima counties. In accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before February 24, 1994.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP–180920," should be submitted by mail to: Public Response and Human Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. In person, bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Margarita Collantes, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: 6th Floor, Crystal Station I, 2800 Jefferson Davis Highway, Arlington, VA 22202 (703–308–8347).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at her discretion, exempt a State agency from any registration provision of FIFRA if she determines that emergency

conditions exist which require such exemption.

The Applicant has requested the Administrator to issue a specific exemption for the use of the bactericide, oxytetracycline, available as Terramycin (EPA Reg. No. 618–104) from Merck and Company, Incorporated, to control fire blight, caused by *E. amylovora*, on up to 3000 acres of Fuji, Braeburn, Gala, and Jonagold apples in Benton, Chelan, Douglas, Grant, Okanogan, and Yakima counties. Information in accordance with 40 CFR part 166 was submitted as part of this request.

According to the Applicant, fire blight is not new to "Red Delicious" apples in Washington. However, due to a major change in the apple cultivar composition, approximately 3,000 acres of new apple cultivars have become extremely susceptible to blight. The Applicant claims that none of the registered pesticides is effective against this disease and that, without an effective control, growers will incur a significant economic loss during the 1994 growing season.

Under the proposed exemption a maximum of 24,000 lbs of formulated product could be used (3,000 acres × 1 lb. per acre × 8 applications = 24,000 lbs) if blight-conducive weather occurred throughout the bloom period on all 3,000 acres. A 60–day preharvest interval will be observed. In addition, livestock will not feed on the crop by-product or graze on the treated orchards. Applications would be made between March 15, 1994, and August 1, 1994.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require that the Agency publish notice of receipt in the **Federal Register** and solicit public comment on an application for a specific exemption if an emergency exemption has been requested or granted for that use in any 3 previous years, and a complete application for registration of that use has not been submitted to the Agency [40 CFR 166.24 (a)(6)]. Exemptions for the use of oxytetracycline on apples have been requested and granted for the past 3 years, and an application for registration of this use has not been submitted to the Agency.

Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above. The Agency will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Washington State Department of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests, Crisis exemptions.

Dated: January 27, 1994.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 94–2702 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPP–180919; FRL 4757–6]

Receipt of Application for Emergency Exemptions to use Propazine; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Oklahoma Department of Agriculture (hereafter referred to as the "Applicant") to use the pesticide propazine (CAS 139–40–2) to treat up to 280,000 acres of sorghum to control various weeds. The Applicant proposes the use of a new (unregistered) chemical; therefore, in accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before February 24, 1994.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP–180919," should be submitted by mail to: Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in Rm. 1132, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location and telephone number: Floor 6, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, (703–308–8791).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at her discretion, exempt a state agency from any registration provision of FIFRA if she determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue a specific exemption for the use of propazine on sorghum to control pigweed. Information in accordance with 40 CFR part 166 was submitted as part of this request.

Sorghum is grown as a rotational crop with cotton and wheat, in order to comply with the soil conservation requirements. Propazine, which was formerly registered for use on sorghum, was voluntarily canceled by the former Registrant, who did not wish to support its re-registration. The Applicant claims that this has left many sorghum growers with no pre-emergent herbicides that will adequately control certain broadleaf weeds, especially pigweed. Until recently, growers have been using up existing stocks of propazine. The Applicant states that other available herbicides have serious limitations on their use, making them unsuitable for control of pigweed in sorghum. Although the original Registrant of propazine has decided not to support this chemical through re-registration, another company has committed to support the data requirements for this use. Propazine was once registered for this use, but has now been voluntarily canceled and is therefore considered to be a new chemical.

The Applicant states that, because growers have been using existing stocks of propazine since the time of its voluntary cancellation, yields have not shown a decrease. However, this is the first season where most growers have depleted their stocks of propazine, and the Applicant claims that significant economic losses will occur without the availability of propazine.

The Applicant proposes to apply propazine at a maximum rate of 1.2 lbs. active ingredient (a.i.), (2.4 pts. of product) per acre, by ground or air, with a maximum of one application per crop growing season. Therefore, use under this exemption could potentially

amount to a maximum total of 336,000 lbs. of active ingredient (84,000 gal. of product). This is the first time that Oklahoma has applied for this use of propazine on sorghum.

Requests for exemptions were also received earlier this year from New Mexico and Texas, and Texas was issued an exemption for this use for last growing season. This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient not contained in any currently registered pesticide). Such notice provides for opportunity for public comment on the application. Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above.

The Agency, accordingly, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Oklahoma Department of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests, Crisis exemptions.

Dated: January 26, 1994.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 94–2700 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPP–30358; FRL–4754–3]

SKW Trostberg AG.; Approval of a Pesticide Product Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application submitted by SKW Trostberg AG, to conditionally register the pesticide product Dormex containing a new active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703–305–7850).

SUPPLEMENTARY INFORMATION: EPA received an application from SKW Trostberg AG, Postfach 1262, D–8223 Trostberg, Federal Republic of Germany, c/o Siemer and Associates, Inc., 4672 W. Jennifer, Suite 103, Fresno, CA 93722, dated May 14, 1990, to conditionally register the pesticide product Dormex, a plant growth regulator containing the active ingredient hydrogen cyanamide at 50 percent, an active ingredient not included in any previously registered product. However, since the notice of receipt of application to register this product was not published in the **Federal Register**, as required by section 3(c)(4) of FIFRA, as amended, interested parties may submit written comments within 30 days from the date of publication of this notice.

The application was approved on November 29, 1993, as Dormex (EPA Registration Number 54555–2) for restricted use on desert grown grapes.

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain information is lacking because a period reasonably sufficient for generation of the information has not elapsed since the Administrator first imposed the requirement, on condition that such information is received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects on the environment; and that use of the pesticide is in the public interest.

The Agency has considered the available data on the risks associated with the proposed use of hydrogen cyanamide and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of hydrogen cyanamide during the period of conditional registration is not expected to cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A), provided that the registrant submits to the EPA an acceptable worker training program which will mitigate worker exposure, by teaching the use of protective personal equipment and engineering controls needed to minimize exposure to hydrogen cyanamide. This conditional registration expires on November 24, 1994.

Consistent with section 3(c)(7)(C), the Agency has determined that this conditional registration is in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

More detailed information on this conditional registration of hydrogen cyanamide is contained in an EPA Pesticide Fact Sheet. A copy of the fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Product Manager. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: January 26, 1994.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 94–2704 Filed 2–8–94; 8:45 am]

BILLING CODE 6560–50–F

[OPPTS-42118A; FRL-4754-8]

Testing Consent Order For Sodium Cyanide; Request To Delete Mallard Reproductive Study.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for Comment.

SUMMARY: This notice invites public comment on the request of chemical substance manufacturers to delete as technically infeasible the mallard reproductive study on sodium cyanide currently required under the testing consent order for sodium cyanide (OPTS-42118).

DATES: Written comments must be submitted on or before March 11, 1994.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA's procedures for requiring the testing of chemical substances under section 4 of the Toxic Substances Control Act (TSCA) include the use of enforceable consent orders. Chemical substance manufacturers of sodium cyanide agreed to a testing program which included a mallard reproduction study (56 FR 6544, December 17, 1991). In a letter dated May 17, 1993 (received July 21, 1993) DuPont Chemicals, requested on behalf of the companies subject to the consent order (Cyanco, Degussa Corporation, E.I. Du Pont de Nemours Company, FMC Corporation and ICI (Americas) Inc.), that the requirement to perform a mallard reproduction study on sodium cyanide be deleted because the completion of this requirement is not technically feasible.

Wildlife International Ltd.(contract laboratory for DuPont), reported to DuPont that the white bobtail quail and mallard LC50-studies with sodium cyanide using waterborne exposure were among the most difficult studies to conduct. From the LC50 study it was learned that mallards exposed to concentrations as low as 100 mg/L of the test substance in water limited their consumption of water to half or less than that of the control birds. That is, they effectively limited their water consumption to the point where many of the deaths may have been related to dehydration. Thus, concentration levels low enough to determine true reproductive effects may not be relevant to the real world dietary exposure situation because the birds will no longer ingest water with even low concentration levels.

DuPont claims, and EPA preliminarily agrees, that completion of the study using the required test standard is not technically feasible. Under 40 CFR 790.68(b)(2)(iii), EPA may make changes that affect the scope of the consent order, but EPA must provide notice and an opportunity for comment before such changes become effective. Furthermore, if comments indicate that no consensus exists among the interested parties on making the change, the issue must be negotiated before any such adjustment can become effective. Interested parties therefore, have 30 days from publication of this notice to provide written comments on the elimination of the mallard reproductive study from the testing consent order on sodium cyanide. If comments indicate that differences of opinion exist regarding this change, EPA will conduct negotiations following the procedures specified in 40 CFR 790.22(b). If the 30 day deadline passes and no adverse public comments have been received, EPA will grant the proposed modification without further notice.

Authority: 15 U.S.C. 2603.

Dated: February 2, 1994.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 94-2973 Filed 2-8-94; 8:45 am]

BILLING CODE 6560-50-F

[FRL-4836-2]

Notice of Proposed Assessment of Clean Water Act Class II Administrative Penalty to Pinewood Sewer Company, and Opportunity to Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposal of a Clean Water Act Class II administrative penalty and notice of public comment period.

SUMMARY: Pursuant to 33 U.S.C. section 1319(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue such orders after the commencement of either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessment pursuant to 33 U.S.C. section 1319(g)(4)(a).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation and Suspension of Permits, 40 CFR part 22. The procedures through which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the procedures by which a Respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty days after publication of this notice.

On the date identified below, EPA commenced the following Class II proceeding for the assessment of penalties:

In the Matter of Pinewood Sewer Company, Inc, (Pinewood Wastewater Treatment Plant), Munds Park, Coconino County, Arizona, Docket No. CWA IX-FY94-12; filed on January 27, 1994 with Steven Armsey, Regional Hearing Clerk, U.S. EPA, Region 9, 75 Hawthorne Street, San Francisco, California 94105, (415) 744-1389; proposed penalty of $60,000, for discharges of pollutants without an NPDES permit.

Concurrently with the commencement of this Class II proceeding, EPA and Pinewood Sewer Company, Inc. entered into a Consent Agreement to resolve this matter for the sum of $60,000.

FOR FURTHER INFORMATION CONTACT: Persons wishing to receive a copy of EPA's Consolidated Rules, review the complaint or other documents filed in this proceeding, comment upon a proposed assessment, or otherwise participate in the proceeding should contact the Regional Hearing Clerk identified above. The administrative record for this proceeding is located in the EPA Regional Office identified above, and the file will be open for public inspection during normal business hours. All information submitted by the Respondent is available as part of the administrative record, subject to provisions of law restricting public disclosure of confidential information.

Dated: January 27, 1994.

Harry Seraydarian,

Director, Water Management Division.

[FR Doc. 94-2967 Filed 2-8-94; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

February 3, 1994.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and

clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street NW., suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission (202) 632–0276. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–3561.

Please note: The Commission has requested expedited OMB review of this item by February 18, 1994, under the provisions of 5 CFR 1320.18.

OMB Number: None

Title: FCC Remittance Advice and Continuation Sheet

Action: New collection

Form Numbers: FCC Form 159 and FCC form 159–S

Respondents: Individuals or households and businesses or other for-profit (including small businesses)

Frequency of Response: On occasion reporting requirement

Estimated Annual Burden: 210,000 responses; .25 hours average burden per response; 52,500 hours total annual burden

Needs and Uses: The Commission has implemented provisions contained in Section 6003(a) of the Omnibus Budget Reconciliation Act of 1993, (Pub. L. 103–66 102–121) approved 8/10/93, which adds a new Section 9 to the Communications Act. This new Section 9 authorizes the Commission to assess and collect annual regulatory fees to recover costs incurred in carrying out its enforcement activities, policy and rulemaking activities, user information services, and international activities. A lockbox bank will be used to collect the regulatory fees. The FCC Forms 159 and 159–S will be used to collect required financial data which will be key entered into the FCC's database. The data captured from the forms will be used for administrative purposes including issuing refunds, responding to public and operational inquiries, monitoring installment payments, and ensuring full payment by all required to pay. The forms will be used primarily for remitting "Section 9" regulatory fees. The forms will be used to enhance the collection of fines or debts due the FCC. The form will also be used by current filers of FCC Form 155 filing multiple applications in the same lockbox, and applicants paying by credit card. In the later two cases, only the FCC Form 159 would be filed out so as not to collect duplicative information. Without this information the Commission's ability to verify proper and full payment would be significantly reduced. The information will establish an audit trail of each transaction (which we currently do not have) so that we can be in full compliance with established financial procedures.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

BILLING CODE 6712–01–M

FEDERAL COMMUNICATIONS COMMISSION

FCC REMITTANCE ADVICE

Approved by OMB 3060- Expires

(Read Instructions carefully BEFORE proceeding.)

See public burden estimate on reverse.

SPECIAL USE

SPECIAL USE

PAGE NO. 1 OF _____

PAYOR INFORMATION

(1) FCC ACCOUNT NUMBER | Did you have a number prior to this? If YES, enter it. | (2) TOTAL AMOUNT PAID (dollars and cents) $.

(3) PAYOR NAME (If paying by credit card, enter name **exactly** as it appears on your card)

(4) STREET ADDRESS LINE NO. 1

(5) STREET ADDRESS LINE NO. 2

(6) CITY | (7) STATE | (8) ZIP CODE

(9) DAYTIME TELEPHONE NUMBER (Include area code) | (10) COUNTRY CODE (if not U.S.A.)

ITEM #1 INFORMATION

(11A) NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR | FCC USE ONLY

(12A) FCC CALL SIGN/OTHER ID | (13A) ZIP CODE | (14A) PAYMENT TYPE CODE | (15A) QUANTITY | (16A) FEE DUE $

(17A) FCC CODE 1 | (18A) FCC CODE 2

(19A) ADDRESS LINE NO. 1 | (20A) ADDRESS LINE NO. 2 | (21A) CITY/STATE OR COUNTRY CODE

ITEM #2 INFORMATION

(11B) NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR | FCC USE ONLY

(12B) FCC CALL SIGN/OTHER ID | (13B) ZIP CODE | (14B) PAYMENT TYPE CODE | (15B) QUANTITY | (16B) FEE DUE $

(17B) FCC CODE 1 | (18B) FCC CODE 2

(19B) ADDRESS LINE NO. 1 | (20B) ADDRESS LINE NO. 2 | (21B) CITY/STATE OR COUNTRY CODE

CREDIT CARD PAYMENT INFORMATION

(22) ☐ Mastercard ☐ Visa

MASTERCARD/VISA ACCOUNT NUMBER:

EXPIRATION DATE: Month Year

(23) **I hereby authorize the FCC to charge my VISA or Mastercard for the service(s)/ authorization(s) herein described.**

AUTHORIZED SIGNATURE DATE

FCC FORM 159

Public recordkeeping burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to the Federal Communications Commission, Records Management Division, AMD-PRS, Washington, DC 20554, and to the Office of Management and Budget, Paperwork Reduction Project (3060-), Washington, DC 20503.

FCC FORM 159

FEDERAL COMMUNICATIONS COMMISSION

FCC SUPPLEMENTAL REMITTANCE ADVICE (CONTINUATION SHEET)

Approved by OMB
3060-
Expires

PAGE NO._____ OF _____

ITEM #___ INFORMATION

NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR				FCC USE ONLY
FCC CALL SIGN/OTHER ID	ZIP CODE	PAYMENT TYPE CODE	QUANTITY	FEE DUE $
FCC CODE 1		FCC CODE 2		
ADDRESS LINE NO. 1	ADDRESS LINE NO. 2		CITY/STATE OR COUNTRY CODE	

ITEM #___ INFORMATION

NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR				FCC USE ONLY
FCC CALL SIGN/OTHER ID	ZIP CODE	PAYMENT TYPE CODE	QUANTITY	FEE DUE $
FCC CODE 1		FCC CODE 2		
ADDRESS LINE NO. 1	ADDRESS LINE NO. 2		CITY/STATE OR COUNTRY CODE	

ITEM #___ INFORMATION

NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR				FCC USE ONLY
FCC CALL SIGN/OTHER ID	ZIP CODE	PAYMENT TYPE CODE	QUANTITY	FEE DUE $
FCC CODE 1		FCC CODE 2		
ADDRESS LINE NO. 1	ADDRESS LINE NO. 2		CITY/STATE OR COUNTRY CODE	

ITEM #___ INFORMATION

NAME OF APPLICANT, LICENSEE, REGULATEE, OR DEBTOR				FCC USE ONLY
FCC CALL SIGN/OTHER ID	ZIP CODE	PAYMENT TYPE CODE	QUANTITY	FEE DUE $
FCC CODE 1		FCC CODE 2		
ADDRESS LINE NO. 1	ADDRESS LINE NO. 2		CITY/STATE OR COUNTRY CODE	

FCC FORM 159-S

Federal Communications Commission Instructions for Using FCC Form 159 (Remittance Advice) and FCC Form 159–S (Supplemental Remittance Advice)

FCC Form 159 and FCC Form 159–S must be used for remitting any type of fee, fine or debt due the FCC. The form will also be used for applicants filing multiple applications in the same lockbox, and applicants paying by credit card. The following information is provided to assist you in completing FCC Forms 159 & 159–S.

(1) FCC Account No.—This is a personal identification number that must consist of ten digits. You have three options to create this FCC Account Number. Option 1—You may use your taxpayer identification number (TIN) with a prefix of "E" (for employer) (i.e., E123456789). Option 2—Your Social Security Number (SSN) with a prefix of "T" (for taxpayer) (i.e., T123456789). Option 3—You may use your ten-digit telephone number (i.e., 5551234567). Your same number must be used each time you are paying for single or multiple fee.

(2) Total Amount Paid.—Enter the total amount of your remittance.

(3) Payor Name.—Enter the name of the person or company (i.e., maker of the check) responsible for payment. Enter an individual name (last, first, middle initial). If a company, enter the name which is used commercially.

(4) Address (Line 1).—The street address or post office box number to which correspondence should be sent.

(5) Address (Line 2).—This line may be used if further identification of the address is required.

(6) City.—The name of the city associated with the given street address.

(7) State.—If you are based in the United States of America, enter the appropriate two-digit state abbreviation as prescribed by the U.S. Post Office. If you are based outside the United States of America, leave this section blank.

(8) Zip Code.—Enter the appropriate five or nine-digit zip code prescribed by the U.S. Post Office. If address is foreign, enter the appropriate zip (postal) code.

(9) Telephone Number.—Enter the payor's ten-digit daytime telephone number, including area code. For foreign telephone numbers include the appropriate country dialing access code, as if you were calling from the United States. [For example a United Kingdom number would have the prefix (011–44) followed by the number within the UK.] This number should tell us where you can be reached during normal business hours in case the need arises.

(10) Country Code.—This section is only for those customers based outside the United States of America. Enter the country's appropriate country code here.

(11) Name of Applicant, Licensee, Regulatee or Debtor.—Enter the name (last, first, middle initial) of the applicant as it appears on the original being submitted. If company, enter name which is used commercially. Each applicant must be listed separately if multiple applications are submitted. If the Applicant, Licensee or Regulatee is the same as the payor it is not necessary to fill out this section.

(12) FCC Call Sign/Other Identifier.—Enter an applicable call sign or unique FCC identifier, if any, as shown on your enclosed correspondence.

(13) Zip Code.—Enter the Applicant, Licensee or Regulatee's five or nine-digit zip code prescribed by the U.S. Post Office. If address is foreign, enter the appropriate country code here. It is not necessary to complete this section if the Payor is the same as the Applicant, Licensee or Regulatee.

(14) Payment Type Code.—Beginning with the first box, enter correct Payment Type Code(s) from the instructional guide. Incorrect Payment Type Codes may result in your application or filing being returned to you without further processing. Each Payment Type code must be listed separately on the Remittance Advance Form. If concurrent actions are necessary on the same application, place any additional codes in the next "Item Information" payment type code block and repeat your FCC Call Sign or other ID. It is not necessary to fill out the applicant's name and address again.

(15) Quantity.—Enter the number of actions required with this submission. Refer to the particular services for further instructions concerning multiple requests.

(16) Amount.—Enter the amount of the fee required for the Payment Type Code used.

(17) FCC Code 1.—Used for special filings. Code will be defined in Public Notice if it is to be used.

(18) FCC Code 2.—(Same as item 17).

(19, 20, 21) Applicant Address.—If the same as Payor address leave these sections blank. If multiple payment codes have been used for the same Applicant, Licensee or Regulatee it is not necessary to complete these sections more than once. However, these sections must be completed the first time. If different from Payor address follow item (4, 5, 6, 7).

(22) Credit Card Data.—If remitting payment by credit card "mark" the appropriate block for the type of credit card being used—Master Card or Visa only. Enter your credit card number and expiration date. If any area required for credit card approval is incomplete, the application will be returned unprocessed.

(23) Authorized Signature.—Sign and date the Remittance Advice Form to authorize all credit card payments. The application will not be processed further if it is not signed here.

FCC Supplemental Remittance Advice (FCC Form 159–S).—Use this form for any additional services required with this filing.

Checks must be drawn on a U.S. Bank and denominated in U.S. currency. No checks drawn on a foreign bank will be accepted.

Special Note

If the Applicant, Licensee, Regulatee or Debtor is the same as the payor, it is not necessary to fill out blocks 11, 13, 19, 29, & 21. However, you must complete all information regarding FCC codes in blocks 12, & 14. FCC codes in blocks 17 & 18 will only be completed when required by public notice). Payment information in blocks 14, 15 & 16 must also be completed.

If more than one fee payment is being made for an individual or organization on the same application, move to the next available "Item Information" section. It is only necessary to complete those sections requesting Name (block 11), Zip Code (block 13), FCC codes (blocks 12 & 14). Complete blocks 17 & 18 as instructed above. Payment Information in blocks 14, 15, & 16 must also be completed. It is not necessary to fill out the applicant's address again (blocks 19, 20 & 21).

If more than one payment is being made on the same application, each for a different individual or organization, then it is necessary to also fill out the blocks requesting the applicant's name and address.

[FR Doc. 94–2932 Filed 2–8–94; 8:45 am]

BILLING CODE 6712–01–C

FEDERAL RESERVE SYSTEM

Agency Forms Under Review

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

BACKGROUND: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act of 1980, as per 5 CFR 1320.9, to approve

of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320.9. Board-approved collections of information will be incorporated into the official OMB inventory of currently approved collections of information. A copy of the SF 83 and supporting statement and the approved collection of information instrument(s) will be placed into OMB's public docket files. The following forms, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority.

DATES: Comments must be submitted on or before February 24, 1994.

ADDRESSES: Comments, which should refer to the OMB Docket number (or Agency form number in the case of a new information collection that has not yet been assigned an OMB number), should be addressed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551, or delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m., and to the security control room outside of those hours. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments received may be inspected in room B–1122 between 9 a.m. and 5 p.m., except as provided in section 261.8 of the Board's Rules Regarding Availability of Information, 12 CFR 261.8(a).

A copy of the comments may also be submitted to the OMB desk officer for the Board: Gary Waxman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed form, the request for clearance (SF 83), supporting statement, instructions, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below. Mary M. McLaughlin, Federal Reserve Board Clearance Officer (202–452–3829), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. For the hearing impaired *only*, Telecommunications Device for the Deaf (TTD) Dorothea Thompson (202–452–3544), Board of Governors of the Federal Reserve System, Washington, DC 20551.

Proposal to approve under OMB delegated authority the extension, with revisions, of the following reports:

1. *Report title:* Weekly Report of Eurodollar Liabilities Held by Selected U.S. Addressees at Foreign Offices of U.S. Banks.

Agency form number: FR 2050.

OMB Docket number: 7100–0068.

Frequency: Weekly.

Reporters: Large foreign branches and banking subsidiaries of U.S. banks.

Annual reporting hours: 11,284.

Estimated average hours per response: 3.5.

Number of respondents: 62 branches, 0 banking subsidiaries. Small businesses are not affected.

General description of report: This information collection is voluntary [12 U.S.C. 248(a)(2)] and is given confidential treatment [5 U.S.C. 552(b)(4)].

This report collects data on overnight and term Eurodollars held by certain U.S. residents in selected foreign branches of U.S. commercial banks and Edge and agreement corporations. The data are used for the construction of the Eurodollar components of the monetary aggregates and for analysis of banks' liability management practices.

The report has been renamed and now includes data formerly collected on the Weekly Report of Foreign Branch Liabilities to, and Custody Holdings for, U.S. Addresses (FR 2077; OMB No. 7100–0176), which has been discontinued. The reporting panel has been broadened to include foreign banking subsidiaries, although currently none meets the cutoff. The panel will be composed of those institutions with a weekly average of $200 million in total Eurodollar liabilities to U.S. addressees other than depository institutions and all money market mutual funds. Other changes include the following:

(1) The overnight Eurodollar item now collected on the FR 2050 and the two term Eurodollar items now collected on the FR 2077 would be collected in the body of the new combined report, with the following redefinitions: (a) The item on negotiable term Eurodollar holdings held in custody would be redefined to exclude those held for depository institutions, consistent with the exclusion of depository institution holdings from the other two items; and (b) all three items would be redefined to also exclude Eurodollar liabilities to all money market mutual funds, which now are included.

(2) A memorandum item would be added to the report to segregate overnight Eurodollars held by institution-only money market mutual funds.

(3) The two term Eurodollar data items would be expanded from single-day (Wednesday) coverage to daily data reported weekly, consistent with the coverage of the overnight Eurodollar item. Daily data also would be collected for the new memorandum item.

The combined report will be implemented as of the reporting week beginning Tuesday, March 29, 1994.

2. *Report title:* Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks.

Agency form number: FR 2502q.

OMB Docket number: 7100–0079.

Frequency: Quarterly.

Reporters: Large foreign branches and banking subsidiaries of U.S. banks.

Annual reporting hours: 9,045.

Estimated average hours per response: 3.75.

Number of respondents: 588 branches, 15 banking subsidiaries. Small businesses are not affected.

General description of report: This information collection is required [12 U.S.C. 248(a)(2), 602, and 625] and is given confidential treatment [5 U.S.C. 552(b)(4)].

This report collects asset and liability information from foreign branches and subsidiaries of U.S. commercial banks and Edge and agreement corporations. The data are used in the construction of the monetary aggregates and to monitor flows of funds between banks and their branches. The report also provides information on foreign branch claims to individual countries, which aids in monitoring the total exposure of U.S. banks to individual countries. Also, data from this report are combined with data from the Department of the Treasury to form the basis of information that is compiled by the Bank for International Settlements (BIS) from all G–10 countries on international banking market developments.

The report has been renamed and now includes some of the data formerly collected on the Monthly Report on Foreign Branch Assets and Liabilities (FR 2502; OMB No. 7100–0078), which has been discontinued. The reporting panel has been broadened to include large foreign banking subsidiaries. The FR 2502 items on customer detail on transactions with U.S. residents and claims and liabilities vis-a-vis other non-U.S. offices of the parent have been reformatted and are collected in the memoranda section. Data on Eurodollar liabilities, both overnight and term, payable to certain U.S. addresses, which excluded liabilities held by depository institutions, have been redefined to also exclude liabilities held by all money

market mutual funds. An item has been added to collect liabilities held by institution-only money market mutual funds. The report's overnight and term Eurodollar items have been expanded from single-day coverage to five days of data. The remaining items from the former FR 2502 report have been dropped, resulting in a 66 percent net decrease in reporting burden.

3. *Report title:* Application for Employment with the Board of Governors of the Federal Reserve System.

Agency form number: N.A.

OMB Docket number: 7100–0181.

Frequency: On occasion.

Reporters: Individuals.

Annual reporting hours: 10,099.

Estimated average hours per response: 1.

Number of respondents: 10,099.Small businesses are not affected.

General description of report: This information collection is required to obtain a benefit (12 U.S.C. 244 and 248(1)) and is given confidential treatment (5 U.S.C. 552(a) and 552(b) (2) and (6)).

The Application for Employment with the Board of Governors of the Federal Reserve System collects information needed to determine the qualifications, suitability, and availability of applications for employment with the Board and of current Board employees for reassignment, reinstatement, transfer, or promotion. The completed form may also be used to examine, rate, or assess the applicant's qualifications and to determine if the applicant is entitled to rights or benefits under certain laws and regulations. The proposed revisions include the deletion of certain items, the addition of items, clarification of Federal Reserve Board personnel policies, and minor editorial changes.

4. *Report title:* Report of Condition and Income for Edge and Agreement Corporations.

Agency form number: FR 2886b.

OMB Docket number: 7100–0086.

Frequency: Quarterly.

Reporters: Edge and Agreement corporations.

Annual reporting hours: 2,301.

Estimated average hours per response: 6.6.

Number of respondents: 49 banking corporations, 38 investment corporations. Small businesses are not affected.

General description of report: This information collection is required and authorized by law [12 U.S.C. 602 and 625]. Certain respondent data are given confidential treatment [5 U.S.C. 552(b)(4)].

This report collects balance sheet and income data from Edge and Agreement corporations. The data are used to supplement examination reports and support the applications process, to monitor aggregate institutional trends, and to measure the effect of and compliance with the Board's Regulation K. The significant revisions proposed consist of the collection of all branch activities of both banking and investment Edge corporations (both domestic and foreign) into one consolidated report; the addition of a new schedule to collect selected items from individual branches; the addition of a new schedule to collect information on risk based capital; the addition of a new schedule to collect additional information on securities to comply with the implementation of Financial Accounting Standards Board (FASB) Statement 115; and the addition of a new balance sheet item to collect information on subordinated notes and debentures.

Proposal To Approve Under OMB Delegated Authority the Extension, Without Revisions, of the Following Reports

1. *Report title:* Request for Proposal; Request for Price Quotations.

Agency form number: N.A.

OMB Docket number: 7100–0180.

Frequency: On occasion.

Reporters: Vendors, suppliers.

Annual reporting hours: 6,580.

Estimated average hours per response: .854

Number of respondents: 7,700. Small businesses are affected.

General description of report: This information collection is required to obtain a benefit [12 U.S.C. 244] and is not given confidential treatment, unless requested otherwise by the respondent.

The Federal Reserve Board utilizes these two procurement forms in obtaining competitive proposals and contracts. Depending upon the product or services for which the Federal Reserve Board is seeking competitive bids, the vendor or supplier is requested to provide either basic price information for providing the goods or services (Request for Price Quotation) or a document covering not only price information, but the means of performing a particular service and a description of the qualification of the contractor's staff who will perform the service (Request for Proposal).

2. *Report title:* Ongoing Intermittent Survey of Households.

Agency form number: FR 3016.

OMB Docket number: 7100–0150.

Frequency: Up to four times a year.

Reporters: Households and individuals.

Annual reporting hours: 240.

Estimated average hours per response: .25.

Number of respondents: 500. Small businesses are affected.

General description of report: This information collection is voluntary [12 U.S.C. 225a, 263, 1828(c), 1842, 1843, and 4008, and 15 U.S.C. 1693b(a)]. No issues of confidentiality arise under the Freedom of Information Act [FOIA] or under the Privacy Act.

This survey provides the Federal Reserve with considerable flexibility in obtaining household-based information specifically tailored to the Federal Reserve's policy and regulatory and operational responsibilities.

Board of Governors of the Federal Reserve System, February 2, 1994.

William W. Wiles,

Secretary of the Board.

[FR Doc. 94–2887 Filed 2–8–94; 8:45 am]

BILLING CODE 6210–01–P

Capitol Bancorp Limited; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of

fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 4, 1994.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Capitol Bancorp Limited*, Lansing, Michigan; to acquire Consolidated Bank Services, Inc., Holland, Michigan, and thereby engage in performing internal audit services on a contract basis, which will be expanded into compliance management and other advisory services for depository institutions, pursuant to § 225.25(b)(11) of the Board's Regulation Y. These services will be provided to Michigan banking institutions.

Board of Governors of the Federal Reserve System, February 2, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–2888 Filed 2–8–94; 8:45 am]

BILLING CODE 6210–01–F

First Bankshares of West Point, Inc.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than March 4, 1994.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *First Bankshares of West Point, Inc.*, West Point, Georgia; to acquire at least 16.11 percent of the voting shares of First Peoples Bank, Pine Mountain, Georgia.

Board of Governors of the Federal Reserve System, February 2, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–2890 Filed 2–8–94; 8:45 am]

BILLING CODE 6210–01–F

Harlan A. Klefstad, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 28, 1994.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Harlan A. Klefstad*, Forman, North Dakota; to acquire an additional 18.9 percent for a total of 38.0 percent; and Steven D. McLaen, Forman, North Dakota, to acquire an additional 16.3 percent for a total of 33.7 percent of the voting shares of Sargent Bankshares, Inc., Forman, North Dakota, and thereby indirectly acquire Sargent County Bank, Forman, North Dakota.

Board of Governors of the Federal Reserve System, February 2, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–2889 Filed 2–8–94; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Partial Support for Children's Nutrition Label Literacy Project; Consideration of Cooperative Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has accepted for consideration a single source application from KIDSNET (a nonprofit, multimedia organization) for partial support for Phase II of the "Kid's Label Literacy Project" in the form of a cooperative agreement. Phase I, which has been completed, was funded from private sources. The goal of this multimedia project is to help create generations of label literate adults by motivating children to look for and to use the new food label on their own and with the help of their parents.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects: Maura C. Stephanos, Division of Contracts and Grants Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

Regarding the programmatic aspects: Sherree Lancaster, Office of the Commissioner (HFA–5), 5600 Fishers Lane, Rockville, MD 20857, 301–443–8122.

SUPPLEMENTARY INFORMATION: FDA is announcing that it has accepted for consideration a single source application from KIDSNET for support of a children's nutrition label literacy project. Competition is limited to KIDSNET because it has developed a unique combination of commitments and partnerships that bring together educators and the broadcast media, as well as nutritionists, food industry representatives, trade associations, and others to launch this multimedia project. Specifically, KIDSNET has: (1) Formed a partnership with the National Education Association, representing more than 2 million teachers, which will help to develop and distribute a curriculum to teachers and to medical, health, and social service professionals via its health information network; (2) arranged for Houghton-Mifflin, the company that holds the rights to the popular children's character "Curious George," to allow the character to be used in television (TV) public service announcements (PSA's), videos, and a

variety of printed materials to educate children about the food label (in a way similar to that in which "Smokey the Bear" educates children about forest fires); (3) received the endorsement from KIDSNET's broadcast industry advisory board, which includes all four TV networks and the major cable TV networks, to produce TV PSA's that will run during the best time slots targeted for children; (4) formed a kid's label literacy media task force representing national broadcast and cable networks and a leading children's production company to develop and implement this project and ensure widespread usage of the PSA's on the major national TV and cable networks; (5) arranged for the Federal Consumers Information Center to distribute a parent and teacher companion brochure which will be promoted during the PSA's; (6) signed-on more than 100 representatives of industry and trade associations and experts in child development and nutrition to participate in this project; (7) identified, met with, and held preliminary discussions with various children's museums to develop and promote a kid's label literacy exhibit; and (8) as a result of KIDSNET's Phase I activities, acquired expertise and recognition in the field of children and label literacy. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's programs are described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into grants or cooperative agreements, FDA carefully considers the benefits that such support will provide the public.

KIDSNET's application for this award will undergo a noncompetitive dual peer review. An external review committee of experts in nutrition, food labeling, and media has reviewed and evaluated the application based on its expressed ability to successfully accomplish the goals of the project. A second level review will be conducted by the National Advisory Environmental Health Sciences Council, which regularly reviews applications for FDA.

I. Background

In 1991, FDA and the U.S. Department of Agriculture initiated a food labeling education campaign to increase consumers' knowledge and effective use of the new food label to assist them in making accurate and sound dietary choices in accordance with the Dietary Guidelines for Americans. The goals of the campaign are to promote awareness of the food label and to motivate consumers to use food label information in making more nutritious food selections in order to achieve healthier diets. A major thrust of the campaign is to encourage and build partnerships among and with health, nutritional, and consumer groups in order to develop, disseminate, and evaluate materials and projects educating children about the new food label. FDA also recognizes that the learning process must be expanded beyond the classroom to include other areas of frequent exposure such as children's TV programming.

In 1992, in support of this campaign, KIDSNET initiated Phase I of the "Kid's Label Literacy Project." This initial phase of the project involved research and development of an outline for an educational and public outreach initiative to educate children about nutrition through food labeling. In December 1991, KIDSNET conducted several children's focus groups to: (1) Examine children's attitudes and behavior regarding food purchasing, preparation, and consumption; (2) determine children's awareness and knowledge of the relationship between food and nutrition; and (3) identify sources of information on food. As part of its efforts to reach out to the various constituencies involved in nutrition education, KIDSNET conducted a seminar in January 1994, with more than 100 representatives from the government, food industry, nutrition and educational health communities, public interest groups, and the media to obtain their insights and cooperation regarding this initiative. During the National Education Association's National Health Conference, held in the spring of 1993, KIDSNET surveyed participants to determine how this labeling initiative should be implemented in the schools. Educators from 10 States volunteered to participate in curriculum development and evaluation. In addition, KIDSNET reviewed various cartoon characters to identify one that would become the key symbol for the project. The character "Curious George" was selected to be the key symbol and will become part of the educational, consumer, TV, and product elements of the initiative.

II. Mechanism of Support

A. Award Instrument

Support for the "Kids Label Literacy Project," if awarded, will be in the form of a cooperative agreement in the anticipated amount of $50,000. The award will be subject to all policies and requirements that govern the programs of the Public Health Service, including the provisions of 45 CFR part 74 and the Public Health Service grants policy statement.

B. Length of Support

The length of support will be 1 year with the possibility of an additional 2 years of noncompetitive support. Continuation beyond the first year will be based upon performance during the preceding year and the availability of Federal fiscal year appropriations.

C. Delineation of Substantive Involvement

1. All PSA's will be reviewed and approved by the FDA for product content.
2. FDA will have full representation on the advisory board.
3. FDA will review and approve all education material distributed by KIDSNET.
4. FDA will be consulted on the implementation of the traveling exhibits.

III. Reasons for Single Source Selection

FDA is offering this cooperative agreement to KIDSNET to encourage continuation of the "Kids Label Literacy Project" by providing partial support of Phase II. FDA believes that there is compelling evidence that KIDSNET is uniquely qualified to fulfill the goals of the children's nutrition label literacy project. While completing Phase I of the project, KIDSNET has obtained expertise and recognition in educating children about nutrition and the food label via the media. Also, KIDSNET has developed a unique combination of partnerships and commitments from various sectors; these include: (1) Major TV networks and cable TV, which will run the PSA's during the best time slots for children; (2) the Federal Consumer Information Center, which will distribute the companion brochure; (3) the National Education Association, which will help write, publish, and distribute a curriculum to schools; (4) release by the company holding the rights to the popular children's character "Curious George," which could be used in the PSA's, videos, and printed materials; and (5) various children's museums throughout the United States, which expose the public to a variety of pertinent and timely information. In the past 2 years, KIDSNET has laid a strong foundation for the successful introduction and implementation of this project. In December 1991, it conducted focus groups on the subject of nutrition and the food label with children. In January 1992, KIDSNET held a national symposium in Washington, DC, with participation from government, public

interest groups, educational organizations, and representatives of the private sector to help focus the project and generate support for such an initiative.

IV. Reporting Requirements

Program progress reports and financial status reports (Standard Form SF–269) will be required quarterly, based on date of award. These reports will be due within 30 days after the last day of each quarter. Final program progress and financial status reports will be due 90 days after expiration of the project period of the grant.

Dated: January 31, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–2883 Filed 2–8–94; 8:45 am]

BILLING CODE 4160–01–F

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992. The experimental phase of the committee process has concluded, and FDA has decided that the committee will now meet semiannually as a regular program. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in March 1994. Drug companies may submit review requests for the March meeting before March 11, 1994.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

FOR FURTHER INFORMATION CONTACT: Deborah Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: FDA regulations at part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations at 21 CFR 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial which may be grounds for the imposition of a hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold. In CDER, a clinical hold is ordered by or on behalf of the director of the Division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 30 days of the imposition of the clinical hold, the Division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 30 days should notify the Division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit this resumption, an investigation may resume only after the Division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations at 21 CFR 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds. First, CDER completed a center-wide review of clinical holds recorded in the management information system. While some differences in practice and procedure were discerned among divisions, it appeared that the procedures specified in the regulations were, in general, being followed, and that holds were scientifically supportable.

Second, FDA established a committee in CDER to review selected clinical holds for scientific and procedural

quality. The committee held pilot meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a manner that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The agency now has decided to make the clinical hold committee review process a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered "anonymously." The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman. The committee will meet semiannually. The March meeting will be the second meeting after the close of the experimental stage of the committee.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should request review when it disagrees with the agency's scientific conclusions.

Requests for committee review of a clinical hold should be submitted to FDA's Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff (with the exception of the Chief Mediator and Ombudsman) are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available from the Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its March meeting. Submissions should be made by March 11, 1994, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: February 2, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–2882 Filed 2–8–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Assistant Secretary for Administration

[Docket No. N–94–3713]

Privacy Act of 1974; Proposed Amendment to a System of Records

AGENCY: Department of Housing and Urban Development.

ACTION: Notification of a proposed amendment to an existing system of records.

SUMMARY: The Department is giving notice that it intends to amend the following Privacy Act system of records: HUD/H–11, Tenant Housing Assistance and Contract Verification Data.

EFFECTIVE DATES: This amendment shall become effective without further notice in 30 calendar days (March 11, 1994) unless comments are received on or before that date which would result in a contrary determination.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title.

A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Jeanette Smith, Privacy Act Officer, Telephone Number (202) 708–2374. This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: HUD/H–11 contains a record for each individual receiving housing assistance from HUD under one of the following programs: Section 8, Public/Indian Housing, Section 236 (including Section 236 RAP), Rent Supplement, Section 221(d)(3) BMIR. Section 811, and Section 202. This amendment is being made to reflect the Department's intention to maintain and use records detailing contractual agreements entered into between HUD and its respective tenants and PHAs/owner/management agents for the aforementioned programs. These records will detail the duration and financial terms of agreed upon contractual agreements. Additionally, a set of records will be maintained detailing a history of all assistance made under the lease. Also, this system of records is being amended to change the name of the system to better reflect program coverage.

The system notice is set forth in its entirety below. Previously, the system and prefatory statement containing the general routine uses applicable to all of the Department's systems of records were published in the "Federal Register Privacy Act Issuances, 1991 Compilation, Volume I."

A report as required by 5 U.S.C. 552(a) of the Privacy Act, has been submitted to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget (OMB) pursuant to paragraph 4B of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," revised June 25, 1993 (58 FR 36068, July 2, 1993).

Authority: 5 U.S.C. 88 Stat. 1896; sec. 7(d) Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Issued at Washington, DC: February 2, 1994.

Marilynn A. Davis,

Assistant Secretary for Administration.

HUD/H–11

SYSTEM NAME:

Tenant Housing Assistance and Contract Verification Data.

SYSTEM LOCATION:

Headquarters and Field Offices. For a listing of Field Offices with addresses, see 24 CFR part 16, appendix A. Decentralized portions of this data may be maintained by selected contractors with research contracts.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This file contains a record for each individual receiving housing assistance from HUD under the following programs: Section 8, Public/Indian Housing, Section 236 (including Section 236 RAP), Rent Supplement, Section 221(d)3 BMIR, Section 811, and Section 202. The file will also contain a record for each PHA/owner/management agent who receives payments for the assisted housing programs mentioned above.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records provides data needed to: (1) Determine the amount of

housing assistance tenants may receive, (2) calculate payments due to public housing agencies, owners/management agents, or contract administrators, (3) forecast budgets and (4) control funds. The system of records also contains manual and automated records consisting of: Identification information such as Name; SSNs for all individuals six (6) years of age and older; Alien Registration Information; address and tenant unit number; financial data such as income, adjustments to income; contract rent amount; tenant rent; tenant characteristics such as number in family, sex of family member, information about the family that would qualify them for certain adjustments or for admission to a project limited to a special population (e.g., elderly, handicapped or disabled); relationships of members of the household to the Head of household (e.g., spouse, child); preference(s) applicable to the family at admission; income status at admission and race and ethnicity of Head of household; unit characteristics such as number of bedrooms; geographic data information obtained by PHA or owner from third parties used to verify data supplied by the applicant or tenant to determine eligibility or level of assistance; information obtained from a state wage information collection agency on wages and claim information; information obtained through computer matching by HUD or a PHA with Federal and State agencies; information on the results of the follow-up phase of owner verifications or a computer match of tenant income (i.e., dollar amount of overpaid assistance, amount repaid, prosecution, termination of assistance, and termination of tenancy); and related correspondence.

Also included are manual and automated records on all contractual agreements, and financial information (i.e., names, addresses, Taxpayer Identification Numbers (TINs) or Social Security Numbers (SSNs), obligations, payments, contract terms) for public housing agencies, and/or owners/management agents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

United States Housing Act of 1937; as amended, 42 U.S.C. 1437 et seq., and the Housing and Community Development Amendments of 1981, Public Law 97–35, 95 Stat. 408.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

See routine uses paragraph in prefatory statement. Other routine uses include:

1. Federal, State, and local agencies (e.g., State agencies administering the State's unemployment compensation laws, State Welfare and food stamp agencies, U.S. Office of Personnel Management, U.S. Postal Service, U.S. Department of Defense, and U.S. Social Security Administration)—to verify the accuracy and completeness of the data provided, to verify eligibility or continued eligibility in HUD's rental assistance programs, and to aid in the identification of tenant errors, fraud and abuse in assisted housing programs through the Department's tenant income computer matching program;

2. Individuals under contract to HUD or under contract to another agency with funds provided by HUD—for the performance of research and statistical activities directly related to the management of HUD's rental assistance programs, to support quality control for tenant eligibility efforts requiring a random sampling of tenant files to determine the extent of administrative errors in making rent calculations, eligibility determinations, etc., and for processing certifications/recertifications.

3. Public Housing Authorities, (PHAs)—to verify the accuracy and completeness of tenant data used in determining eligibility and continued eligibility and the amount of housing assistance received;

4. Private Owners of assisted housing—to verify the accuracy and completeness of applicant and tenant data used in determining eligibility and continued eligibility and the amount of assistance received.

5. Private owners of assisted housing—to verify the accuracy and completeness of applicant and tenant data used in determining eligibility and continued eligibility and the amount of assistance received.

6. To PHAs, owners/management agents and contract administrators—to identify and resolve discrepancies in tenant data;

7. To the Internal Revenue Service—to report income using IRS Form 1099; and,

8. Social Security Administration and Immigration and Naturalization Service—to verify alien status and continued eligibility in HUD's rental assistance programs.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folder; magnetic tape/disk.

RETRIEVABILITY:

Name of tenant and all household members, address, SSN, or other identification number. Name of owners/management agents by name, SSN or TIN.

SAFEGUARDS:

File folders, automated records kept in a secured area. Access restricted to authorized individuals.

RETENTION AND DISPOSAL:

Obsolete records are destroyed or sent to a storage facility in accordance with HUD Handbook 2235.6, Records Disposition Management; HUD Records Schedules.

SYSTEM MANAGER AND ADDRESS:

For Section 8, Section 236 (including Section 236 RAP), Rent Supplement, Section 221(d)3 BMIR, Section 811, and Section 202—Office of the Assistant Secretary for Housing: Director, Housing Information and Statistics Division, Office of Management; Director, Planning and Procedures Division, Office of Multifamily Housing Management, Deputy Assistant Secretary for Multifamily Housing Programs; Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410.

For Public and Indian Housing and Section 8 existing and Mod Rehab Programs—Office of Assistant Secretary for Public and Indian Housing: Office of Public Housing, Chief, Occupancy Branch, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410.

For Computer Matching Activities—Director, Computer Matching Activities Division, Office of Public and Indian Housing Comptroller, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410.

NOTIFICATION PROCEDURES:

For information assistance, or inquiry about the existence of records, contact the Privacy Act Officer at the appropriate location, in accordance with 24 CFR part 16. A list of all locations is given in appendix A.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned appear in 24 CFR part 16. If additional information or assistance is required, contact the Privacy Act Officer at the appropriate location. A list of all locations is given in appendix A.

CONTESTING RECORD PROCEDURES:

The Department's rule for contesting the contents of records and appealing

initial denials by the individual concerned appear in 24 CFR part 16. If additional information or assistance is needed in relation to contesting the contents of records, it may be obtained by contacting the Privacy Act Officer at the appropriate location. A list of all locations is given in appendix A. If additional information or assistance is needed in relation to appeals of initial denials, it may be obtained by contacting the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Subject individuals, other individuals and organizations, Federal, State, and local agencies. PHA staff/private owners/management agents.

[FR Doc. 94–2946 Filed 2–8–94; 8:45 am]

BILLING CODE 4210–01–M

Office of Administration

[Docket No. N–94–3712]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507, section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: February 2, 1994.

Kay Weaver

Acting Director, IRM Policy and Management Division.

Proposal: Proposed Rule on Seven Unit Limitation Section 203(k) Program (FR–2713).

Office: Housing.

Description of the need for the information and its proposed use: The rule requires State and local governments to submit a plan to HUD describing the program of neighborhood redevelopment. HUD must accept the plan before exempting a section 203(k) rehabilitation loan from the seven unit rule.

Form number: None.

Respondents: State or Local Governments.

Frequency of submission: On occasion.

Reporting burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Plan	10		1		160		1,600

Total Estimated burden hours: 1,600.

Status: Reinstatement.

Contact: Ken Crandall, HUD, (202) 708–4998, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: February 2, 1994.

[FR Doc. 94–2944 Filed 2–8–94; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. N–94–3711]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comment on the subject proposals.

ADDRESSES: Interested persons are invited to submit comment regarding these proposals. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals for the collections of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8)

whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 24, 1994.

John T. Murphy,

Director, IRM Policy and Management Division.

Proposal: Legal Instructions Concerning Applications for Full Insurance Benefits Assignment of Multifamily Mortgages to the Secretary.

Office: General Counsel.

Description of the need for the information and its proposed use: Holders of HUD-insured multifamily mortgages may receive mortgage insurance benefits, in the event of a default, by assigning the mortgage to HUD. This information collection describes the legal documents to be submitted by the mortgagee and the procedures for submission.

Form number: None.

Respondents: State or Local Governments, businesses or other for-profit, and Federal Agencies or Employees.

Frequency of submission: On occasion.

Reporting burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Information collection	359		1		26		9,334

Total estimated burden hours: 9,334.

Status: Reinstatement.

Contact: Donald Franck, HUD, (202) 708–4167, Joseph F. Lackey, Jr., OMB, (202) 395–6880.

Dated: January 24, 1994.

Proposal: Real Estate Settlement Procedures Act (RESPA), Amendments to RESPA in the Housing and Community Development Act of 1992 (FR–3382).

Office: Housing.

Description of the need for the information and its proposed use: This rule proposes to amend 24 CFR Part 3500, the implementing regulations for RESPA, to reflect amendments to RESPA in the Housing and Community Development Act of 1992 which adds a new class of covered transactions—subordinate mortgages and proposes a new Settlement Statement (HUD–1A).

Form Number: HUD–1A.

Respondents: Businesses or other for-profit.

Frequency of submission: On occasion.

Reporting burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD–1A	115,000		13.12		.35		528,025

Total estimated Burden Hours: 528,025.

Status: Extension.

Contact: Ivy M. Jackson, HUD, (202) 708–4560, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: January 24, 1994.

Proposal: Default Status Report on Multifamily Housing Projects.

Office: Housing.

Description of the need for the information and its proposed use: Mortgagees use this report to notify HUD that a project owner has defaulted and that an assignment of acquisition will result if HUD and the mortgagor do not develop a plan for reinstating the loan. The report triggers HUD's negotiation with the mortgagor.

Form Number: HUD–92426.

Respondents: Businesses or other for-profit.

Frequency of submission: Monthly.

Reporting burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information collection	2,000		3		.25		1,500
Recordkeeping	500		1		2.00		1,000

Total estimated Burden Hours: 2,500.

Status: Extension.

Contact: James J. Tahash, HUD, (202) 708–3944, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: January 10, 1994.

Proposal: Issuer's Monthly Accounting Report.

Office: Government National Mortgage Association.

Description of the need for the information and its proposed use: Issuers will use these forms to report monthly on their securities accounting. The information is necessary to assure issuers are performing pursuant to the guaranty agreement and investors are receiving all funds due them.

Form number: HUD–117110A, 1710B, 1710C, 11710D, and 11710E.

Respondents: Businesses or other for-profit.

Frequency of submission: On occasion and monthly.

Reporting burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours.
HUD–11710A	824		4,287		.012036		42,517
HUD–1710B	13		12		.25		39
HUD–1710C	10		2		.16		3

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours.
HUD–11710D	824		12		.25		2,472
HUD–11710E	824		24		.16		3,164

Total estimated burden hours: 48,195.
Status: Reinstatement.
Contact: Brenda Countee, HUD, (202) 708–1535, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: January 10, 1994.

Proposal: Summary of Guaranty Agreement—Graduated Payment and Growing Equity.

Office: Government National Mortgage Association (GNMA).
Description of the need for the information and its proposed use: In compliance with Section 306(g) of the National Housing Act, GNMA is authorized to guarantee the timely payment of principal and interest on securities which are based on or backed by a pool composed of mortgages. Issuers of mortgage-backed securities polls use these forms to report monthly on their securities accounting.
Form number: HUD–1746, 11748–A, 11748–B, and 11748–C.
Respondents: Businesses or other for-profit.
Frequency of submission: On occasion.
Reporting burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours.
Information collection	824		4.4		.25		900

Total estimated burden hours: 900.
Status: Reinstatement.
Contact: Charles Clark, HUD, (202) 708–1535, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: January 10, 1994.

Proposal: Application Submission Requirements: Section 202 Housing for the Elderly and Section 811 Housing for Persons with Disabilities.

Office: Housing.
Description of the need for the information and its proposed use: This information is needed to facilitate a prompt and orderly conversion of the Section 202 Direct Loan Pipeline Projects to the Section 202 or Section 811 Capital Advance Programs. This information will be used to assist HUD in determining the owner's eligibility and capacity to finalize the development of a housing project under the Capital Advance Program.
Form number: HUD–92446–CA, 92476A, 9066–CA, 90165–CA, 9064–CA, 90171–CA, 90163–CA, 92450–CA, 91732A, 92531B–CA, 90167–CA, 90177–CA, 90170–CA, and 90176–CA.
Respondents: Non-profit institutions.
Frequency of submission: On occasion and monthly.
Reporting burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours.
Information collection	260		1		43.17		11,225

Total estimated burden hours: 11,225.
Status: Extension.
Contact: Evelyn Berry, HUD, (202) 708–2866, Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: January 12, 1994.

[FR Doc. 94–2945 Filed 2–8–94; 8:45 am]
BILLING CODE 4210–01–M

Office of the Assistant Secretary for Housing; Federal Housing Commissioner

[Docket No. N–94–3696; FR–3576–N–02]

Extension of Application Due Date for NOFA for Federally Assisted Low Income Housing Drug Elimination Grants—FY–1994

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of extension of application due date for Notice of Funding Availability (NOFA) for Fiscal Year (FY) 1994.

SUMMARY: On January 20, 1994, HUD published a NOFA that announced HUD's FY 1994 funding of $12,306,000 for Federally Assisted Low Income Housing Drug Elimination Grants. The purpose of this Notice is to extend the application period from March 7, 1994 to April 8, 1994, and to clarify that all eligible applicants may apply for funding whether or not they applied for or received funding under previous NOFAs.

DATES: All applications must be received by the appropriate HUD Regional Office no later than 4 p.m. (local time) on April 8, 1994. Applications by fax will not be accepted.

ADDRESSES: Applications (original and one copy) must be received by the deadline at the appropriate HUD Regional Office with jurisdiction over the applicant project, Attention: Director of Housing Management.

FOR FURTHER INFORMATION CONTACT: Application documents may be obtained from The Multifamily Housing Clearinghouse by dialing 1–800–955–2232. Application material and project-specific guidance may also be obtained from the Office of the Director of Housing in the HUD Regional Office having jurisdiction over the project(s) in question. These are listed, by Region as follows:

I	Boston	John McInerney	(617) 565–5112
II	New York	Joyce Biase	(212) 264–5837
III	Philadelphia	Diane Lello	(215) 597–4650

IV	Atlanta	Marcia Ringo	(404) 331–4122
V	Chicago	Mary Watkins	(312) 353–6950
VI	Fort Worth	Pete Drennon	(817) 885–5809
VII	Kansas City	Carleta R. Foltz	(913) 551–5506
VIII	Denver	Karla Martinez	(303) 672–5369 Ext. 1128
IX	San Francisco	Rose Hamilton	(415) 556–7317
X	Seattle	Vincent Gonzales	(206) 220–5226

SUPPLEMENTARY INFORMATION: A Notice of Funding Availability (NOFA) announcing HUD's FY 1994 funding of $12,306,000 for Federally Assisted Low Income Housing Drug Elimination Grants was published on January 20, 1994 (59 FR 3282). This Notice amends that NOFA by extending the application due date. Due to the disruption caused by the earthquake in California and other administrative considerations within the Department of Housing and Urban Development, the due date for receipt of FY 1994 applications is extended from March 7, 1994, to Friday, April 8, 1994. The time for receipt and location for receipt of applications remain the same.

In response to inquiries received by the Department, this Notice also serves to clarify that all eligible applicants may apply for funding, whether or not they applied for or received funding under previous Notices of Funding Availability for this program.

Authority: 42 U.S.C. 11901 *et seq.*

Dated: February 3, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commmissioner.

[FR Doc. 94–2947 Filed 2–8–94; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–067–04–4210–05; CACA 12736]

Termination of Land Classification; Imperial County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Termination of R&PP land classification.

SUMMARY: Bureau of Land Management (BLM) Order of Classification for Recreation and Public Purposes, CACA 12736, dated August 20, 1982, is hereby terminated in its entirety under the authority of 43 CFR 2461.5 as to all the lands found suitable for classification under the Recreation and Public Purposes Act of June 14, 1926, as amended (43 U.S.C. 869 *et seq.*) located in section 24, T. 15 S, R. 23 E., SBBM (containing 304.00 acres). The land is opened to operation of the public land laws and mining laws, only to the extent such opening is consistent with and subject to the segregative effect of Secretarial Order 10/16/1931.

DATES: Effective February 9, 1994.

ADDRESSES: Comments or concerns may be addressed to the El Centro Resource Area Office at 1661 S. 4th Street, El Centrol, CA 92243.

FOR FURTHER INFORMATION CONTACT: Lynda Kastoll, Realty Specialist, (telephone (619) 353–7461.

Dated: January 26, 1994.

Henri R. Bisson,

District Manager.

[FR Doc. 94–2958 Filed 2–8–94; 8:45 am]

BILLING CODE 4310–40–M

[ID–020–406A–02]

Road Closures

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of temporary closures of public lands in Cassia and Twin Falls Counties, Idaho.

SUMMARY: Notice is hereby given that certain public lands in Idaho within Cassia and Twin Falls Counties shall be closed to prevent erosion and rutting of the roads traveled by motor vehicles during wet or snowy conditions. The roads will be closed immediately until April 11, 1994. All roads will be posted at the entrance to public lands.

The legal land descriptions for the road closures are as follows:

The Indian Springs Road, (BLM, road #4214), from the Foothill Road to the U.S. Forest Service boundary, a distance of approximately 4.5 miles. Road is located at T.12S., R.18E., section 4 in Twin Falls County.

Cherry Springs Road, (BLM road #4223), from the Rock Creek Road southwest to its intersection with the Indian Springs Road, just north of the U.S. Forest Service boundary. This is a distance of approximately 6 miles. Road is located at T.12S., R.18E., section 2 in Twin Falls County.

East Side of North Cottonwood Road, (BLM road #4221), from the Foothill Road to the junction of the North Cottonwood Creek Road, approximately 6 miles. Legal description is T.12S., R.17E., southeast ¼ of section 35, in Twin Falls County.

West Side of North Cottonwood Creek Road, (BLM road #4221), from the Foothill road to the U.S. Forest Service boundary, a distance of approximately 5 miles, and back to the Foothill Road, a loop approximately 11 miles total. Legal description is T.12S., R.18E., section 11, for the start, and ending at T.12E., R.18E. section 6, in Twin Falls County.

Curtis Spring Road, (BLM road #42163), from the Foothill Road for approximately 3.5 miles. Legal description is T.12S., R.17E., section 2, in Twin Falls County.

Squaw Joe Road, (BLM road #4220), south of the Nat-Soo-Pah Warm Springs, to the U.S. Forest Service boundary, approximately 5.5 miles. Legal description is T.12S., R.17E., sections 2, in Twin Falls County.

Lost Creek-Hot Creek road, (BLM road #4203), southeast of Highway 93, approximately 22.5 miles. Legal description is T.14S., R.16E., section 30, in Twin Falls County.

The West Fork of Dry Creek Road (BLM road #1610), from the Tugaw Ranch southwest to the U.S. Forest Service boundary, a distance of approximately 7 miles. Legal description is T.12S., R.19E. section 11, in Cassia County.

The East Rock of Dry Creek off Foothill Road, (BLM road #1609), southeast to the U.S. Forest Service boundary, a distance of approximately 7 miles. Legal description is T.11S., R.19E., section 1, in Cassia County.

No person may use, drive, move, transport, let stand, park, or have charge of control over any type of motorized vehicle on the closed routes.

Exemptions to this order are granted to the following:

Law enforcement patrol and emergency services and administratively approved access for actions such as monitoring, research studies, grazing activity, and access to private lands.

Employees of valid right-of-way holders in the course of duties associated with the right-of-way.

Holders of valid lease(s) and/or permit(s) and their employees in the course of duties associated with the lease an/or permit.

Other actions would be considered on a case by case basis.

EFFECTIVE DATE: This closure is effective immediately and shall remain in effect until April 11, 1994 or until rescinded by the Authorized Officer.

FOR FURTHER INFORMATION CONTACT: Tom Dyer, Snake River Resource Area Manager, Rt. 3, Box 1, Burely, ID 83318, (208) 678–5514. A map showing vehicle routes of travel is available from the Burely BLM Office.

SUPPLEMENTARY INFORMATION: Authority for this closure and restriction order may be found in 43 CFR 8364.1. Violation of this closure is punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Dated: January 28, 1994.

Marvin R. Bagley,

Associated District Manager.

[FR Doc. 94–2948 Filed 2–8–94; 8:45 am]

BILLING CODE 4310–GG–M

DEPARTMENT OF DEFENSE

DEPARTMENT OF THE AIR FORCE

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-930-04-4060-02]

Draft Environmental Impact Statement, Idaho; Correction

AGENCIES: Air Force, Department of Defense; Bureau of Land Management, Department of the Interior.

ACTION: Correction, Draft Environmental Impact Statement, Draft Plan Amendment, and Realty Action; Elmore County, Idaho.

SUMMARY: In notice document 93-30763, appearing on page 65971 in the issue of Friday, December 17, 1993, in the heading (above), change Elmore County, Idaho, to Owyhee County, Idaho. Under "ACTION," change Elmore County, Idaho, to Owyhee County, Idaho. On page 65972, first column after the legal description, change Elmore County, Idaho, to Owyhee County, Idaho.

FOR FURTHER INFORMATION CONTACT: C. Vernon (Butch) Peugh, BLM Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83704. (208) 384-3074.

Dated: January 19, 1994.

Delmar D. Vail,

State Director, Bureau of Land Management.

Dated: February 1, 1994.

Grace T. Rowe,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 94-2960 Filed 2-8-94; 8:45 am]

BILLING CODE 4310-GG

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–911–04–4740–02]

Utah Bureau of Land Management: Use of Explosive Materials, Destructive Devices, and Fireworks on the Public Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Establishment of a supplementary rule prohibiting individuals from using explosive materials, destructive devices, and Class A and B fireworks on the Public Lands in Utah without authorization.

SUMMARY: This supplementary rule prohibits public-land visitors from using Explosive Materials as defined by the Secretary of Treasury under Title 18, U.S.C. Section 1101, Destructive Devices as defined in Title 26, U.S.C. 5845, and Class A and B Fireworks as defined in 49 CFR on Public Lands in Utah administered by the Bureau of Land Management without the approval of the Bureau.

DATES: These rules will go into effect on February 9, 1994 and will remain in effect until rescinded or modified by the authorized officer.

ADDRESSES: State Director (UT–911), Bureau of Land Management, Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145–0155.

FOR FURTHER INFORMATION CONTACT: Martin Phillips, Special Agent-in-Charge, Utah State Office, (801) 539–4084.

SUPPLEMENTARY INFORMATION: This rule is necessary to ensure public safety and protect public land resources. The rule does not alter the use of Explosive Materials on public lands, e.g., mining uses, where explicitly allowed by regulation for authorized purposes. Personnel exempt from the requirements of this notice include any Federal, State, or local officer, members of any organized rescue or fire-fighting force in the performance of an official duty, or any person authorized by the Bureau. This supplementary rule is issued under the authority of 43 CFR 8365.1–6. Violation is punishable by fines and/or imprisonment under 43 CFR 8360.0–7 and other Federal and State laws as applicable.

James M. Parker,

State Director.

[FR Doc. 94–2982 Filed 2–8–94; 8:45 am]

BILLING CODE 4310–DQ–M

[ES–020–04–4410–02; 4–00157 ILM]

Availability of Draft Florida Resource Management Plan and Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM), Eastern States, Jackson District, announces the availability of the Draft Florida Resource Management Plan and Environmental Impact Statement (RMP/EIS) for public review. This document, prepared in accordance with section 202 of the Federal Land Policy and Management Act of 1976 and section 202(c) of the National Environmental Policy Act of 1969, presents alternatives for managing BLM-administered public lands throughout the State of Florida.

PUBLIC PARTICIPATION: Reading copies will be available at the following public libraries:

Lykes Memorial Library, 238 Howell Avenue, Brooksville, FL.

Staffordene Foggia Library, 6335 Blackbird Avenue, Brooksville, FL.

State Library of Florida, Documents Section, R. A. Gray Building, 500 S. Bronough Street, Tallahassee, FL.

Walton—De Funiak Library, 100 Circle Drive, De Funiak Springs, FL.

West Florida Regional Library, 200 West Gregory Street, Pensacola, FL.

Palm Beach County Public Library, Reference Section, 3650 Summit Blvd., West Palm Beach, FL.

Copies will be available from the Jackson District, 411 Briarwood Drive, suite 404, Jackson, MS 39206, phone (601) 977–5400. Public reading copies will be available for review at the following BLM locations:

Office of External Affairs, Main Interior Building, 18th and C Streets, NW., Washington DC 20240.

Office of External Affairs, Eastern States, 7450 Boston Blvd., Springfield, VA 22153.

Comments on the Draft RMP/EIS must be submitted or postmarked no later than May 19, 1994. Comments may be submitted at three public meetings to be held:

April 5, 1994, 7–10 p.m., Florida National Guard Armory, Post of Brooksville, 16386 Spring Hill Drive, Brooksville, FL.

April 6, 1994, 7–10 p.m., Department of Environmental Protection, Marjory Stoneman Douglas Building, 3900 Commonwealth Blvd., Tallahassee, FL.

April 7, 1994, 7–10 p.m., De Funiak Springs Community Center, 505 N. 10th Street, De Funiak Springs, FL.

ADDRESSES: Comments should be addressed to Duane Winters, RMP Team Leader, Bureau of Land Management, Jackson District, 411 Briarwood Drive, suite 404, Jackson, Mississippi 39206.

FOR FURTHER INFORMATION CONTACT: Duane Winters, RMP Team Leader, (601) 977–5400.

SUPPLEMENTARY INFORMATION: The Draft RMP/EIS presents and analyzes four alternatives for managing BLM-administered public lands throughout the State of Florida. These lands include approximately 395,000 acres of split-estate federal mineral ownership (where federal ownership is limited to mineral interests and the surface estate is owned by either the State of Florida or private interests) and several hundred acres of public land, comprised of small surface tracts, located in seven counties throughout the State.

The RMP/EIS evaluates three tracts for Area of Critical Environmental Concern (ACEC) designation.

Under the Preferred Alternative, a portion (approximately 60 acres) of the Jupiter Inlet tract, located in Palm Beach County, would be designated an ACEC. The ACEC would be managed to maintain a viable scrub vegetation community and improve habitat conditions for Florida scrub jay, gopher tortoise, and other endemic scrub species, and to interpret natural and cultural resources to provide recreation opportunities.

Motorized vehicle use would be limited to designated routes. The ACEC would be withdrawn from entry under the 1872 mining law, closed to mineral material sales and mineral lease, and would be an avoidance area for rights-of-way. The ACEC would be available for cooperative management with other government agencies and/or private organizations, or for conveyance under the Recreation and Public Purposes Act, provided that the proposed use would follow the stated management objectives and land-use allocations.

The Walton Beach tracts, located in Walton County, are considered for designation as the Walton Beach ACEC in Alternative 3. Under the Preferred Alternative, however, these three tracts would not be designated an ACEC. Under ACEC designation, as considered in Alternative 3, these tracts would be managed for the protection and enhancement of the dune system and associated habitat, and to provide opportunities for non-motorized recreation. The tracts would be classified as an avoidance area for rights-of-way, would be closed to motorized vehicle use, would be withdrawn from entry under the 1872 mining law, and closed to mineral material sales and lease of solid minerals. Oil and gas leasing would be subject to a no surface occupancy stipulation. The tracts would be available for cooperative management with other government agencies and/or private organizations, or for conveyance under the Recreation and Public Purposes Act, provided that the proposed use would follow the stated management objectives and land-use allocations.

The Cape San Blas tract, located in Gulf County, is considered for ACEC designation in Alternative 3. Under the Preferred Alternative, however, it would not be designated an ACEC. Under ACEC designation, as considered in Alternative 3, the tract would be managed to protect the coastal dune habitat. The tract would be closed to motorized vehicle use, would be classified as an avoidance area for rights-of-way, would be withdrawn from entry under the 1872 mining law, and closed to mineral material sales and lease of solid minerals. Oil and gas leasing would be subject to a no surface occupancy stipulation. The tract would be available for cooperative management with other government agencies and/or private organizations, or for conveyance under the Recreation and Public Purposes Act, provided that the proposed use would follow the stated management objectives and land-use allocations. A tract of public land adjacent to the Peace River was evaluated to determine if it was eligible to be studied for possible inclusion in the National Wild and Scenic River System. It was determined that it was ineligible for further study because it would be unmanageable due to the lack of other public lands adjacent to the river. The 37-acre tract of BLM-administered land adjacent to the river comprises only one percent of the land area within a corridor of one-quarter mile on either side of the River for the nine-mile segment evaluated. The remaining acres in the corridor are predominantly under private ownership and are used for agricultural or ranchland purposes.

Dated: February 3, 1994.

Robert V. Abbey,

District Manager.

[FR Doc. 94–2913 Filed 2–8–94; 8:45 am]

BILLING CODE 4310–GJ–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–345]

Notice of Commission Determination To Apply a Modified Procedure for Considering the Presiding Administrative Law Judge's Final Initial Determination and for Deciding Whether There Is a Violation of Section 337 of the Tariff Act of 1930

In the Matter of Certain Anisotropically Etched One Megabit and Greater Drams, Components Thereof, and Products Containing Such Drams

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined, pursuant to rule 201.4(b), to waive in part the interim rules normally applicable to consideration by the Commission of the final initial determination (ID) issued by the presiding administrative law judge (ALJ), and to follow instead a modified procedure for considering the ALJ's final ID in the above-captioned investigation and for deciding whether there is a violation of section 337 of the Tariff Act of 1930.

FOR FURTHER INFORMATION CONTACT: Judith M. Czako, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3093.

SUPPLEMENTARY INFORMATION: On or before February 18, 1994, the ALJ will issue a final ID in this investigation. Ordinarily, final IDs are processed in accordance with the deadlines set forth in Commission interim rules 210.53–.56. In this investigation, however, the Commission has determined to waive in part the application of those interim rules and instead to apply a revised procedure. The revised procedure is similar, but not identical, to the procedure set forth in proposed final rule 210.46(a), published in the **Federal Register** on November 5, 1992 (57 FR 52830, 52883). The interim rules are waived for this investigation to the extent that they conflict with the procedure set forth below.

Commission rule 201.4(b) provides for waiver of rules when in the judgment of the Commission there is good and sufficient reason therefor. The Commission believes these criteria are met here. As noted in the explanatory notes to the proposed final rules (57 FR at 52847), the Commission has proposed an amended and streamlined procedure for review of final IDs. In order to assess

the effectiveness of the amended procedure, the Commission has determined to apply a similar procedure in several section 337 investigations, including this one.

Accordingly, consideration of the ALJ's final ID in this investigation will be according to the following procedure:

1. Petitions for review must be filed no later than March 7, 1994.

2. Responses to the petitions for review must be filed no later than March 16, 1994.

3. Reply submissions must be filed no later than March 21, 1994.

4. Approximately 45 days after issuance of the ID, the Commission may issue a notice requesting written submissions from the parties, other federal agencies, and interested members of the public on the issues of remedy, the public interest, and bonding by the respondents. The notice also may require the parties to file supplemental briefs on violation issues selected by the Commission. The notice will set deadlines for the submission of any such written submissions or briefs.

5. The Commission will issue an order and a **Federal Register** notice on or before June 20, 1994 (the statutory deadline for completion of the investigation) announcing the Commission's decisions on violation of section 337, and, if necessary, on remedy, the public interest, and bonding.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337, 19 U.S.C. 1335), and § 201.4(b) of the Commission's Rules of Practice and Procedure (19 CFR 201.4(b)). Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

By order of the Commission.

Issued: February 3, 1994.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–2977 Filed 2–8–94; 8:45 am]

BILLING CODE 7020–02–P

[Investigation No. 731–TA–683 (Preliminary)]

Fresh Garlic From the People's Republic of China

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of a preliminary antidumping investigation.

SUMMARY: The Commission hereby gives notice of the institution of preliminary antidumping investigation No. 731–TA–683 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from The People's Republic of China of fresh or frozen garlic or cloves thereof, whether or not peeled (skins removed), provided for in subheadings 0703.20.00, 0710.80.70, and 0710.80.97 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value. The Commission must complete preliminary antidumping investigations in 45 days, or in this case by March 17, 1994.

For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: January 31, 1994.

FOR FURTHER INFORMATION CONTACT: Larry Reavis (202–205–3185), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background.—This investigation is being instituted in response to a petition filed on January 31, 1994, by the Fresh Garlic Producers Association, consisting of the A&D Christopher Ranch, Gilroy, CA; Belridge Packing Co., Wasco, CA; Colusa Produce Corp., Colusa, CA; Denice & Filice Packing Co., Hollister, CA; El Camino Packing, Gilroy, CA; The Garlic Company, Shafter, CA; and Vessey and Company, Inc., El Centro, CA.

Participation in the investigation and public service list.—Persons (other than petitioners) wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven (7) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this preliminary investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made not later than seven (7) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Operations has scheduled a conference in connection with this investigation for 9:30 a.m. on February 22, 1994, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Larry Reavis (202–205–3185) not later than February 18, 1994, to arrange for their appearance. Parties in support of the imposition of antidumping duties in this investigation and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in §§ sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before February 25, 1994, a written brief containing information and arguments pertinent to the subject matter of the investigation. Parties may file written testimony in connection with their presentation at the conference no later than three (3) days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with §§ sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.12 of the Commission's rules.

Issued: February 2, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94-2980 Filed 2-8-94; 8:45 am]

BILLING CODE 7020-02-P

[Investigation No. 731-TA-653 (Final)]

Sebacic Acid From the People's Republic of China

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of a final antidumping investigation.

SUMMARY: The Commission hereby gives notice of the institution of final antidumping investigation No. 731-TA-653 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from the People's Republic of China ("China") of sebacic acid,[1] provided for in subheading 2917.13.00 of the Harmonized Tariff Schedule of the United States.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: January 4, 1994.

FOR FURTHER INFORMATION CONTACT: Douglas Corkran (202-205-3177), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

SUPPLEMENTARY INFORMATION:

Background

This investigation is being instituted as a result of an affirmative preliminary determination by the Department of Commerce that imports of sebacic acid from China are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on July 19, 1993, by Union Camp Corp., Wayne, NJ.

Participation in the investigation and public service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than twenty-one (21) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this final investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made not later than twenty-one (21) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in this investigation will be placed in the nonpublic record on May 10, 1994, and a public version will be issued thereafter, pursuant to section 207.21 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with this investigation beginning at 9:30 a.m. on May 24, 1994, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before May 18, 1994. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on May 20, 1994, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2), 201.13(f), and 207.23(b) of the Commission's rules. Parties are strongly encouraged to submit as early in the investigation as possible any requests to present a portion of their hearing testimony *in camera*.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.22 of the Commission's rules; the deadline for filing is May 18, 1994. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.23(b) of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.24 of the Commission's rules. The deadline for filing posthearing briefs is June 2, 1994; witness testimony must be filed no later than three (3) days before the hearing. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before June 2, 1994. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to section 207.20 of the Commission's rules.

Issued: February 2, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94-2978 Filed 2-8-94; 8:45 am]

BILLING CODE 7020-02-P

[Investigations Nos. 731-TA-639 and 640 (Final)]

Stainless Steel Flanges From India and Taiwan

Determinations

On the basis of the record[1] developed in the subject investigations, the Commission determines,[2] pursuant to section 735(b) of the Tariff Act of 1930

[1] For purposes of this investigation, sebacic acid is defined as all grades of the dicarboxylic acid with the formula $(CH_2)_8(COOH)_2$.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Brunsdale and Commissioner Crawford dissenting.

(19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is threatened with material injury by reason of imports from India and Taiwan of stainless steel flanges,[3] provided for in subheadings 7307.21.10 and 7307.21.50 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV). The Commission further determines, pursuant to 19 U.S.C 1673d(b)(4)(B), that it would not have found material injury but for the suspension of liquidation of entries of merchandise under investigation.

Background

The Commission instituted these investigations effective August 2, 1993, following preliminary determinations by the Department of Commerce that imports of stainless steel flanges from India and Taiwan were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the institution of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of September 1, 1993 (58 FR 46212). The hearing was held in Washington, DC, on December 22, 1993, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on February 2, 1994. The views of the Commission are contained in USITC Publication 2724 (February 1994), entitled "Stainless Steel Flanges from India and Taiwan: Investigations Nos. 701–TA–639 and 640 (Final)."

Issued: February 3, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–2979 Filed 2–8–94; 8:45 am]

BILLING CODE 7020–02–P

[3] As defined by Commerce, the flanges covered by these investigations are forged stainless steel flanges, both finished and unfinished, generally manufactured to American Society for Testing and Materials (ASTM) specification ASTM A–182, and made in alloys such as 304, 304L, 316, and 316L. The scope includes 5 general types of flanges. They are weld neck, used for butt-weld line connections; threaded, used for threaded line connections; slip-on & lap joint, used with stub end/butt-weld line connections; socket weld, used to fit pipe into machined recessions; and blind, used to seal off lines. The sizes of the flanges covered in the scope range generally from 1 to 6 inches. However, all sizes of the above-described merchandise are included within the scope.

[Investigation No. 337–TA–355]

Certain Vehicle Security Systems and Components Thereof; Initial Determination Terminating Respondent on the Basis of Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding administrative law judge in the above captioned investigation terminating the following respondent on the basis of a settlement agreement: Audiovox Corporation.

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Under the Commission's rules, the presiding officer's initial determination will become the determination of the Commission thirty (30) days after the date of its service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon parties on February 1, 1994.

Copies of the initial determination, the settlement agreement, and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

WRITTEN COMMENTS: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondents. The original and 14 copies of all such documents must be filed with the Secretary to the Commission, 500 E Street, SW., Washington, DC 20436, no later than 10 days after publication of this notice in the **Federal Register**. Any person desiring to submit a document (or portions thereof) to the Commission in confidence must request confidential treatment. Such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why confidential treatment should be granted. The Commission will either accept the submission in confidence or return it.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, Telephone (202) 205–1802.

Issued: February 1, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–2981 Filed 2–8–94; 8:45 am]

BILLING CODE 7020–02–P

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32454]

Gateway Eastern Railway Co.—Trackage Rights Exemption—Gateway Western Railway Co. and SPCSL Corp.

Gateway Western Railway Company (GWRC) and SPCSL Corp. (SP) have agreed to grant nonexclusive overhead trackage rights to Gateway Eastern Railway Company (GERC) over approximately 12.2 miles of rail line, between milepost 275.0 at "WR" Tower, Granite City, IL, and milepost 287.2 at Church, IL. GERC will also acquire the right to use both GWRC's Venice Yard (milepost 279.0) and East St. Louis Yard (milepost 285.4). GERC is a noncarrier but has filed a notice of exemption, in Gateway Eastern Railway Company—Acquisition and Operation Exemption—Lines of Consolidated Rail Corporation, Finance Docket No. 32304 (ICC served July 2, 1993) (58 FR 35977), to acquire two lines from Consolidated Rail Corporation (Conrail): (1) A 14.79-mile line between milepost 243.5 at "WR" Tower and milepost 0.91 at East Alton, IL, and (2) a 1.9-mile line between milepost 238.7 at "Q" Tower in East St. Louis, IL, and milepost 236.8 at "Willows" interlocking in East St. Louis.[1] The 14.79-mile line connects at "WR" Tower with the 12.2 miles of trackage rights at issue here. By giving GERC direct access to GWRC's Venice and East St. Louis Yards, these trackage rights will facilitate the interchange of traffic between GERC and GWRC. The

[1] GERC also assumed by assignment Conrail's overhead trackage rights on 5.25 miles of line belonging to the Terminal Railroad Association of St. Louis between "WR" Tower and a point near "Willows" interlocking.

trackage rights were to become effective on or after January 28, 1994.[2]

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: William C. Sippel, Two Prudential Plaza, 45th Floor, 180 North Stetson Avenue, Chicago, IL 60601.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: February 3, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–2983 Filed 2–8–94; 8:45 am]

BILLING CODE 7035–01–P

[2] Neither these trackage rights nor the ones in Finance Docket No. 32307 (where GWRC filed a notice of exemption to acquire overhead trackage on a portion of the 1.9 mile line being acquired in Finance Docket No. 32304) can become effective until GERC consummates the acquisition and operation in Finance Docket No. 32304 and becomes a carrier entitled to use the exemption procedures in 49 CFR 1180.2(d)(7). Because a noncarrier may file, but not consummate, exemptions under section 1180.2(d) before becoming a carrier, the notice of exemption was not rejected as requested by the United Transportation Union, Illinois Legislative Board (UTU), on January 27, 1994, in a petition to stay, reject, and/or revoke.

GERC may not consummate the acquisition and operation exemption in Finance Docket No. 32304 until the petition for exemption is granted in Finance Docket No. 32306 or a valid voting trust is filed under 49 CFR 1013.3. In Finance Docket No. 32306, GWRC, which wholly owns GERC, and Wertheim Schroder & Co., Inc., which controls GWRC, seek an exemption under 49 U.S.C. 10505 from the prior approval requirements of 49 U.S.C. 11343 *et seq.* to continue in control of GERC when it becomes a carrier. While that exemption petition was pending, a draft voting trust agreement was informally submitted to, and approved by, Commission personnel, consistent with the procedures of 49 CFR 1013.3, in a letter dated January 14, 1994.

UTU petitioned to stay the effective date of the notice of exemption filed in the instant proceeding and the notices of exemption issued in Finance Docket Nos. 32304 and 32307. UTU also sought revocation of the instant exemption and has pending with the Commission petitions to revoke the latter two notices of exemption. The stay petition, although timely filed, was not received in time for action before the January 28, 1994 effective date of the instant exemption, and the latter two exemptions had already become effective. The Commission will entertain in a consolidated decision: (1) UTU's petition to revoke in the instant proceeding, (2) the pending petitions to revoke by UTU and others in Finance Docket Nos. 32304 and 32307, and (3) the continuance in control exemption in Finance Docket No. 32306.

These proceedings are all related to Finance Docket No. 32305, where GERC and GWRC jointly seek an exemption under 49 U.S.C. 10505 from the prior approval requirements of 49 U.S.C. 10901 to construct a connection between GWRC's lines and the 1.9-mile line in Finance Docket No. 32304 and that was the subject of the trackage rights agreement between GERC and GWRC in Finance Docket No. 32307. The construction and trackage rights are intended to give GWRC direct access to Conrail's Rose Lake Yard.

They are also related to the Commission's decision in *Gateway Western Railway Company—Construction Exemption—St. Clair County, IL, et al.*, Finance Docket Nos. 32158 and 32158 (Sub-No. 1) (ICC served May 11, 1993). In these proceedings, the Commission conditionally granted GWRC an exemption to construct and operate a rail line in East St. Louis but requested additional evidence on whether the construction of a Conrail connection was intended and the anticipated traffic consequences of such a connection. Petitions to reopen and revoke these exemptions are now pending before the Commission.

[Finance Docket No. 32456]

Peninsula Corridor Joint Powers Board—Renewal of Trackage Rights Exemption—Southern Pacific Transportation Co.

Peninsula Corridor Joint Powers Board (JPB) has filed a verified notice under 49 CFR 1180.2(d)(7) to exempt Southern Pacific Transportation Company's extension through February 1, 1997, of the term of an agreement granting JPB passenger commuter service trackage rights over rail lines in California between milepost 44.0 at or near Santa Clara Junction and milepost 48.7 at or near Tamien.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the exemption's effectiveness. Pleadings must be filed with the Commission and served on Michael N. Conneran, Hanson, Bridgett, Marcus, Vlahos & Rudy, 333 Market Street, suite 2300, San Francisco, CA 94105.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: February 3, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–2984 Filed 2–8–94; 8:45 am]

BILLING CODE 7035–01–P

[Finance Docket No. 32449]

San Bernardino Associated Governments—Acquisition Exemption—Southern Pacific Transportation Co.

San Bernardino Associated Governments (SANBAG) has filed a notice of exemption to acquire from Southern Pacific Transportation Company (SP), approximately 21.86 miles of SP's Baldwin Park Branch line between mileposts 515.82 and 537.68, all in San Bernardino County, CA. According to SANBAG, the acquisition took place on April 19, 1991, when SANBAG was a noncarrier.[1]

This notice is filed under 49 CFR 1150.31.[2] If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Charles A. Spitulnik, Hopkins & Sutter, 888 16th St., NW, suite 700, Washington, DC 20006.

Decided: January 31, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 94–2985 Filed 2–8–94; 8:45 am]

BILLING CODE 7035–01–P

[1] This proceeding is related to Docket No. AB–12 (Sub-No. 158X), *Southern Pacific Transportation Company—Discontinuance of Service Exemption—San Bernardino, CA*, wherein SP seeks an exemption under 49 U.S.C. 10505 from the prior approval requirements of 49 U.S.C. 10903 *et seq.* to discontinue service over a 15.70-mile portion of the Baldwin Park Branch between mileposts 519.80 and 535.50. The Commission has deferred issuing a decision on SP's petition pending SANBAG's response concerning its possible unauthorized acquisition of the line. SANBAG responded by filing this notice of exemption.

[2] SANBAG requests that exemption be considered *nunc pro tunc*; however, we note that the class exemption involved here provides only for prospective application. Under the class exemption procedures, this exemption became effective on January 17, 1994, seven days after it was filed with the Commission on January 10, 1994.

DEPARTMENT OF LABOR

Office of the Secretary

Commission on the Future of Worker-Management Relations; Notice of Meeting

AGENCY: Office of the Secretary of Labor.

ACTION: Notice of public meeting.

SUMMARY: The Commission on the Future of Worker-Management Relations

was established in accordance with the Federal Advisory Committee Act (FACA) Public Law 92–463. Pursuant to Section 10(a) of FACA, this is to announce that the Commission will meet at the time and place shown below:

TIME AND PLACE: The meeting will be held on Thursday, February 24, 1994 from 10 a.m. to 4:30 p.m. in room N–3437 A–D, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

AGENDA: The agenda for the meeting is as follows:

The meeting will be devoted to procedural and substantive issues of representation. It will receive testimony on the facts of the representation process and what, if any, changes in the present legal framework are required to enhance cooperative behavior, improve productivity, and reduce conflict and delay.

The meeting will be organized around two panels, one in the morning and one in the afternoon. The morning panel will be comprised of two representatives of labor, one a lawyer and one a union officer concerned with organizing campaigns, and two representatives of management, one a lawyer and one a human resources executive.

The afternoon panel will be drawn from academic specialists including professors of labor law and academics reporting on research concerning representation issues.

The members of the panels will each be allotted ten minutes of prepared presentations and then engage in discussion of the issues with each other and with members of the Commission.

PUBLIC PARTICIPATION: The meeting will be open to the public. It will be in session from 10 a.m. until 12:30 p.m. when it will adjourn for lunch and will return at 1:45 p.m. Seating will be available to the public on a first-come, first-served basis. Handicapped individuals wishing to attend should contact the Commission to obtain appropriate accommodations. Individuals or organizations wishing to submit written statements should send 15 copies to Mrs. June M. Robinson, Designated Federal Official, Commission on the Future of Worker-Management Relations, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 219–9148.

Signed at Washington, DC this 2nd day of February, 1994.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 94–2926 Filed 2–8–94; 8:45 am]

BILLING CODE 4510–23–M

Pension and Welfare Benefits Administration

[Application No. D–9578, et al.]

Proposed Exemptions; Richmond, Fredericksburg and Potomac Railway Company Employee Thrift and Investment Plan, et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** notice. Comments and request for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Richmond, Fredericksburg and Potomac Railway Company Employee Thrift and Investment Plan (the Plan) Located in Richmond, Virginia [Application No. D–9578]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed sale by the Plan of a guaranteed investment contract, No. GA–5250 (the GIC) issued by Mutual Benefit Life Insurance Company of New Jersey (Mutual Benefit) to the Richmond, Fredericksburg & Potomac Corporation (RFP), a party in interest with respect to the Plan; provided the following conditions are satisfied: (1) The sale is a one-time transaction for cash; (2) the Plan receives no less than the fair market value of the GIC at the time of the sale; (3) the Plan's trustee, acting as independent fiduciary for the Plan, has

determined that the proposed sale price is not less than the current fair market value of the GIC; and (4) the Plan's trustee has determined that the proposed transaction is appropriate for and in the best interests of the Plan and its participants and beneficiaries.

Summary of Facts and Representations

1. The Plan is a defined contribution individual-account plan with provisions for salary reduction contributions. As of June 30, 1993, the Plan had total assets of approximately $10,796,703. The Plan had 130 participants as of December 31, 1992. The Plan is sponsored by the Richmond, Fredericksburg and Potomac Railway Company (the Rail Company), a Delaware Corporation with its principal place of business in Richmond, Virginia. Investment decisions with respect to Plan assets are made by the individual participants, who direct the investment of their Plan accounts among investment options chosen by an investment committee (the Committee) comprised of three employees of the Rail Company. The custodial trustee of the Plan is NationsBank of Virginia, N.A. (the Trustee).

2. RFP is a Virginia corporation with its principal place of business in Richmond, Virginia. RFP formerly owned and operated a railroad, which was sold to the Rail Company effective October 10, 1991. When RFP sold the railroad, most RFP employees engaged in the railroad operations were hired by the Rail Company. In addition, the section 401(k) profit sharing plan (the Previous Plan) which RFP had maintained for its employees was adopted and renamed the Plan's current name by the Rail Company when it bought the railroad.[1]

3. Under the Previous Plan, participants were offered several options for the investment of the salary reduction contributions in their accounts, including a "guaranteed fund" (the G Fund) which invested primarily in guaranteed investment contracts issued by insurance companies, as selected by the Committee. The assets in the G Fund, now included among the assets of the Plan, included the GIC, contract No. GA–5250 issued by Mutual Benefit on January 1, 1991. RFP represents that the GIC is a guaranteed investment contract bearing interest on deposits at the rate of 8% per annum for three years.

4. On July 16, 1991, Mutual Benefit was placed into rehabilitation proceedings by the New Jersey Commissioner of Insurance. As a result of these proceedings, payments on Mutual Benefits group annuity contracts, including the GIC held by the Plan, have been suspended indefinitely.[2] On July 18, 1991, the Committee directed the Trustee to discontinue deposits under the GIC. The Committee also notified Plan participants that until further notice, withdrawals from the G Fund are limited to the participants' interests in G Fund assets other than the GIC. RFP represents that it is uncertain whether or to what extent Mutual Benefit will be able to make any further payments or honor any withdrawal requests pursuant to the terms of the GIC.

RFP represents that it wishes to enter into the proposed transaction in order to protect the accounts of Plan participants and beneficiaries from the effects of a prolonged rehabilitation process and from any potential loss if, as anticipated, the assets of Mutual Benefit are not sufficient to meet its obligations under the GIC.[3] RFP also represents that the proposed purchase of the GIC would make funds available to the Plan which are currently due under the terms of the contract. RFP represents that the Plan will not incur any expenses with respect to the sale of the GIC.

5. RFP proposes to protect the interests of the affected participants by purchasing the GIC from the Plan at its accumulated book value. The accumulated book value is defined as the sum of all amounts deposited under the terms of the GIC, plus accrued interest, less any amounts withdrawn from the GIC by the Plan. Accrued interest is calculated at the contract rate of 8% until December 31, 1993, the maturity date. For the period beginning on January 1, 1994 and ending on the purchase date, interest will be credited at a rate equal to 3.5%. The proposed rate of interest for periods after the maturity date are the rates that would apply to the GIC for those periods according to the proposed plan of rehabilitation set forth by the Superior Court of New Jersey. RFP represents that a request for a closing agreement has been filed with the Internal Revenue Service pursuant to Internal Revenue Procedure 92–16.[4]

6. The Trustee, acting as the Plan's independent fiduciary with respect to this transaction, has reviewed the proposed transaction on behalf of the Plan. The Trustee represents that it has determined that the proposed purchase price for the GIC is at least equal to the fair market value of the GIC. In addition, the Trustee represents that it has determined that the proposed transaction is appropriate for the Plan and in the best interests of its participants and beneficiaries. Immediately prior to the actual sale of the GIC to RFP, the Trustee will re-examine the appropriateness of the proposed transaction for the Plan, including the fair market value of the GIC.

7. In summary, the applicant represents that the proposed transaction satisfies the criteria of section 408(a) of the Act because: (1) The Plan will receive cash for the GIC in the amount of the accumulated book value of the Guaranteed Investment Contract, which the Plan's independent fiduciary has determined to be not less than the fair market value of the GIC; (2) the transaction will enable the Plan and its participants and beneficiaries to avoid any risk associated with the continued holding of the GIC, and to exercise all of their rights under the Plan to request distributions, loans, withdrawals and investment transfers with respect to amounts currently invested in the GIC; (3) the Plan's Trustee, acting as the Plan's independent fiduciary, has determined that the sale at the proposed price is in the best interests of the participants and beneficiaries of the Plan; and (4) immediately prior to the sale, the Trustee will determine if the proposed transaction is appropriate for and in the best interests of the Plan and its participants and beneficiaries.

Notice to Interested Persons

Notice of the proposed exemption will be provided to all interested persons within 5 days of the publication

[1] The applicant has informed the Department that all participants in the Previous Plan, including RFP employees who were not hired by the Rail Company when it bought the railroad, became participants in the Plan and all assets of the Previous Plan became assets of the Plan when the Rail Company bought the railroad. RFP has subsequently established a new 401(k) Plan for its employees. Consequently, immediately following the purchase of the GIC by RFP, the Plan will transfer to RFP's new 401(k) plan the amounts credited to the accounts of participants who have continued in RFP's employ.

[2] The Department notes that the decisions to acquire and hold the GIC are governed by the fiduciary responsibility requirements of Part 4, Subtitle B, Title I of the Act. In this regard, the Department is not herein proposing relief for any violations of Part 4 which may have arisen as a result of the acquisition and holding of the GIC issued by Mutual Benefit.

[3] RFP previously applied for, and received, an administrative exemption allowing for an extension of credit from RFP to the Plan which would enable the Plan to make distributions to Plan participants. RFP represents that the extension of credit never occurred because RFP never received approval from the Internal Revenue Service for the proposed loan.

[4] Internal Revenue Procedure 92–16 provides for a temporary closing agreement program to settle certain tax liabilities that arise out of transactions between an employer-sponsor and the trust of a qualified defined contribution plan.

of the notice of proposed exemption in the Federal Register. The notice will include a copy of the notice of proposed exemption as published in the Federal Register and it will be provided to all participants and beneficiaries by first class mail. The notice will inform interested persons of their right to comment on and/or to request a hearing with respect to the proposed exemption. Written comments and requests for a public hearing are due within 35 days of publication of the notice of proposed exemption in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Ms. Virginia J. Miller of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

Stroh Brewery Company, Inc. Salaried Employees' Thrift Plan (the Plan) Located in Detroit, Michigan

[Application No. D–9580]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990). If the exemption is granted, the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale (the Sale) of certain pooled fund units from the Plan to Stroh Brewery Company, Inc., a party in interest with respect to the Plan.

This proposed exemption is conditioned upon the following requirements: (1) All terms and conditions of the Sale are at least as favorable to the Plan as those obtainable in an arm's-length transaction; (2) the Sale is a one-time cash transaction; (3) the Plan is not required to pay any commissions, costs or other expenses in connection with this transaction; and (4) the Plan receives a sales price equal to the fair market value of its residual interest in the Convertibles Fund.

Effective Date: This exemption, if granted, would be effective as of December 31, 1993.

Summary of Facts and Representations

1. The Plan is a 401(k) plan sponsored by the Stroh Brewery Company, Inc., (the Employer), an Arizona corporation engaged in the business of brewing beverages. As of July 31, 1993, the Plan had total assets of $73,440,876 and 589 participants.

2. The Plan is comprised of three funds—the equity fund, the fixed investment fund and the balanced fund. In 1973, the Plan's equity fund commenced participation in the Morgan Guaranty Trust Company of New York Convertibles Fund (the Convertibles Fund), which is a pooled asset fund. The Convertible Fund has traditionally been comprised of limited partnerships and convertible securities, principally debt instruments convertible into equity. From 1973 until the current time, various amounts have been invested in and withdrawn by the Plan from the Convertible Fund. The cumulative annual rate of return for the Convertibles Fund has been 10.96 percent.

In late 1990, three large investors (the Investors) in the Convertibles Fund sought to withdraw their investment from the Convertibles Fund. Because of the lack of new investors, the Investor's withdrawal would have left virtually no liquidity in the Convertibles Fund. Therefore, Morgan determined that all investors would be required to remain in the Convertibles Fund until it could be completely liquidated. In February 1991, Morgan Guaranty Trust Company of New York (Morgan) commenced liquidation of the Convertibles Fund. At the current time, Morgan has liquidated all of the Convertibles Fund's underlying assets which were readily disposable on a recognized market. The remaining assets in the Convertibles Fund include miscellaneous items such as private placements and limited partnership interests which have no readily discernable market. Morgan estimates that it will take three to five years to liquidate these remaining assets in the Convertible Fund.

Morgan values the Convertibles Fund monthly based upon: (1) Limited partnerships: limited partnerships are valued based upon valuation information obtained from the general partners; (2) public securities: public securities are priced at market, with some discount taken for liquidity; (3) bankrupt securities: bankrupt securities are currently being carried and regularly priced at zero to ten percent of their original value; and (4) private securities: private securities are priced by determining the net present value of the projected stream of cash flow, discounted for liquidity.

As of November 10, 1993, Morgan placed the fair market value of the Convertibles Fund at $620.68 per unit. However in November of 1993, Morgan split the Convertibles Fund's price per unit by ten. This was done in an effort to facilitate an efficient liquidation of the Convertibles Fund by allowing distributions of smaller amounts on a more frequent basis. Therefore, the price per unit after the split was $62.06 a unit. As of December 17, 1993, the Plan's residual investment in the Convertibles Funds was 832 units (the Units). As of December 17, 1993, the applicant represents that Morgan valued the price per unit at $64.63, making the total value of the Units equal to $53,772.

3. Effective January 1, 1994, Fidelity Management Trust Company (Fidelity) will become the trustee of the Plan and intends to make the Plan a section 404(c) plan within the meaning of regulation 29 CFR 2550.404(c)-1 of the Department and to comply with all the relevant requirements of that regulation. However, this objective cannot be met until the Units are converted into cash. Because Morgan cannot readily liquidate the remaining units in the Convertibles Fund (see Paragraph #2 above), the Plan proposes to sell the Units to the Employer for cash for their fair market value. The Employer will then hold on to the Units until the liquidation is completed. The fair market value will be based on the most recent monthly valuation of the Convertibles Fund provided by Morgan. The Sale will be a one-time cash transaction, and the Plan will incur no expenses with respect to the transaction. Accordingly, the Employer requests an administrative exemption from the Department to permit the Sale from the Plan to the Employer under the terms and conditions described herein.

5. In summary, the applicant represents that the proposed transaction will satisfy the statutory criteria for an exemption under Section 408(a) of the Act because: (1) The terms of the Sale will be at least as favorable as those the Plan could obtain in an arm's-length transaction; (2) the Sale will be a one-time cash transaction; (3) the Plan will not be required to pay any commissions, costs or other expenses in connection with this transaction; and (4) the Plan will receive a sales price equal to the fair market value of its residual interest in the Convertibles Fund.

FOR FURTHER INFORMATION CONTACT: Kathryn Parr of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

CS Holding and Affiliates Located in New York, New York

[Application No. D–9605]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If

the exemption is granted, CS Holding and each of its affiliates (collectively, CS Holding), except Banque Leu Luxembourg (BLL), shall not be precluded from functioning as a "qualified professional asset manager" pursuant to Prohibited Transaction Exemption 84–14 (PTE 84–14, 49 FR 9494, March 13, 1984) solely because of a failure to satisfy Section I(g) of PTE 84–14, as a result of affiliation with BLL, including any current or future affiliate of CS Holding, other than BLL, which in the future may become eligible to serve as a QPAM under PTE 84–14.

Effective Date: This exemption, if granted, will be effective as of December 17, 1993.

Summary of Facts and Representations

1. CS Holding is a publicly-owned holding company organized under Swiss law and located in Zurich, Switzerland. Through the international operations of its affiliated components, CS Holding provides a variety of financial services. Its affiliates include BLL, a financial institution organized under the laws of the Grand Duchy of Luxembourg. Prior to July 10, 1990 BLL was not affiliated with CS Holding or any of its affiliates. On that date, Leu Holding, a subsidiary of CS Holding, acquired the parent of BLL. BLL became a wholly-owned subsidiary of Leu Holding in December 1990 as a result of corporate restructuring. CS Holding currently owns approximately 96.8 percent of Leu Holding. BLL engages primarily in private banking, investment counseling, and portfolio management. CS Holding represents that BLL has not in the past acted, nor is it presently acting or intending in the future to act, as a fiduciary with respect to any employee benefit plans subject to the Act or the Code.

2. On December 17, 1993, BLL entered a plea of guilty (the Plea) in the U.S. District Court for the Northern District of California in response to an information filed by the U.S. Attorney's Office (the Information) charging BLL with one count of money laundering in violation of 18 U.S.C. section 1957. The Information charges that between February 20, 1989 and February 28, 1990, a BLL account officer (the Officer) engaged in monetary transactions involving criminally derived property by transferring cashier's checks from BLL in Luxembourg to certain U.S. banks, on behalf of two related BLL customer bank accounts. The Information charges that the Officer, who is no longer employed by BLL, acted knowingly or with conscious avoidance of knowledge that the checks represented proceeds of illegal activity. CS Holding represents that the Plea represents BLL's acceptance of responsibility for the isolated actions of a former employee, and that in connection with the Plea, BLL has entered into a plea agreement (the Plea Agreement) with the U.S. Attorney's Office which filed the Information, obligating BLL to certain sanctions and certain corrective measures, described below.

CS Holding notes that the Plea relates solely to BLL, which was not an affiliate of CS Holding at the time of the Officer's actions involved in the Information. CS Holding states that all of the facts forming the factual basis of the Information occurred prior to the date that CS Holding acquired control of BLL, and that neither CS Holding nor any of its affiliates was aware of such facts until after CS Holding acquired control of BLL. The transaction through which CS Holding acquired an indirect interest in BLL (the Acquisition) was consummated in July 1990, several months after the last illegal check transfer involved in the Information. CS Holding represents that prior to the Acquisition BLL operated independently of CS Holding, and that officials of CS Holding did not become aware of the conduct described in the Information until more than one year after CS Holding acquired control of BLL.

6. CS Holding represents that although the Officer's actions did not involve any investment management activities of BLL or any assets of plans covered by the Act, the plea of guilty to the criminal activities described above would preclude each component of CS Holding, as an affiliate of BLL, from serving as a "qualified professional asset manager" (QPAM) pursuant to sections I(g) and V(d) of PTE 84–14. Section I(g) of PTE 84–14 precludes a person who otherwise qualifies as a QPAM from serving as a QPAM if such person or an affiliate[5] thereof has within the 10 years immediately preceding the transaction been either convicted or released from imprisonment as a result of certain criminal activity. CS Holding requests an exemption to enable CS Holding affiliates to function as QPAMs despite their failure to satisfy section I(g) of PTE 84–14 due to affiliation with BLL and the Pleas entered by BLL.

7. The proposed exemption is requested on behalf of CS Holding affiliates that are banks, investment banking firms, or registered investment advisers, which are, or may become, eligible to serve as QPAMs. The proposed exemption would also apply to CS Holding affiliates that are acquired in the future. CS Holding represents that the requested exemption, to enable access to the exemptive relief afforded by PTE 84–14, is needed for CS Holding affiliates to engage in the full range of transactions that can be executed by investment managers who qualify as QPAMs. CS Holding represents that PTE 84–14 is not relevant for most transactions involving the purchase or sale of U.S. exchange-traded securities, securities lending, investment in short-term instruments, or certain residential mortgage pools, since these transactions may be effected pursuant to other applicable class exemptions. However, CS Holding represents that PTE 84–14 is necessary where the CS Holding affiliates have discretion over investments by plans covered by the Act in real estate, mortgages fixed income securities, foreign securities, derivatives, foreign currency and other commodities, since there is no other class exemption permitting an investment manager to purchase property from, sell or lease property to, borrow money from, or engage in principal transactions in fixed income securities , foreign currency and commodities with parties-in-interest with respect to the investing employee benefit plans.

8. CS Holding represents that various measures have been taken to ensure that conduct such as that involved in the Plea will not recur. Among the steps taken by CS Holding are the following:

(A) Promptly after BLL learned of the investigation into this matter, in November 1991, BLL terminated the employment of the Officer.

(B) In November and December 1991, BLL conducted an extensive internal review of its private banking accounts to determine if there were any other accounts indicative of suspicious activity. A follow-up investigation was conducted in February 1992. CS Holding represents that the reviews conducted by BLL's internal audit department found no evidence that any other accounts were being used for money laundering activities.

(C) In January 1992, BLL adopted additional internal auditing procedures for private banking activities, requiring monthly audits of all new accounts. In addition, in February 1992, BLL issued new instructions regarding business relationships with private banking customers, including procedures for acceptance of deposits and expanded reporting responsibilities of account officers.

[5] For purposes of section I(g) of PTE 84–14, an "affiliate" of a person is defined, in relevant part, as "any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with the person * * *" (PTE 84–14 section V(d)). As such, under this definition, CS Holding and all its subsidiaries (collectively, CS Holding) would be considered affiliates of BLL.

(D) In February 1992 BLL elected to adopt the Swiss Federal Bank Commission's guidelines for the prevention of money laundering. In March 1992, BLL instituted an electronic data processing system which automatically records all incoming and outgoing payments with the time and date, facilitating the early recognition of possible money laundering activities.

(E) Effective May 1, 1992, BLL established a new management position responsible for the implementation and enforcement of anti-money laundering procedures. A new managerial position also was created effective June 1, 1992 to oversee back-office control procedures, including supervision and inspection of payment traffic and securities transactions.

(F) At the time of the Plea, BLL agreed, under the terms of the Plea Agreement, (1) to forfeit $2.3 million to the United States, (2) to pay a fine of $60,000, and (3) to retain Price Waterhouse to prepare, and file with the U.S. Attorney's Office, annual Special Purpose Reports to be issued on April 15, 1994, April 15, 1995, and April 15, 1996. In addition, the Plea Agreement requires BLL to prepare a monograph with yearly updates providing information about money laundering laws, currency regulations, forfeiture laws, laws prohibiting the structuring of transactions to avoid reporting requirements, and methods of detecting and preventing illegal money laundering, to be distributed to employees of BLL involved in servicing customer accounts, all correspondent banks of BLL, and various European financial institutions and regulatory bodies.

9. CS Holding asserts that failure to grant the requested exemption will prohibit employee benefit plans for which CS Holding affiliates act as investment managers from engaging in transactions with parties in interest that would otherwise be permitted under PTE 84–14, and will cause the plans to forego attractive investment opportunities, due to the large number of service providers engaged by client plans, and the wide array of services offered by CS Holding affiliates to plans. CS Holding states that many of its affiliates would be deprived of their abilities to offer and render the full range of specialized investment advisory services demanded by employee benefit plans covered by the Act. CS Holding notes that the actions involved in the Information did not involve the operations of any CS Holding affiliates, other than BLL prior to its affiliation with CS Holding, and that, accordingly, such actions should not impair or relate to the abilities of CS Holding affiliates to serve as QPAMs. CS Holding represents that many of the employee benefit plans which are clients of CS Holding affiliates are plans with assets in excess of $50 million, with a significant portion of such plans having assets in excess of $100 million, and that such plans benefit from the investment sophistication and access to resources necessary to properly and independently monitor the performance of investment managers engaged on their behalf. CS Holding represents that the CS Holding affiliates which are eligible to serve as QPAMs are subject to regulation under U.S. securities or banking laws, and that the CS Holding affiliates serving as investment advisers registered under the Investment Advisers Act of 1940 are subject to that Act's substantive requirements and the jurisdiction of the Securities and Exchange Commission, including unannounced audits and annual disclosure requirements.

10. In summary the applicant represents that the proposed exemption satisfies the criteria of section 408(a) of the Act for the following reasons: (A) The criminal activity involved in the Plea occurred prior to CS Holding's acquisition of any interest in BLL, and did not involve any criminal charges against any affiliates of CS Holding other than BLL; (B) CS Holding has taken substantial measures to prevent any recurrence of the criminal activity; (C) CS Holding affiliates will be able to engage in a broader variety of investment services on behalf of employee benefit plans which demand such services; (D) The criminal acts in question were neither authorized nor condoned by BLL or any other component of CS Holding; and (E) The other conditions of PTE 84–14, combined with the measures taken by CS Holding, afford ample protection of the interests of participants and beneficiaries of employee benefit plans.

For Further Information Contact: Ronald Willett of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Residential Funding Corporation (RFC), Residential Funding Mortgage Securities, Inc. (RFMSI), Residential Funding Mortgage Exchange Corporation (RFMEC), Residential Funding Securities Corporation (RFSC), GMAC Auto Receivables Corporation (GMAC Auto), General Motors Acceptance Corporation (GMAC), GMAC Mortgage Corporation (GMAC Mortgage) and GMAC Mortgage Securities II, Inc. (GMAC Mortgage Securities; together, the Applicants) Located in Minneapolis, Minnesota (RFC, RFMSI, RFMEC and RFSC), Wilmington, Delaware (GMAC Auto), New York, New York (GMAC), and Elkins Park, Pennsylvania (GMAC Mortgage and GMAC Mortgage Securities)

[Application Nos. D–9112 and D–9113]

Proposed Exemption

I. Transactions

A. Effective June 9, 1992, the restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan when the sponsor, servicer, trustee or insurer of a trust, the underwriter of the certificates representing an interest in the trust, or an obligor is a party in interest with respect to such plan;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.A. (1) or (2).

Notwithstanding the foregoing, section I.A. does not provide an exemption from the restrictions of sections 406(a)(1)(E), 406(a)(2) and 407 for the acquisition or holding of a certificate on behalf of an Excluded Plan by any person who has discretionary authority or renders investment advice with respect to the assets of that Excluded Plan.[6]

B. Effective June 9, 1992, the restrictions of sections 406(b)(1) and 406(b)(2) of the Act and the taxes

[6] Section I.A. provides no relief from sections 406(a)(1)(E), 406(a)(2) and 407 for any person rendering investment advice to an Excluded Plan within the meaning of section 3(21)(A)(ii) and regulation 29 CFR 2510.3–21(c).

imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1)(E) of the Code shall not apply to:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and a plan when the person who has discretionary authority or renders investment advice with respect to the investment of plan assets in the certificates is (a) an obligor with respect to 5 percent or less of the fair market value of obligations or receivables contained in the trust, or (b) an affiliate of a person described in (a); if:

(i) The plan is not an Excluded Plan;

(ii) Solely in the case of an acquisition of certificates in connection with the initial issuance of the certificates, at least 50 percent of each class of certificates in which plans have invested is acquired by persons independent of the members of the Restricted Group and at least 50 percent of the aggregate interest in the trust is acquired by persons independent of the Restricted Group;

(iii) a plan's investment in each class of certificates does not exceed 25 percent of all of the certificates of that class outstanding at the time of the acquisition; and

(iv) immediately after the acquisition of the certificates, no more than 25 percent of the assets of a plan with respect to which the person has discretionary authority or renders investment advice are invested in certificates representing an interest in a trust containing assets sold or serviced by the same entity.[7] For purposes of this paragraph B.(1)(iv) only, an entity will not be considered to service assets contained in a trust if it is merely a subservicer of that trust;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates, provided that the conditions set forth in paragraphs B.(1) (i), (iii), and (iv) are met; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.B. (1) or (2).

C. Effective June 9, 1992, the restrictions of sections 406(a), 406(b) and 407(a) of the Act, and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c) of the Code, shall not apply to transactions in connection with the servicing, management and operation of a trust, provided:

(1) such transactions are carried out in accordance with the terms of a binding pooling and servicing arrangement; and

(2) the pooling and servicing agreement is provided to, or described in all material respects in the prospectus or private placement memorandum provided to, investing plans before they purchase certificates issued by the trust.[8]

Notwithstanding the foregoing, section I.C. does not provide an exemption from the restrictions of section 406(b) of the Act or from the taxes imposed by reason of section 4975(c) of the Code for the receipt of a fee by a servicer of the trust from a person other than the trustee or sponsor, unless such fee constitutes a "qualified administrative fee" as defined in section III.S.

D. Effective June 9, 1992, the restrictions of sections 406(a) and 407(a) of the Act, and the taxes imposed by sections 4975(a) and (b) of the Code by reason of sections 4975(c)(1) (A) through (D) of the Code, shall not apply to any transactions to which those restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in section 3(14) (F), (G), (H), or (I) of the Act or section 4975(e)(2) (F), (G), (H), or (I) of the Code), solely because of the plan's ownership of certificates.

II. General Conditions

A. The relief provided under Part I is available only if the following conditions are met:

(1) The acquisition of certificates by a plan is on terms (including the certificate price) that are at least as favorable to the plan as they would be in an arm's-length transaction with an unrelated party;

(2) The rights and interests evidenced by the certificates are not subordinated to the rights and interests evidenced by other certificates of the same trust;

(3) The certificates acquired by the plan have received a rating at the time of such acquisition that is in one of the three highest generic rating categories from either Standard & Poor's Corporation (S&P's), Moody's Investors Service, Inc. (Moody's), Duff & Phelps Inc. (D & P) or Fitch Investors Service, Inc. (Fitch);

(4) The trustee is not an affiliate of any member of the Restricted Group. However, the trustee shall not be considered to be an affiliate of a servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of a pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer;

(5) The sum of all payments made to and retained by the underwriters in connection with the distribution or placement of certificates represents not more than reasonable compensation for underwriting or placing the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trust represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith; and

(6) The plan investing in such certificates is an "accredited investor" as defined in Rule 501(a)(1) of Regulation D of the Securities and Exchange Commission under the Securities Act of 1933.

B. Neither any underwriter, sponsor, trustee, servicer, insurer, or any obligor, unless it or any of its affiliates has discretionary authority or renders investment advice with respect to the plan assets used by a plan to acquire certificates, shall be denied the relief provided under Part I, if the provision of subsection II.A.(6) above is not satisfied with respect to acquisition or holding by a plan of such certificates, provided that (1) such condition is disclosed in the prospectus or private placement memorandum; and (2) in the case of a private placement of certificates, the trustee obtains a representation from each initial purchaser which is a plan that it is in compliance with such condition, and obtains a covenant from each initial purchaser to the effect that, so long as such initial purchaser (or any transferee of such initial purchaser's certificates) is

[7] For purposes of this exemption, each plan participating in a commingled fund (such as a bank collective trust fund or insurance company pooled separate account) shall be considered to own the same proportionate undivided interest in each asset of the commingled fund as its proportionate interest in the total assets of the commingled fund as calculated on the most recent preceding valuation date of the fund.

[8] In the case of a private placement memorandum, such memorandum must contain substantially the same information that would be disclosed in a prospectus if the offering of the certificates were made in a registered public offering under the Securities Act of 1933. In the Department's view, the private placement memorandum must contain sufficient information to permit plan fiduciaries to make informed investment decisions.

required to obtain from its transferee a representation regarding compliance with the Securities Act of 1933, any such transferees will be required to make a written representation regarding compliance with the condition set forth in subsection II.A.(6) above.

III. Definitions

For purposes of this exemption:

A. "Certificate" means:

(1) a certificate

(a) that represents a beneficial ownership interest in the assets of a trust;

(b) that entitles the holder to pass-through payments of principal, interest, and/or other payments made with respect to the assets of such trust; and

(c) with respect to which (i) one of the Applicants or any of their affiliates is the sponsor, and an entity which has received from the Department an individual prohibited transaction exemption relating to certificates which is similar to this exemption is the sole underwriter or the manager or co-manager of the underwriting syndicate or a selling or placement agent; or (ii) one of the Applicants is the sole underwriter or the manager or co-manager of the underwriting syndicate or a selling or placement agent; or

(2) A certificate denominated as a debt instrument -

(a) That represents an interest in a Real Estate Mortgage Investment Conduit (REMIC) within the meaning of section 860D(a) of the Code; and

(b) That is issued by and is an obligation of a trust with respect to which (i) one of the Applicants or any of its affiliates is the sponsor, and an entity which has received from the Department an individual prohibited transaction exemption relating to certificates which is similar to this exemption is the sole underwriter or the manager or co-manager of the underwriting syndicate or a selling or placement agent or (ii) one of the Applicants is the sole underwriter or the manager or co-manager of the underwriting syndicate, or a selling or placement agent.

For purposes of this exemption, references to "certificates representing an interest in a trust" include certificates denominated as debt which are issued by a trust.

B. "Trust" means an investment pool, the corpus of which is held in trust and consists solely of:

(1) either

(a) secured consumer receivables that bear interest or are purchased at a discount (including, but not limited to, home equity loans and obligations secured by shares issued by a cooperative housing association);

(b) secured credit instruments that bear interest or are purchased at a discount in transactions by or between business entities (including, but not limited to, qualified equipment notes secured by leases, as defined in section III.T);

(c) obligations that bear interest or are purchased at a discount and which are secured by single-family residential, multi-family residential and commercial real property, (including obligations secured by leasehold interests on commercial real property);

(d) obligations that bear interest or are purchased at a discount and which are secured by motor vehicles or equipment, or qualified motor vehicle leases (as defined in section III.U);

(e) "guaranteed governmental mortgage pool certificates," as defined in 29 CFR 2510.3–101(i)(2);

(f) fractional undivided interests in any of the obligations described in clauses (a)–(e) of this section B.(1);

(2) property which had secured any of the obligations described in subsection B.(1);

(3) undistributed cash or temporary investments made therewith maturing no later than the next date on which distributions are to made to certificateholders; and

(4) rights of the trustee under the pooling and servicing agreement, and rights under any insurance policies, third-party guarantees, contracts of suretyship and other credit support arrangements with respect to any obligations described in subsection B.(1).

Notwithstanding the foregoing, the term "trust" does not include any investment pool unless: (i) The investment pool consists only of assets of the type which have been included in other investment pools, (ii) certificates evidencing interests in such other investment pools have been rated in one of the three highest generic rating categories by S&P's, Moody's, D & P, or Fitch for at least one year prior to the plan's acquisition of certificates pursuant to this exemption, and (iii) certificates evidencing interests in such other investment pools have been purchased by investors other than plans for at least one year prior to the plan's acquisition of certificates pursuant to this exemption.

C. "Underwriter" means:

(1) any of the Applicants;

(2) any person directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with any of the Applicants;

(3) any member of an underwriting syndicate or selling group of which any of the Applicants or a person described in (2) is a manager or co-manager with respect to the certificates; or

(4) an entity which has received from the Department an individual prohibited transaction exemption relating to certificates which is similar to this exemption.

D. "Sponsor" means the entity that organizes a trust by depositing obligations therein in exchange for certificates.

E. "Master Servicer" means the entity that is a party to the pooling and servicing agreement relating to trust assets and is fully responsible for servicing, directly or through subservicers, the assets of the trust.

F. "Subservicer" means an entity which, under the supervision of and on behalf of the master servicer, services loans contained in the trust, but is not a party to the pooling and servicing agreement.

G. "Servicer" means any entity which services loans contained in the trust, including the master servicer and any sub-servicer.

H. "Trustee" means the trustee of the trust, and in the case of certificates which are denominated as debt instruments, also means the trustee of the indenture trust.

I. "Insurer" means the insurer or guarantor of, or provider of other credit support for, a trust.

Notwithstanding the foregoing, a person is not an insurer solely because it holds securities representing an interest in a trust which are of a class subordinated to certificates representing an interest in the same trust.

J. "Obligor" means any person, other than the insurer, that is obligated to make payments with respect to any obligation or receivable included in the trust. Where a trust contains qualified motor vehicle leases or qualified equipment notes secured by leases, "obligor" shall also include any owner of property subject to any lease included in the trust, or subject to any lease securing an obligation included in the trust.

K. "Excluded Plan" means any plan with respect to which any member of the Restricted Group is a "plan sponsor" within the meaning of section 3(16)(B) of the Act.

L. "Restricted Group" with respect to a class of certificates means:

(1) Each underwriter;

(2) Each insurer;

(3) The sponsor;

(4) The trustee;

(5) Each servicer;

(6) Any obligor with respect to obligations or receivables included in

the trust constituting more than 5 percent of the aggregate unamortized principal balance of the assets in the trust, determined on the date of the initial issuance of certificates by the trust; or

(7) Any affiliate of a person described in (1)–(6) above.

M. "Affiliate" of another person includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee, relative (as defined in section 3(15) of the Act), a brother, a sister, or a spouse of a brother or sister of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

N. "Control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

O. A person will be "independent" of another person only if:

(1) Such person is not an affiliate of that other person; and

(2) The other person, or an affiliate thereof, is not a fiduciary who has investment management authority or renders investment advice with respect to any assets of such person.

P. "Sale" includes the entrance into a forward delivery commitment (as defined in section Q below), provided:

(1) The terms of the forward delivery commitment (including any fee paid to the investing plan) are no less favorable to the plan than they would be in an arm's length transaction with an unrelated party;

(2) The prospectus or private placement memorandum is provided to an investing plan prior to the time the plan enters into the forward delivery commitment; and

(3) At the time of the delivery, all conditions of this exemption applicable to sales are met.

Q. "Forward delivery commitment" means a contract for the purchase or sale of one or more certificates to be delivered at an agreed future settlement date. The term includes both mandatory contracts (which contemplate obligatory delivery and acceptance of the certificates) and optional contracts (which give one party the right but not the obligation to deliver certificates to, or demand delivery of certificate from, the other party).

R. "Reasonable compensation" has the same meaning as that term is defined in 29 CFR 2550.408c–2.

S. "Qualified Administrative Fee" means a fee which meets the following criteria:

(1) The fee is triggered by an act or failure to act by the obligor other than the normal timely payment of amounts owing in respect of the obligations;

(2) The servicer may not charge the fee absent the act or failure to act referred to in (1);

(3) The ability to charge the fee, the circumstances in which the fee may be charged, and an explanation of how the fee is calculated are set forth in the pooling and servicing agreement; and

(4) The amount paid to investors in the trust will not be reduced by the amount of any such fee waived by the servicer.

T. "Qualified Equipment Note Secured By A Lease" means an equipment note:

(a) Which is secured by equipment which is leased;

(b) Which is secured by the obligation of the lessee to pay rent under the equipment lease; and

(c) With respect to which the trust's security interest in the equipment is at least as protective of the rights of the trust as would be the case if the equipment note were secured only by the equipment and not the lease.

U. "Qualified Motor Vehicle Lease" means a lease of a motor vehicle where:

(a) The trust holds a security interest in the lease;

(b) The trust holds a security interest in the leased motor vehicle; and

(c) The trust's security interest in the leased motor vehicle is at least as protective of the trust's rights as would be the case if the trust consisted of motor vehicle installment loan contracts.

V. "Pooling and Servicing Agreement" means the agreement or agreements among a sponsor, a servicer and the trustee establishing a trust. In the case of certificates which are denominated as debt instruments, "Pooling and Servicing Agreement" also includes the indenture entered into by the trustee of the trust issuing such certificates and the indenture trustee.

Effective Date: This exemption, if granted, will be effective for transactions occurring on or after June 9, 1992.

II. Summary of Facts and Representations

1. The Applicants can be described as follows:

(a) *RFC.* RFC is owned indirectly by General Motors Corporation through a chain of wholly owned subsidiaries. RFC is an indirect wholly owned subsidiary of GMAC Mortgage, which is a wholly owned subsidiary of GMAC, which in turn is a wholly owned subsidiary of General Motors Corporation. RFC buys conventional mortgage loans under several loan purchase programs from mortgage loan originators or sellers nationwide that meet its seller eligibility requirements and sells certain of the loans either directly or through RFMSI in the secondary market. RFC conducts operations from its headquarters in Minneapolis and from offices located in California, Georgia, New York, Texas and Rhode Island. In 1986, RFC commenced the master servicing of loans purchased under its modified loan purchase programs. At August 30, 1993, RFC was master servicing a loan portfolio of approximately $21.7 billion.

(b) *RFMSI.* RFMSI is a wholly owned subsidiary of GMAC Mortgage, which is a wholly owned subsidiary of GMAC. RFMSI was organized for the purpose of serving as a private secondary mortgage market conduit. RFMSI purchases loans from RFC or other sellers, or exchanges certificates for loans from sellers. RFMSI issued approximately $10.8 billion in conduit mortgage pass-through certificates during 1992. RFMSI does not have, nor is it expected in the future to have, any significant assets.

(c) *RFMEC.* RFMEC is an indirect wholly owned subsidiary of GMAC Mortgage and a wholly owned subsidiary of RFC. RFMEC maintains its principal office in Minneapolis, Minnesota. RFMEC does not have, nor is it expected to have, any significant assets.

(d) *RFSC.* RFSC is a wholly owned subsidiary of an indirect parent of RFMSI. RFSC was first registered as a broker-dealer on April 23, 1990, and a principal function of RFSC will be to sell conduit-mortgage pass-through certificates of RFMSI.

(e) *GMAC Auto.* GMAC Auto, a wholly owned subsidiary of GMAC, was organized for the limited purpose of purchasing receivables from GMAC, transferring such receivables to third parties, and any activities incidental to and necessary or convenient for the accomplishment of such purposes.

(f) *GMAC.* GMAC, a wholly owned subsidiary of General Motors Corporation, was incorporated in 1919 under the New York Banking Law relating to investment companies. Operating directly and through subsidiaries and associated companies in which it has equity investments, GMAC provides a wide variety of automotive-related financial services to and through franchised General Motors dealers in many countries throughout the world. Other financial services

include insurance, mortgage banking, marine financing and investment services. As of December 31, 1992, on a consolidated basis, GMAC had total assets of $93.6 billion and total shareholder's equity of $8 billion. For the year ended December 31, 1992, on a consolidated basis, GMAC had gross revenues of $13.6 billion and net income of $936 million.

(g) *GMAC Mortgage*. GMAC Mortgage is a wholly owned subsidiary of GMAC. Mortgage banking operations are conducted in the United States through GMAC Mortgage and its subsidiaries. The mortgage banking activity involves the origination and marketing to investors of single-family and commercial mortgage loans and the subsequent servicing of these loans on behalf of investors. GMAC also offers home equity loans in selected states. Typically, GMAC Mortgage funds loans for 60 to 90 days, pending assembly and delivery to investors. Thereafter, GMAC Mortgage earns an on-going fee for loan services including billing, collecting and forwarding payments to investors, taxing authorities and insurance companies.

(h) *GMAC Mortgage Securities*. GMAC Mortgage Securities, a wholly owned subsidiary of GMAC Mortgage, was organized for the purpose of purchasing mortgage loans and depositing such mortgage assets into trust, and selling certificates representing interests in such trusts, as well as any other activities incidental to or necessary or convenient for the accomplishment of such purposes.

Trust Assets

2. The Applicants seek exemptive relief to permit plans to invest in pass-through certificates representing undivided interests in the following categories of trusts: (1) single and multi-family residential or commercial mortgage investment trusts;[9] (2) motor vehicle receivable investment trusts; (3) consumer or commercial receivables investment trusts; and (4) guaranteed governmental mortgage pool certificate investment trusts.[10]

3. Commercial mortgage investment trusts may include mortgages on ground leases of real property. Commercial mortgages are frequently secured by ground leases on the underlying property, rather than by fee simple interests. The separation of the fee simple interest and the ground lease interest is generally done for tax reasons. Properly structured, the pledge of the ground lease to secure a mortgage provides a lender with the same level of security as would be provided by a pledge of the related fee simple interest. The terms of the ground leases pledged to secure leasehold mortgages will in all cases be at least ten years longer than the term of such mortgages.

Trust Structure

4. Each trust is established under a pooling and servicing agreement among a sponsor, a servicer and a trustee. The sponsor or servicer of a trust selects assets to be included in the trust. These assets are receivables which may have been originated by a sponsor or servicer of the trust, an affiliate of the sponsor or servicer, or by an unrelated lender and subsequently acquired by the trust sponsor or servicer.

Prior to or concurrently with the closing date, the sponsor acquires legal title to all assets selected for the trust, establishes the trust and designates an independent entity as trustee. On the closing date, the sponsor conveys to the trust legal title to the assets, and the trustee issues certificates representing fractional undivided interests in the trust assets. The certificates are either publicly or privately offered. In certain cases, the certificates will be represented by physical certificates registered in the name of a depository entity or a nominee of the depository.

Certificateholders are entitled to receive monthly, quarterly or semi-annual installments of principal and/or interest, or lease payments due on the receivables, adjusted, in the case of payments of interest, to a specified rate—the pass-through rate—which may be fixed or variable.

When installments or payments are made on a semi-annual basis, funds are not permitted to be commingled with the servicer's assets for longer than would be permitted for a monthly-pay security. A segregated account is established in the name of the trustee (on behalf of certificateholders) to hold funds received between distribution dates. The account is under the sole control of the trustee, who invests the account's assets in short-term securities which have received a rating comparable to the rating assigned to the certificates. In some cases, the servicer may be permitted to make a single deposit into the account once a month. When the servicer makes such monthly deposits, payments received from obligors by the servicer may be commingled with the servicer's assets during the month prior to deposit. Usually, the period of time between receipt of funds by the servicer and deposit of these funds in a segregated account does not exceed one month. Furthermore, in those cases where distributions are made semi-annually, the servicer will furnish a report on the operation of the trust to the trustee on a monthly basis. At or about the time this report is delivered to the trustee, it will be made available to certificateholders and delivered to or made available to each rating agency that has rated the certificates.

5. Some of the certificates will be multi-class certificates. The Applicants request exemptive relief for two types of multi-class certificates: "strip" certificates and "fast-pay/ slow-pay" certificates. Strip certificates are a type of security in which the stream of interest payments on receivables is split from the flow of principal payments and separate classes of certificates are established, each representing rights to disproportionate payments of principal and interest.[11]

"Fast-pay/slow-pay" certificates involve the issuance of classes of certificates having different stated maturities or the same maturities with different payment schedules. Interest and/or principal payments received on the underlying receivables are distributed first to the class of certificates having the earliest stated maturity of principal, and/or earlier

[9] The Department notes that PTE 83-1 [48 FR 895, January 7, 1983], a class exemption for mortgage pool investment trusts, would generally apply to trusts containing single-family residential mortgages, provided that the applicable conditions of PTE 83-1 are met. The Applicants request relief for single-family residential mortgages in this exemption because it would prefer one exemption for all trusts of similar structure. However, the Applicants have stated that they may still avail themselves of the exemptive relief provided by PTE 83-1.

[10] Guaranteed governmental mortgage pool certificates are mortgage-backed securities with respect to which interest and principal payable is guaranteed by the Government National Mortgage Association (GNMA), the Federal Home Loan Mortgage Corporation (FHLMC), or the Federal National Mortgage Association (FNMA). The Department's regulation relating to the definition of plan assets (29 CFR 2510.3-101(i)) provides that where a plan acquires a guaranteed governmental mortgage pool certificate, the plan's assets include the certificate and all of its rights with respect to such certificate under applicable law, but do not, solely by reason of the plan's holding of such certificate, include any of the mortgages underlying such certificate. The applicants are requesting exemptive relief for trusts containing guaranteed governmental mortgage pool certificates because the certificates in the trusts are plan assets.

[11] It is the Department's understanding that where a plan invests in REMIC "residual" interest certificates to which this exemption applies, some of the income received by the plan as a result of such investment may be considered unrelated business taxable income to the plan, which is subject to income tax under the Code. The Department emphasizes that the prudence requirement of section 404(a)(1)(B) of the Act would require plan fiduciaries to carefully consider this and other tax consequences prior to causing plan assets to be invested in certificates pursuant to this exemption.

payment schedule, and only when that class of certificates has been paid in full (or has received a specified amount) will distributions be made with respect to the second class of certificates. Distributions on certificates having later stated maturities will proceed in like manner until all the certificateholders have been paid in full. The only difference between this multi-class pass-through arrangement and a single-class pass-through arrangement is the order in which distributions are made to certificateholders. In each case, certificateholders will have a beneficial ownership interest in the underlying assets. In neither case will the rights of a plan purchasing certificates be subordinated to the rights of another certificateholder in the event of default on any of the underlying obligations. In particular, if the amount available for distribution to certificateholders is less than the amount required to be so distributed, all senior certificateholders then entitled to receive distributions will share in the amount distributed on a pro rata basis.[12]

6. For tax reasons, the trust must be maintained as an essentially passive entity. Therefore, both the sponsor's discretion and the servicer's discretion with respect to assets included in a trust are severely limited. Pooling and servicing agreements provide for the substitution of receivables by the sponsor only in the event of defects in documentation discovered within a limited time after the issuance of trust certificates. Any receivable so substituted is required to have characteristics substantially similar to the replaced receivable and will be at least as creditworthy as the replaced receivable.

In some cases, the affected receivable would be repurchased, with the purchase price applied as a payment on the affected receivable and passed through to certificateholders.

Parties to Transactions

7. The originator of a receivable is the entity that initially lends money to a borrower (obligor), such as a homeowner or automobile purchaser, or leases property to the lessee. The originator may either retain a receivable in its portfolio or sell it to a purchaser, such as a trust sponsor.

Originators of receivables included in the trusts will be entities that originate receivables in the ordinary course of their business, including finance companies, for whom such origination constitutes the bulk of their operations, financial institutions for whom such origination constitutes a substantial part of their operations, and any kind of manufacturer, merchant, or service enterprise for whom such origination is an incidental part of its operations. Each trust may contain assets of one or more originators. The originator of the receivables may also function as the trust sponsor or servicer.

8. The sponsor will be RFC, RFMSI, RFMEC, GMAC Auto, GMAC, GMAC Mortgage, GMAC Mortgage Securities or one of their brother or sister affiliates. The sponsor may be the servicer. Where the sponsor is not also the servicer, the sponsor's role will generally be limited to acquiring the receivables to be included in the trust, establishing the trust, designating the trustee, and assigning the receivables to the trust.

9. The trustee of a trust is the legal owner of the obligations in the trust. The trustee is also a party to or beneficiary of all the documents and instruments deposited in the trust, and as such is responsible for enforcing all the rights created thereby in favor of certificateholders.

The trustee will be an independent entity, and therefore will be unrelated to the trust sponsor, the servicer or underwriter or placement agent. The Applicants represent that the trustee will be a substantial financial institution or trust company experienced in trust activities. The trustee receives a fee for its services, which will be paid by the sponsor, servicer or out of trust assets. The method of compensating the trustee will be specified in the pooling and servicing agreement and disclosed in the prospectus or private placement memorandum relating to the offering of the certificates.

10. The servicer of a trust administers the receivables on behalf of the certificateholders. The servicer's functions typically involve, among other things, notifying borrowers of amounts due on receivables, maintaining records of payments received on receivables and instituting foreclosure or similar proceedings in the event of default. In cases where a pool of receivables has been purchased from a number of different originators and deposited in a trust, it is common for the receivables to be "subserviced" by their respective originators and for a single entity to "master service" the pool of receivables on behalf of the owners of the related series of certificates. Where this arrangement is adopted, a receivable continues to be serviced from the perspective of the borrower by the local subservicer, while the investor's perspective is that the entire pool of receivables is serviced by a single, central master servicer who collects payments from the local subservicers and passes them through to certificateholders.

In most cases, the originator and servicer of receivables to be included in a trust and the sponsor of the trust (though they themselves may be related) will be unrelated to the underwriter or placement agent, although in some cases they will be related to RFSC, which will sell conduit-mortgage pass-through certificates of RFMSI. In certain cases, a depositary entity or its nominee will have the certificates registered in its name, and will maintain procedures for distribution of notices, reports, distributions and statements to certificateholders.

Certificate Price, Pass-Through Rate and Fees

11. Where the sponsor of a trust is not the originator of receivables included in a trust, the sponsor generally purchases the receivables in the secondary market, either directly from the originator or from another secondary market participant. The price the sponsor pays for a receivable is determined by competitive market forces, taking into account payment terms, interest rate, quality, and forecasts as to future interest rates.

As compensation for the receivables transferred to the trust, the sponsor receives certificates representing the entire beneficial interest in the trust, or the cash proceeds of the sale of such certificates, or a combination of certificates and cash. If the sponsor receives certificates from the trust, the sponsor sells all or a portion of these certificates for cash to investors or securities underwriters. In some transactions, the sponsor or an affiliate may retain a portion of the certificate for its own account. The transfer of the receivables to the trust by the sponsor, the sale of certificates to investors, and the receipt of the cash proceeds by the sponsor generally take place simultaneously.

12. The price of the certificates, both in the initial offering and in the secondary market, is affected by market forces including investor demand, the pass-through interest rate on the certificates in relation to the rate payable on investments of similar types and quality, expectations as to the effect on yield resulting from prepayment of underlying receivables, and expectations as to the likelihood of timely payment.

[12] If a trust issues subordinate certificates, holders of such subordinate certificates may not share in the amount distributed on a pro rata basis. The Department notes that the exemption does not provide relief for plan investment in such subordinated certificates.

The pass-through rate for certificates is equal to the interest rate on receivables included in the trust minus a specified servicing fee.[13] This rate is generally determined by the same market forces that determine the price of a certificate. The price of a certificate and its pass-through, or coupon, rate together determine the yield to investors. If an investor purchases a certificate at less than par, that discount augments the stated pass-through rate; conversely, a certificate purchased at a premium yields less than the stated coupon.

13. As compensation for performing its servicing duties, the servicer (who may also be the sponsor, and receive fees for acting in that capacity) will retain the difference between payments received on the receivables in the trust and payments payable (at the pass-through rate) to certificateholders, except that in some cases a portion of the payments on receivables may be paid to a third party, such as a fee paid to a provider of credit support. The servicer may receive additional compensation by having the use of the amounts paid on the receivables between the time they are received by the servicer and the time they are due to the trust (which time is set forth in the pooling and servicing agreement). The servicer will be required to pay the administrative expenses of servicing the trust, including the trustee's fee, out of its servicing compensation.

The servicer is also compensated to the extent it may provide credit enhancement to the trust or otherwise arrange to obtain credit support from another party. This "credit support fee" may be aggregated with other servicing fees, and is either paid out of the interest income received on the receivables in excess of the pass-through rate or paid in a lump sum at the time the trust is established.

14. The servicer may be entitled to retain certain administrative fees paid by a third party, usually the obligor. These administrative fees fall into three categories: (a) Prepayment fees; (b) late payment and payment extension fees; and (c) fees and charges associated with foreclosure or repossession, or other conversion of a secured position into cash proceeds, upon default of an obligation.

Compensation payable to the servicer will be set forth or referred to in the pooling and servicing agreement and described in reasonable detail in the prospectus or private placement memorandum relating to the certificates.

15. Payments on receivables may be made by obligors to the servicer at various times during the period preceding any date on which pass-through payments to the trust are due. In some cases, the pooling and servicing agreement may permit the servicer to place these payments in non-interest bearing accounts in itself or to commingle such payments with its own funds prior to the distribution dates. In these cases, the servicer would be entitled to the benefit derived from the use of the funds between the date of payment on a receivable and the pass-through date. Commingled payments may not be protected from the creditors of the servicer in the event of the servicer's bankruptcy or receivership. In those instances when payments on receivables are held in non-interest bearing accounts or are commingled with the servicer's own funds, the servicer is required to deposit these payments by a date specified in the pooling and servicing agreement into an account from which the trustee makes payments to certificateholders.

16. Participating underwriters or placement agents will receive a fee in connection with the securities underwriting or private placement of certificates. In a firm commitment underwriting, this fee would consist of the difference between what such underwriter receives for the certificates that it distributes and what it pays the sponsor for those certificates. In a private placement, the fee normally takes the form of an agency commission paid by the sponsor.

The arrangements among underwriters are typically set forth in an "Agreement Among Underwriters", which gives the managing underwriter, as lead manager of the offering, the authority to act on behalf of all the underwriters. This agreement also imposes customary restrictions on the underwriters' dealings in the offered securities as are necessary to comply with securities laws and to ensure the orderly distribution of the offered securities.

Purchase of Receivables by the Servicer

17. The Applicants represent that as the principal amount of the receivables in a trust is reduced by payment, the cost of administering the trust generally increases, making the servicing of the trust prohibitively expensive at some point. Consequently, the pooling and servicing agreement generally provides that the servicer may purchase a receivable included in the trust when the aggregate unpaid balance payable on the receivables is reduced to a specified percentage (usually between 5 and 10 percent) of the initial aggregate unpaid balance. The terms of such repurchase are specified in the pooling and servicing agreement and will be at least equal to the unpaid principal balance on the receivables plus accrued interest, less any unreimbursed advances of principal made by the servicer.

Certificate Ratings

18. The certificates will have received one of the three highest ratings available from either S&P's, Moody's, D&P or Fitch. Insurance or other credit support will be obtained by the trust sponsor to the extent necessary for the certificates to attain the desired rating. The amount of this credit support is set by the rating agencies at a level that is a multiple of the worst historical net credit loss experience for the type of obligations included in the issuing trust.

Provision of Credit Support

19. In some cases, the master servicer, or an affiliate of the master servicer, may provide credit support to the trust (i.e. act as an insurer). Typically, in these cases, the master servicer, in its capacity as servicer, will first advance funds to the full extent that it determines that such advances will be recoverable (a) out of late payments by the obligors, (b) from the credit support provider (which may be itself) or, (c) in the case of a trust that issues subordinated certificates, from amounts otherwise distributable to holders of subordinated certificates, and the master servicer will advance such funds in a timely manner. In some transactions, however, the master servicer may not be obligated to advance funds, but instead would be called upon to provide funds to cover defaulted payments to the full extent of its obligations as insurer. When the servicer is the provider of the credit support and provides its own funds to cover defaulted payments, it will do so either on the initiative of the trustee, or on its own initiative on behalf of the trustee, but in either event it will provide such funds to cover payments to the full extent of its obligations under the credit support mechanism.

If the master servicer fails to advance funds, fails to call upon the credit support mechanism to provide funds to cover defaulted payments, or otherwise fails in its duties, the trustee would be required and would be able to enforce the certificateholders' rights, as both a party to the pooling and servicing agreement and the owner of the trust estate, including rights under the credit support mechanism. Therefore, the

[13] The pass-through rate on certificates representing interests in trusts holding leases is determined by breaking down lease payments into "principal" and "interest" components based on an implicit interest rate.

trustee, who is independent of the servicer, will have the ultimate right to enforce the credit support arrangement.

When a master servicer advances funds, the amount so advanced is recoverable by the servicer out of future payments on receivables held by the trust to the extent not covered by credit support. However, where the master servicer provides credit support to the trust, there are protections in place to guard against a delay in calling upon the credit support to take advantage of the fact that the credit support declines proportionally with the decrease in the principal amount of the obligations in the trust as payments on receivables are passed through to investors. These safeguards include:

(a) There is often a disincentive to postponing credit losses because the sooner repossession or foreclosure activities are commenced, the more value that can be realized on the security for the obligation;

(b) The master servicer has servicing guidelines which include a general policy as to the allowable delinquency period after which an obligation ordinarily will be deemed uncollectible. The pooling and servicing agreement will require the master servicer to follow its normal servicing guidelines and will set forth the master servicer's general policy as to the period of time after which delinquent obligations ordinarily will be considered uncollectible;

(c) As frequently as payments are due on the receivables included in the trust (monthly, quarterly or semi-annually, as set forth in the pooling and servicing agreement), the master servicer is required to report to the independent trustee the amount of all past-due payments and the amount of all servicer advances, along with other current information as to collections on the receivables and draws upon the credit support. Further, the master servicer is required to deliver to the trustee annually a certificate of an executive officer of the master servicer stating that a review of the servicing activities has been made under such officer's supervision, and either stating that the master servicer has fulfilled all of its obligations under the pooling and servicing agreement or, if the master servicer has defaulted under any of its obligations, specifying any such default. The master servicer's reports are reviewed at least annually by independent accountants to ensure that the master servicer is following its normal servicing standards and that the master servicer's reports conform to the master servicer's internal accounting records. The results of the independent accountants' review are delivered to the trustee; and

(d) In cases where the master servicer and the insurer are affiliated or the same entity, the credit support has a "floor" dollar amount that protects investors against the possibility that a large number of credit losses might occur towards the end of the life of the trust, whether due to servicer advances or any other cause. The floor amount may be a fixed dollar amount or a multiple of the balance of one or more of the largest obligations outstanding. Once the floor amount has been reached, the servicer lacks an incentive to postpone the recognition of credit losses because the credit support amount becomes a fixed dollar amount, subject to reduction only for actual draws. From the time that the floor amount is effective until the end of the life of the trust, there are no proportionate reductions in the credit support amount caused by reductions in the pool principal balance. Indeed, where the floor is a fixed dollar amount, the amount of credit support ordinarily increases as a percentage of the pool principal balance during the period that the floor is in effect.

Disclosure

20. In connection with the original issuance of certificates, a prospectus or private placement memorandum will be furnished to investing plans. The prospectus or private placement memorandum will contain information material to a fiduciary's decision to invest in the certificates, including:

(a) Information concerning the payment terms of the certificates, the rating of the certificates, and any material risk factors with respect to the certificates;

(b) A description of the trust as a legal entity and a description of how the trust was formed by the seller/servicer or other sponsor of the transaction;

(c) Identification of the independent trustee for the trust;

(d) A description of the receivables contained in the trust, including the types of receivables, the diversification of the receivables, their principal terms, and their material legal aspects;

(e) A description of the sponsor and servicer;

(f) A description of the pooling and servicing agreement, including a description of the seller's principal representations and warranties as to the trust assets and the trustee's remedy for any breach thereof; a description of the procedures for collection of payments on receivables and for making distributions to investors, and a description of the accounts into which such payments are deposited and from which such distributions are made; identification of the servicing compensation and any fees for credit enhancement that are deducted from payments on receivables before distributions are made to investors; a description of periodic statements provided to the trustee, and provided to or made available to investors by the trustee; and a description of the events that constitute events of default under the pooling and servicing contract and a description of the trustee's and the investors' remedies incident thereto;

(g) A description of the credit support;

(h) A general discussion of the principal federal income tax consequences of the purchase, ownership and disposition of the pass-through securities by a typical investor;

(i) A description of the underwriters' plan for distributing the pass-through securities to investors; and

(j) Information about the scope and nature of the secondary market, if any, for the certificates.

21. Reports indicating the amount of payments of principal and interest are provided to certificateholders at least as frequently as distributions are made to certificateholders. Certificateholders will also be provided with periodic information statements setting forth material information concerning the underlying assets, including, where applicable, information as to the amount and number of delinquent and defaulted loans or receivables.

22. In the case of a trust that offers and sells certificates in a registered public offering, the trustee, the servicer or the sponsor will file such periodic reports as may be required to be filed under the Securities Exchange Act of 1934. Although some trusts that offer certificates in a public offering will file quarterly reports on Form 10–Q and Annual Reports on Form 10–K, many trusts obtain, by application to the Securities and Exchange Commission, a complete exemption from the requirement to file quarterly reports on Form 10–Q and a modification of the disclosure requirements for annual reports on Form 10–K. If such an exemption is obtained, these trusts normally would continue to have the obligation to file current reports on Form 8–K to report material developments concerning the trust and the certificates. While the Securities and Exchange Commission's interpretation of the periodic reporting requirements is subject to change, periodic reports concerning a trust will be filed to the extent required under the Securities Exchange Act of 1934.

23. At or about the time distributions are made to certificateholders, a report

will be delivered to the trustee as to the status of the trust and its assets, including underlying obligations. Such report will typically contain information regarding the trust's assets, payments received or collected by the servicer, the amount of prepayments, delinquencies, servicer advances, defaults and foreclosures, the amount of any payments made pursuant to any credit support, and the amount of compensation payable to the servicer. Such report also will be delivered to or made available to the rating agency or agencies that have rated the trust's certificates. This report will also provide to certificateholders (either by the trustee, the servicer or, in certain cases, the depository of the certificates) a summary statement of information regarding the trust and its assets. Such statement will include information regarding the trust and its assets, including underlying receivables. Such statement will typically contain information regarding payments and prepayments, delinquencies, the remaining amount of the guaranty or other credit support, a breakdown of payments between principal and interest and other material information concerning the underlying assets, including, where applicable, information as to the number and amount of delinquent and defaulted receivables. The summary statement provided to the certificateholders will be part of the report to the trustee described in this paragraph. If this information is to be furnished by the depository of the certificates, the trustee and the servicer will have no control over distribution to certificateholders.

Secondary Market Transactions

24. In general, it is the policy of many underwriters to attempt to make a market for securities for which they are the lead or co-managing underwriter. In general, it is also the policy of many placement agents to facilitate sales by investors who purchase certificates if such entity has acted as agent or principal in the original private placement of the certificates and if such investors request such entity's assistance.

Retroactive Relief

25. The Applicants do not believe that they have engaged in any prohibited transactions that would be covered by the requested exemption. However, it is possible that some transactions may have occurred that would be prohibited. For example, because many certificates are held in street or nominee name, it is not always possible to identify whether the percentage interest of plans in a trust is or is not "significant" for purposes of the Department's regulation relating to the definition of plan assets (29 CFR 2510.3–101(f)). These problems are compounded as transactions occur in the secondary market. In addition, with respect to the "publicly-offered security" exception contained in that regulation (29 CFR 2510.3–101(b)), it is difficult to determine whether each purchaser of a certificate is independent of all other purchasers. Therefore, the relief requested herein is retroactive to June 9, 1992, which is the date upon which the Applicants originally filed their exemption application with the Department.

Summary

26. In summary, the Applicants represent that the transactions for which exemptive relief is requested satisfy the statutory criteria of section 408(a) of the Act due to the following:

(a) The trusts contain "fixed pools" of assets. There is little discretion on the part of the trust sponsor to substitute receivables contained in the trust once the trust has been formed;

(b) Certificates in which plans invest will have been rated in one of the three highest rating categories by S&P's, Moody's, D&P or Fitch. Credit support will be obtained to the extent necessary to attain the desired rating;

(c) All transactions for which the Applicants and their affiliates seek exemptive relief will be governed by the pooling and servicing agreement, which is made available to, or described in the prospectus or private placement memorandum made available to plan fiduciaries for their review prior to the plan's investment in certificates;

(d) Exemptive relief from sections 406(b) and 407 for sales to plans is substantially limited; and

(e) Many underwriters have made, and the Applicants anticipate that such underwriters will continue to make, a secondary market in certificates sponsored by RFC, RFMSI, RFMEC, GMAC Auto, GMAC, GMAC Mortgage or GMAC Mortgage Securities.

Discussion of Proposed Exemption

I. Differences Between Proposed Exemption and Class Exemption PTE 83–1

The exemptive relief proposed herein is similar to that provided in PTE 81–7 (46 FR 7520, January 23, 1981), Class Exemption for Certain Transactions Involving Mortgage Pool Investment Trusts, amended and restated as PTE 83–1 (48 FR 895, January 7, 1983).

PTE 83–1 applies to mortgage pool investment trusts consisting of interest-bearing obligations secured by first or second mortgages or deeds of trust on single-family residential property. The exemption provides relief from sections 406(a) and 407 for the sale, exchange or transfer in the initial issuance of mortgage pool certificates between the trust sponsor and a plan, when the sponsor, trustee or insurer of the trust is a party-in-interest with respect to the plan, and the continued holding of such certificates, provided that the conditions set forth in the exemption are met. PTE 83–1 also provides exemptive relief from section 406(b)(1) and (b)(2) of the Act for the above-described transactions when the sponsor, trustee or insurer of the trust is a fiduciary with respect to the plan assets invested in such certificates, provided that additional conditions set forth in the exemption are met. In particular, section 406(b) relief is conditioned upon the approval of the transaction by an independent fiduciary. Moreover, the total value of certificates purchased by a plan must not exceed 25 percent of the amount of the issue, and at least 50 percent of the aggregate amount of the issue must be acquired by persons independent of the trust sponsor, trustee or insurer. Finally, PTE 83–1 provides conditional exemptive relief from section 406(a) and (b) of the Act for transactions in connection with the servicing and operation of the mortgage trust.

Under PTE 83–1, exemptive relief for the above transactions is conditioned upon the sponsor and the trustee of the mortgage trust maintaining a system for insuring or otherwise protecting the pooled mortgage loans and the property securing such loans, and for indemnifying certificateholders against reductions in pass-through payments due to defaults in loan payments or property damage. This system must provide such protection and indemnification up to an amount not less than the greater of one percent of the aggregate principal balance of all trust mortgages or the principal balance of the largest mortgage.

The exemptive relief proposed herein differs from that provided by PTE 83–1 in the following major respects: (1) The proposed exemption provides individual exemptive relief rather than class relief; (2) The proposed exemption covers transactions involving trusts containing a broader range of assets than single-family residential mortgages; (3) Instead of requiring a system for insuring the pooled receivables, the proposed exemption conditions relief upon the certificates having received one of the three highest ratings available from S&P's, Moody's, D&P or Fitch (insurance or other credit support

would be obtained only to the extent necessary for the certificates to attain the desired rating); and (4) The proposed exemption provides more limited section 406(b) and section 407 relief for sales transactions.

II. Ratings of Certificates

After consideration of the representations of the Applicants and information provided by S&P's, Moody's, D&P and Fitch, the Department has decided to condition exemptive relief upon the certificates having attained a rating in one of the three highest generic rating categories from S&P's, Moody's, D&P or Fitch. The Department believes that the rating condition will permit the applicant flexibility in structuring trusts containing a variety of mortgages and other receivables while ensuring that the interests of plans investing in certificates are protected. The Department also believes that the ratings are indicative of the relative safety of investments in trusts containing secured receivables. The Department is conditioning the proposed exemptive relief upon each particular type of asset-backed security having been rated in one of the three highest rating categories for at least one year and having been sold to investors other than plans for at least one year.[14]

III. Limited Section 406(b) and Section 407(a) Relief for Sales

The Applicants represent that in some cases a trust sponsor, trustee, servicer, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates may be a pre-existing party in interest with respect to an investing plan.[15] In these cases, a direct or indirect sale of certificates by that party in interest to the plan would be a prohibited sale or exchange of property under section 406(a)(1)(A) of the Act.[16] Likewise, issues are raised under section 406(a)(1)(D) of the Act where a plan fiduciary causes a plan to purchase certificates where trust funds will be used to benefit a party in interest.

Additionally, the Applicants represent that a trust sponsor, servicer, trustee, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates representing an interest in a trust may be a fiduciary with respect to an investing plan. The Applicants represent that the exercise of fiduciary authority by any of these parties to cause the plan to invest in certificates representing an interest in the trust would violate section 406(b)(1), and in some cases section 406(b)(2), of the Act.

Moreover, the Applicants represent that to the extent there is a plan asset "look through" to the underlying assets of a trust, the investment in certificates by a plan covering employees of an obligor under receivables contained in a trust may be prohibited by sections 406(a) and 407(a) of the Act.

After consideration of the issues involved, the Department has determined to provide the limited sections 406(b) and 407(a) relief as specified in the proposed exemption.

FOR FURTHER INFORMATION CONTACT: Mr. Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 3rd day of February, 1994.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 94–2912 Filed 2–8–94; 8:45 am]

BILLING CODE 4510–29–P

[14] In referring to different "types" of asset-backed securities, the Department means certificates representing interests in trusts containing different "types" of receivables, such as single family residential mortgages, multi-family residential mortgages, commercial mortgages, home equity loans, auto loan receivables, installment obligations for consumer durables secured by purchase money security interests, etc. The Department intends this condition to require that certificates in which a plan invests are of the type that have been rated (in one of the three highest generic rating categories by S&P's, D&P, Fitch or Moody's) and purchased by investors other than plans for at least one year prior to the plan's investment pursuant to the proposed exemption. In this regard, the Department does not intend to require that the particular assets contained in a trust must have been "seasoned" (e.g., originated at least one year prior to the plan's investment in the trust).

[15] In this regard, we note that the exemptive relief proposed herein is limited to certificates with respect to which the Applicants or any of their affiliates are either (a) the sole underwriter or manager or co-manager of the underwriting syndicate, (b) a selling or placement agent, or (c) the sponsor, in which case an entity which has received from the Department an individual prohibited transaction exemption relating to certificates which is similar to this exemption is the sole underwriter or the manager or co-manager of the underwriting syndicate or a selling or placement agent.

[16] The Applicants represent that where a trust sponsor is one of the Applicants or its affiliate, sales to plans by the sponsor may be exempt under PTE 75–1, Part II (relating to purchases and sales of securities by broker-dealers and their affiliates), if none of the Applicants is a fiduciary with respect to plan assets to be invested in certificates.

NATIONAL SCIENCE FOUNDATION

Antarctic Conservation Act of 1978; Notice of Permit Modification

AGENCY: National Science Foundation.

SUMMARY: The Foundation modified a permit to conduct activities regulated under the Antarctic Conservation Act of 1978 (Public Law 95–541; Code of Federal Regulations title 45, part 670).

FOR FURTHER INFORMATION CONTACT: Thomas F. Forhan, 703–306–1013.

Permit Office, room 755, Office of Polar Programs, National Science Foundation, Arlington, Virginia 22230.

APPLICANT: Pete Peterson; Antarctic Support Associates, Englewood, Colorado 80112.

DESCRIPTION OF PERMIT AND MODIFICATION: The Foundation issued a permit to Mr. Peterson, an official of the Foundation's antarctic support contractor, on 1 April 1992 after posting a notice in the 5 February 1992 **Federal Register**. Public comments were not received. The permit allows removal of elephant seals from the pier at Palmer Station, Antarctica, so that they and equipment operators will not be endangered during station and ship operations. The removal is done by walking behind the seal and herding it towards the water.

A separate review by the National Marine Fisheries Service established that such action does not require a Marine Mammals Protection Act permit.

The modification, issued by the Foundation on 28 January 1994, allows removal of any animals, not just elephant seals, whose proximity to equipment operations on and around the pier endanger the animals or the equipment operators. Other animals that occasionally wander on to the pier include crabeater seals and penguins.

LOCATION: Palmer Station, Antarctica.

DATES: 1/28/94–4/30/97.

Thomas F. Forhan,

Permit Office, Office of Polar Programs.

[FR Doc. 94–2959 Filed 2–8–94; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Graduate Education & Research Development; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Graduate Education & Research Development.

Date & Time: February 16–17, 1994; 8:30 a.m. to 5 p.m.

Place: Rosslyn Westpark Hotel, 1900 N. Fort Myer Drive, Arlington, VA 22209.

Type of Meeting: Closed.

Contact Person: Sonia Ortega, Program Director, 4201 Wilson Boulevard, room 907, Arlington, VA 22230, Telephone: (703) 306–1697.

Purpose of Meeting: To provide advice and recommendations concerning nominations to the Presidential Faculty Fellows Program (PFF).

Agenda: Review and evaluate PFF Program nominations.

Reason for Closing: The nominations being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions 4 and 6 of 5 U.S.C. 552b.(c) (4) and (6) of the Government in the Sunshine Act.

Reason for Late Notice: Complications with meeting logistics.

Dated: February 4, 1994.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 94–2976 Filed 2–8–94; 8:45 am]

BILLING CODE 7555–01–M

DOE/NSF Nuclear Science Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: February 25, 1994 from 9 a.m. to 5 p.m.

Place: Department of Energy, Forrestall Building, Room 1E–245, 1000 Independence Ave., SW., Washington, DC 20585.

Type of Meeting: Open.

Contact Person: John W. Lightbody, Program Director for Nuclear Physics, National Science Foundation, 4201 Wilson Blvd, Arlington, VA 22230. Telephone: (703) 306–1890.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To advise the National Science Foundation and the Department of Energy on scientific priorities within the field of basic nuclear science research.

Agenda: Discussion of Budgets and Status of DOE and NSF Nuclear Physics Program—Discussion of Future Long-Range Planning Activities—Public Comments (*)

(*) Persons wishing to speak should make arrangements through the Contact Person identified above.

Dated: February 4, 1994.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 94–2975 Filed 2–8–94; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes; Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The Advisory Committee on the Medical Uses of Isotopes (ACMUI) will hold an open meeting on February 24, 1994, to provide the members of the committee an opportunity to prepare for a meeting with the Chairman and the Commissioners of the Nuclear Regulatory Commission. The ACMUI meeting with the Commission is scheduled for February 25, 1994, at 10 a.m., in the Commissioners' Conference Room in NRC's One White Flint Building. This meeting will be noticed separately.

The committee has no advance agenda for this meeting; the members will address topics of mutual interest for discussion at the meeting with the Commission. NRC staff will provide supplemental information and other support at the committee's request.

DATES: The meeting will be held at 12:30 p.m., on February 24, 1994.

LOCATION: Holiday Inn, Crown Plaza, 1750 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION, CONTACT: Sally M. Merchant, Office of Nuclear Material Safety and Safeguards, MS 6–H–3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 504–2637.

Conduct of the Meeting

Barry Siegel, M.D. will chair the meeting. Dr. Siegel will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting.

1. Persons may submit written comments by sending a reproducible copy to the Secretary of the Commission, ATTN: Advisory Committee Management Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Comments must be received by February 18, 1994, to ensure consideration at the meeting. The transcript of the meeting will be kept open until March 10, 1994, for inclusion of written comments.

2. Persons who wish to make oral statements should inform Ms. Merchant, in writing, by February 18, 1994. The Chairman will rule on requests to make oral statements. Given the nature and duration of this meeting, the Chairman may determine that oral statements will not be permitted.

Opportunity for members of the public to make oral statements will be based on the order in which requests are received. In general, oral statements should be limited to approximately 5 minutes. Oral statements must be supplemented by detailed written statements, for the record. Ruling on who may speak, the order of presentation, and time allotments may be obtained by calling Ms. Merchant, (301) 504–2637, between 9 a.m. and 5 p.m. EST, on February 22, 1994.

3. At the meeting, questions from attendees other than committee

members, NRC consultants, and NRC staff will be permitted at the discretion of the Chairman.

4. The transcript, minutes of the meeting, and written comments will be available for inspection, and copying for a fee, at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20555, on or about March 11, 1994.

5. Seating for the public will be on a first-come, first-served basis.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a) the Federal Advisory Act (5 U.S.C. App) and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, part 7.

Dated: February 3, 1994.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 94–2928 Filed 2–8–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–373 and 50–374]

Commonwealth Edison Co.; Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards; Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License Nos. NPF–11 and NPF–18 issued to Commonwealth Edison Company, (the licensee) for operation of the LaSalle County Nuclear Station, Units 1 and 2, located in LaSalle County, Illinois.

The proposed amendment would extend the functional test interval from Monthly to Quarterly for the following:

1. Reactor protection system instrumentation surveillances for Main Steam Line Isolation Valve Closure, Turbine Stop Valve Closure, and Turbine Control Valve Fast Closure Valve Trip System Oil Pressure Low; and
2. EDC–RPT system instrumentation surveillances for Turbine Stop Valve Closure, and Turbine Control Valve Fast Closure.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6), for amendments to be granted under exigent circumstances the NRC staff must determine that the amendment request involves no significant hazards consideration Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Commonwealth Edison has evaluated the proposed Technical Specification Amendment which extends the Surveillance Test Interval (STI) for certain instruments in the Reactor Protection System (RPS) and the End-of-Cycle Recirculation Pump Trip (EOC–RPT) system for LaSalle County Station, Units 1 and 2, and determined that they do not constitute a Significant Hazards Consideration. Based on the criteria for defining a significant hazards consideration established in 10 CFR 50.92, operation of LaSalle County Station, Units 1 and 2 in accordance with the proposed amendment will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because:

The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed changes increase the STI for actuation instrumentation supporting RPS and EOC–RPT trip functions. There are no changes in any of the affected systems themselves. Because of this there is no change in the probability of occurrence of an accident or the consequences of an accident or the consequences of malfunction of equipment. With respect to the malfunction of equipment, topical reports prepared by GE demonstrated that there is a reduction in scram frequency for the RPS. This offsets the slight increase in trip function unavailability determined by GE. This was judged acceptable by GE. The NRC concurred with this conclusion in its review of the topical reports (NEDC–30851P–A). For EOC–RPT GE demonstrated that the trip function unavailability when the surveillance interval is extended from 1 to 3 months is lower for the turbine stop valve trip function and slightly higher for the turbine control valve trip function than the same trip functions for RPS-scram. However, GE concluded that the small increase in EOC–RPT unavailability (represented by small increased risk of a MCPR violation) is offset by the benefits associated with the similar approved STI and AOT changes for the RPS-scram function. Therefore, GE concluded that the STI changes for EOC-RPT trip function are bounded by the approved RPS analysis (Reference 5). The NRC accepted the conclusions of GE by a SER included in Reference 9. The proposed changes are consistent with the Safety Evaluation Reports issued in these topical reports. The proposed changes therefore do not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated because:

The proposed changes do not create the possibility for an accident or malfunction of a different type than any evaluated previously in the UFSAR. The proposed changes increase the STI for the RPS and EOC–RPT Instrumentation. There are no changes in the instrumentation of these systems. Since there are no such changes there is no possibility for an accident or malfunction of a different type than any previously evaluated.

(3) Involve a significant reduction in the margin of safety because:

The proposed changes do not reduce the margin of safety as defined in the basis for any Technical Specification. The proposed changes do not change any setpoints in the above mentioned systems or their levels of redundancy. Setpoints are based upon the drift occurring during an 18 month calibration interval. The bases in the Technical Specifications either do not discuss STI, or state "* * * one channel may be inoperable for brief intervals to conduct required surveillance." The proposed changes are bounded by the analyses of References 5 and 9. These analyses, which were prepared by GE and approved by the NRC, examined the effects of extending STI and found that the proposed changes would not involve a significant reduction in a margin of safety. LaSalle Station Units 1 and 2 RPS and EOC–RPT systems have been compared to the generic analyses and verified to be bounded.

This proposed amendment does not involve a significant relaxation of the criteria used to establish safety limits, a significant relaxation of the bases for the limiting safety system settings or a significant relaxation of the bases for the limiting conditions for operations. Therefore, based on the guidance provided in the Federal Register and the criteria established in 10 CFR 50.92(c), the proposed change does not constitute a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the

Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P–223, Phillips Building, 7920 Norfork Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555.

The filing of requests, for hearing and petitions for leave to intervene is discussed below.

By February 24, 1994, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Public Library of Illinois Valley Community College, Route No. 1, Oglesby, Illinois 61348. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the preceding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to James E. Dyer: Petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for

amendment dated September 10, 1993 as supplemented on November 17, 1993, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room, located at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Dated at Rockville, Maryland, this 2nd day of February 1994.

For the Nuclear Regulatory Commission.

Anthony T. Gody, Jr.,

Project Manager, Project Directorate III-2, Division of Reactor Projects—III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 94–2923 Filed 2–8–94; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50–458]

Entergy Operations, Inc.; River Bend Station, Unit 1

Exemption

I

On November 20, 1985, the Commission issued Facility Operating License No. NPF–47 to Gulf States Utilities Company (GSU) and Cajun Electric Power Cooperative (the licensees) for River Bend Station, Unit 1. The license provided, among other things, that the facility is subject to all rules, regulations, and orders of the Commission.

II

Appendix J of part 50 of title 10 of the Code of Federal Regulations, "Primary Reactor Containment Leakage Testing for Water-Cooled Reactors," Section III.D.3 requires that Type C leak rate tests be performed each reactor shutdown for refueling, but in no case at intervals to exceed 2 years.

By letter dated November 18, 1993, as supplemented by letter dated December 21, 1993, GSU requested a one-time exemption to the schedular requirements for performing Appendix J, Type C, leak rate testing. River Bend was last shutdown for refueling from March 12, 1992, to September 8, 1992 and the Type C local leak rate testing was performed. River Bend experienced several forced outages since then which, combined with the 6-month refueling outage have impacted the 24-month surveillance interval required by Technical Specifications. Consequently, the first of these surveillances are due to be performed 29 days before the next scheduled refueling outage. This exemption would provide an extension of 29 days to allow the testing of 20 containment isolation valves to be delayed until the upcoming refueling outage currently scheduled to begin April 16, 1994. This would allow the licensee to avoid the thermal transients and personnel exposures associated with shutting the plant down solely to perform leakage testing. The licensee will make a good faith effort to complete the surveillance tests within the current frequency if an outage of sufficient length occurs prior to the refueling outage.

The licensee has demonstrated that the valves in question are not subject to degradation based on the results of leakage tests from the previous refueling outage. These tests showed that substantial margin existed between the allowed leakage and the as-left leakage and that the affected valves provide only a small contribution to the overall allowable leakage rate.

III

Section 50.12 of the Commission's regulations permit the granting of an exemption from the regulations when special circumstances are present. According to 50.12(a)(2)(ii), special circumstances are present whenever application of the regulation in question is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of Appendix J, Section III.D.3 is to assure a leak tight containment to mitigate the consequences of an accident. The past leak rate data and available margin to that allowed by the Technical Specifications is sufficient to assure that the underlying purpose of Appendix J, Section III.D.3 is fulfilled. Therefore, the staff has determined that the special circumstances as described in 10 CFR 50.12(a)(2)(ii) exist in that the application of the regulation is not necessary to achieve the underlying purpose of the rule.

IV

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security.

Accordingly, the Commission hereby grants an exemption from 10 CFR part 50, Appendix J, Section III.D.3.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of the Exemption will have no significant impact on the environment (58 FR 68969).

This Exemption is effective upon issuance.

Dated at Rockville, Maryland, this 2nd day of February 1994.

For the Nuclear Regulatory Commission.

John A. Zwolinski,

Acting Director, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 94–2924 Filed 2–8–94; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50–331]

Iowa Electric Light & Power Co., et al.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 195 to Facility Operating License No. DPR–49, issued to Iowa Electric Light and Power Company, Central Iowa Power Cooperative, and the Corn Belt Power Cooperative, which revised the Technical Specifications for operation of the Duane Arnold Energy Center located in Linn County, Iowa. The amendment was effective as of the date of issuance.

The amendment revised Technical Specification 5.5 based on the limitations necessary to maintain stored fuel k_{eff} less than or equal to 0.95 for the reracking of the spent fuel pool. The revision also made some editorial changes and added two references. Page 3 of the Facility Operating License was revised to reflect the Updated Final Safety Analysis Report and the letter of March 23, 1993, requesting this amendment change.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the **Federal Register** on July 30, 1993 (58 FR 40841). No request for a hearing or petition for leave to intervene was filed following this notice.

The Commission has prepared an Environmental Assessment related to the action and has determined not to prepare an Environmental Impact Statement. Based upon the Environmental Assessment, the Commission has concluded that the issuance of this amendment will not have a significant effect on the quality of the human environment.

For further details with respect to the action see (1) the application for amendment dated March 23, 1993, and supplemented September 12 and November 23, 1993, and January 10, 1994; (2) Amendment No. 195 to License No. DPR–49, (3) the Commission's related Safety Evaluation dated February 2, 1994, and (4) Environmental Assessment dated January 6, 1994 (59 FR 786). All of these items are available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street NW., Washington, DC, and at the Cedar Rapids Public Library, 500 1st Street, SE., Cedar Rapids, Iowa 52401.

Dated at Rockville, Maryland this 2nd day of February 1994.

For the Nuclear Regulatory Commission.

Robert M. Pulsifer,

Project Manager, Project Directorate III–3, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 94–2925 Filed 2–8–94; 8:45 am]

BILLING CODE 7590–01–M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

Notice of Final Adoption of 1994 Columbia River Basin Fish and Wildlife Program

January 31, 1994.

AGENCY: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

SUMMARY: Pursuant to the Pacific Electric Power Planning and Conservation Act (16 U.S.C. 839 *et seq.*) the Pacific Northwest Electric Power and Conservation Planning Council (Council) has adopted a comprehensive version of the Columbia River Basin Fish and Wildlife Program (program), which includes all program amendments adopted since 1987. Copies of the new program in typescript and the Council's responses to comments are available on request. See **FOR FURTHER INFORMATION**, below.

BACKGROUND: The Council has completed a multi-year process to amend the Columbia River Basin Fish and Wildlife Program (program). As the final step in this process, the Council has adopted a version of the program that incorporates all program amendments adopted since 1987, including amendments regarding anadromous fish, resident fish and wildlife. The Council adopted the new program and a response to comments on January 12, 1994. Currently, the new program is available in typescript. Printed copies of the program (with minor editorial revisions) are expected to be available in April.

FOR FURTHER INFORMATION: For copies of the 1994 Columbia Basin Fish and Wildlife Program (request document no. 94–2), the response to comments (request document no. 94–6), or other information, contact the Council's Public Affairs Division, 851 SW., Sixth Avenue, suite 1100, Portland, Oregon 97204 or (503) 222–5161, toll free 1–800–222–3355.

Edward W. Sheets,

Executive Director.

[FR Doc. 94–2949 Filed 2–8–94; 8:45 am]

BILLING CODE 0000–00–M

PHYSICIAN PAYMENT REVIEW COMMISSION

Commission Meeting

AGENCY: Physician Payment Review Commission.

ACTION: Notice of meeting.

SUMMARY: The Commission will hold meetings February 24–25, 1994 at the Embassy Suites Hotel, 1250 22nd Street NW., Washington, DC, in the Consulate Room to review and revise the draft of its Annual Report to Congress due March 31, 1994. During the public session of the meeting on February 24, the Commission will review all major conclusions and recommendations to be contained in the report. That review is scheduled to begin at 10 a.m. and is expected to follow the chapter outline of the report, although there may be some last-minute changes in the order. That outline is as follows:

1. Context for Reform

Reforming the Health System: Cost, Quality, and Access

2. The Structure of Reform
3. Cost Containment and Expenditure Limits
4. Design Issues for Expenditure Limits
5. Regulating Plan Premiums
6. Rate Setting
7. Structuring the Health Insurance Market
8. Establishing Equitable Premiums: Community Rating and Risk Adjustment
9. Ensuring Access for the Poor
10. Widening or Narrowing the Gap? The Effect of Health System Reform on Medical and Medicaid Payments
11. Quality Assurance

Reforming the Health System: Complementary Policies

12. Coverage Decisions and Technology Assessment
13. Graduate Medical Education Reform
14. Nonphysician Practitioners
15. Medical Malpractice Reform
16. Developing a National Data Strategy

Medicare and Medicaid

17. Beneficiaries and the Medicare Fee Schedule
18. Physicians and the Medicare Fee Schedule
19. Ensuring Fair and Accurate Payment under the Medicare Fee Schedule
20. Bonus Payments in Health Professional Shortage Areas
21. A Look Back at Implementation and Impact of Volume Performance Standards
22. Enhancing Medicare Policy to Restrain Volume Growth
23. Access for Medicaid Beneficiaries

After the Commission has reviewed the recommendations for the annual report, it will adjourn into Executive Session for editorial review of the report chapters. It is expected that the February 25 meeting will be held entirely in Executive Session.

ADDRESS: Please note that the Commission has a new address: 2120 L Street NW./suite 200/Washington, DC 20037. The telephone number is 202/653–7220.

FOR FURTHER INFORMATION CONTACT: Lauren LeRoy, Deputy Director, or Annette Hennessey, Executive Assistant, at 202/653–7220.

SUPPLEMENTARY INFORMATION: Because of the meeting's format, no agenda will be issued. You may confirm the meeting time by calling the Commission's office at 202–653–7220.

Paul B. Ginsburg,

Executive Director.

[FR Doc. 94–2922 Filed 2–8–94; 8:45 am]

BILLING CODE 6820–SE–M

RESOLUTION TRUST CORPORATION

Coastal Barrier Improvement Act; Property Availability; Campobello Island Estates, New Brunswick, Canada

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the properties known as Trinity Ranch, located in Fort Worth and Benbrook, Tarrant County, Texas, and Campobello Island Estates, located on Campobello Island, New Brunswick, Canada, are affected by section 10 of the Coastal Barrier Improvement Act of 1990 as specified below. This notice is a republication of the notice of availability for Campobello Island Estates, initially published on June 29, 1993 (FR Vol. 58: 34845/34836), clarifying the description of the property and its size.

DATES: Written notices of serious interest to purchase or effect other transfer of all or any portion of these properties may be mailed or faxed to the RTC until May 10, 1994.

ADDRESSES: Copies of detailed descriptions of these properties, including maps, can be obtained from or are available for inspection by contacting the following person:

Trinity Ranch:

Mr. Steven Reid, Resolution Trust Corporation, Dallas Field Office, 3500 Maple Avenue, Reverchon Plaza, suite 300, Dallas, TX 75219–3935, (214) 443–4738; Fax (214) 443–6574.

Campobello Island Estates:

Mr. Steven J. Vranka, Resolution Trust Corporation, c/o Nevander Asset Management, Inc., 4665 MacArthur Court, suite 200, Newport Beach, CA 46655, (714) 851–2530; Fax (714) 752–7057.

SUPPLEMENTARY INFORMATION: The Trinity Ranch property is located in the cities of Fort Worth and Benbrook along both sides of U.S. Highway 377 approximately 2.5 miles southwest of the IH–20 and Loop 820 interchange in southwest Tarrant County, Texas. The site is situated in an undeveloped floodplain(s) and is contiguous with an area known as the Benbrook Project which is managed by the U.S. Army Corps of Engineers for natural resource conservation purposes. The Trinity Ranch property consists of approximately 2,005 acres of undeveloped land. The property is irregular in shape and consists of two non-contiguous tracts divided by U.S. Highway 377 which bisects the property in a northeast/southwest direction. The terrain is gently rolling and mostly open space with a few heavily wooded riparian areas.

The Campobello Island Estates property is located on Campobello Island, New Brunswick, Canada. The site has frontage on the Atlantic Ocean, contains endangered species, and is adjacent to the Roosevelt Campobello International Park which is managed jointly by the United States and Canada. The Campobello Island Estates property consists of approximately 3,419.67 acres of land of which 3,040.17 acres are undeveloped and are not subdivided, 354.8 acres are subdivided and 24.7 acres are improved parcels. The property is situated in a coastal zone regulated by the New Brunswick Department of Environmental Affairs and contains a number of home lots designed for recreational purposes and an abandoned fish processing plant. These properties are covered properties within the meaning of section 10 of the Coastal Barrier Improvement Act of 1990, Public Law 101–591 (12 U.S.C. 1441a–3).

Written notice of serious interest in the purchase or other transfer of all or any portion of these properties must be received on or before May 10, 1994 by the Resolution Trust Corporation at the appropriate address stated above.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government;

2. Agencies or entities of State or local government; and

3. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest must be submitted in the following form:

Notice of Serious Interest

RE: [insert name of property] **Federal Register** Publication Date: _____ [insert **Federal Register** publication date]

1. Entity name.

2. Declaration of eligibility to submit Notice under criteria set forth in the Coastal Barrier Improvement Act of 1990, Public Law 101–591, section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)), including, for qualified organizations, a determination letter from the United States Internal Revenue Service regarding the organization's status under section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 170(h)(3)).

3. Brief description of proposed terms of purchase or other offer for all or any portion of the property (e.g., price and method of financing).

4. Declaration of entity that it intends to use the property for wildlife refuge, sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes as provided in a clear written description of the purpose(s) to which the property will be put and the location and acreage of the area covered by each purpose(s) including a declaration of entity that it will accept the placement, by the RTC, of an easement or deed restriction on the property consistent with its intended conservation use(s) as stated in its notice of serious interest.

5. Authorized Representative (Name/Address/Telephone/Fax).

List of Subjects

Environmental protection.

Dated: February 2, 1994.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Secretary.

[FR Doc. 94–2908 Filed 2–8–94; 8:45 am]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–33570; File No. SR–CSE–92–08]

Self-Regulatory Organizations; Cincinnati Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Delegation of Securities Committee's Authority to an Exchange Officer to Approve Designated Issues and Dealers

February 1, 1994.

On July 27, 1992, the Cincinnati Stock Exchange, Inc. ("CSE" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] a proposed rule change to delegate authority to an Exchange officer to approve Designated Issues and Dealers. On October 1, 1992, the CSE submitted to the Commission Amendment No. 1 to the proposed rule change.[3]

The proposed rule change was published for comment in Securities Exchange Act Release No. 31451 (November 13, 1992), 57 FR 54878 (November 20, 1992). No comments were received on the proposal.

The rule change amends Article VI, Section 3.1(b) of the CSE's Code of Regulations ("By-Laws") to expressly authorize the Securities Committee to delegate to an Exchange officer its authority to approve Designated Issues and Dealers.[4] The following is the text of the rule change (additions are italicized):

> The Securities Committee shall have the authority to adopt operating procedures necessary and appropriate for the Exchange's automated interface with the Intermarket Trading System (ITS). *The Securities Committee also may delegate its authority in Rule 11.9 to approve Designated Dealers and Designated Issues to an officer of the Exchange.*

Under Rule 11.9, when the CSE lists or obtains unlisted trading privileges on an issue, the Securities Committee may designate that issue for inclusion in the national Securities Trading System ("NSTS"), an electronic securities communication and execution facility through which bids and offers of

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1993).

[3] See letter from Kevin S. Fogarty, General Counsel, CSE, to Elizabeth Cosgrove, Attorney, SEC, dated July 30, 1992. The amendment made minor clarifying changes to the proposed rule change.

[4] The terms "Designated Issuer" and "Designated Dealer" are defined in the CSE Code of Regulations, Rule 11.9.

competing dealers, as well as public orders, are consolidated for review and execution by users of the system.[5] The Securities Committee also approves proprietary members of the Exchange as Designated Dealers who perform market functions by entering bids and offers for Designated Issues into the System.[6]

The Exchange states that it adds issues quite frequently to the NSTS, and that it is impractical to assemble the Securities Committee to designate each issue or to approve Designated Dealers for those issues. The Exchange notes that the rule change does not affect the Securities Committee's authority to reassign issues in light of market maker performance or to establish general policy; nor doe it delegate any authority with respect to applications for membership or listing. In adtlition, the officer to whom the authority is granted will prepare a report of his or her actions on a semi-annual basis to be submitted to the Securities Committee for ratification.[7] The Securities Committee retains authority to overturn any action by the Officer, and members affected by the officer's actions will be so advised at the time the actions are taken.[8] Any person aggrieved by an action of the officer has the same rights under the Exchange's rules for review as if the Securities Committee had acted and does not have to wait for ratification of the officer's action before pursuing those rights.[9]

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of sections 6(b).[10] In particular, the Commission believes the proposal is consistent with the section 6(b)(5) requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, and, in general, to protect investors and the public, in that it promotes a more efficient administration of Exchange business by allowing Designated Issues and Dealers to be approved by an officer instead of requiring the Securities Committee to convene for that purpose. In addition, persons affected by the actions of the officer will retain any rights and remedies previously available under the CSE's Constitution and Code of Regulations.[11]

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR–CSE–92–08) is approved.

For the Commission, by the Division of market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–2893 Filed 2–8–94; 8:45 am]

BILLING CODE 8010–01–M

[5] The NSTS combines the display of both the limit order file and current quotation/last sale information to users with the matching and execution of like-priced orders, bids and offers according to programmed price/time and agency/principal priorities in order to give users the ability to perform the brokerage and market making functions performed on other exchanges. In addition, the NSTS provides for the automatic execution of orders under predetermined conditions. CSE Code of Regulations, Rule 11.9(a)(1).

[6] CSE Code of Regulations, Rule 11.9(c).

[7] See letter from Robert Ackermann, Vice President, Regulation, CSE, to Sandra Sciole, Special Counsel, Division of Market Regulation, SEC, dated January 25, 1994.

[8] *Id.*

[9] See CSE Code of Regulations, Chapter X (Adverse Action).

[10] 15 U.S.C. 78f(b) (1988).

[11] See *supra* note 9 and accompanying text.

[12] 15 U.S.C. 78s(b)(2) (1988).

[13] 17 CFR 200.30–3(a)(12) (1993).

[Release No. 34–33569; File No: SR–CSE–93–06]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Cincinnati Stock Exchange, Inc. Relating to the Exchange's Listing and Maintenance Standards for Preferred Stocks

February 1, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 20, 1993, the Cincinnati Stock Exchange, Inc. ("CSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CSE hereby proposes to amend the Exchange's listing and maintenance standards for preferred stocks to conform them to the standards used by the New York Stock Exchange ("NYSE")[3] and the American Stock Exchange ("Amex").[4]

The Exchange requests the Commission to find good cause, pursuant to section 19(b)(2) of the Act, for approving the proposed rule change prior to the thirtieth day after publication in the **Federal Register.** Accelerated approval would allow the CSE to have in place listing and maintenance standards which conform to those currently used by the NYSE and Amex.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization 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 III below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed amendment is to Article IV, Section 1 of the CSE By-Laws, Rule 1.3(2). It will apply to listed preferred stock and will conform the rules of the Exchange to those currently in place at the NYSE and Amex. The proposed standards for preferred stocks will apply to both initial and maintenance requirements for those securities.[5]

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1993).

[3] The Commission notes that the NYSE has not set any minimum numerical criteria for the listing of preferred stock. The NYSE states that the preferred stock must be of sufficient size and distribution to warrant trading in the Exchange market system. NYSE Listed Company Manual ¶ 703.05. The NYSE, however, has set certain numerical delisting criteria for preferred stock, stating that it will "normally give consideration to suspending or removing a preferred stock if the aggregate market value of publicly-held shares is less than $2,000,000 and the number of publicly-held shares is less than 100,000." *Id.* These two measures are the minimum standards which the CSE is proposing to add to its listing requirements for preferred stock.

[4] The CSE's proposed listing requirements for preferred stock are the same as the current Amex requirements. See Amex Company Guide § 103. The numerical size and earning criteria for companies to list on the Exchanges remain different for the NYSE, Amex, and CSE. See NYSE Listed Company Manual ¶ 102.01; Amex Company guide § 101; CSE By-Laws Article IV, Section 1.3.

[5] The CSE Rules do not contain separate maintenance requirements for listed securities. The

Continued

2. Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act in general and furthers the objectives of section 6(b)(5) in particular in that it will promote just and equitable principles of trade and 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 CSE 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

No written comments were solicited or received with respect to the proposed rule change.

III. 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 at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CSE. All submissions should refer to File No. SR-CSE-93-06 and should be submitted by March 2, 1994.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the CSE's proposal to increase its listing standards for preferred stock is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act[6] in that it will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Commission believes that the development and enforcement of adequate standards governing the listing of securities on an exchange is of critical importance to exchange markets and to the investing public. Listing standards serve as a means for the self-regulatory organizations ("SROs") to screen issuers and to provide listed status only to bona fide companies with substantial float, investor base, and trading interest to ensure sufficient liquidity for fair and orderly markets.

The proposed rule change increases in some respects the CSE's listing standards for preferred stock. The old standards required 500 recordholders for which trading privileges had been granted or were requested, 200,000 shares for which trading privileges had been granted or were requested exclusive of the holdings of officers and directors, and a class of common stock that was listed on the Exchange or was otherwise eligible for listing. For issuers whose common stock is traded on the CSE, NYSE, or Amex, the rule change requires 100,000 publicly held shares,[7] an aggregate market value of $2 million, and a price of $10. For issuers of preferred stock not listed on the CSE, NYSE, or Amex, the rule change requires 400,000 publicly held preferred shares, 800 public round-lot holders, an aggregate market value of $4 million, and a price of $10.

The Commission believes that the initial listing and maintenance criteria for preferred sock, as described above, are consistent with section 6(b)(5) of the Act in that these criteria should help to ensure the maintenance of fair and orderly markets, as well as enhance benefits and protections for investors who trade in these securities. Requiring a minimum number of publicly held shares, and a minimum aggregate market value and price per share should help ensure a wide public distribution of the securities, which should decrease the opportunities for manipulation, as well as help create a more liquid market for trading.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission believes that accelerated approval of the proposal is appropriate in order to allow the CSE to conform its listing standards for preferred stocks with those of the NYSE and Amex. The rule change serves to create a uniformity of enhanced listing standards among the various exchanges, which benefits the marketplace as a whole, and thereby serves the public's interest.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act[8] that the proposed rule change is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94-2894 Filed 2-8-94; 8:45 am]

BILLING CODE 8010-01-M

CSE Rule for the delisting of securities, however, states that a security may be delisted if it fails to meet the listing standards. CSE By-Laws, Article IV, Section 3, Rule 3.1(c).

[6] 15 U.S.C. 78f(b)(5) (1988).

[7] Publicly held shares excludes the holdings of officers, directors, controlling shareholders and other concentrated or family holdings,and restricted securities.

[8] 15 U.S.C. 78s(b)(2) (1988).

[9] 17 CFR 200.30-3(a)(12) (1993).

[Release No. IC-20053; 813-126]

DLJ LBO Plans Management Corporation; Application for Exemption

February 2, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANT: DLJ LBO Plans Management Corporation ("DLJ Management"), on behalf of certain limited liability companies (the "Companies").

RELEVANT ACT SECTIONS: Applicant seeks an order under section 6(b) granting an exemption from all provisions of the Act except sections 7, 8(a), and 9, certain provisions of section 17, sections 36 through 53, sections 2 through 5 to the extent necessary to implement the other sections, and the rules and regulations related to these sections.

SUMMARY OF APPLICATION: Applicant, on behalf of the Companies, seeks an order that would grant the Companies an exemption from most provisions of the Act, and would permit certain affiliated and joint transactions. Each Company would be an employees' securities company within the meaning of section 2(a)(13) of the Act.

FILING DATES: The applications was filed on August 2, 1993, and amended on December 2, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be

issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 28, 1994, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549; Applicant, 140 Broadway, New York, New York 10005–1285.

FOR FURTHER INFORMATION CONTACT: John V. O'Hanlon, Senior Attorney, at (202) 272–3922, or Elizabeth G. Osterman, Branch Chief, at (202) 272–3016 (Division of Investment Management, Office of Investment Company Regulations).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representatives

1. DLJ Management is a Delaware corporation and a wholly-owned subsidiary of Donaldson, Lufkin & Jenrette, Inc. ("DLJ Inc.," together with any person that directly or indirectly is controlled by DLJ Inc., "DLJ"). DLJ Inc. is a diversified financial services holding company which, directly and through its subsidiaries, provides investment, financing, and related services. DLJ Inc.'s principal subsidiary, Donaldson, Lufkin & Jenrette Securities Corporation, is a broker-dealer registered under the Securities Exchange Act of 1934.

2. DLJ Management, or another direct or indirect wholly-owned subsidiary of DLJ Inc. formed for such purpose, will be the manager of the Companies (the "Manager").

3. Each Company will be a Delaware limited liability company formed as an "employees' securities company" within the meaning of section 2(a)(13) of the Act, and will operate as a closed-end, non-diversified, management investment company.[1] Each Company will be governed by a limited liability company agreement ("LLC Agreement").

4. Investors in the Companies ("Members"), other than the Manager, will be current, highly-compensated employees, officers, or directors of DLJ ("Eligible Employees"), who are also "accredited investors" under subsection 6 of rule 501(a) of Regulation D under the Securities Act of 1933 (the "Securities Act"). In addition, these Members will be experienced professionals in the investment banking and securities business, or in administrative, financial, accounting, legal, or operational activities related thereto. They will be sophisticated investors able to fend for themselves without benefit of regulatory safeguards. All Members will be aware that (a) interests in the Companies will be sold in a transaction exempt under section 4(2) of the Securities Act or Regulation D under the Securities Act, and thus are offered without registration under the Securities Act; and (b) although registered under the Act, the Companies will be exempt from most provisions of the Act.

5. The Companies will enable Eligible Employees to pool their investment resources and to receive the benefit of certain investment opportunities that come to the attention of DLJ. Each Company will acquire equity and equity-related investments, excluding any investment in a company which is an investment company as defined in section 3(a) of the Act, in (a) companies which are the subject of DLJ transactions involving leveraged or management buyouts, recapitalizations, bankruptcies, reorganizations, start-up and expansion financings, or other similar investments or restructurings ("Merchant Banking Transactions") structured by DLJ Merchant Banking Partners, L.P., DLJ Offshore Partners, C.V., or DLJ International Partners, C.V. (together with any similar funds created hereafter, the "DLJ Merchant Banking Funds"), or with respect to which a DLJ Merchant Banking Fund assisted in the consummation and, in each case, in which DLJ has a long-term equity or equity-related investment ("Fund Investments"); and/or (b) companies other than DLJ which are the subject of transactions structured by DLJ's investment banking or merchant banking groups or with respect to which either group assisted in the consummation, in which DLJ has a long-term equity or equity-related investment, and which are not Fund Investments ("Non-Fund Investments") (together with Fund Investments, the "DLJ Investments"). The LLC Agreement may provide for limitations on the amount of investments in Non-Fund Investments.

6. At least two plans will be available to Eligible Employees. Eligible Employees in the "DLJ Plan" will invest in all investments made by a Company and share in the net profits or losses of the Company for each investment period in proportion to their capital accounts. The "DLJMB Plan" is available only to Eligible Employees who are deemed important to DLJ's business through their involvement in Merchant Banking Transactions. Eligible Employees in the DLJMB Plan may only invest in Merchant Banking Transactions in which they have been directly involved and will share in the net profits or losses of each such investment in proportion to the capital accounts of the DLJMB Plan participants relating to that particular investment.[2]

7. Because of the difference in the eligibility of membership and the nature of the interests held in the two plans, DLJ may create separate Companies for each plan, although DLJ may create only one Company for both plans, with separate capital accounts and allocations for each plan. To the extent a DLJMB Plan Company co-invests with a DLJ Plan Company in DLJ Investments, the amount of a particular investment made available to each company will be governed by the terms of the agreement described in paragraph 9 below.

8. Applicant expects that a new Company will be established each year (or other relevant period), although, depending upon investment activity, it may not be necessary or desirable to form a new Company after only one year of activity.[3]

9. To assure each DLJ Plan Company that it will have the ability to acquire an interest in every DLJ Investment, and to assure each DLJMB Plan Company that it will have the ability to acquire an interest in every DLJ Investment on which DLJMB Plan Company participants worked, each Company will enter into an agreement with DLJ Inc. (the "DLJ Agreement"). Under the DLJ Agreement, unless a committee comprised of senior professionals at DLJ

[1] A limited liability company generally is treated as a corporation for limited liability purposes and under certain circumstances as a partnership for federal income tax purposes. Applicant reserves the right to implement this structure through a limited partnership arrangement.

[2] Applicant reserves the flexibility to utilize the Companies for additional DLJ employee plans, subject generally to the representations in the application.

[3] Applicant reserves the right to establish a single long-term Company, in which the interests for each year (or other relevant period) would be held in separate and distinct portfolios with different classes of interests, capital accounts, and allocations of income and loss applicable for each such year (or other relevant period). Each of these portfolios would comply with rule 18f–2 under the Act.

(the "administrative Committee") approves a determination by the Manager that a Company not participate in a particular investment, each Company will be obligated to purchase from DLJ Inc. or an affiliate of DLJ Inc., and DLJ Inc. will agree to sell or cause an affiliate of DLJ Inc. to sell to the Company, a fixed percentage of such entity's long-term equity or equity-related investment in each DLJ Investment that closes during a period specified in the DLJ Agreement (the "Investment Period") (other than investments held by Designated Funds or Designated Subsidiaries, and Exempted Investments, as defined below).

10. For DLJ Plan Companies, it is expected that a Company will be obligated to purchase from DLJ and DLJ will be obligated to sell to the Company not less than 20% and not more than 30% of DLJ's long-term equity or equity-related investment in DLJ Investments, to be determined at the beginning of each Investment Period depending on, among other factors, availability of capital and compensation objectives.

11. For DLJMB Plan Companies, a Company will be obligated to purchase from DLJ and DLJ will be obligated to sell to the Company a percentage of DLJ's long-term equity or equity-related investment in DLJ Investments to be determined on an investment by investment basis no later than two weeks following DLJ's acquisition, depending principally on the number of Members who will be participating in each investment, the size of the DLJ Investment, and the quality of work done. No employee will be obligated to take the portion of the investment offered under the DLJMB Plan.[4]

12. Each DLJ Agreement will provide that a Company will acquire DLJ Investments from DLJ as soon as practicable after DLJ purchases the investment, but in no event later than one month after the later of such purchase or organization of the Company, at a price equal to the cost to DLJ of purchasing the investment.[5]

13. Each DLJ Agreement will provide that a Company may not sell any security purchased under the DLJ Agreement or any Other Investment, as defined below, so long as DLJ Inc. or any direct or indirect wholly-owned affiliate of DLJ Inc. has an investment in a stock or security which is identical, substantially similar, or economically equivalent to such security, absent the consent of the administrative Committee. A Company will be required to participate in any public or private sale by DLJ Inc. and/or any wholly-owned affiliate of DLJ Inc. of securities owned by them or for their benefit which are identical, substantially similar, or economically equivalent to the securities held by a Company. The DLJ Agreement provides that the Company must sell no less than its *pro rata* share of such securities but may, with the consent of the Administrative Committee, sell more than its *pro rata* share of these securities.

14. Although each Company will be required to purchase DLJ Investments, the Company will not be required to participate in sales by non-wholly-owned affiliates of DLJ (such as other partnerships established by DLJ Inc.) in which DLJ Inc. or its wholly-owned affiliates do not participate. The rationale underlying the differing requirements is that while DLJ Inc. has the ability to make all DLJ Investments available to the Companies, DLJ Inc. and its wholly-owned affiliates may not have the authority to require that a non-wholly-owned affiliate permit a Company to participate in its disposition of such investments.

15. The Administrative Committee will have no involvement in disposition decisions where a portfolio security is held by a Company and a non-wholly-owned affiliate, but not by DLJ Inc. or a wholly-owned affiliate. In such circumstances, the timing of the disposition will be determined by the Manager in the exercise of its fiduciary responsibilities.

16. Pursuant to the DLJ Agreement, certain funds managed by DLJ (the "Designated Funds") will not be obligated under the DLJ Agreements to sell DLJ Investments to the Companies. The Designated Funds include certain merchant banking funds established by DLJ Inc., the investors of which are limited partners unaffiliated with DLJ Inc. Because of certain provisions in the documents establishing the Designated Funds, DLJ Inc. lacks the ability to compel the sale of any of the Designated Funds' portfolio securities to the Companies. At the present time, the DLJ Merchant Banking Funds, DLJ Merchant Banking, L.P., DLJ Merchant Banking, Inc., and DLJ Offshore Management N.V. are the only Designated Funds. To the extent that a substantial portion of DLJ's activities in initiating and structuring Fund Investments is conducted through the DLJ Merchant Banking Funds, and DLJ is obligated to co-invest with such funds, each Company will be assured of the ability to acquire an interest in several DLJ Investments.

17. Pursuant to the DLJ Agreement, certain investment subsidiaries and affiliates of DLJ Inc. ("Designated Subsidiaries") will not be obligated under the DLJ Agreements to sell DLJ Investments to the Companies. Many of the investments in which the Designated Subsidiaries invest would be unsuitable investments for a Company due to the size of the investment, the maturity of the portfolio company, or other relevant factors. The Designated Subsidiaries at present include The Sprout Group; Wood, Struthers & Winthrop Management Corp.; and the DLJ Bridge Fund.

18. Each DLJ Agreement will provide that DLJ will not be obligated to offer a Company any portion of securities (a) which it receives as compensation for providing investment banking or other services, (b) which it acquires solely in the capacity of underwriter or principal market maker or in connection with block positioning, proprietary trading accounts, risk arbitrage, or other broker dealer activities, or (c) in other circumstances enumerated as exceptions to DLJ's obligation to offer an investment opportunity to a DLJ Merchant Banking Fund, as set forth in the fund's organizational document (collectively, "Exempted Investments"). The circumstances in which DLJ acquires any Exempted Investment generally are not of the type making those investments appropriate for acquisition by the Companies.

19. A Company may invest in an investment made by a Designated Fund or a Designated Subsidiary if the Company is offered the opportunity to invest in such investment and if the Administrative Committee approves a determination by the Manager that the Company's participation in such investment is appropriate.

20. A Company will not invest in investments made by DLJ that are not DLJ Investments or are Exempted Investments ("Other Investments") unless the Company is offered the opportunity to invest in such Other Investments and the Administrative Committee approves a determination by the Manager that the Company's participation in such investments is appropriate.

[4] The DLJ Bridge Fund purchases short-term securities to provide bridge financing for acquisitions. In transactions in which the DLJ Bridge Fund has provided a bridge loan in connection with the transaction, (a) the percentage to be purchased under the DLJMB Plan will be determined upon full repayment of the bridge loan, unless the Administrative Committee approves an earlier determination by the Manager; and (b) in addition to the fixed percentage to be purchased under the DLJ Plan, after the bridge loan is fully repaid, DLJ may offer an additional equity portion of the investment to the Company.

[5] In certain transactions, a Company may acquire its investment directly from the issuer, concurrently with DLJ.

21. Pending investment, and prior to distribution, Company funds will be invested in: (a) United States Government obligations with maturities of no more than one year and one day; (b) high grade commercial paper with maturities of no more than six months and one day; (c) interest-bearing deposits maturing within one year in any bank or trust company organized or licensed under the laws of the United States or any state thereof and having an unrestricted surplus of at least $250 million; or (d) any money market fund distributed or managed by DLJ, Alliance Capital Management L.P., or Wood, Struthers & Winthrop Management Corp. (each such investment, a "Temporary Investment"). Consistent with section 12(d)(1)(A)(i) of the Act, no Company will acquire more than 3% of the total outstanding voting stock of any investment company. Also, the Manager temporarily may invest any portion of Company funds attributable to its own capital contributions by making unsecured demand loans to DLJ for working capital purposes. Such a loan would be made at a return rate equal to the Manager's Preferred Return, as defined below.

22. The Manager, in addition to performing all management and administrative services necessary for the operation of the Companies, will make a substantial investment in each Company. For DLJ Plan Companies, upon the formation of each Company, and for both DLJ Plan Companies and DLJMB Plan Companies, at the time of each investment by a Company, the Manager will contribute 1% of the total cash contributions made by all the Members (excluding the Manager's other capital contribution obligations described in the following sentence). In addition, at the time of each investment by the Company in DLJ Investments and Other Investments, the Manager generally will make an additional capital contribution to the Company equal to approximately 65% of the aggregate amount that the Company proposes to invest.[6]

23. The Manager will be entitled to receive a cumulative annual return on its contribution to the capital of a Company (other than its 1% capital contribution described above) from the time contributed until the repayment of such capital at (a) the rate of interest publicly announced by Citibank, N.A. as its prime rate or base lending rate, or, if no such rate has been announced by Citibank, N.A., then the rate of interest so announced by another major money center bank in New York City selected by the Manager in its sole discretion, plus (b) 1¾% per annum (the "Preferred Return").

24. Company profits, excluding those derived from Temporary Investments, will be allocated as follows: first, to the Manager in an amount necessary to provide it the Preferred Return; second, to the Members, including the Manager, in the same proportions, in reverse order, as any previously allocated losses, up to the amount of such losses; and third, to the Members, including the Manager only to the extent of its 1% contribution, in proportion to their capital accounts.

25. Company losses not derived from Temporary Investments will be allocated to the Members, including the Manager, in the same proportions as any profits would be allocated pursuant the third item of paragraph 24 above

26. Profits and losses of a Company derived from Temporary Investments of capital contributions pending investments in portfolio investments will be allocated to the Members, including the Manager, in proportion to their capital accounts. Profits and losses of each Company from Temporary Investments of distributions held for the account of the Members, including the Manager, pending termination of the Manager's right to purchase interests during the Forfeiture Period, as defined below, will be allocated to the Members, including the Manager, for whose account such distributions are retained.

27. Each member will have a limited obligation to restore to a Company, upon liquidation, such Member's negative capital account balance, if any. The Member's obligation will not exceed the value of the Member's interests in specified other Companies created under the application and other employee benefit, compensation, and similar plans established by DLJ.

28. All of the Manager's directors and principal officers will be directors or officers of DLJ, and a majority of such directors and principal officers will be Eligible Employees under the DLJ Plan. No compensation will be paid to the Manager or its officers or directors for its services. The Manager will bear all expenses incurred in connection with the organization, business operations, winding up, and liquidation of the Companies.

29. The Manager will register as an investment adviser under the Investment Advisers Act of 1940. The Manager believes that its relationships with the Companies will fully comply with the provisions of the Advisers Act.

30. The Members may remove a Manager upon the approval of at least 90% of the entire ownership interest of the Members of a Company, excluding the Manager. The remaining Members may elect to continue the Company following such removal.

31. All Company interests will be non-transferable. However, with the consent of the Manager, in its sole discretion, a Member may assign his economic interest to a member of the assignor's immediate family.

32. In the DLJ Plan, a participant's investment generally will become vested at the rate of 33⅓% annually beginning on March 31 of the year after the Company's formation, except as provided below. If a participant ceases to be an active employee of DLJ (a "Departing Member") by reason of (a) death, (b) retirement on or after age 65 or on any other date qualifying the participant for early or disability retirement, or (c) termination of a participant's employment with DLJ for any reason (other than for cause, as defined in the LLC Agreement) within 24 months after a change of control, as defined in the LLC Agreement, of DLJ, such Departing Member's investment will be fully vested; provided that if a participant's employment with DLJ is terminated at any time for cause, any previous vesting will be forfeited, and all of the Department Member's investment shall be subject to repurchase, as explained in paragraph 34 below, during the period from the termination date to the later of (i) December 31 of the year following the year in which the participant's employment is terminated and (ii) the last day of the eighteenth calendar month following the month in which the participant's employment is terminated (the "Forfeiture Period"). If a Member voluntarily resigns his or her employment with DLJ, any unvested interests similarly will be subject to repurchase.

33. In the DLJMB Plan, a participant's investment will be vested 25% annually beginning 18 months after the investment date for each particular investment, except as provided below. If (a) a participant's employment with DLJ is terminated at any time for cause, or (b) a participant voluntarily terminates his employment and during the Forfeiture Period the participant becomes employed by, or a partner in, consultant to, or otherwise joins any firm that the Manager determines, in its reasonable discretion, to be competitive with DLJ's merchant banking or investment banking (including high

[6] If a particular employee plan does not involve as much leverage as the DLJ Plan and the DLJMB Plan, it is possible that DLJ will not contribute capital to the Company other than its 1% capital contribution, and instead will hold a substantially similar investment outside of the Company.

yield) businesses or any other business of DLJ, any previous vesting will be forfeited and all of the Departing Member's investment shall be subject to repurchase, as explained in paragraph 34 below. Notwithstanding the foregoing, however, if the participant's employment is terminated for any reason, other than for cause, within 24 months after a change in control, such Departing Member's investment will be fully vested.

34. In both the DLJ Plan and the DLJMB Plan, upon termination of a participant's employment with DLJ, the Manager may decide at any time during the Forfeiture Period to purchase for cash all or a portion of the unvested interests. Upon any such purchase, the Manager will pay the Departing Member an amount determined under a prescribed formula set forth in the application.

35. Each Company will send audited annual financial statements to the Members within 120 days of the end of the fiscal year, or as soon as practicable thereafter. In addition, a copy of each Member's Internal Revenue Service Schedule "K–1" will be transmitted to such Member.

36. The Companies and the Manager permanently will maintain and preserve such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements that are to be provided to each Member or that are necessary or appropriate to record its transactions with the Company. All such records will be subject to examinatic n by the Commission and its staff.

Applicant's Legal Analysis

1. On behalf of the Companies, applicant requests an exemption under section 6(b) of the Act from all provisions of the Act except (a) sections 7, 8(a), 9, 36, and 37, and the rules and regulations under those sections; (b) certain provisions of section 17, and the related rules and regulations under those sections; (c) sections 2 through 5 to the extent necessary to implement the other sections; and (d) sections 38 through 53, and the rules and regulations under those administrative and jurisdictional sections necessary to enforce compliance with the terms of any order granted.

2. Applicant requests an exemption from section 17(a) of the Act to the extent necessary to permit DLJ to engage in any transaction as principal with a Company. The exemption is requested to permit the Companies to (a) purchase portfolio investments from DLJ on a principal basis pursuant to the DLJ Agreement; (b) purchase interests or property in a company or other investment vehicle in which DLJ already owns securities, or where such company or other investment vehicle is otherwise affiliated with DLJ Inc. or a Company; (c) sell, put or tender, or grant options in securities or interests in a company or other investment vehicle back to such entity, where that entity is affiliated with DLJ; (d) participate as a selling security holder in a public offering that is underwritten by DLJ or in which DLJ acts as a member of the underwriting or selling group; and (e) make short-term Temporary Investments purchased from, and sold to, DLJ or its affiliates.

3. Applicant requests an exemption from section 17(d) under the Act to permit the Companies to engage in transactions in which affiliated persons of the Companies may also be participants. Applicant states that such an exemption is necessary in view of the fact that the Companies will be required to invest their capital contributions in DLJ Investments in which DLJ will retain an interest.

4. Applicant requests an exemption from section 17(f) to the extent necessary to permit DLJ to act as custodian without a written contract. Applicant asserts that because there is such a close association between the Companies and DLJ, a written contract would cause a burden and expense where none is necessary.

5. Applicant requests an exemption from section 17(g) and rule 17(g)(1) to permit the Manager's officers and directors, who may be deemed "interested persons," to take actions and make the determinations set forth in the rule. In addition, applicant requests an exemption from section 17(j) and rule 17j–1 (except for paragraph (a) thereof) because the "access person" requirements are unnecessary in this context.

6. Applicant submits that the exemptions requested pursuant to section 6(b) are consistent with the protection of investors. Applicant asserts that the exemptions are necessary or relevant to the operations of the Companies as an investment program uniquely adapted to the needs of employees of DLJ. Applicant further submits that the requested relief is consistent with the legislative history relating to employees' securities companies. In support of these assertions, applicant cites the nature of the Companies as employees' securities companies under the Act and their intended manner of operation.

7. Applicant asserts that a substantial community of economic and other interests exists among DLJ and the Members, including the Manager, which obviates the need for protection of investors under the Act. The Companies were conceived and will be organized and managed by persons who will be investing in the Companies, and will not be promoted by persons seeking to profit from fees or investment advice or from the distribution of securities. Applicant also submits that the terms of the proposed affiliated transactions will be reasonable and fair and free from overreaching.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–2892 Filed 2–8–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20054; 812–8408]

Janus Aspen Series, et al.

February 3, 1994.

AGENCY: Securities and Exchange Commission ("SEC or the "Commission").

ACTION: Notice of application for exemptions under the Investment Company Act of 1940 (the "1940 Act" or "Act").

APPLICANTS: Janus Aspen Series (the "Trust") and Janus Capital Corporation ("Janus Capital").

RELEVANT 1940 ACT SECTIONS: Order requested under Section 6(c) for exemptions from Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act and Rules 6e-2(b)(15) and 6e-3(T)(b)(15) thereunder.

SUMMARY OF APPLICATION: Applicants seek an order to the extent necessary to permit shares of the Trust and shares of any other investment company that is designed to fund insurance products and for which Janus Capital, or any of its affiliates, serves as investment adviser, administrator, manager, principal underwriter or sponsor (the Trust and such other investment companies collectively, "funds") to be sold to and held by (a) variable annuity and variable life insurance separate accounts of both affiliated and unaffiliated life insurance companies ("Participating Insurance Companies") and (b) qualified pension and retirement plans outside of the separate account context ("Qualified Plan" or "Plans").

FILING DATE: The application was filed on May 21, 1993, and amended on December 9, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be

issued unless the commission orders a hearing. Interested persons may request a hearing on the application by writing to the Secretary of the SEC and serving the Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the Commission by 5:30 p.m. on February 28, 1994 and should be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate. hearing requests should state the nature of the request and the issues contested. Persons may request notification of the date of a hearing by writing to the secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, 100 Fillmore Street, suite 300, Denver, Colorado 80206–4923.

FOR FURTHER INFORMATION CONTACT: Joyce M. Pickholz, Senior Attorney, or Wendell Mr. Faria, Deputy Chief, on (202) 272–2060, Office of Insurance Products (Division of Investment management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Trust was organized as a business trust under the laws of the State of Delaware on May 19, 1993. The Trust is a registered open-end management investment company comprised of six separately managed series. Additional series could be added to the Trust in the future.

2. Janus Capital is the investment adviser and administrator for each of the Trust's series. Kansas City Southern Industries, Inc. ("KCSI") owns approximately 81% of the outstanding voting stock of Janus Capital. KCSI is a publicly traded holding company whose primary subsidiaries are engaged in transportation, financial services and real estate.

3. Shares of each series of the Trust may be offered only to insurance company separate accounts that fund variable annuity and variable life insurance contracts ("Contracts"). The Trust initially intends to offer its shares exclusively to variable annuity separate accounts established by Western Reserve Life Assurance Co. of Ohio ("Western Reserve") or its affiliates and variable annuity separate accounts established by insurance companies that are not affiliated with Western Reserve. It is contemplated that, shares of each series of the Trust also would be offered to one or more variable life insurance separate accounts established by insurance companies that are not affiliated with Western Reserve. It is anticipated that Participating Insurance Companies will rely on Rule 6e–2 or 6e–3(T) under the 1940 Act. Shares or each series of the Trust also would be offered directly to Qualified Plans outside of the separate account context.

4. Qualified Plans may choose any of the Funds as the sole investment under the Plan or as one of several investments. Plan participants may or may not be given an investment choice depending on the Plan itself. Shares of any of the Funds sold to Qualified Plans would be held by the trustee(s) of said Plans as mandated by Section 403(a) of the Employee Retirement Income Security Act ("ERISA"). Janus Capital will not act as investment adviser to any of the Qualified Plans that will purchase shares of any of the Funds.

5. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts is commonly referred to as mixed funding. The use of a common investment company as the underlying investment medium for separate accounts of unaffiliated insurance companies is commonly referred to as shared funding.

Applicants' Legal Analysis

1. In connection with scheduled premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–2(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act to the extent that those sections have been deemed by the Commission to require "pass-through" voting with respect to an underlying investment company's shares. The exemptions granted to a separate account by Rule 6e–2(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies which offer their shares exclusively to variable life insurance separate accounts of the life insurer, or of any affiliated life insurance company. Therefore, the relief granted by Rule 6e–2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an investment company that also offers its shares to a variable annuity separate account of the same or of any affiliated or unaffiliated insurance company. Also, the relief granted by Rule 6e–2(b)(15) is not available if shares of the underlying investment company are offered to variable annuity or variable life insurance separate accounts of unaffiliated insurance companies. Moreover, because the relief under Rule 6e–2(b)(15) is available only where shares are offered exclusively to separate accounts, additional exemptive relief is necessary if the shares of the Funds are also to be sold to Qualified Plans.

2. The Applicants state that the promulgation of Rules 6e–2(b)(15) and 6e–3(T)(b)(15) preceded the issuance of the Treasury Regulations which made it possible for shares of an investment company to be held by the trustee of a Qualified Plan without adversely affecting the ability of shares in the same investment company to also be held by the separate accounts of insurance companies in connection with their variable contracts. Thus, the sale of shares of the same investment company to separate accounts and Qualified Plans could not have been envisioned at the time of the adoption of Rules 6e–2(b)(15) and 6e–3(T)(b)(15), given the then-current tax law.

3. According to the Applicants, various factors have kept more insurance companies from offering variable annuity and variable life insurance Contracts than currently do so. These factors include the costs of organizing and operating a funding medium, the lack of expertise with respect to investment management (principally with respect to stock and money market investments) and the lack of public name recognition as investment experts. In particular, some smaller life insurance companies may not find it economically feasible, or within their investment or administrative expertise, to enter the Contract business on their own. The Applicants submit that use of the Funds as common investment media for Contracts would ameliorate these concerns.

4. Applicants assert that Participating Insurance Companies would benefit not only from the investment advisory and administrative expertise of Janus Capital, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Therefore, making the Funds available for mixed and shared funding will encourage more insurance companies to offer Contracts. This should result in increased competition with respect to both Contract design and pricing, which can be expected to result in more product variation and lower charges. Contract owners would benefit because mixed and shared funding eliminates a significant portion of the costs of establishing and administering separate funds. Moreover, sale of the shares of

Funds to Qualified Plans should result in an increased amount of assets available for investment by such Funds. This, in turn, should inure to the benefit of Contract owners by promoting economies of scale, by permitting greater safety through greater diversification, and by making the addition of new portfolios to the Trust more feasible.

5. In connection with flexible premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the Act to the extent that those sections have been deemed by the Commission to require "pass-through" voting with respect to an underlying investment company's shares. The exemptions granted to a separate account by Rule 6e–3(T)(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies which offer their shares exclusively to separate accounts of the life insurer, or of any affiliated life insurance company, offering either scheduled premium variable life insurance contracts or flexible premium variable life insurance contracts, or both; or which also offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company. Therefore, Rule 6e–3(T) permits mixed funding for flexible premium variable life insurance. However, Rule 6e–3(T) does not permit shared funding, because the relief granted by Rule 6e–3(T)(b)(15) is not available with respect to a flexible premium variable life insurance separate account that owns shares of an investment company that also offers its shares to separate accounts (including flexible premium variable life insurance separate accounts) of unaffiliated life insurance companies.

6. According to the Applicants, the relief granted by Rule 6e–3(T) is in no way affected by the purchase of shares of the Funds by Qualified Plans. However, because the relief under Rule 6e–3T) is available only where shares are offered exclusively to separate accounts, additional exemptive relief is necessary if the shares of the Funds are also to be sold to Plans.

7. Applicants state that they are not aware of any stated rational for the exclusion of separate accounts and investment companies engaged in shared funding from the exemptive relief provided under Rules 6e–2(b)(15) and 6e–3(T) (b)(15) or for the exclusion of separate accounts and investment companies engage in mixed funding from the exemptive relief provided under Rule 6e–2(b)(15). Similarly, Applicants are not aware of any stated rationale for excluding Participating Insurance Companies from the exemptive relief requested because the Funds may also sell their respective shares to Qualified Plans. If the Funds were to sell their respective shares only to Qualified Plans, no exemptive relief would be necessary. The relief provided under Rules 6e–2(b)(15) and 6e–3(T) (b)(15) does not relate to qualified pension and retirement plans or to a registered investment company's ability to sell its shares to such plans. Exemptive relief is requested in the application only because the separate accounts investing in the Funds are themselves investment companies seeking relief under Rules 6e–2 and 6e–3(T) and do not wish to be denied such relief if the Funds sell shares to Qualified Plans.

8. Section 9(a) of the 1940 Act provides that it is unlawful for any company to serve as investment adviser or principal underwriter of any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Section 9(a)(1) or (2). However, Rules 6e–2(b)(15) (i) and (ii) and 6e–3(T)(b)(15) (i) and (ii) provide partial exemptions from Section 9(a) under certain circumstances, subject to the limitations discussed above on mixed and shared funding. These exemptions limit the disqualification to affiliated individuals or companies that directly participate in the management or administration of the underlying investment company.

9. Applicants argue that the exemptions contained in Rules 6e–2(b)(15) and 6e–3(T) (b)(15) recognize that it is unnecessary to apply Section 9(a) to the thousands of individuals who may be involved in a large insurance company but would have no connection with the investment company funding the separate accounts. Applicants believe that it is unnecessary to limit the applicability of the rules merely because shares of the Funds may be sold in connection with mixed and shared funding. The Participating Insurance Companies are not expected to play any rule in the management or administration of the Funds. Therefore, applying the restrictions of Section 9(e) serves no regulatory purpose. Indeed, applying such restrictions would increase the monitoring costs incurred by the Participating Insurance Companies and, therefore, would reduce the net rates of return realized by Contract owners. Moreover, the relief requested herein will in no way be affected by the proposed sale of shares of Funds to Qualified Plans. The insulation of the Trust from those individuals who are disqualified under the Act remains in place. Since the Qualified Plans are not investment companies and will not be deemed to be affiliated solely by virtue of their shareholdings, no additional relief is necessary.

10. Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) assume that Contract owners are entitled to pass-through voting privileges with respect to investment company shares held by a related separate account. However, if the limitations on mixed and shared funding are satisfied, Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) provide exemptions from the pass-through voting requirements in limited situations.

11. Rules 6e–2(b)(15) (iii)(A) and 6e–3(T)(b) (15)(iii)(A) provide that an insurance company may disregard the voting instructions of its contract owners with respect to the investments of an underlying investment company or any contract between an investment company and its investment adviser, when an insurance regulatory authority so requires. Rules 6e–2(b)(15) (iii)(B) and 6e–3(T)(b) (15)(iii)(B) provide that the insurance company may disregard contract owners' voting instructions with regard to changes initiated by the contract holders in the investment company's investment policies, principal underwriter or investment adviser. Under the rules, voting instructions with respect to a change in investment policies may be disregarded only if the insurance company makes a good faith determination that such change would: (1) violate state law; (2) result in investments that were not consistent with the investment objectives of the separate account; or (3) result in investments that would vary from the general quality and nature of investments and investment techniques used by other separate accounts of the company or of an affiliated life insurance company with similar investment objectives. Voting instructions with respect to a change in an investment adviser may be disregarded only if the insurance company makes a good faith determination that: (1) the adviser's fee would exceed the maximum rate that may be charged against the separate account's assets; (2) the proposed adviser may be expected to employ investment techniques that vary from the general techniques used by the current adviser; or (3) the proposed adviser may be expected to manage the

investment company's investments in a manner that would be inconsistent with its investment objectives or in a manner that would result in investments that vary from certain standards.

12. Applicants submit that Rule 6e–2 recognizes that variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation of insurance. Thus, in adopting Rule 6e–2, the Commission expressly recognized that exemptions from pass-through voting requirements were necessary to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer. Flexible premium variable life insurance contracts and variable annuity contracts are subject to substantially the same state insurance regulatory authority, and therefore, the corresponding provisions of Rule 6e–3(T) (which apply to flexible premium insurance contracts and which permit mixed funding) presumably were adopted in recognition of the same considerations as the Commission applied in adopting Rule 6e–2. These considerations are no less important or necessary when an insurance company funds its separate accounts in connection with shared and mixed funding. Such funding does not compromise the goals of the insurance regulatory authorities or of the Commission. While the Commission may have wished to reserve wide latitude with respect to the once unfamiliar variable annuity product, that product is now familiar and there appears to be no reason for the maintenance of prohibitions against mixed and shared funding arrangements. Indeed, permitting such arrangements eliminates needless duplication of start-up and administrative expenses and potentially increases an investment company's assets, thereby making effective portfolio management strategies easier to implement, as well as promoting other economies of scale.

13. In addition, Applicants assert that the Funds' sale of shares to Qualified Plans will not have any impact on the relief requested. Shares of the Funds sold to such Plans would be held by the trustees of said Plans as mandated by Section 403(a) of ERISA. Section 403(a) also provides that the trustee(s) must have exclusive authority and discretion to manage and control the plan with two exceptions: (1) When the plan expressly provides that the trustee(s) are subject to the direction of a named fiduciary who is not a trustee, in which case the trustees are subject to proper directions made in accordance with the terms of the plan and not contrary to ERISA, and (2) when the authority to manage, acquire or dispose of assets of the plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA. Unless one of the two exceptions stated in Section 403(a) applies, plan trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the shares held unless the right to vote such shares is reserved to the trustees or the named fiduciary. In any event, there is no-pass through voting to the participants in such plans. Accordingly, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present with Qualified Plans.

14. Applicants assert that no increased conflicts of interest would be present if the Commission grants the requested exemptive relief. Shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. For example, when different Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require action that is inconsistent with the requirements of insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. That possibility, however, is no different and no greater than exists when a single insurer and its affiliates offer their insurance products in several states, as currently is permitted.

15. According to the Applicants, affiliations do not reduce the potential, if any exists, for differences in state regulatory requirements. In any event, the conditions discussed below (which are adapted from the conditions included in Rule 6e–3(T)(b)(15)) are designed to safeguard against any adverse effects that differences among state regulatory requirements may produce. If a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Funds.

16. Similarly, affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company could disregard Contract owner voting instructions. The potential for disagreement is limited by the requirement that disregarding voting instructions be reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard Contract owner voting instructions represents a minority position or would preclude a majority vote approving a particular change, such Participating Insurance Company may be required, at the election of the relevant Fund, to withdraw its separate account's investment in that fund and no charge or penalty will be imposed as a result of such withdrawal.

17. Applicants state that there is no reason why the investment policies of a Fund with mixed funding would or should be materially different from what they would or should be if such investment company or series thereof funded only variable annuity or only variable life insurance Contracts. Hence, there is no reason to believe that conflicts of interest would result from mixed funding. Moreover, the Funds will not be managed to favor or disfavor any particular insurer or type of Contract.

18. Section 817(h) of the Internal Revenue Code of 1986 ("Code") is the only section in the Code where separate accounts are discussed. Section 817(h) imposes certain diversification standards on the underlying assets of variable annuity contracts and variable life contracts held in the portfolios of management investment companies. Treasury Regulation 1.817–5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits, among other things, "qualified pension or retirement plans" and separate accounts to share the same underlying management investment company. Therefore, neither the Code, the Treasury Regulations nor Revenue Rulings thereunder present any inherent conflicts of interest if Qualified Plans, variable annuity separate accounts and variable life separate accounts all invest in the same management investment company.

19. Applicants submit that while there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Qualified Plans, the tax consequences do not raise any conflicts of interest. When distributions are to be made, and the separate account or the Qualified Plan cannot net purchase payments to make the distributions, the separate account or the Plan will redeem shares of the Trust at their net asset value. The Qualified

Plan will then make distributions in accordance with the terms of the Plan and the life insurance company will make distributions in accordance with the terms of the variable contract.

20. Applicants state that the ability of Funds to sell their respective shares directly to Qualified Plans does not create a "senior security," as such term is defined under Section 18(g) of the 1940 Act, with respect to any Contract owner as opposed to a participant under a Qualified Plan. As noted above, regardless of the rights and benefits of participants under the Qualified Plans, or Contract holders under Contracts, the Qualified Plans and the separate accounts have rights only with respect to their respective shares of the Trust. They can only redeem such shares at their net asset value. No shareholder of any of the Funds has any preference over any other shareholder with respect to distribution of assets or payment of dividends.

21. Applicants submit that there are no conflicts between the Contract owners of the separate accounts and the participants under the Qualified Plans with respect to the state insurance commissioners' veto powers over investment objectives. The state insurance commissioners have been given the veto power in recognition of the fact that insurance companies cannot simply redeem their separate accounts out of one fund and invest in another. Time-consuming, complex transactions must be undertaken to accomplish such redemptions and transfers. On the other hand, trustees of Qualified Plans can make the decision quickly and implement the redemption of their shares from a Fund and reinvest in another funding vehicle without the same regulatory impediments or, as is the case with most Plans, even hold cash pending suitable investment. Based on the foregoing, even if there should arise issues where the interests of Contract holders and the interests of Qualified Plans are in conflict, the issues can be almost immediately resolved because the trustees of the Qualified Plans can, on their own, redeem the shares out of the Trust.

Applicants' Conditions

Applicants have consented to the following conditions if the requested order is granted:

1. A majority of the Trustees or Board of Directors (each, a "Board") of each Fund will consist of persons who are not "interested persons" thereof, as defined by Section 2(a)(19) of the 1940 Act and the Rules thereunder and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of the death, disqualification, or bona fide resignation of any trustee or director, then the operation of this condition shall be suspended (a) for a period of 45 days if the vacancy or vacancies may be filled by the Board, (b) for a period of 60 days if a vote of shareholders is required to fill the vacancy or vacancies, or (c) for such longer period as the Commission may prescribe by order upon application.

2. The Boards will monitor their respective Funds for the existence of any material irreconcilable conflict between the interests of the Contract owners of all separate accounts investing in the Funds. An irreconcilable material conflict may arise for a variety of reasons, including: (a) an action by any state insurance regulatory authority; (b) a change in applicable federal and state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling or any similar action by insurance, tax, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Funds are being managed; (e) a difference in voting instructions given by variable annuity Contract owners and variable life insurance Contract owners; or (f) a decision by a Participating Insurance Company to disregard the voting instructions of Contract owners.

3. Participating Insurance Companies and Janus Capital (or any other investment adviser of a Fund) will report any such potential or existing conflicts to the Board of any relevant Fund. Participating Insurance Companies will be responsible for assisting the appropriate Board in carrying out its responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This includes, but is not limited to, an obligation by a Participating Insurance Company to inform the Board whenever it has determined to disregard Contract owner voting instructions. The responsibility to report such information and conflicts and to assist the Boards will be contractual obligations of all insurers investing in Funds under their agreements governing participation in the Funds, and these responsibilities will be carried out with a view only to the interest of Contract owners. If it is determined by a majority of the Board of a Fund, or by a majority of its disinterested trustees or directors, that a material irreconcilable conflict exists, the relevant Participating Insurance Companies will, at their expense and to the extent reasonably practicable (as determined by a majority of the disinterested trustees or directors), take whatever steps are necessary to remedy or eliminate the irreconcilable material conflict, which steps could include: (a) withdrawing the assets allocable to some or all of the separate accounts from the Fund or any series and reinvesting such assets in a different investment medium, which may include another series of a Fund or another Fund, or submitting the question of whether such segregation should be implemented to a vote of all affected Contract owners and, as appropriate, segregating the assets of any appropriate group (i.e., variable annuity Contract owners or variable life insurance Contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected Contract owners the option of making such a change; and (b) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of an insurer's decision to disregard Contract owner voting instructions and that decision represents a minority position or would preclude a majority vote, the insurer may be required, at the election of the fund, to withdraw its separate account's investment in such Fund, and no charge or penalty will be imposed as a result of such withdrawal. The responsibility of taking remedial action in the event of a Board determination of an irreconcilable material conflict and bearing the cost of such remedial action will be a contractual obligation of all Participating Insurance Companies under their agreements governing participating in the Funds and these responsibilities will be carried out with a view only to the interests of Contract owners.

4. For purposes of this condition 4, a majority of the disinterested members of the applicable Board will determine whether or not any proposed action adequately remedies any irreconcilable material conflict, but in no event will the Fund be required to establish a new funding medium for any Contract. No Participating Insurance Company shall be required by this condition 4 to establish a new funding medium for any Contract if an offer to do so has been declined by vote of a majority of Contract owners materially and adversely affected by the irreconcilable material conflict.

5. Any Board's determination of the existence of an irreconcilable material conflict and its implications will be

made known promptly to all Participating Insurance Companies.

6. Participating Insurance Companies will provide pass-through voting privileges to all Contract owners so long as the Commission interprets the 1940 Act to require pass-through voting privileges for Contract owners. Accordingly, the Participating Insurance Companies will vote shares of a Fund held in their separate accounts in a manner consistent with voting instructions received from Contract owners. Participating Insurance Companies will be responsible for assuring that each of their separate accounts calculates voting privileges in a manner consistent with other Participating Insurance Companies. The obligation to calculate voting privileges in a manner consistent with all other separate accounts investing in the Fund will be a contractual obligation of all Participating Insurance Companies under the agreements governing participation in the Fund. Each Participating Insurance Company will vote shares for which it has not received voting instructions as well as shares attributable to it in the same proportion as it votes shares for which it has received instructions.

7. All reports of potential or existing conflicts received by a Board, and all Board action with regard to determining the existence of a conflict, notifying Participating Insurance Companies of a conflict, and determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the appropriate Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

8. Each Fund will notify all Participating Insurance Companies, that separate account prospectus disclosure regarding potential risks of mixed and shared funding may be appropriate. Each Fund will disclose in its prospectus that: (a) Shares of the Fund are offered in connection with mixed and shared funding, (b) mixed and shared funding may present certain conflicts of interest, and (c) the Board of such Fund will monitor for the existence of any material conflicts and determine what action, if any, should be taken.

9. Each Fund will comply with all provisions of the 1940 Act requiring voting by shareholders (which, for these purposes, shall be the persons having a voting interest in shares of the Fund), and, in particular, each such Fund will either provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the 1940 Act not to require such meetings) or comply with Section 16(c) of the Act, (although the Funds are not within the trusts described in Section 16(c) of the Act), as well as Section 16(a), and, if applicable, Section 16(b) of the Act. Further, each Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors and with whatever rules the Commission may promulgate with respect thereto.

10. If and to the extent that Rules 6e–2 and 6e–3(T) are amended (or if Rule 6e–3 under the Act is adopted) to provide exemptive relief from any provisions of the Act of the rules there under with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Funds and the Participating Insurance Companies, as appropriate, shall take such steps as may be necessary to comply with Rules 6e–2 and 6e3–(T), as amended, and rule 6e–3, as adopted, to the extent applicable.

11. No less than annually, the Participating Insurance Companies and/or Janus Capital shall submit to the Boards such reports, materials, or data as such Boards may reasonably request so that the Boards may carry out fully the obligations imposed upon them by the conditions contained in the Application. Such reports, materials and date shall be submitted more frequently if deemed appropriate by the applicable Boards. The obligations of the Participating Insurance Companies to provide these reports, materials and data to the Boards shall be a contractual obligation of all Participating Insurance Companies under the agreements governing their participation in the Funds.

12. If a Qualified Plan shareholder should become an owner of 10% or more of the assets of a Fund, such Qualified Plan shareholder will execute a participation agreement with such Fund. A Qualified Plan shareholder will execute an application containing an acknowledgment of this condition at the time of its initial purchase of shares of the Fund.

Conclusion

For the reasons and upon the facts stated above, Applicants believe that the requested exemptions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–2962 Filed 2–8–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20052; 811–5640]

Templeton Value Fund, Inc.; Application for Deregistration

February 2, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Templeton Value Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on December 9, 1993 and amended on January 14, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 28, 1994, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 700 Central Avenue, St. Petersburg, Florida 33701.

FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 272–2511, or C. David Messman, Branch Chief, (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end diversified management investment company organized as a Maryland

corporation. On August 19, 1988, applicant registered under section 8(a) of the Act and filed a registration statement pursuant to section 8(b) of the Act and the Securities Act of 1933. The registration statement was declared effective and the initial public offering commenced on October 20, 1988. Applicant operated as a closed-end investment company from October 27, 1988 through February 28, 1991.

2. On October 14, 1990, applicant filed a registration statement pursuant to the Securities Act of 1933 to register an indefinite number of shares as an open-end investment company. The registration statement was declared effective on March 1, 1991.

3. On May 27, 1993, applicant's Board of Directors approved an Agreement and Plan of Reorganization (the "Reorganization") between applicant and Templeton Smaller Companies Growth Fund, Inc. (the "Growth Fund"). In accordance with rule 17a–8 of the Act, applicant's directors determined that the sale of applicant's assets to Growth Fund was in the best interest of applicant's shareholders, and that the interests of the existing shareholders would not be diluted as a result.[1]

4. On or about September 8, 1993, proxy materials related to the Reorganization were distributed to applicant's shareholders. At a special meeting held on October 13, 1993, holders of a majority of the outstanding voting shares of applicant approved the Reorganization.

5. On October 22, 1993 (the "Closing Date"), Growth Fund acquired all or substantially all of the assets of applicant in exchange for shares of Growth Fund and the assumption by Growth Fund of all of applicant's known liabilities. The number of shares of Growth Fund issued to applicant was determined on the basis of the relative net asset values of applicant and Growth Fund as of the Closing Date. Each shareholder of applicant received that number of shares of Growth Fund having an aggregate net asset value equal to the aggregate net asset value of such shareholder's shares of applicant as of the Closing Date.

6. On the Closing Date, applicant had 10,759,620 shares outstanding with a net asset value of $10.07 per share and an aggregate net asset value of $108,307,279.

7. The expenses related to the Reorganization totaled approximately $120,300. Such expenses included the cost of printing and mailing proxy statements as well as $65,427 in commissions that were paid to transfer ownership of some small foreign portfolio securities. Applicant, Growth Fund, and Templeton Investment Counsel, Inc., the investment adviser, each paid one-third of the expenses incurred in connection with the Reorganization.

8. At the time of filing of the application, applicant had no assets or liabilities. Applicant has no shareholders and is not a party to any litigation or administrative proceedings. Applicant is not engaged in, and does not propose to engage in, any business activities other than those necessary for the winding up of its affairs.

9. Applicant intends to file a certificate of dissolution in accordance with the laws of the State of Maryland.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–2891 Filed 2–8–94; 8:45 am]

BILLING CODE 8010–01–M

[1] Applicant and the Growth Fund may be deemed to be affiliated persons of each other by reason of having a common investment adviser, common directors, and common officers. Although purchases and sales between affiliated persons generally are prohibited by section 17(a) of the Act, rule 17a–8 provides an exemption for certain purchases and sales among investment companies that are affiliated persons of one another solely by reason of having a common investment adviser, common directors, and/or common officers.

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2697; Amendment #1]

California; Declaration of Disaster Loan Area

The above-numbered Declaration is hereby amended, effective January 19, 1994, to include Orange and Ventura Counties in the State of California as a disaster area as a result of damages caused by an earthquake and aftershocks on January 17, 1994 and continuing.

In addition, applications for economic injury loans from small businesses located in the contiguous California counties of Riverside, San Diego, and Santa Barbara may be filed until the specified date at the previously designated location.

All other information remains the same, i.e., the termination date for filing applications for physical damage is March 18, 1994, and for economic injury the deadline is October 17, 1994.

The economic injury number for California is 815900.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: February 1, 1994.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 94–2939 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2697]

California; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on January 17, 1994, I find that Los Angeles County in the State of California constitutes a disaster area as a result of damages caused by an earthquake and aftershocks on January 17, 1994 and continuing. Applications for loans for physical damage may be filed until the close of business on March 18, 1994, and for loans for economic injury until the close of business on October 17, 1994, at the address listed below: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853–4795

or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous counties of Kern, Orange, San Bernardino, and Ventura in the State of California may be filed until the specified date at the above location.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	7.250
Homeowners without credit available elsewhere	3.625
Businesses with credit available elsewhere	7.700
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 269702. For economic injury the number is 815900.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: January 19, 1994.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 94–2940 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

U.S. SMALL BUSINESS ADMINISTRATION

Notification of Extension of Filing Deadline

This is to give notice that the deadline for filing applications for physical disaster loans as a result of the Midwest floods has been extended to February 15, 1994 for three of the nine states that had counties Presidentially declared as disaster areas. Those states and their respective declaration numbers are:

Illinois—2662
Iowa—2661
Missouri—2663

All other information remains the same, i.e., the termination date for filing applications for economic injury loans will remain as previously published for each state.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: January 19, 1994.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 94–2938 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

SMALL BUSINESS ADMINISTRATION

Hartford District Advisory Council; Public Meeting

The U.S. Small Business Administration Hartford District Advisory Council will hold a public meeting at 8:30 a.m. on Wednesday, March 16, 1994, at 2 Science Park, New Haven, Connecticut, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Jo-Ann Van Vechten, District Director, U.S. Small Business Administration, 330 Main Street, Hartford, Connecticut 06106, (203) 240–4670.

Dated: February 2, 1994.

Dorothy A. Overal,

Acting Assistant Administrator, Office of Advisory Councils.

[FR Doc. 94–2936 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

Honolulu District Advisory Council; Public Meeting

The U.S. Small Business Administration Honolulu District Advisory Council will hold a public meeting at 9:30 a.m. on Thursday, March 3, 1994, at the Prince Kuhio Federal Building, 300 Ala Moana Boulevard, Conference Room 4113A, Honolulu, Hawaii, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Andrew K. Poepoe, District Director, U.S. Small Business Administration, 300 Ala Moana Boulevard, room 2314, Honolulu, Hawaii 96850, (808) 541–2965.

Dated: February 2, 1994.

Dorothy A. Overal,

Acting Assistant Administrator, Office of Advisory Council.

[FR Doc. 94–2937 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

Boston District Advisory Council; Public Meeting

The U.S. Small Business Administration Boston District Advisory Council will hold a public meeting at 9:30 a.m. on Friday, February 25, 1994, at the Federal Reserve Bank of Boston, 600 Atlantic Avenue, 32nd floor, Boston, Massachusetts, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Joseph D. Pellegrino, District Director, U.S. Small Business Administration, 10 Causeway Street, room 265, Boston, Massachusetts 02222–1093, (617) 565–5560.

Dated: January 31, 1994.

Dorothy A. Overal,

Acting Assistant Administrator, Office of Advisory Councils.

[FR Doc. 94–2935 Filed 2–8–94; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Application of Grand Airways, Inc., for Issuance of Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 94–12) Docket 49044.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order (1) finding Grand Airways, Inc., fit, willing, and able and (2) awarding it a certificate of public convenience and necessity to engage in interstate and overseas scheduled air transportation of persons, property and mail.

DATES: Persons wishing to file objections should do so no later than February 14, 1994.

RESPONSES: Objections and answers to objections should be filed in Docket 49044 and addressed to the Documentary Services Division (C–55, room 4107), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590 and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Mr. James A. Lawyer, Air Carrier Fitness Division, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–064.

Dated: February 3, 1994.

Patrick V. Murphy,

Acting Assistant Secretary for Policy and International Affairs.

[FR Doc. 94–2987 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–62–P

Fitness Determination of Virgin Islands Seaplane Shuttle

AGENCY: Department of Transportation.

ACTION: Notice of Commuter Air Carrier Fitness Determination—Order 94–2–13, Order to Show Cause.

SUMMARY: The Department of Transportation is proposing to find Caribbean Air Transport, Inc. d/b/a Virgin Islands Seaplane Shuttle fit, willing, and able to provide commuter air service under section 419(e) of the Federal Aviation Act.

RESPONSES: All interested persons wishing to respond to the Department of Transportation's tentative fitness determination should file their responses with the Air Carrier Fitness Division, P–56, Department of Transportation, 400 Seventh Street, SW., room 6401, Washington, DC 20590, and serve them on all persons listed in Attachment A to the order. Responses shall be filed no later than February 18, 1994.

FOR FURTHER INFORMATION CONTACT: Carol Woods, Air Carrier Fitness Division (P–56, room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2340.

Dated: February 3, 1994.

Patrick V. Murphy,

Acting Assistant Secretary for Policy and International Affairs.

[FR Doc. 94–2986 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–62–P

Federal Aviation Administration

Centers of Excellence in Airport Pavement Research; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of information meeting for FAA Centers of Excellence (COE) in airport pavement research.

SUMMARY: Notice is hereby given of an information meeting regarding aviation research grant proposals for an FAA Center of Excellence in Airport Pavement Research.

DATES: The meeting will be held March 16, 1994, from 10 am to 4 pm.

ADDRESSES: The meeting will be held in the Auditorium of the Federal Aviation Administration Technical Center, First floor Technical Building, Atlantic City International Airport, Atlantic City, New Jersey, 08405.

FOR FURTHER INFORMATION CONTACT: The Office of Research and Technology Applications, ACL, Building 270, Atlantic City International Airport, Atlantic City, New Jersey, 08405, telephone 609–485–5043.

NOTICE: The FAA will hold an information meeting on March 16, 1994, to explain further the FAA research needs, procedures, and criteria for the selection of the Center of Excellence in Pavement Research. Suggestions from attendees will be addressed at this meeting. Interested parties are encouraged, but not required, to attend the informational meeting.

SUPPLEMENTARY INFORMATION: The FAA intends to award a grant to establish a COE in airport pavement research at a qualified college or university. The Center will conduct basic research in four major areas: modeling of airport pavement structures, constitutive behavior of pavement materials, material characterization, and new technologies in pavement evaluation.

The FAA is responsible for developing standards for airport pavement design, evaluation, and maintenance. Together with the airport operators and industry, the FAA spends nearly $2 billion annually for airport construction and maintenance. Plans for the introduction of new, larger, and heavier aircraft weighing in excess of 1.0 million pounds has necessitated re-examination of the current pavement design methodologies. The COE for pavement research will assist the FAA in the pursuit of developing advanced design methodologies which are validated through full scale testing.

The FAA grant award will provide funding over a long-term period to establish and operate the COE in support of pavement technology. The grant recipient is required to match FAA funds with non-Federal funding over the term of the grant.

The COE will be selected on the basis of the following criteria:

—The extent to which the needs of the State in which the applicant is located are representative of the needs of the region for improved air transportation services and facilities.
—The demonstrated research and extension resources available to the applicant for carrying out the intent of the legislation.
—The capability of the applicant to provide leadership in making national and regional contributions to the solution of both long-range and immediate air transportation problems.
—The extent to which the applicant has an established air transportation program.
—The demonstrated ability of the applicant to disseminate results of air transportation research and educational programs through a statewide or regionwide continuing education program.
—The projects that the applicant proposes to carry out under the grant.

Those persons wishing to attend this informational meeting must register by no later than March 2, 1994. To register for the meeting or to obtain more information about the meeting, contact Ms. Patricia Watts, Office of Research and Technology Applications at the FAA Technical Center, Building 270, Atlantic City International Airport, Atlantic City, New Jersey, 08405, telephone 609–485–5043, or facsimile 609–485–6509.

Issued in Atlantic County, New Jersey on January 24, 1994.

Harvey B. Safeer,

Director, FAA Technical Center.

[FR Doc. 94–2930 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–13–M

Federal Highway Administration

General Material Requirements; Buy America Requirements

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of nationwide waiver of Buy America for ferryboat equipment and machinery.

SUMMARY: The FHWA is hereby granting a nationwide waiver of the Buy America requirements for certain steel items used in the construction of ferryboats. This action permits the use of specifically identified steel equipment and machinery manufactured outside of the United States in Federal-aid highway construction projects for ferryboats.

EFFECTIVE DATE: February 9, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. David R. Geiger, Office of Engineering (202) 366–0355 or Mr. Wilbert Baccus, Office of the Chief Counsel (202) 366–0780, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal Federal holidays.

SUPPLEMENTARY INFORMATION: In accordance with 23 CFR 635.410(c)(6), the FHWA hereby provides notice that it is granting a nationwide waiver of the requirements of 23 CFR 635.410, Buy America requirements, for certain ferryboat equipment and machinery items. Section 635.410 provides, with exceptions, that no Federal-aid highway construction project using steel or iron materials is to be authorized to proceed unless all manufacturing processes including the application of coatings for such materials occur in the United States. Because the construction of ferryboats is increasingly difficult within the requirements of Buy America, a nationwide waiver of these requirements is being granted for certain ferryboat equipment and machinery items. The items included in the waiver are marine diesel engines, electrical switchboards and switchgear, electric motors, pumps, ventilation fans, boilers, electrical controls, and electronic equipment. Items not included in the waiver are products which are readily available in the United States such as steel and stainless steel plate and shapes, sheet steel and stainless steel, steel and stainless steel pipe and tubing, and galvanized steel products. Items not specifically included in the waiver remain subject to the Buy America requirements.

The basis for the nationwide waiver is that certain equipment and machinery are not manufactured in the United States, using exclusively United States steel and iron, in sufficient and reasonably available quantities to avoid an enormous administrative burden on the State, contractor, and suppliers. Therefore, imposing Buy America requirements in this limited instance is not in the public interest.

On June 16, 1993 the FHWA published a notice (58 FR 33295) and requested comments on the proposed nationwide waiver and the availability of a domestic supply of the items included in the waiver. Two comments were received to FHWA Docket No. 93–22. Both commentors were supportive of the waiver. They both requested that the waiver be expanded to include more items. Their comments were basically the same; the two sought to include items such as bearings, fasteners, valves,

and outfitting in the waiver. The FHWA does not agree that these items should be specifically included in the waiver. Bearings, fasteners, and valves are available in sufficient quantity and satisfactory quality from domestic manufacturers. Bearings, fasteners, and valves furnished as individual items are therefore not waived. However, bearings, fasteners, and valves included as a component of waived equipment and machinery are considered an integral part of the waived equipment and machinery and are included in the waiver. Outfitting is not included in the waiver. The FHWA believes that including outfitting in the waiver would allow the waiver to be applied to items which are domestically available in sufficient quantity and satisfactory quality.

The FHWA's Buy America requirements contained in 23 CFR 635.410 are based on section 165 of the Surface Transportation Assistance Act of 1982 (Pub. L. 97–424, Section 165, 96 Stat. 2097, 2136), as amended by Public Law 98–229, Section 10, 98 Stat. 55, 57, and Public Law 102–240, Sections 1041, 1048, 105 Stat. 1914, 1993, 1999.

Authority: 23 U.S.C. 315; 49 CFR 1.48; 23 CFR 635.410

Issued on: January 28, 1994.

Rodney E. Slater,

Federal Highway Administrator.

[FR Doc. 94–2906 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–22–P

Sunshine Act Meetings

Federal Register
Vol. 59, No. 27
Wednesday, February 9, 1994

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).

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. § 552b), notice is hereby given of the following meeting of the Board:

TIME AND DATE: 2:00 p.m., February 24, 1994.

PLACE: Public Hearing Room, Suite 700, 625 Indiana Avenue, N.W., Washington, DC 20004.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Board's continuing review of the Department of Energy's development of policies, directives, and guidance that bear upon the protection of the workforce from the radiological and chemical hazards at Department of Energy defense nuclear facilities.

The Department of Energy will take appropriate measures to safeguard any classified or controlled nuclear information it presents at this meeting.

CONTACT PERSONS FOR MORE INFORMATION: Robert M. Andersen, General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW, Suite 700, Washington, DC 20004, (202) 208–6387. This is not a toll free number.

SUPPLEMENTARY INFORMATION: The Board will discuss and deliberate upon DOE's implementation of the new safety directive (DOE Order 5480.23, "Safety Analysis Reports") that requires DOE to preserve and strengthen the protection of public health and safety. The Board will focus on the supplementary guidance DOE has been developing on the treatment of worker safety in nuclear facility safety analysis reports. The meeting will include presentations by DOE and possibly the Board's Technical Staff relating to protecting workers from hazards of the Department of Energy's defense nuclear facilities.

A transcript of the meeting will be made available by the Board for inspection by the public at the Defense Nuclear Facilities Safety boards's Washington office.

The Board reserves its right to further schedule and otherwise regulate the course of the meeting, to recess, reconvene, postpone, or adjourn the meeting, and otherwise exercise its powers as provided by law.

Dated: February 7, 1994.

Robert M. Andersen,

General Counsel.

[FR Doc. 94–3177 Filed 2–7–94; 2:41 pm]

BILLING CODE 6820–KD–M

federal register

Wednesday
February 9, 1994

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 356

Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N-033A]

RIN 0905-AA06

Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) oral antiseptic drug products (drug products used to help decrease the chance of infection in wounds in the mouth) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by August 8, 1994. Because new testing procedures for OTC oral antiseptic drug products are included in this tentative final monograph, the agency is allowing a period of 180 days for comments and objections instead of the normal 60 days. New data by February 9, 1995. Comments on the new data by April 10, 1995. Written comments on the agency's economic impact determination by August 8, 1994.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1982 (47 FR 22760), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC oral health care drug products, together with the recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by August 23, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by September 22, 1982. In the **Federal Register** of July 30, 1982 (47 FR 32953), in response to a request for an extension of time, the comment period and reply comment period for OTC oral health care drug products were extended to November 22, 1982 and December 22, 1982, respectively.

In the **Federal Register** of December 28, 1982 (47 FR 57739), the reply comment period was extended to January 21, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, 11 drug manufacturers, 3 professional organizations, 4 health professionals, and 1 individual consumer submitted comments. Copies of the comments received are on public display in the Dockets Management Branch (address above).

FDA is issuing the tentative final monograph for OTC oral health care drug products in several segments. This document is the third segment to be published, and it contains the agency's responses to comments on OTC oral antiseptic drug products and to comments on the drug or cosmetic status of certain oral antiseptic ingredients and claims. The first segment of the tentative final monograph covering OTC oral health care anesthetic/analgesic, astringent, debriding agent/oral wound cleanser, and demulcent drug products was published in the **Federal Register** of January 27, 1988 (53 FR 2436). The second segment, an amendment to the tentative final monograph to include OTC relief of oral discomfort drug products, was published in the **Federal Register** of September 24, 1991 (56 FR 48302). Another part of the OTC oral health care drug products rulemaking involves antiplaque and antiplaque-related products. The agency published a call-for-data for OTC antiplaque ingredients in the **Federal Register** of September 19, 1990 (55 FR 38560). The data received in response to that call-for-data are currently being evaluated by the Dental Products Panel. The Panel's recommendations to the agency regarding the safety and effectiveness of antiplaque and antiplaque-related drug products will be published in an advance notice of proposed rulemaking in a future issue of the **Federal Register**.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on May 25, 1982 (47 FR 22760), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated as a "tentative final monograph." In this tentative final monograph (proposed rule) to amend part 356 (21 CFR part 356) (proposed in the **Federal Register** of January 27, 1988, 53 FR 2436), FDA states for the first time its position on the establishment of a monograph for OTC oral antiseptic drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC oral health care drug products and will include oral antiseptic drug products.

This proposal constitutes FDA's tentative adoption of the Oral Cavity Panel's conclusions and recommendations on OTC oral antiseptic drug products, as modified on the basis of the comments received and the agency's independent evaluation of that report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC drug procedural regulations (21 CFR 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required)

at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II or III, the term "nonmonograph conditions" is used. This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC oral health care drug products (47 FR 22760), the agency suggested that the conditions included in the monograph (Category I) be effective 6 months after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 6 months after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to these products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

In the event that new data submitted to the agency during the allotted 12-month comment and new data period are not sufficient to establish "monograph conditions" for OTC oral antiseptic drug products, the final rule will declare these products to be new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), for which new drug applications approved under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 are required for marketing. That rule would also declare that in the absence of an approved new drug application, these products would be misbranded under section 502 of the act (21 U.S.C. 352). The rule will then be incorporated into 21 CFR part 310, subpart E—Requirements for Specific New Drugs or Devices, instead of into an OTC drug monograph in part 356.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Registers** of January 30, 1973 (38 FR 2781) (dental drug products) and July 20, 1973 (38 FR 19444) (oral health care drug products) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Oral Antiseptic Ingredients

1. Several comments objected to the recommendation of the majority of the Oral Cavity Panel that only one Category III indication is appropriate for oral antiseptics, i.e., for the treatment of sore mouth and sore throat. One comment contended that antiseptic mouthwashes are not intended to be used primarily in the treatment of sore mouth and sore throat. Two comments maintained that the Oral Cavity Panel's recommendations that antiseptic mouthwashes be used solely for this indication is inconsistent with the commonly accepted purpose of these products. Another comment stated that the use of oral antiseptics solely for the treatment of sore mouth or sore throat, as the Panel recommended, would result in a disservice to consumers by depriving them of safe, familiar products upon which they depend. A number of comments discussed the use of oral antiseptic ingredients to reduce dental plaque, gingivitis, or both.

The agency notes that the Oral Cavity Panel used the term "antimicrobial agent" to describe an ingredient that kills microorganisms or prevents or inhibits their growth and reproduction. In this tentative final monograph, in order to be consistent with terminology proposed in the tentative final monograph for OTC first aid antiseptic drug products in the **Federal Register** of July 22, 1991 (56 FR 33644), the agency is proposing to replace the Panel's term "antimicrobial" with the term "antiseptic."

The Oral Cavity Panel only reviewed antiseptic ingredients for sore mouth and sore throat claims and did not specifically evaluate the effectiveness of oral antiseptics to inhibit plaque formation. Although data on plaque reduction as a measure of the effectiveness of OTC oral antiseptics were presented to that Panel, it did not accept such data because it believed that "the rationality of plaque reduction as a criterion of effectiveness of antimicrobial agents for use in the mouth and throat is highly debatable, and evidence of the validity of the method is scant" (47 FR 22760 at 22840 to 22842). The Panel was not charged with reviewing drug products used to treat dental or periodontal diseases, and

it did not address ingredients with antiplaque claims.

Because no advisory review panel reviewed the safety and effectiveness data on particular ingredients, including oral antiseptics, for antiplaque or gingivitis indications, the agency announced a call-for-data for ingredients contained in products bearing antiplaque and antiplaque-related claims in the **Federal Register** of September 19, 1990 (55 FR 38560). A substantial amount of information has been submitted to the agency pursuant to that call-for-data. The safety and effectiveness data submitted to the agency for various antiplaque and antiplaque-related ingredients are currently being evaluated by the Dental Products Panel. That Panel will advise the Commissioner of Food and Drugs on the promulgation of a monograph establishing conditions under which oral antiseptic drugs for antiplaque and antiplaque-related use are generally recognized as safe and effective and not misbranded.

In the call-for-data, the agency stated that, in order to be eligible for review under the OTC drug review procedures, an ingredient must have been marketed in a product with the relevant indication to a material extent and for a material time (21 U.S.C. 321(p)(2)). The agency specifically requested information demonstrating such marketing. The marketing data submitted to the agency by various manufacturers includes data on ingredients marketed in the United States, as well as data on ingredients that have only been marketed in other countries. Agency policy currently requires ingredients to have been marketed in the United States as of a certain date (December 4, 1975) to be eligible for consideration in the OTC drug review. Because of the passage of time, some antiplaque ingredients have entered the marketplace since 1975 and have been marketed for a number of years. The agency is reevaluating its policy for eligibility in the OTC drug review in relation to the statutory language "used to a material extent and for a material time" within the meaning of 21 U.S.C. 321(p)(2). The agency is also reevaluating its longstanding policy that foreign marketing alone is not an adequate basis for an ingredient to be considered in the OTC drug review. The agency's conclusions on these matters will affect many other therapeutic categories of drugs in addition to antiplaque products. For example, the agency is currently reviewing petitions to include sunscreens and phytomedicines marketed only in Europe in the OTC drug review. The ultimate review status of some of the antiplaque ingredient(s) is dependent on the resolution of this broader policy, which will be discussed in a future issue of the **Federal Register**.

The agency agrees with the comments that more than one indication may be appropriate for oral antiseptics. Although the Oral Cavity Panel's recommended indication for temporary relief of sore throat and sore mouth remains in Category III in this tentative final monograph, the agency is proposing a Category I indication for oral antiseptics used to help in the prevention of infection in minor sore mouth conditions. The agency is also requesting additional data to support the Panel's recommended Category III indication. (For a further discussion regarding the indications for OTC oral antiseptic drug products, see section I.K., comment 22.)

2. Two comments maintained that the safety of oral antiseptics is well established. One of the comments noted that the Oral Cavity Panel had initially placed oral antiseptic active ingredients in Category I for safety, but after questions were raised about the carcinogenic, teratogenic, and mutagenic potential of these ingredients, the Panel placed them in Category III. Maintaining that the chemical nature and the extensive scientific history of oral antiseptics do not lead to the conclusion that these materials are carcinogenic, teratogenic, or mutagenic, the comment noted that the review of quaternary ammonia compounds written for the Panel by one of its members concludes that quaternary ammonia compounds are safe for use in the oral cavity. The comment also quoted the following from the tentative final monograph for OTC topical antimicrobial drug products published in the **Federal Register** of January 6, 1978 (43 FR 1210 at 1238 and 1239):

> The Commissioner disagrees with the Panel that carcinogenicity, mutagenicity, or teratogenicity studies must be completed. The Commissioner concludes that, in the absence of any data suggesting that * * * has any carcinogenic, mutagenic, or teratogenic potential, testing for these properties should not be required.

The comment contended that "the parallel with oral antiseptics is striking and conclusive."

Both comments disagreed with the Panel that long-term use of oral antiseptics could cause harmful shifts of the oral flora, arguing that no such effects have been reported for this class of products and the available evidence suggests that their occurrence is unlikely. As an example, one comment stated that fungal overgrowth leading to thrush (candidiasis or moniliasis) that is commonly associated with the administration of broad spectrum antibiotics is one type of floral shift that could be troublesome. However, the comment asserted that there is no basis for supposing that frequent or even abusive use of OTC antiseptic mouthwashes could lead to thrush because part of the testing procedure for active antiseptic ingredients has been an in vitro test showing effectiveness against the fungus *Candida albicans*, which is the organism principally responsible for thrush.

Regarding the Oral Cavity Panel's suggestion that antiseptic mouthwashes could selectively eliminate "beneficial" organisms from the mouth, opening the way to the adverse effects of pathogenic flora, the comment asserted that in "all the literature of the microbial etiology of oral disease there are no reports stating or implying such an adverse shift of oral flora." In support of this statement, the comment cited reviews by Socransky (Ref. 1) and Loesche (Ref. 2). The comment also cited a report by Volpe et al. (Ref. 3) that no harmful floral shift resulted when mouthwashes containing cetylpyridinium chloride, benzethonium chloride, or hexachlorophene were used.

The comment stated that members of the Nonprescription Drug Manufacturers Association (NDMA) Task Group (formerly known as The Proprietary Association Task Group) estimate that, over a period of 10 years, its companies have conducted studies of antiseptic mouthwashes involving over 5,000 subjects for intervals ranging from 1 week to 1 year. Professional supervision and examination have demonstrated no instances of adverse effects resulting from floral shifts. The comment asserted that this is conclusive evidence of the safety of oral antiseptics.

The comment noted that another example of an occasional and undesirable effect of the prolonged use of antibiotics is lingua nigra or black hairy tongue. Maintaining that this condition is associated with *Candida* and with members of the related genera, *Actinomyces*, *Nocardia*, and *Streptomyces*, the comment asserted that because in vitro testing of oral antiseptics by the NDMA Task Group included proof of effectiveness against *Actinomyces* as well as *Candida*, there is no reason to believe that black hairy tongue would result from any use of oral antiseptics.

The Oral Cavity Panel evaluated the adverse effects of antiseptic ingredients contained in oral health care drug products from the following two

standpoints: (1) Short-term use to treat sore mouth and sore throat and (2) long-term use for cleansing, elimination of mouth odors, and other purposes where no symptoms of a disease exist (47 FR 22760 at 22848). The Panel did not consider OTC oral health care drug products appropriate for prophylactic use to prevent the development of symptoms or disease states of the mouth and throat (47 FR 22778). It concluded that antiseptic ingredients should be used for oral health care only when specific symptoms (e.g., sore throat or sore mouth) are present to justify the need for a specific product whose effectiveness has been established (47 FR 22834).

Although the Oral Cavity Panel placed no oral antiseptics in Category I, it placed 25 antiseptic ingredients in Category III for effectiveness. Additionally, the Panel determined that 16 of those 25 ingredients are safe for short-term use in the oral cavity. It did not determine that any antiseptic ingredients are safe (i.e., Category I) for long-term use in the oral cavity. Ingredients considered by the Panel to be safe for short-term use as OTC antiseptics in the oral cavity (i.e., Category III for effectiveness and Category I for safety) include phenol, carbamide peroxide in anhydrous glycerin, ethyl alcohol, and hydrogen peroxide. Ingredients placed in Category III for safety and effectiveness by the Panel include cetylpyridinium chloride, domiphen bromide, and povidone-iodine. The Panel also recommended labeling for oral antiseptics in OTC oral health care drug products that includes a warning restricting use to not more than 2 days (47 FR 22850).

The Panel did not clearly distinguish between the use of oral antiseptic ingredients in mouthwashes (long-term) and oral first aid products (short-term). The agency believes that many of these ingredients were placed in Category III for safety by the Panel because the ingredients are used in mouthwashes that are recommended by manufacturers for long-term use on a daily basis. (For a discussion of the time limits for use of oral antiseptics, see section I.K., comment 25.) The agency believes that the Panel's concerns are not necessarily relevant to the short-term use of these ingredients (i.e., up to 7 days). For example, the Panel stated that "extensive clinical observations also indicate that PVP-I [povidone-iodine] is generally nonirritating and nonsensitizing when applied to the skin and mucous membranes" (47 FR 22760 at 22884) and that dequalinium chloride has a low degree of toxicity similar to other quaternary ammonia compounds (quats) (47 FR 22760 at 22867). Nevertheless, the Panel placed povidone-iodine and dequalinium chloride in Category III for safety. The Panel recognized the safety of the commercially available concentrations of domiphen bromide, but stated that because controlled studies had not been done on the effects of domiphen bromide when used on a long-term basis, its safety could not be assumed (47 FR 22868 and 22869).

Accordingly, the agency concludes that the assessment of short-term safety of oral antiseptics should be determined on an individual basis based upon customary use (see section I.E., comment 8; section I.G., comment 12; and section I.I., comment 15). The agency invites comment on the safety of specific ingredients for use on a short-term basis.

When OTC oral antiseptics are indicated for short-term use and there is an absence of data suggesting that the ingredients evaluated by the Oral Cavity Panel have any carcinogenic, mutagenic, or teratogenic activities, the agency agrees with the Panel that the sponsor of a product should not be expected to conduct studies to obtain data on their tumorigenicity, mutagenicity, or teratogenicity. Such studies are often conducted by the National Cancer Institute and other agencies when necessary. The agency notes that benzethonium chloride is currently being evaluated for carcinogenic potential in the National Toxicology Program (NTP). (See section I.C., comment 5.)

The safety of long-term daily usage of OTC oral antiseptic ingredients in the oral cavity will be evaluated by the Dental Products Panel as part of its safety and effectiveness review of OTC antiplaque ingredients and will be discussed in a subsequent segment of the rulemaking for OTC oral health care drug products, to be published in a future issue of the **Federal Register**. (See section I.A., comment 1.)

References

(1) Socransky, S. S., "Microbiology of Periodontal Disease—Present Status and Future Considerations," *Journal of Periodontology*, 48:497–504, 1977.

(2) Loesche, W. J., "Chemotherapy of Dental Plaque Infections," *Oral Sciences Review*, 9:65–107, 1976.

(3) Volpe, A. R. et al., "Antimicrobial Control of Bacterial Plaque and Calculus and the Effects of the Agents on Oral Flora," *Journal of Dental Research*, 48:832–841, 1969.

3. Several comments and two reply comments disagreed with the Oral Cavity Panel's recommendation that OTC oral health care drug products containing pharmacologically active concentrations of antimicrobial ingredients should not be used to achieve a cosmetic effect, such as a reduction of mouth odor (47 FR 22760 at 22844). The comments contended that the use of ingredients in cosmetic mouthwash products is outside the scope of the OTC drug review procedure, which is limited to drug actions and drug claims. Arguing that the Panel's recommendation advocates the position that the regulatory classification of a product is dependent solely on the ingredient it contains, the comments maintained that it is a well-established regulatory policy that the intended use of a product determines whether it is regulated as a drug or as a cosmetic and that the intended use is determined by the manufacturer's representations and labeling claims. The comments stated that claims for the reduction or suppression of mouth odor and for oral cavity cleansing or refreshing are cosmetic claims. To support their contentions, many of the comments cited the definitions of "drug" and "cosmetic" in sections 201(g) and 201(i) of the act (21 U.S.C. 321(g) and 321(i)), the legislative history of the act, and prior case law. Some comments also quoted the following statement delivered to the Oral Cavity Panel in 1974 by the then FDA chief counsel:

> Generally, a product label will be the determining factor as to how a product will be classified, i.e., a drug or cosmetic. The overall safety of a product will also be a major factor in such classification. For example: The claim "kills germs that cause odor," would be considered a cosmetic claim; the claim "kills germs that cause disease" would be considered a drug claim * * *. (Ref. 1)

Several comments stated that the agency has a long-standing policy that cosmetics containing antimicrobial ingredients or other pharmacologic agents are not drugs unless drug claims are made for them. Some of the comments pointed out that FDA's policy concerning drug versus cosmetic status has been stated in many documents, including the procedural regulations governing the OTC drug review (37 FR 9464 to 9475) and official trade correspondence, and that the policy was restated in the tentative final monograph for OTC antiperspirant drug products, published in the **Federal Register** of August 20, 1982 (47 FR 36492), and in the report of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (Vaginal Panel), published in the **Federal Register** of October 13, 1983 (48 FR 46694). Many comments pointed out that in both the OTC antiperspirant

drug products rulemaking and the OTC topical antimicrobial drug products rulemaking, the FDA agreed that a product that contains antimicrobial ingredients to reduce microbial flora solely for the purpose of cleansing or reducing odor is a cosmetic and not a drug and that such cosmetic uses are outside the scope of OTC drug monographs. Concluding that the Oral Cavity Panel's recommendations are without legal foundation and are contrary to the provisions of the act and the legal precedents established for more than 40 years, the comments requested that FDA reject the Panel's recommendations and adhere to the traditional drug/cosmetic distinctions.

One comment stated that the Oral Cavity Panel appeared to base its proposal to delete all cosmetic indications for antimicrobial mouthwash products on the finding that topical antimicrobials as a class are unsafe and ineffective. Asserting that action to be contrary to the substantial scientific evidence presented to that Panel and to the Advisory Review Panels on OTC Topical Antimicrobial Drug Products (the Antimicrobial I and II Panels), the comment stated that antimicrobial ingredients, used appropriately, are no less safe than other ingredients commonly used as cosmetics. A reply comment added that there are extensive scientific data demonstrating the effectiveness of an antimicrobial mouthwash in suppressing mouth odor.

Another reply comment agreed with the Panel that cosmetic claims are not acceptable as "indications" for the OTC oral health care drug products rulemaking insofar as cosmetic claims are not drug indications. However, the reply comment stated that this should not preclude truthful and nonmisleading information about the cosmetic usefulness in the product's labeling and mentioned antidandruff shampoos and anticaries toothpastes as two examples of OTC products with both drug and cosmetic claims. The reply comment argued that dual claims should be permitted for an OTC oral health care drug product, e.g., that it refreshes or deodorizes the mouth (a cosmetic claim) and aids in the temporary relief of discomfort due to occasional sore throat or sore mouth (a drug claim), just as such dual claims are permitted for antidandruff shampoos, which are represented to clean hair (a cosmetic claim) and to prevent dandruff (a drug claim), and for anticaries toothpastes, which are represented to clean teeth and to prevent tooth decay.

The comments requested that the agency recognize the following phrases as cosmetic claims for OTC oral health care products and, therefore, consider them as outside the scope of the OTC drug review: "Kills germs that cause bad breath," "mouth refreshment," "clean feeling," "control of mouth odor," "control of bad breath," "an aid to the daily care of the mouth," and "causing the mouth to feel clean." Two comments argued that terms such as "antimicrobial," "antiseptic," "kills germs," "kills germs by millions on contact," "antibacterial," and other synonymous phrases can be properly used to describe cosmetic functions, i.e., cleansing or refreshing and deodorizing, without creating drug connotations. The comments stated that when used in connection with oral hygiene and deodorizing representations, such claims are cosmetic claims because the context in which they appear connotes cosmetic purposes only. These comments concluded that mouthwashes, rinses, and gargles labeled solely with traditional cosmetic claims for cleansing, refreshing, or deodorizing the mouth or breath are subject to regulation only as cosmetics and not as drugs.

The Oral Cavity Panel stated that claims for the suppression of mouth odor in the labeling of OTC antiseptic health care products are drug claims because they are linked to a drug action, i.e., antimicrobial activity (47 FR 22760 at 22844). Concluding that such claims "* * * indicate that a product is used for cosmetic purposes but imply that the product exerts a therapeutic effect" (47 FR 22857), the Panel classified claims for the suppression of mouth odor as well as claims for the cleansing or freshening of the mouth in Category II.

The act provides the statutory definitions that differentiate a drug from a cosmetic. A "drug" is defined as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body * * *," (21 U.S.C. 321(g)(1)(B) and 321(g)(1)(C)). A "cosmetic," on the other hand, is defined as an article intended to be "* * * applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * *" (21 U.S.C. 321(i)(1)). The agency agrees with the comments that the intended use of a product is the primary determining factor as to whether it is a drug, a cosmetic, or both. This intended use may be inferred from the product's labeling, promotional material, advertising, and any other relevant factor. (See, e.g., *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).)

In determining whether a product is a drug or a cosmetic, the intended use may be established from the type and amount of ingredient(s) present, as well as the product's labeling. For example, in some instances, the mere presence of certain therapeutically active ingredients could make a product a drug even in the absence of drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g., fluoride in a dentifrice). However, in other instances, the presence of an ingredient (e.g., an antimicrobial), in and of itself, does not make a product a drug when no drug claim is made.

The agency does not agree with the Panel that claims for the suppression of mouth odor in the labeling of an oral product containing an antiseptic ingredient necessarily makes that product a drug. Oral products that contain antiseptic ingredients are considered "cosmetics," and not "drugs," if only deodorant (or other cosmetic) claims are made for the products. The agency stated in the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648) that the mere presence of an antimicrobial ingredient in a product labeled for deodorant use, with the ingredient identified only in the ingredient list and no reference to its antimicrobial properties stated elsewhere in the labeling, would not cause the product to be considered a drug. Claims such as "mouth refreshment," "clean feeling," "control of mouth odor," "control of bad breath," and "for causing the mouth to feel clean" are considered cosmetic claims in accordance with section 201(i) of the act and are not included in this tentative final monograph.

However, any broader claims that represent or suggest a therapeutic use for the product would subject it to regulation as a drug. For example, the agency considers the phrase "an aid to daily care of the mouth" to be a drug claim because it implies that the product exerts a therapeutic benefit. The agency also considers terms such as "antibacterial," "antimicrobial," "antiseptic," or "kills germs" in the labeling of oral products to imply that the product will have a therapeutic effect. The agency concludes that such statements would constitute a drug claim for the product because consumers would perceive the intended effect to be achieved by a drug action. Likewise, any of the cosmetic statements mentioned above could become part of a drug claim if additional statements are included. For example, cosmetic claims such as

"control of mouth odor" and "for causing the mouth to feel clean" become drug claims when therapeutic terms are added as follows: (1) "antimicrobial for control of mouth odor," or (2) "kills germs to help the mouth feel clean." Furthermore, use of the term "active ingredient(s)" in the labeling of these products would imply that the product possesses a drug-like property and, thus, would cause the product to be considered a drug.

Products marketed only as cosmetics are not subject to this rulemaking, but are subject to the provisions of sections 601 and 602 of the act (21 U.S.C. 361 and 362) relating to adulteration and misbranding of cosmetics. The final OTC drug monograph for these products will cover only the drug use of the active ingredients listed therein. The concentration range, limitations, warnings, and directions established for the ingredients in the monograph may not apply to the use of the same ingredients in products intended solely as cosmetics. However, some of these factors may be considered by the agency in determining the safety of an ingredient for cosmetic uses. Those products intended for both drug and cosmetic use will be required to conform to the requirements of the final monograph. However, such products, in addition to bearing the indications allowed for OTC oral health care drug products, may also be labeled for cosmetic uses, such as deodorancy or cleansing, in conformity with section 602 of the act and the provisions of 21 CFR parts 701 and 740.

In accordance with the revised labeling requirements for OTC drug products, it is the agency's view that cosmetic claims may not appear within the boxed area designated "APPROVED USES." As discussed in the final rule on the agency's "exclusivity policy" (51 FR 16258 at 16264 (paragraph 14)), cosmetic terminology is not reviewed and approved by FDA in the OTC drug monographs and therefore could not be placed in the box. Cosmetic claims may appear elsewhere in the labeling, should manufacturers choose the labeling alternative provided in § 330.1(c)(2)(i) or (c)(2)(iii) for labeling drug/cosmetic products. Although the agency does not specifically prohibit commingled drug and cosmetic labeling in other than the indications section, such claims should be appropriately described so that consumers will more readily be able to differentiate the drug aspects from the cosmetic aspects of such labeling. If commingled drug and cosmetic labeling claims are confusing or misleading, the product's labeling could be misleading within the meaning of the act and misbranded under sections 502(a) and 602(a) of the act (21 U.S.C. 352(a) and 362(a)).

Reference

(1) Summary Minutes of the Advisory Review Panel on OTC Oral Health Care Drug Products, June 13 and 14, 1974, OTC Vol. 130PA2, Dockets Management Branch.

B. Comment on Alcohol

4. One comment expressed confusion regarding the Oral Cavity Panel's discussion and conclusions on ethyl alcohol (47 FR 22760 at 22871 to 22873). As an example, the comment mentioned that the Panel considered ethyl alcohol to be safe for use in the oral cavity while also stating that "Ethyl alcohol above 20 percent is considered to be an irritant * * *." Pointing out that the Panel also mentioned 70 percent alcohol (47 FR 22873), the comment questioned if it was permissible to use 70 percent alcohol as a solvent. The comment also wondered how the Panel determined that "The quantity [of alcohol] absorbed from the mouth and throat is not significant," (47 FR 22872). The comment concluded that, because it appears that the Panel's report lacks sufficient proof of safety and effectiveness of alcohol in concentrations over 20 percent and because of the high vulnerability of elderly people and children to alcohol, oral health care products containing more than 20 percent alcohol should not be permitted to stay on the market.

The agency reviewed the Oral Cavity Panel's discussion regarding ethyl alcohol (alcohol) as an active ingredient in OTC oral health care drug products and did not find any statement concerning alcohol above 20 percent being considered an irritant. However, in a report on OTC agents for the relief of oral discomfort published concurrently with the Oral Cavity Panel's report in the **Federal Register** of May 25, 1982 (47 FR 22712), the Dental Panel stated that alcohol above 20 percent is an irritant to the dental pulp and, therefore, concentrations above 20 percent should not be used in agents for the relief of toothache in an open tooth cavity (47 FR 22712 at 22726).

The Oral Cavity Panel concluded that alcohol is safe for use as an OTC oral antimicrobial ingredient (47 FR 22760 at 22872). However, the Panel did not clearly define a safe concentration of alcohol. The Panel also stated that commercially available mouthwashes contain alcohol as a solvent in concentrations up to 35 percent, but that concentrations above 35 percent cause burning of the mucous membranes (47 FR 22872). The Panel specifically stated that concentrations of alcohol that kill bacteria, e.g., 70 percent alcohol, cause burning and intense discomfort and are too irritating when applied to inflammations of the mucous membranes of the oral cavity (47 FR 22873). For the above reasons and because alcohol has a marked potential for abuse, the Panel recommended that the quantity of alcohol used as a solvent in pharmaceutical preparations should be limited to 35 percent.

In its report on OTC agents for the relief of oral discomfort (47 FR 22712 at 22737), the Dental Panel accepted the safety of 1.5 percent phenol in 70 percent alcohol for direct application to the gums for up to 7 days. That Panel concluded that up to 70 percent alcohol was an appropriate vehicle for 5 to 20 percent benzocaine with a maximum dosage of 1 milliliter (mL) and that compound benzoin tincture (74 to 80 percent alcohol) and benzoin tincture (75 to 83 percent alcohol) were safe for occasional application to small areas of the oral mucosa regardless of the high alcohol content (47 FR 22746).

The Oral Cavity Panel considered alcohol ineffective as an antimicrobial ingredient at concentrations below 70 percent (47 FR 22872 to 22873). However, that Panel also postulated that the lower concentrations of alcohol used as a solvent for an antimicrobial ingredient could act synergistically with the antimicrobial ingredient to produce an enhanced antimicrobial effect. The Panel concluded that there were insufficient data from controlled studies to establish the effectiveness of alcohol alone as an antiseptic ingredient for the treatment of symptoms such as sore mouth and sore throat, and the Panel placed it in Category III.

In the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use (47 FR 22324), the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) stated that the "irritant action of alcohols is particularly marked on mucosa. The more concentrated the alcohol, the more pronounced are its irritant effects." That Panel recommended caution in the topical use of 60 to 95 percent alcohol and 50 to 91.3 percent isopropyl alcohol on the mucous membranes (47 FR 22324 at 22327) and placed the indication "For application to mucous membranes" in Category II (47 FR 22332). In the tentative final monograph for OTC first aid antiseptic drug products, the agency discussed this indication and stated that the use of alcohol on the mucous membranes of the mouth and throat would be addressed in the rulemaking

for OTC oral health care drug products (56 FR 33644 at 33656).

The agency is aware of a recent study (Ref. 1) indicating that men and women using mouthwashes with 25 percent or higher alcohol content on a regular long-term basis have a slightly increased risk of oral and pharyngeal cancers. Moreover, the risk rose with longer and more frequent mouthwash use. After adjusting for tobacco and alcohol consumption, men had a 40-percent higher risk and women had a 60-percent higher risk of these cancers, compared to those who did not use a mouthwash product. Although these findings do not firmly establish the risk relationship between use of an alcohol-containing mouthwash product and these cancers, they show a need to look further at this relationship. The agency is also aware of three earlier studies demonstrating an apparent association between long-term mouthwash use and an increased risk of oral and pharyngeal cancers (Refs. 2, 3, and 4). Although these studies may have no bearing on the safety of the short-term use of drug products containing alcohol, the agency believes that serious consideration must be given to the results of these studies to determine whether there is a need to limit the amount of alcohol permitted in oral health care drug products.

In 1992, the agency sent letters to two manufacturers' associations requesting data and information on the relationship between alcohol-containing drug products and oral and pharyngeal cancers and the extent of alcohol in OTC oral health care drug products (Refs. 5 and 6). In response, the associations jointly submitted a list of OTC mouthwashes, their alcohol content, and their 1990 sales data (Ref. 7), a reanalysis (Ref. 8) of the study on the association between the use of alcohol-containing mouthwashes and oral/pharyngeal cancer (Ref. 1) discussed previously, and a review (Ref. 8) of related medical and scientific literature pertaining to the etiology of oral cancer. The agency is currently evaluating the data and information submitted.

The agency notes that alcohol is used as a solvent in many OTC oral health care drug products currently on the market. When alcohol is included in oral antiseptic products, the agency believes that the amount of alcohol absorbed from topical application of the product to the mouth and throat to be insignificant. Such products are usually formulated as mouthwashes (oral rinses) or gargles and are retained in the mouth for a short period of time (usually 1 minute or less) and then spit out, or are applied as very small amounts of the product to discreet areas of the oral mucosa. However, the agency believes that alcohol should be included in OTC oral health care drug products only if the alcohol is necessary to dissolve the active ingredient(s).

The agency is currently evaluating the use of alcohol in all OTC drug products. On December 17, 1992 (Ref. 9), the OTC Drugs Advisory Committee discussed the use of alcohol in OTC drug products for oral ingestion and recommended to the agency that such products should not contain more than the minimum amount of alcohol needed as a solvent for the active ingredient, for preservative purposes, or for taste enhancement. The Committee specifically recommended the following:

1. For persons 12 years of age and above, a maximum alcohol concentration up to and including 10 percent volume-to-volume;
2. For children age 6 to under 12, a maximum alcohol concentration up to and including 5 percent volume-to-volume; and
3. For children under 6 years of age, a maximum alcohol concentration up to and including 0.5 percent volume-to-volume.

Based on the Committee's recommendations, the agency published a proposed rule on OTC drug products intended for oral ingestion that contain alcohol in the **Federal Register** of October 21, 1993 (58 FR 54466). That proposal would establish a maximum concentration limit for alcohol as an inactive ingredient in OTC drug products intended for oral ingestion.

In conclusion, the agency is evaluating the use of alcohol in all OTC drug products, is investigating a possible link between the regular use of alcohol-containing mouthwashes and oral and pharyngeal cancers, and is considering limiting the amount of alcohol permitted in such products. Although the agency is not proposing in this tentative final monograph to limit the amount of alcohol used as a solvent in OTC oral health care drug products, it urges all manufacturers to limit the alcohol content of all OTC drug products to the smallest amount compatible with the dissolution of the active ingredient(s).

References

(1) Blot, W. J. et al., "Mouthwash Use and Oral Conditions in the Risk of Oral and Pharyngeal Cancer," *Cancer Research*, 51:3044–3047, 1991.

(2) Wynder, E. L. et al., "Oral Cancer and Mouthwash Use," *Journal of the National Cancer Institute*, 70:255–260, 1983.

(3) Blot, W. J., D. M. Winn, and J. F. Fraumeni, "Oral Cancer and Mouthwash," *Journal of the National Cancer Institute*, 70:251–253, 1983.

(4) Weaver, A., S. M. Fleming, and D. B. Smith, "Mouthwash and Oral Cancer: Carcinogen or Coincidence?" *Journal of Oral Surgery*, 37:250–253, 1979.

(5) Letter from W. E. Gilbertson, FDA, to E. E. Kavanaugh, Cosmetic, Toiletry and Fragrance Association, coded LET 17, Docket No. 81N–0033, Dockets Management Branch.

(6) Letter from W. E. Gilbertson, FDA, to J. D. Cope, Nonprescription Drug Manufacturers Association (NDMA) coded LET 16, Docket No. 81N–0033, Dockets Management Branch.

(7)Comment No. LET25, Docket No. 81N–0033, Dockets Management Branch.

(8) Comment No. 53, Docket No. 81N–0033, Dockets Management Branch.

(9) Summary Minutes of the Nonprescription Drugs Advisory Committee Meeting, December 16 and 17, 1992, OTC Vol. 13CTFM.

C. Comment on Benzethonium Chloride

5. One comment disagreed with the Oral Cavity Panel's classification of benzethonium chloride in Category III for safety. The comment criticized the Panel's statement that "Adequate data on absorption and attainment of toxic blood levels and the metabolic fate of quats [quaternary ammonium compounds] are not available" (47 FR 22760 at 22860). The comment contended that information on the absorption of benzethonium chloride is available and that submissions to the Panel (Refs. 1 and 2) contained extensive data on the absorption and distribution of benzethonium chloride in chickens and in pregnant rats and their fetuses.

The comment also objected to the Oral Cavity Panel's statement that "No data are available on the mutagenic, tumorigenic, or teratogenic effects of benzethonium chloride when used in mouthrinses or gargles for long-term use on a daily basis for oral health care" (47 FR 22860). The comment contended that five studies submitted to the Panel (Refs. 3 through 7) show that tumorigenicity and teratogenicity of benzethonium chloride are not a problem. The comment mentioned several other studies that were available to the Panel and supposedly further substantiate that benzethonium chloride is not a teratogen and does not impede fertility or adversely affect postnatal survival of pups (Refs. 8 through 12).

The comment pointed out that the Oral Cavity Panel made several comments in its discussion of benzalkonium chloride (47 FR 22760 at 22858 to 22860) indicating concerns similar to those raised regarding benzethonium chloride, but the Panel still placed benzalkonium chloride in Category I for safety. The comment

stated that it could not understand how the Panel could conclude that benzalkonium chloride is safe while concluding that benzethonium chloride is not safe, when the supporting data for benzalkonium chloride were not as extensive. Adding that 88 million units of a mouthrinse containing benzethonium chloride have been used without any serious toxicity reported, the comment noted that out of this large population of users, some must have been pregnant. The comment contended that this use experience further supports the rat and rabbit fertility and teratogenicity studies. The comment requested that benzethonium chloride be reclassified in Category I for safety.

Although acknowledging that quats are, in general, nonirritating and nontoxic in their effective dosage ranges, the Oral Cavity Panel was concerned about the effect of long-term, daily use of these compounds. The Panel stated that adequate data are not available on: (1) The absorption and attainment of toxic blood levels and the metabolic fate of the quats and (2) the cumulative effects from continued use on a day-to-day basis over the span of years or a lifetime as would be the case when these ingredients are incorporated in mouthwashes (47 FR 22760 at 22860). The Panel was also concerned about the absence of data on the mutagenic, tumorigenic, or teratogenic effects of quats when used on a long-term daily basis in the oral cavity. The Oral Cavity Panel placed most of the quats it evaluated in Category III for safety. Nevertheless, in spite of these concerns, the Panel recommended that benzalkonium chloride and cetalkonium chloride be considered safe for OTC use in the oral cavity.

Regarding the comment's contention that the Oral Cavity Panel was inconsistent in its evaluation of benzethonium chloride and benzalkonium chloride, the agency cannot determine from the Panel's discussion of the two ingredients (47 FR 22760 at 22858 to 22861) what caused the Panel to recommend that one ingredient was safe and the other not safe. However, the Panel made its safety decisions based upon an assumption that oral antiseptics were used on a long-term daily basis. As discussed above, the agency is proposing in this tentative final monograph that data relating to the long-term safety of oral antiseptics is not relevant to the determination of safety for short-term use in the oral cavity (see section I.A., comment 2). Therefore, the agency agrees with the Panel's safety evaluation of benzalkonium chloride and is proposing that benzalkonium chloride is safe for short-term use as an oral antiseptic.

The agency has reevaluated the data submitted to the Oral Cavity Panel as well as new information regarding the safety of benzethonium chloride and concludes that benzethonium chloride should remain in Category III. The agency agrees with the Panel that the studies originally submitted to the Panel (Refs. 1 through 7) do not support the safety of benzethonium chloride.

Regarding the data on absorption and attainment of adequate blood levels and the metabolic fate of quats, the data referred to by the comment (Refs. 1 and 2) do not answer the Panel's concerns. The most meaningful data presented on absorption were contained in the rat maternal and fetal absorption study (Ref. 2). Low levels of C^{14} were detected in maternal blood and urine following oral dosing of pregnant rats with C^{14} labeled benzethonium chloride. After 15 days of dosing with 1.125 milligrams/kilogram (mg/kg) per day labeled benzethonium chloride, 1.5 nanogram/gram of the labeled compound was detected in maternal blood. The urinary level of labeled benzethonium chloride found in this group was 28 nanograms per milliliter (mL). These data suggest poor absorption, but there is no correlation with toxic blood levels. Furthermore, the metabolic fate of benzethonium is unknown and is not addressed in any of the studies mentioned by the comment.

Two studies demonstrate that subcutaneous injection of benzethonium chloride produces fibrosarcomas at the injection site in rats (Ref. 6), but not in mice (Ref. 4). Another study demonstrates that this ingredient is cytotoxic (Ref. 7). These data indicate that benzethonium chloride is a weak carcinogen according to the classification scheme proposed by Grasso and Golberg (Ref. 13).

In one study, rats were injected with the maximally tolerated dose of 3 mg/kg and three lower doses twice weekly for 1 year (Ref. 6). Two hundred animals were treated; 80 were in the high dose group. The study also included 120 each in negative and vehicle control groups. Observation continued for 6 months after termination of treatment. Cumulative data from all dose groups show a 16-percent incidence of tumors at the injection site in males and a 10-percent incidence in females. No injection site tumors were noted in the vehicle control animals; one injection site tumor was observed in the negative control group. At other tested sites, tumor incidence numbers of the treated animals were not different from the control groups. However, there was a clear dose-related effect at the injection site. As stated above, these data indicate that benzethonium chloride is a weak carcinogen.

The teratology studies (Refs. 9, 10, and 12) indicate that benzethonium chloride has very slight teratogenic potential. Effects on the fetus are largely related to the retardation of growth, which is also evident in the dams. Maternal effects also influence fetal viability, especially evident in rabbits (Ref. 12). Increased ossification variations were significant only in the high dose groups (i.e., 35.6 mg/kg/day) in rats (Ref. 10). Effects at lower doses that were apparent in one study (Ref. 9) might be attributed to variability as evidenced by the difference in the two control groups of one of the other studies (Ref. 10). The reproductive capacity of rats does not appear to be affected, although weight gains are affected in both parents (Ref. 8).

The agency does not believe that sufficient data and information are available at this time to categorize benzethonium chloride as safe for use in the oral cavity and invites further comments and data on this matter. The agency is aware that the NTP has undertaken studies to characterize and evaluate the toxicological potential, including carcinogenicity, of benzethonium chloride in laboratory animals. The results of these studies may aid the agency in its determinations regarding the safety of benzethonium chloride. At this time, benzethonium chloride remains in Category III for safety in this tentative final monograph.

References

(1) Research Report No. 23–19, "A Study to Determine Radioactive Residue Levels in Eggs, Tissues, and Excreta from Laying Hens Which Were Fed C^{14}–Hyamine 1622 Sanitized Water," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(2) "Rat Maternal and Fetal Absorption of C^{14}–Benzethonium Chloride (C^{14}14–BTC)," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(3) Pinnegan, J. K. et al., "Pharmacologic Observations on Two Quaternary Ammonium Germicides," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(4) Kirschstein, R. L., "Toxicology and Carcinogenicity of Preservatives Used in the Preparation of Biological Products," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(5) "Six Month Toxicity Study with BTC and $ZnCl_2$ on Rats," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(6) "Toxicology and Carcinogenesis of Various Chemicals Used in the Preparation of Vaccines," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(7) "Final Report, Contract PH–43–67–677, Project C–173," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(8) "Project 75–1343, Segment I Rat Fertility Study," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(9) "Project 75–1344, Segment II Rat Teratology Study," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(10) "Project 76–1495A, Segment II Rat Teratology Study," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(11) "Project 75–1345, Segment III Rat Peri and Post Natal Study," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(12) "Project 75–1346, Segment II Rabbit Teratology Study," Comment No. C00009, Docket No. 81N–0033, Dockets Management Branch.

(13) Grasso, P., and L. Golberg, "Subcutaneous Sarcoma as an Index of Carcinogenic Potency," *Food and Cosmetic Toxicology*, 4:297–320, 1966.

D. Comments on Boric Acid

6. One comment stated that the Oral Cavity Panel's discussion on the safety and effectiveness of boric acid as an antimicrobial ingredient (47 FR 22760 at 22850) should be considered arbitrary because it is based on a limited search of the literature and a minimum effort to evaluate this literature. The comment contended that the Panel's statements that "absorption of boric acid occurs readily from the mucous membranes of the mouth, throat * * * " and that "it is also absorbed from the surface of the vagina, the lining of the conjunctival sac * * *" (47 FR 22850) are not mentioned in the discussion of this ingredient in the paper by George (Ref. 1) which the Panel cited as the source of this information. The comment added that the only statement this author makes regarding mucous membrane absorption of boric acid is an inference taken from another reference (Ref. 2), which in turn provided no chemical or laboratory evidence to support the previous statements.

The comment also objected to the Oral Cavity Panel's statement "Death has occurred from ingestion of less than 5 grams (g) [of boric acid] in infants and from 5 to 20 g in adults," (47 FR 22760 at 22850), stating that these reported lethal doses are found in review articles and appear repeatedly as a result of frequent cross-referencing from publications used in the medical field. The comment contended that the only absolute statement on a toxic dose of boric acid appeared in a 1906 New York Medical Bulletin which discussed an autopsy report on a 62-year-old man who had ingested 15 g of boric acid on prescription for a bladder infection; however, no conclusion was made that boric acid was the cause of death. The comment added that the published reports on poisonings by boric acid resulted from special circumstances, i.e., in the course of therapeutic treatments, erroneous use of boric acid in place of other substances in hospitals, or similar misuse, and usually only estimated dosages were reported. Although the comment stated that boric acid should not be used indiscriminately, it contended that the Panel made an inadequate study of the literature concerning the safety of boric acid. The comment added that the only carefully controlled clinical study on the ingestion of borax and boric acid by humans was a study by Wiley, published in 1904 (Ref. 3). The comment expressed surprise that this reference was not cited by the Panel and has not been cited by other authors who have conducted a literature review on boric acid. The comment reported that this study, conducted by the "poison squad" who eventually made up the staff of FDA, involved ingestion of borax or boric acid at varying dosages up to 5 g per day (as a single dose) for periods up to 50 days. The comment claimed that no fatalities or chronic irreversible pathological conditions were observed in any of the participants.

The comment also expressed concern about the Oral Cavity Panel's classification of boric acid in Category II for effectiveness (47 FR 22760 at 22850) on what it considered a minimum effort to investigate and evaluate the literature. For example, the comment mentioned that the Panel cited a paper by Novak and Taylor (Ref. 4). In this study, the investigators found that concentrations higher than 2 percent boric acid may inhibit phagocytosis. The comment contended that although the Panel acknowledged this finding, it ignored the absence of this action at lower concentrations. The comment also referred to another paper by these same authors (Ref. 5), which discusses the antibacterial action of boric acid. The comment stated that this article appeared in the same journal immediately following the article by Novak and Taylor but was not cited by the Panel in its list of references on boric acid. The comment concluded that the references cited as evidence to support the Panel's conclusions on effectiveness are limited to one reference, which is general in nature with no primary references or data presented.

The agency has reviewed the article by George (Ref. 1) cited in the Oral Cavity Panel's report and the reference cited therein (Ref. 2) and agrees with the comment that these references do not present adequate evidence to support the Panel's conclusion that boric acid is absorbed from mucous membranes. Although the literature contains many incidences of boric acid toxicity resulting from the absorption of the drug after application to abraded skin or from ingestion, there is a lack of data and information on the degree of absorption of boric acid from mucous membranes (Refs. 6 through 9).

The agency agrees with the comment that the human lethal doses used in the Oral Cavity Panel's report appear in review articles and other biomedical publications as a result of cross-referencing from older literature. However, because most reports of poisoning with boric acid are due to accidental ingestion of the drug, exact doses cannot be determined; thus, varying human lethal doses, such as 15 to 30 g in adults and 3 to 6 g in children, are reported in the literature (Refs. 8, 9, and 10).

The agency notes that the study by Wiley (Ref. 3) was conducted to determine the effects of borax and boric acid upon digestion and overall human health. At the end of this study, Wiley reported that the continuous administration of borax and boric acid created disturbances of appetite, digestion, and health.

As more reports of the toxic effects of boric acid appeared and more effective antiseptics were developed, the Vaginal Panel noted that this ingredient fell into disfavor except for a few minor uses (48 FR 46694 at 46712). This may have been due in part to the findings of Novak and Taylor (Ref. 4) who suggested that normal phagocytosis is inhibited by boric acid in concentrations greater than 2 percent, thus counteracting the drug's antibacterial action.

The agency reviewed the second study by Novak and Taylor (Ref. 5) and notes that this in vitro study was designed to determine the bacteriostatic action of boric acid, in the presence of tears, against three species of bacteria commonly found in minor eye infections. The authors reported that boric acid in concentrations from 0.5 to 2 percent was bacteriostatic against the three species of bacteria tested. However, the agency does not consider this in vitro study to be a valid substitute for a well-controlled clinical study in the intended target population. The agency believes that the Panel did not include this study in the list of references cited for boric acid because it did not consider the study relevant to the efficacy of this ingredient in OTC oral health care drug products. The

agency concludes that this study does not support the effectiveness of boric acid for antiseptic use in OTC oral health care drug products.

The agency points out that the Oral Cavity Panel's discussion concerning the safety and effectiveness of boric acid was not intended to include all available information on the subject, but was intended to be representative of the available data. The Panel members selected the studies to be cited according to their best scientific judgment at that time. In addition, because the comment did not submit new data or information that offer evidence contrary to the Panel's conclusion and other information that exists in the literature (as discussed above), the agency is proposing in this tentative final monograph that boric acid remain in Category II (not safe and not effective) as an antiseptic agent in OTC oral health care drug products.

References

(1) George, A. J., "Toxicity of Boric Acid through Skin and Mucous Membranes," *Food and Cosmetic Toxicology*, 3:99–101, 1965.

(2) Gleason, M. N. et al., "Borate Section III, Therapeutics Index" in "Clinical Toxicology of Commercial Products: Acute Poisoning (Home & Farm)," The Williams and Wilkins Co., Baltimore, p. 122, 1957.

(3) Wiley, H. W., "1. Boric Acid and Borax," in "Influence of Food Preservatives and Artificial Colors on Digestion and Health," U. S. Department of Agriculture, Bureau of Chemistry-Bulletin No. 84, pp. 254–255, 1904.

(4) Novak, M., and W. I. Taylor, "Phagocyticidal and Antibacterial Action of Boric Acid," *Journal of the American Pharmaceutical Association* (Scientific Edition), 40:428–430, 1951.

(5) Novak, M., and W. I. Taylor, "Antibacterial Action of Boric Acid in Lacrima (Tears)," *Journal of the American Pharmaceutical Association* (Scientific Edition), 40:430–432, 1951.

(6) Pfeiffer, C. C. et al., "Boric Acid Ointment: A Study of Possible Intoxication in the Treatment of Burns," *Journal of the American Medical Association*, 128:266–274, 1945.

(7) Goldbloom, R. B., and A. Goldbloom, "Boric Acid Poisoning—Report of Four Cases and a Review of 109 Cases from the World Literature," *The Journal of Pediatrics*, 43:631–643, 1953.

(8) Kingma, H., "The Pharmacology and Toxicology of Boron Compounds," *Canadian Medical Association Journal*, 78:620–622, 1958.

(9) McNally, W. D., and C. A. Rust, "The Distribution of Boric Acid in Human Organs in Six Deaths Due to Boric Acid Poisoning," *Journal of the American Medical Association*, 90:382–383, 1928.

(10) Valdes-Dapena, M. A., and J. B. Arey, "Boric Acid Poisoning: Three Fatal Cases with Pancreatic Inclusions and a Review of the Literature," *Journal of Pediatrics*, 61:531–546, 1962.

7. Referring to the Oral Cavity Panel's statement that "Boric acid is used as a pharmaceutical necessity for buffering as well as for an active ingredient (Ref. 1)" (47 FR 22760 at 22850), one comment stated that the cited reference discusses only the use of boric acid as a pharmaceutical necessity, but not as a buffer or as an active ingredient. The comment contended that the Panel's statement as written gives the connotation that the buffering action of boric acid and its use as an active ingredient are both cited in the reference. The comment recommended that the statement be amended to read "Boric acid is used as a pharmaceutical necessity (Ref. 1) for buffering * * *."

The comment is correct in stating that the cited pages of the National Formulary (Ref. 1) discuss the use of boric acid as a pharmaceutical necessity, but the cited pages do not discuss its use as a buffer or as an active ingredient. The agency notes, however, that boric acid is discussed as a buffering agent on pages 935 to 936 of the same reference (Ref. 2), and that these pages should have been included as part of the citation. The agency also agrees with the comment that the National Formulary does not discuss the use of boric acid as an active ingredient.

References

(1) "National Formulary," 14th ed., American Pharmaceutical Association, Washington, pp. 776–777, 1975.

(2) "National Formulary," 14th ed., American Pharmaceutical Association, Washington, pp. 935–936, 1975.

E. Comments on Cetylpyridinium Chloride

8. Two comments contended that cetylpyridinium chloride at concentrations of up to 0.1 percent is safe for use as an OTC antiseptic agent and should be placed in Category I. The first comment described the results of various safety testing (e.g., acute toxicity, oral mucosal and eye irritation, subchronic, and teratology studies) on cetylpyridinium chloride alone and on cetylpyridinium chloride in combination with domiphen bromide. The comment also submitted a safety report (Ref. 1) prepared from data available through August, 1982. The comment stated that, in all these studies, there have been no remarkable pathologic findings and thus 0.045 percent cetylpyridinium chloride is safe for OTC oral use as a single ingredient and in combination with 0.005 percent domiphen bromide.

The other comment stated that cetylpyridinium chloride is the active ingredient in a commercially available mouthwash that has been used by millions of consumers for over 40 years and that the product continues to be the subject of an approved application based on the established safety of the product. The comment summarized the safety data that had been submitted to the Oral Cavity Panel, including long-term usage studies involving acute and subacute toxicity exposure to cetylpyridinium chloride and related compounds in humans and animals (Ref. 2). The comment contended that these studies failed to reveal evidence of any teratogenic effects and added that in studies involving life time exposure of mice and rats to benzalkonium chloride, a representative quat, no evidence of carcinogenic or mutagenic potential was found. The comment concluded that these experimental data, in conjunction with the extremely low order of toxicity seen in the more than four decades of human use, reinforce and justify the National Cancer Institute's (NCI) apparent lack of concern regarding the carcinogenicity and mutagenicity of cetylpyridinium chloride and other quats.

The comment added that the safety of cetylpyridinium chloride is further substantiated by the infrequent number of adverse drug experience reports, particularly when considered in relation to the extensive usage of products containing this ingredient. For example, marketing studies in 1979 indicated that one mouthwash product was used by approximately 13 million consumers and that 500,000 people had used the product more or less continuously for a 10-year period. The comment stated that, in the 20-year period between 1963 and 1982, there were only 110 drug experience reports, an average of 5.5 reports per year. The comment contended that these reports show that cetylpyridinium chloride is safe because it has not been associated with any deleterious effects of a significant nature when routinely used as an oral hygiene product. The comment also submitted the results of several clinical evaluations of irritation and/or allergic reactions of mucous membrane and skin surface exposure to cetylpyridinium chloride-containing solutions (Ref. 3). The comment concluded that the drug experience reports and clinical evaluations support a Category I classification of cetylpyridinium chloride for safety.

As part of FDA's Drug Efficacy Study Implementation (DESI) program, mouthwash products containing povidone-iodine, cetylpyridinium chloride, and other ingredients were reviewed by the National Academy of Sciences-National Research Council,

Drug Efficacy Study Group (NAS-NRC/DESG) and found ineffective for claims relating to antimicrobial, antiseptic, germicidal, and analgesic uses (35 FR 12423). In a subsequent notice published in the **Federal Register** of December 2, 1971 (36 FR 23000), the agency stated that because of the implementation of the OTC drug review, mouthwash and gargle products reviewed under the DESI program would now be under the purview of the OTC drug review; thus, final agency action on these products would be deferred pending evaluation of the data and information concerning such products under the OTC drug review.

The agency believes that many of the oral antiseptic ingredients reviewed by the Oral Cavity Panel, including cetylpyridinium chloride, were placed in Category III for safety because they were used commercially in mouthwashes that were recommended for long-term use on a daily basis. The agency believes that the Panel's concerns regarding the safety of the long-term OTC use of oral antiseptic ingredients are not necessarily relevant to the short-term OTC use of these ingredients (see section I.A., comment 2).

The Oral Cavity Panel discussed the results of several cetylpyridinium chloride toxicity studies in its report (47 FR 22760 at 22865). According to the Panel, the LD_{50} of cetylpyridinium chloride is 250 kg/mg subcutaneously, 6 mg/kg intraperitoneally, 30 mg/kg intravenously, and 200 mg/kg orally. When 50 mg/kg cetylpyridinium chloride in water was administered daily for 60 days to rats, no toxic effects or alterations in the rate of growth were noted. Doses of 5 to 10 mg/kg administered through the esophagus showed no toxic effects over a 6-day period.

The Panel noted that a 1:3,000 (0.033 percent) solution of cetylpyridinium chloride is irritating to the mucous membranes of the conjunctiva, but not to the skin (47 FR 22865). It also stated that a 1:200 (0.5 percent) alcoholic or aqueous solution of cetylpyridinium chloride does not cause skin irritation. The Panel added that percutaneous absorption of cetylpyridinium chloride is not believed to be significant. However, the agency notes that the presence of the cetyl group on the basic quat molecule increases the lipid solubility of the molecule and, thus, cetylpyridinium chloride has a potential for increased absorption and irritation (47 FR 22865).

The agency has reviewed its adverse reaction files covering 1969 to August 1993 (Ref. 4). During those years, 249 cases of adverse reactions were associated with the use of products containing cetylpyridinium chloride. None of the adverse reaction reports could be attributed solely to cetylpyridinium chloride. Of these cases, 10 had a serious outcome (e.g., death, coma, or hospitalization). Two reports involved children under 4 years of age who died after ingesting unknown amounts of a mouthwash containing cetylpyridinium chloride and 14 percent alcohol. In both cases, alcohol was the most likely cause of death.

Four adverse reaction reports described coma as an outcome. Two involved young children (3 and 4 years old) who lapsed into comas after ingesting unknown amounts of a mouthwash product containing cetylpyridinium chloride and 14 percent alcohol. As is the case with the deaths described above, these comas are more likely due to alcohol ingestion than cetylpyridinium chloride ingestion. One adverse reaction report in which coma is listed as the outcome involved an individual who ingested 44 cetylpyridinium chloride-containing lozenges, became gradually and imperceptively unconscious, and caused a head-on automobile collision. Another report described a middle-aged male with a history of alcoholism who was hospitalized in a coma after possibly ingesting a mouthwash containing cetylpyridinium chloride.

Two anaphylactic-type reactions were reported. One was determined to be an allergic reaction to bisulfites. The other was not clear-cut because the subject had experienced several similar anaphylactic-like attacks, only one of which followed use of a cetylpyridinium chloride-containing product.

Two cases reported the hospitalization of people who had severe allergic-type reactions. One report described a 21-year-old female with swelling in her throat, a sensation of feeling hot and flushed, followed by dyspnea, dysphagia, angioedema of the face (especially the eyelids), hands, and feet, and near faintness following the ingestion of one cetylpyridinium chloride lozenge. Another case report described a young male (8 years old) with a burning sensation, redness, and swelling on areas of the skin (chin and neck) where a cetylpyridinium chloride-containing mouthwash was spilled during gargling.

The most frequently reported less serious events are as follows: 26 cases of stomatitis, 13 reports of pain, 12 reports of taste perversion, 10 cases of nausea, 9 cases of contact dermatitis, 9 cases of pharyngitis, 8 cases of malaise, and 7 cases of allergic responses. Other less frequently reported reactions included rash, tooth caries, dry mouth, and rhinitis.

The agency believes that the information contained in its adverse reaction files regarding cetylpyridinium chloride demonstrates that the ingredient can be safely used in an OTC drug product. None of the adverse reaction reports could be attributed solely to cetylpyridinium chloride. All reports involved products containing many ingredients in addition to cetylpyridinium chloride. In addition, other drugs (e.g., alcohol) were implicated in the most serious cases.

The agency believes that the information contained in its adverse reaction files, 30 years of safe marketing of an OTC mouthwash containing cetylpyridinium chloride (NDA 14-598), and the safety data evaluated by the Oral Cavity Panel are sufficient to conclude that 0.025 to 0.1 percent cetylpyridinium chloride is safe as an OTC oral antiseptic when labeled for short-term use (not to exceed 7 days). However, the agency is concerned that using cetylpyridinium chloride where excessive gum irritation or bleeding exists could increase the absorption and systemic load of the ingredient and possibly lead to some of the toxicological effects discussed by the Oral Cavity Panel (e.g., neuromuscular blocking of nicotinic and muscarinic receptors) (47 FR 22760 at 22865). Therefore, the agency is proposing labeling that would caution consumers not to use a product containing cetylpyridinium chloride if excessive gum irritation or bleeding exists unless directed to do so by a doctor or dentist as follows: "Do not use this product if gums are irritated or bleeding unless directed to do so by a doctor or dentist." This labeling will be included in the final monograph for OTC oral antiseptics if cetylpyridinium chloride becomes Category I in that rulemaking. The agency requests comment regarding this proposed labeling.

Data on the combination of cetylpyridinium chloride and domiphen bromide are discussed in section I.L., comments 30 and 31.

References

(1) Comment No. C00013, Docket No. 81N-0033, Dockets Management Branch.

(2) OTC Vol. 130167.

(3) Attachment C, Comment No. C00015, Docket No. 81N-0033, Dockets Management Branch.

(4) Food and Drug Administration, Center for Drug Evaluation and Research, Adverse Reaction Summary Listing for Cetylpyridinium Chloride for the years 1969

to August 1993, OTC Vol. 13CTFM, Docket No. 81N–0033, Dockets Management Branch.

9. Two comments contended that 0.025 to 0.1 percent cetylpyridinium chloride is an effective antiseptic agent and should be placed in Category I. One comment stated that complete proof of the ability of cetylpyridinium chloride to kill bacteria in vitro had been submitted to the Oral Cavity Panel (Ref. 1) and that this proof had been accepted at the time by the Panel. The comment also discussed several tests (Ref. 2) purporting to demonstrate the effectiveness of 0.045 percent cetylpyridinium chloride in combination with 0.005 percent domiphen bromide and stated that these tests supported the antiseptic effectiveness of cetylpyridinium chloride. The other comment discussed data from seven in vitro studies designed to demonstrate the antiseptic activity of cetylpyridinium chloride (Ref. 3). The comment stated that two of these studies fulfilled the in vitro guidelines established by the Oral Cavity Panel (47 FR 22760 at 22890 to 22893) and that the other five studies demonstrated complementary activity against other test organisms (Ref. 3). The comment also summarized a number of in vivo studies designed to demonstrate the antimicrobial activity of cetylpyridinium chloride. The comment mentioned that all of these in vitro and in vivo studies had been submitted to the Oral Cavity Panel.

That Panel discussed in vitro and in vivo testing protocol guidelines for upgrading oral antiseptic ingredients to Category I (47 FR 22760 at 22890 to 22893). The in vitro studies submitted by the second comment (Ref. 3) do not fulfill the guidelines recommended by the Panel. For example, in one study (Ref. 4), the protocol closely resembled that recommended by the Panel. However, the incubation conditions used to prepare the test cultures were unlike those recommended by the Panel, and some culture conditions were not specified (i.e., whether the cultures were grown aerobically or anaerobically). The test method used in this study was also different from the method recommended by the Panel in that culture tubes that showed no growth after 48 hours incubation were not transferred to 90 mL of sterile inactivating media and further incubated for 1 week. In another study where the protocol was similar to that recommended by the Panel (Ref. 5), a product containing cetylpyridinium chloride was used as the test material, but cetylpyridinium chloride alone was not tested. Therefore, there is no way of knowing whether or not other ingredients in the test product affected its antimicrobial activity. Several other in vitro studies (Refs. 6 through 9) tested the antiseptic effectiveness of cetylpyridinium chloride and cetylpyridinium chloride-containing products against organisms other than those recommended by the Panel. One study (Ref. 10) tested the effectiveness of several mouthwash formulations against pooled human saliva. Critical killing times against the organisms in the saliva were determined, but specific organisms were not identified.

Fifteen of the in vivo studies submitted were based upon plaque reduction. The Panel had considered using plaque reduction as a criterion for antiseptic activity in the oral cavity, but discarded it (47 FR 22760 at 22840). The Panel did not accept plaque reduction as a criterion for determining the effectiveness of oral antiseptics, and the agency agrees. A subsequent segment of the rulemaking for OTC oral health care drug products will cover plaque-related claims and ingredients used for the reduction of plaque. (See section I.A., comment 1 and section I.M., comment 32.)

The agency believes that the other in vivo studies submitted (Ref. 3) are not adequate to demonstrate the effectiveness of cetylpyridinium chloride in reducing the bacterial population of the oral cavity. These studies were not designed to demonstrate the antibacterial activity of the ingredient cetylpyridinium chloride alone. They were designed to demonstrate the antibacterial activity of products such as commercial mouthwashes or lozenges containing cetylpyridinium chloride and other ingredients that could affect the antibacterial activity of the product. The complete formulations of these products were not identified, and the antiseptic activity of the ingredient cetylpyridinium chloride was not compared to the activity of a placebo containing all of the ingredients in the commercial product except for the cetylpyridinium chloride. Therefore, any antiseptic activity demonstrated in those studies cannot be solely attributed to the presence of cetylpyridinium chloride. In order to demonstrate antiseptic activity of cetylpyridinium chloride, studies must be designed with one arm consisting of the ingredient cetylpyridinium chloride alone to demonstrate that cetylpyridinium chloride decreases the number of microorganisms in the oral cavity. In addition, the agency is not aware of any data from clinical studies demonstrating a therapeutic benefit from the OTC use of cetylpyridinium chloride as an antiseptic in the oral cavity. Data on the combination of cetylpyridinium chloride and domiphen bromide are discussed in section I.L., comments 30 and 31.

The agency concludes that additional data are needed to establish the effectiveness of cetylpyridinium chloride as an oral antiseptic to help prevent infection in the oral cavity. The agency believes that the Panel's proposed in vitro and in vivo testing guidelines and its discussion of clinical studies represent a good starting point for the design of studies to upgrade a Category II or Category III oral antiseptic ingredient to Category I. (See section I.M., comment 33 for a further discussion of testing guidelines.) However, the agency notes that specific testing guidelines for upgrading ingredients to monograph status are not included in the tentative final monograph. (See part II. paragraph A.2.—*Testing of Category II and Category III conditions.*) All such testing should be designed using the most current technology available. The agency will meet with industry representatives or other interested parties at their request to discuss testing protocols. Any party interested in conducting studies should request a meeting at its earliest convenience.

References

(1) OTC Vols. 130007 through 130011, 130089, 130090, and 130167 through 130171.

(2) Comment No. C00013, Docket No. 81N–0033, Dockets Management Branch.

(3) Comment No. C00015, Docket No. 81N–0033, Dockets Management Branch.

(4) Project Report No. M–75–03, OTC Vol. 130167.

(5) Project Report No. M–77–03, OTC Vol. 130167.

(6) Project Report No. M–76–05, OTC Vol. 130167.

(7) Myers, G. E., J. K. Logan, and V. J. Mitchell, "Microbiological Problems in Oral Hygiene," OTC Vol. 130167.

(8) "An In-Vitro Evaluation of Cepacol," OTC Vol. 130167.

(9) Hicks, G. F., L. L. Nisonger, and I. Ruchman, "Germicidal Effects of Various Combinations of Cetyl Pyridinium Chloride Against Antibiotic-Resistant *Staphylococci*," OTC Vol. 130167.

(10) "Comparison of the Antibacterial Activity of Colgate 100®, Listerine®, Lavoris®, Micrin®, and Cepacol®," OTC Vol. 130167.

F. Comments on Chlorophyllin Copper Complex

10. One comment complained that the Oral Cavity Panel's discussion of chlorophyllin under the heading "Antimicrobial Agents" (47 FR 22760 at 22866 to 22867) contains inaccurate and misleading statements about other

properties of the ingredient. The comment specifically objected to the statement that chlorophyllin "has fallen into disuse over recent years since it has not been demonstrated that it is an effective deodorant" and added that support for this statement was one unidentified reference to a study in which ingested chlorophyll decreased halitosis in dogs but had no effect on the odor in the dogs' coats (hair).

The comment maintained that 15 laboratory and human clinical studies demonstrating the deodorancy effectiveness of chlorophyll were submitted to the Panel (Ref. 1). Emphasizing that chlorophyllin has not fallen into disuse as a deodorant, the comment asserted that chlorophyllin is widely used in hospitals and nursing homes as a deodorant for ostomy patients and incontinent patients. The comment cited an article by Young and Beregi (Ref. 2) to support the wide use of chlorophyllin as an aid in controlling odors of incontinent patients. The comment suggested that "a less frequent but pertinent" indication for chlorophyllin is to reduce odor from cancer of the oral cavity.

The agency notes that chlorophyllin copper complex is the name adopted for chlorophyllin by the United States Adopted Names Council (Ref. 3). Therefore, chlorophyllin copper complex is the name used for this ingredient in this tentative final monograph.

The agency agrees with the comment that chlorophyllin copper complex is appropriate for use in hospitals and nursing homes as an internal deodorant for ostomy patients and incontinent patients. In the final monograph for OTC deodorant drug products for internal use published in the **Federal Register** of May 11, 1990 (55 FR 19862), the agency concluded that chlorophyllin copper complex (100 to 200 mg daily) is generally recognized as safe and effective for OTC (internal) use in controlling ostomy odors and in controlling the odors of fecal and urinary incontinence. The agency considers the local deodorancy effect of chlorophyllin copper complex when used topically in the oral cavity to be a cosmetic rather than a drug effect and, as such, would not be subject to the rulemaking for OTC oral health care drug products. (For a discussion of the cosmetic uses of OTC oral health care drug products, see section I.A., comment 3.) However, if a product containing this ingredient makes a claim that the product "reduces odor from cancer of the oral cavity," this claim would need to be supported by data from appropriate studies in patients with cancer of the oral cavity.

References

(1) OTC Vol. 130015.

(2) Young, R. W., and J. S. Beregi, Jr., "Use of Chlorophyllin in the Care of Geriatric Patients," *Journal of the American Geriatrics Society*, 28:46, 1980.

(3) "USAN and the USP Dictionary of Drug Names," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 136, 1993.

11. Noting that the Oral Cavity Panel had classified chlorophyllin solely as an "antimicrobial agent," one comment stated that its antibacterial properties are less significant than its healing effects. The comment asserted that the data submitted to the Panel emphasized that chlorophyllin is primarily a healing agent that acts to relieve discomfort due to minor irritations, inflammation, and other lesions by encouraging tissue repair and reducing inflammation. The comment contended that there should be a classification for ingredients, such as chlorophyllin, that encourage repair of minor irritations or inflammation. Acknowledging that there might be some problems with using the term "healing agents" for OTC drug products, the comment suggested using the term "tissue-repair agents" for products containing this ingredient. The comment referred to the statement in the Panel's report that no data were submitted or are available from controlled studies to substantiate a wound healing claim (47 FR 22760 at 22867) and argued that its own submission to the Panel contained many controlled studies on the wound healing effects of chlorophyllin.

The agency has reviewed the submissions on chlorophyllin copper complex made to the Oral Cavity Panel (Refs. 1 and 2) as well as submissions made to the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (Dental Panel) (Refs. 3 and 4). Although no antiseptic claims appear in the labeling of chlorophyllin copper complex-containing products submitted to these panels, the submissions contain data purporting to show the bacteriostatic effectiveness of water-soluble chlorophyllins as well as data to support the wound healing claims (Refs. 1 and 3). The Oral Cavity Panel evaluated the data submitted in support of the antiseptic effectiveness of chlorophyllin copper complex, and the Dental Panel evaluated the data submitted to support the wound healing claims.

The Oral Cavity Panel concluded that chlorophyllin copper complex is safe, but that there are insufficient data available to permit final classification of its effectiveness as an OTC antiseptic active ingredient for topical use on the mucous membranes of the mouth and throat (47 FR 22760 at 22866). Because no additional data were submitted to the agency in support of the antiseptic effectiveness of chlorophyllin copper complex, the agency concludes that the Panel's Category III classification is appropriate. Therefore, in this tentative final monograph, the agency is proposing a Category III classification for chlorophyllin copper complex as an OTC oral health care antiseptic ingredient.

In its report on OTC oral mucosal injury drug products published in the **Federal Register** of November 2, 1979 (44 FR 63270), the Dental Panel concluded that water-soluble chlorophyllins are safe, but that there were insufficient effectiveness data available to permit final classification of water-soluble chlorophyllins as oral wound healing agents (44 FR 63270 at 63286). Therefore, the Dental Panel classified water-soluble chlorophyllins in Category III. In response to the publication of the Panel's report, the agency received no comments regarding chlorophyllin copper complex as an OTC oral wound healing agent. Therefore, in the tentative final monograph for OTC oral mucosal injury drug products published in the **Federal Register** of July 26, 1983 (48 FR 33984), the agency accepted the Panel's evaluation and proposed a Category III classification for chlorophyllin copper complex as an oral wound healing agent. Again, the agency received no comments regarding chlorophyllin copper complex in response to the publication of the tentative final monograph for OTC oral mucosal injury drug products. Accordingly, in the final rule for OTC oral wound healing agents published in the **Federal Register** of July 18, 1986 (51 FR 26112), the agency concluded that there was insufficient evidence to support the effectiveness of chlorophyllin copper complex as an oral wound healing agent. Therefore, chlorophyllin copper complex is considered a nonmonograph oral wound healing ingredient.

References

(1) OTC Vol. 130015.
(2) OTC Vol. 130088.
(3) OTC Vol. 080043.
(4) OTC Vol. 080168.

G. Comments on Domiphen Bromide

12. One comment requested that the agency approve domiphen bromide at concentrations of up to 0.1 percent for safety. The comment described the results of various safety testing (e.g.,

acute toxicity, oral mucosal and eye irritation, subchronic, and teratology studies) on domiphen bromide alone and on domiphen bromide in combination with cetylpyridinium chloride. The comment also included a safety report (Ref. 1) prepared from data available through August 1982. The comment stated that, in all these studies, there have been no remarkable pathologic findings and thus up to 0.1 percent domiphen bromide is safe for OTC oral use as a single ingredient.

As stated in section I.A., comment 2, the agency believes that many of the oral antiseptic ingredients reviewed by the Oral Cavity Panel, including domiphen bromide, were placed in Category III for safety because they were used commercially in mouthwashes that were recommended for long-term use on a daily basis. The agency believes that the Panel's concerns regarding the safety of the long-term OTC use of oral antiseptic ingredients are not necessarily relevant to the short-term OTC use of these ingredients.

The agency has reevaluated the data submitted to the Oral Cavity Panel regarding the safety of domiphen bromide in light of labeling that would limit use of oral antiseptic drug products to 7 days or less. The Panel noted in its discussion of domiphen bromide (47 FR 22760 at 22868 to 22869) that "the concentrations of domiphen bromide used in commercial lozenges and mouthwashes appear to be nontoxic." It cited several studies in which no toxicity could be demonstrated. According to the Panel, the intravenous LD_{50} was determined to be 18 mg/kg for rats, 31 mg/kg for mice, and 11 to 12 mg/kg for rabbits. An oral LD_{50} (species unspecified) could not be determined because marked diarrhea resulted, but it was suspected to be above 800 mg/kg/day. The intraperitoneal LD_{50} was 40 to 45 mg/kg for rats and 10 to 20 mg/kg for guinea pigs. One study (Ref. 2) discussed in the Panel's report concluded that clinical use of a mouthwash containing 0.01 percent domiphen bromide two to six times daily for up to 52 weeks resulted in no apparent toxicity.

The Panel noted that only six adverse reactions were reported between 1958 and 1970 for a lozenge product containing domiphen bromide (47 FR 22869). These included one complaint of lack of effectiveness, two cases of burns on the tongue, one case of soreness of the mouth, one case of fungal growth after use of the product, and one case of chalk-like taste. The agency has reviewed its adverse reaction files covering 1969 to May 1993. During those years, no adverse event reports associated with domiphen bromide were received.

The agency tentatively concludes that the safety data evaluated by the Oral Cavity Panel, 30 years of safe marketing of an OTC mouthwash product containing domiphen bromide (NDA 14–598), and the lack of adverse event reports in its files are sufficient to conclude that up to 0.1 percent domiphen bromide is safe as an OTC oral antiseptic when labeled for short-term use (not to exceed 7 days). However, when this ingredient is used in conjunction with cetylpyridinium chloride as an oral antiseptic (see section I.E., comment 8), the agency is concerned that using domiphen bromide where excessive gum irritation or bleeding exists could increase the absorption and systemic load of the ingredient and possibly lead to some of the toxicological effects discussed by the Oral Cavity Panel (e.g., convulsions, central nervous system depression followed by death due to the curare-like action of quats) (47 FR 22760 at 22869). Therefore, the agency is proposing labeling that would caution consumers not to use a product containing domiphen bromide if excessive gum irritation or bleeding exists unless directed to do so by a doctor or dentist as follows: "Do not use this product if gums are irritated or bleeding unless directed to do so by a doctor or dentist." This labeling will be included in the final monograph for OTC oral antiseptics if domiphen bromide becomes Category I in that rulemaking. The agency requests comment regarding this proposed labeling.

Data on the combination of cetylpyridinium chloride and domiphen bromide are discussed in section I.L., comments 30 and 31.

References

(1) Comment No. C00013, Docket No. 81N–0033, Dockets Management Branch.

(2) Kutscher, A. H., and J. Budowsky, "Observations on the Clinical Use of Bradosol," *Oral Surgery, Oral Medicine, and Oral Pathology*, 7:873–875, 1954.

13. One comment requested that the agency approve 0.05 percent domiphen bromide for effectiveness. The comment stated that effectiveness was proven in tests against three organisms, and that the results of these tests were included in the comment (Ref. 1) and had been reported to the Oral Cavity Panel (Ref. 2). The comment added that the protocol for these studies was reviewed and approved by the Panel. The comment mentioned that, in several votes taken over a period of more than 3 years, the Panel placed domiphen bromide in Category I. The comment added that, at its next-to-last meeting, the Panel rescinded its action and placed domiphen bromide, along with all other antiseptic ingredients, in Category III for effectiveness. The comment argued that the Panel's decision was ill-advised and urged the agency to give monograph status to domiphen bromide.

The agency believes that there are not enough data to conclude that domiphen bromide is an effective oral antiseptic. The effectiveness studies (Refs. 1 and 2) were conducted according to the July 12, 1977, version of tentative guidelines developed and submitted to the Panel by the NDMA (formerly known as The Proprietary Association) (Ref. 3). Those guidelines were under consideration by the Oral Cavity Panel, but were subsequently revised as described in the Panel's 1982 report (47 FR 22760 at 22890 to 22893). A notable revision made by the Panel was to increase the inoculum of test culture; the 1977 NDMA guidelines provided for a 1 mL aliquot of a 1 to 4 dilution of inoculum added to 10 mL of the mouthwash product or active ingredient, while the Panel's final guidelines specified 1 mL of undiluted culture in 9 mL of product or active ingredient. The Panel also proposed additional in vitro testing that included a determination of the minimum inhibitory concentration (MIC) of the antiseptic agent, and testing of freshly obtained clinical isolates from mouth and throat infections to provide updated, relevant data on the susceptibility of these isolates to the antiseptic agent (47 FR 22760 at 22890 to 22891). Since publication of the Panel's report, no such data for domiphen bromide have been provided to the agency. In addition, the agency is not aware of any data from clinical studies demonstrating a therapeutic benefit from the OTC use of domiphen bromide in the oral cavity. The agency concludes that additional data are necessary to establish the effectiveness of domiphen bromide as an oral antiseptic to help prevent infection in the oral cavity.

The agency believes that the Panel's 1982 proposed testing guidelines and its discussion of clinical studies represent a good starting point for the design of studies to upgrade a Category II or Category III oral antiseptic ingredient to Category I. (See section I.M., comment 33 for a further discussion of testing guidelines.) Since testing requirements are subject to change over time because of technological advancements, the agency notes that specific testing guidelines for upgrading ingredients to monograph status are not included in the tentative final monograph. (See part

II. paragraph A.2.—*Testing of Category II and Category III conditions.*) All such testing should be designed using the most current technology available. The agency will meet with industry representatives or other interested parties at their request to discuss testing protocols. Any party interested in conducting studies should request a meeting at its earliest convenience.

References

(1) Comment No. C00013, Docket No. 81N–0033, Dockets Management Branch.
(2) OTC Vol. 130134.
(3) OTC Vol. 130131.

H. Comment on Phenol

14. One comment requested that the agency classify 1.4 to 1.5 percent phenol in Category I as an antiseptic mouthwash. The comment stated that until its next-to-last meeting, the Oral Cavity Panel believed that the antiseptic capability of a mouthwash could be demonstrated through the use of in vitro and in vivo studies, but that the Panel arbitrarily decided to reverse its long-standing position without additional evidence. The comment further stated it had presented documentation to the Panel prior to its reversal that phenol met the requirements of both the in vitro and in vivo protocols. The comment resubmitted the same studies it had submitted to the Panel and requested that the agency accept these data (Ref. 1).

The agency has evaluated the studies submitted to the Panel and concludes that they are not adequate to establish the effectiveness of phenol as an OTC oral antiseptic. The comment's data include one in vitro study and two in vivo efficacy studies. No data from clinical studies were submitted to the agency to demonstrate a therapeutic benefit from the OTC use of phenol in the oral cavity.

The in vitro study was conducted according to the July 12, 1977, NDMA tentative guidelines that had been submitted to the Panel (Ref. 2). Those guidelines were under consideration by the Oral Cavity Panel at the time the comment's studies were conducted, but were subsequently revised as described in the Panel's report (47 FR 22760 at 22890). A notable revision made by the Panel was to increase the inoculum of test culture; the 1977 NDMA guidelines provided for a 1 mL aliquot of a 1 to 4 dilution of inoculum added to 10 mL of the product or active ingredient, while the Panel's final guidelines specified 1 mL of undiluted culture in 9 mL of product or active ingredient. The Panel also proposed additional in vitro testing that included a determination of the MIC of the antiseptic agent, and testing of freshly obtained clinical isolates from mouth and throat infections to provide updated, relevant data on the susceptibility of these isolates to the antiseptic agent (47 FR 22760 at 22890 to 22891). No such data were provided for phenol following the Panel's final recommendations.

The two in vivo studies were also designed following tentative guidelines (Ref. 3) under consideration by the Panel. According to those guidelines, an oral antiseptic ingredient that reduced the accumulation of dental plaque was considered to reduce microorganisms, and thus was deemed an oral antiseptic. The Panel had originally considered this in vivo method, based on plaque reduction on the teeth and periodontal tissues, as a criterion for antiseptic activity in the oral cavity, but subsequently discarded it, stating that the method was inexact and had no rational basis because dental plaque is not a disease per se (47 FR 22760 at 22840). There was considerable discussion of this issue by the Panel, and in making its final determination, the Panel relied upon the opinions of consultants and statisticians who are experts in the field, as well as on the expertise of the Panel members (47 FR 22840 to 22842). In its final report, the Panel did not accept plaque reduction as a criterion for determining effectiveness of antiseptic agents, and the agency agrees. A subsequent segment of the rulemaking for OTC oral health care drug products will cover plaque-related claims and ingredients. (See section I.M., comment 32.)

The agency disagrees with the comment that the Oral Cavity Panel arbitrarily reversed its position regarding in vitro and in vivo studies. Rather, after careful deliberations, the Panel modified its tentative in vitro guidelines, and replaced its tentative in vivo guidelines with others it believed were more appropriate. The agency believes that the Panel's proposed testing guidelines and its discussion of clinical studies represent a good starting point for the design of studies to upgrade a Category II or Category III oral antiseptic ingredient to Category I. (See section I.M., comment 33 for a further discussion of testing guidelines.) However, the agency notes that specific testing guidelines for upgrading ingredients to monograph status are not included in the tentative final monograph. (See part II. paragraph A.2.—*Testing of Category II and Category III conditions.*) All such testing should be designed using the most current technology available. The agency will meet with industry representatives or other interested parties at their request to discuss testing protocols. Any party interested in conducting studies should request a meeting at its earliest convenience.

References

(1) Comment No. C00014 and OTC Vol. 130131, Docket No. 81N–0033, Dockets Management Branch.
(2) Letter from J. D. Cope, NDMA (formerly The Proprietary Association), dated July 15, 1977, OTC Vol. 130PA3.
(3) Letter from J. D. Cope, NDMA (formerly The Proprietary Association), dated February 23, 1977, OTC Vol. 130110–B.

I. Comments on Povidone-Iodine

15. Three comments objected to the Oral Cavity Panel's conclusion that there are insufficient data available to permit classification of povidone-iodine as safe for OTC topical antimicrobial use on the mucous membranes of the mouth and throat. One comment (Ref. 1) stated that most of the safety concerns raised by the Oral Cavity Panel had been fully addressed by data submitted earlier to several other OTC drug rulemakings: (1) Topical antimicrobial drug products, (2) contraceptive and other vaginal drug products, (3) topical acne drug products, and (4) antifungal drug products. The comment contended that had the data and testimony to these other panels been considered by the Oral Cavity Panel, many safety concerns would have been resolved and duplicative efforts precluded. Another comment maintained that the Panel's conclusion that there are insufficient data available to permit classification of povidone-iodine as safe for antiseptic use on the mucous membranes of the mouth and throat is in error. A third comment mentioned that a commercially available mouthwash containing povidone-iodine has been marketed under an approved new drug application (NDA) (NDA 10–290) for a quarter century without reports of any significant adverse effects related to this product.

One comment contended that clinical and experimental studies have shown that povidone-iodine can reduce infection in wounds or surgical procedures without impairing wound healing or causing adverse reactions. The comment submitted several studies to support its statement (Refs. 2 through 9). Another comment also submitted data to establish that povidone-iodine preparations do not inhibit normal wound healing (Refs. 10, 11, and 12). The comment stated that the concern as to whether povidone-iodine accelerates or delays wound healing was addressed in detail in the Antimicrobial II Panel's report on the antifungal use of

povidone-iodine, published in the **Federal Register** of March 23, 1982 (47 FR 12480 at 12545).

One comment submitted three studies (Refs. 13, 14, and 15), one of which (Ref. 13) was also submitted by another comment, designed to demonstrate that no carcinogenic or mutagenic effects are associated with the use of povidone-iodine. Another comment submitted data regarding the capability of povidone-iodine to alter DNA in living cells. These data were also presented to the Vaginal Panel in 1978 (Refs. 15 and 16). A third comment maintained that all data relevant to the mutagenic potential of povidone-iodine had been considered by the Vaginal Panel, which concluded that povidone-iodine is not carcinogenic, teratogenic, or mutagenic. The comment submitted a review of the available data (Ref. 17).

One comment discussed the Oral Cavity Panel's statement that "chronic, indiscriminate use of PVP-I [povidone-iodine] has been associated with iodism, an increase in protein-bound iodine, and altered thyroid function," (47 FR 22760 at 22883). The comment agreed that indiscriminate use of any substance may cause harm and stated that one of the functions of proper OTC drug labeling is to instruct the consumer with appropriate directions so that indiscriminate use of pharmaceutical products can be avoided. The comment submitted FDA approved labeling (from NDA 10–290) (Ref. 18) for a commercially-available product and noted that the labeling should eliminate concerns about chronic, indiscriminate use of the product. The comment added that application of povidone-iodine to mucosal tissue does not affect normal thyroid function and stated that data had been submitted to FDA in support of this contention (Ref. 19).

One comment indicated that the Oral Cavity Panel's basis for the following statement was misdirected: "The toxic effects of PVP-I [povidone-iodine] are due to the release of free iodine and since the release occurs slowly, its toxicity and irritancy is low," (47 FR 22883). The comment agreed with the Panel that the toxicity and irritancy of povidone-iodine is low; however, the comment maintained that the low toxicity and irritancy exhibited by povidone-iodine is due to the kinetics of the available iodine dynamic equilibrium as well as the physical and chemical properties of the iodine moiety in povidone-iodine rather than the slow release of free iodine as suggested by the Panel.

One comment stated that povidone-iodine has been the subject of extensive scientific study for decades and that the medical literature contains approximately 4,000 references, including extensive long-term feeding studies in animals and humans. The comment pointed out the Oral Cavity Panel reported that povidone-iodine is nontoxic and that the free iodine released from povidone-iodine has low toxicity and irritancy (47 FR 22760 at 22883). The comment mentioned that the Panel also stated that "Povidone is practically nontoxic," "povidone is not metabolized," and "the greatest portion [of povidone] is excreted unchanged by the kidney." The comment submitted a toxicology review of data to show no biologically significant toxicity or other adverse effects of povidone-iodine following oral administration (Refs. 20 through 23). The comment contended that povidone-iodine is completely safe for use on either a short- or long-term basis.

One comment stated that the rate of absorption of povidone and iodine from the povidone-iodine complex through intact skin, vaginal mucosa, and the peritoneal cavity has been shown to be insignificant or virtually nonexistent. The comment submitted data to support its statement (Refs. 20, 24, 25, and 26). Citing "dental academicians," the comment contended that a valid comparison can be made between the histology and function of the vaginal mucosa and the oral mucosa. One comment asserted that the safety concerns raised by the Oral Cavity Panel regarding the use of povidone-iodine in the oral cavity are based upon uses of povidone-iodine solution that are not relevant to the use of low concentrations of povidone-iodine in the oral cavity. For example, the comment noted that the Panel's concern about the behavior of povidone-iodine after parenteral administration is not pertinent to the safety of oral health care drug products used topically on the mouth and throat (47 FR 22760 at 22883 to 22884). Another comment stated that because the oral mucosa and the peritoneum are very different histologically and functionally, studies on the peritoneum cited by the Oral Cavity Panel cannot be applied to the use of povidone-iodine in the oral cavity.

The agency has considered the data submitted in support of the safety of povidone-iodine, the Oral Cavity Panel's discussion of the safety of povidone-iodine (47 FR 22760 at 22883 to 22884), and the other advisory panels' evaluations of the safety of povidone-iodine. Based on this information, FDA concludes that povidone-iodine should be classified in Category I for safety as an OTC antiseptic ingredient for short-term (i.e., no more than 7 days) topical use on the mucous membrane of the mouth and throat.

As stated elsewhere in this document (see section I.A., comment 2), the agency believes that many of the oral antiseptic ingredients reviewed by the Panel, including povidone-iodine, were placed in Category III for safety because they were used commercially in mouthwashes that were recommended for long-term use on a daily basis. The agency believes that the Oral Cavity Panel's concerns regarding the safety of the long-term OTC use of oral antiseptic ingredients are not necessarily relevant to the short-term OTC use of these ingredients. In its discussion of povidone-iodine (47 FR 22760 at 22884), the Panel stated that extensive clinical observations indicated that povidone-iodine is generally nonirritating and nonsensitizing when applied to skin and mucous membranes. The Panel concluded that although povidone-iodine may be safe for occasional application to the mucous membranes, there were insufficient data to establish its safety for long-term daily use.

The Oral Cavity Panel's concern about povidone-iodine's effect on wound healing was based upon a statement in the Antimicrobial I Panel report on antimicrobial drug products published in the **Federal Register** of September 13, 1974 (39 FR 33102) that "conflicting data [had been presented] concerning the role of PVP-iodine use on the rate of wound healing." Some data presented to the Antimicrobial I Panel suggested that povidone-iodine had no effect on the rate of wound healing, while other data suggested a delay in wound healing after povidone-iodine use in animal model studies (39 FR 33102 at 33131). In its evaluation of povidone-iodine as a topical antifungal ingredient, the Antimicrobial II Panel relied on new data as well as the recommendations of the Antimicrobial I Panel. In its report, the Antimicrobial II Panel specifically addressed the effects of povidone-iodine on wound healing (47 FR 12480 at 12545), concluded that povidone-iodine has no adverse effects on wound healing, and determined that 10 percent povidone-iodine is safe for OTC use as an antifungal agent. In the tentative final monograph for OTC first aid antiseptic drug products, the agency evaluated additional new data regarding the effect of povidone-iodine on wound healing and concluded that this ingredient does not delay wound healing (56 FR 33644 at 33662). The agency has no reason to believe that the mechanism for wound healing in the oral cavity is significantly different from the mechanism for skin wound healing. Therefore, the agency

believes that the data discussed above are applicable to wound healing in the oral cavity. The agency tentatively concludes that povidone-iodine does not inhibit normal wound healing in the oral cavity.

In the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661 to 33662), the agency discussed data from published and unpublished studies to show that povidone-iodine does not alter thyroid function. The agency reviewed the data and agreed that thyroid disfunction does not occur from topical use of povidone-iodine. In addition, studies following the application of povidone-iodine to the mucous membranes (vagina) and intact and damaged skin in humans and animals reported protein-bound iodine elevations, but no alterations in thyroid function. The agency concluded that 0.5 to 5 percent povidone-iodine is safe for OTC use as a topical first aid antiseptic.

The agency also agrees with one comment that the currently available information indicates that povidone-iodine is not mutagenic or carcinogenic. In its evaluation of povidone-iodine as a topical antifungal ingredient, the Antimicrobial II Panel relied on new safety data as well as the recommendations of the Antimicrobial I Panel (39 FR 33102 at 33129). In its report, the Antimicrobial II Panel specifically discussed data on the mutagenicity potential of povidone-iodine (47 FR 12480 at 12545) and concluded that povidone-iodine has no significant mutagenic or carcinogenic capabilities. That Panel determined that 10 percent povidone-iodine is safe for OTC use as an antifungal agent. The Vaginal Panel reviewed a povidone-iodine migration and absorption study in three experimental animal species using radioactively tagged povidone-iodine (48 FR 46694 at 46705). Although there was evidence of absorption of iodine from the vagina into the systemic circulation, the experiments showed little or no flow of radioactively tagged povidone into the uterus from the vagina. Stating that "the weight of evidence is sufficient to conclude that povidone-iodine does not have a significant mutagenic or carcinogenic effect" (48 FR 46694 at 46705), that Panel classified povidone-iodine as Category I for the relief of minor vaginal irritations. In addition, the agency has searched the scientific literature covering 1982 through May 1993, and has not found any information indicating that povidone-iodine might be mutagenic or carcinogenic.

The agency has reviewed its adverse reaction files covering 1970 to August 1993 (Ref. 26). During those years there were no cases of adverse reactions associated with the use of povidone-iodine as an oral antiseptic. There were numerous cases of adverse reactions associated with the use of topical products containing povidone-iodine, e.g., first aid antiseptics or surgical scrubs. Of these cases, 20 were classified as serious. Five deaths occurred. However, each death occurred after the professional use of povidone-iodine as a health care antiseptic in a hospital setting (i.e., (1) use as surgical scrub on a patient who had previously been exposed to multiple radiographic examinations, (2) use to sterilize the peritoneal cavity after surgery, (3) administration concurrent with an electrolyte solution by enema and subsequently through a nasogastric tube, and (4) continuous irrigation of a hip wound). The other serious case reports involved chest pain, contact dermatitis, or chemical burns resulting from the preoperative use of povidone-iodine solutions as health-care antiseptics. These cases resulted in prolonged hospitalizations and/or disability (e.g., loss of vision or burns of varying degrees). The most frequently reported events included: reports of rash, reports of contact dermatitis, reports of application site reactions, reports of vaginitis, and reports of pain. Other less frequently reported reactions (i.e., 1 or 2 reports per reaction) included conjunctivitis, anaphylactic shock, iodism, rhinitis, and dry skin. The agency notes that the majority of these cases were the result of povidone-iodine products being used by health care professionals on people who were in the hospital for surgery or who were otherwise compromised. In addition, the povidone-iodine concentration in the products used in these cases was 5 to 10 percent, which is much higher than its concentration in oral antiseptic products (0.5 percent). The agency does not believe that these reports are relevant to the use of povidone-iodine as an oral antiseptic product used in small amounts in the oral cavity for a limited period of time (i.e., up to 7 days).

The agency believes that the information contained in its adverse reaction files and the safety data evaluated by the Oral Cavity Panel are sufficient to conclude that 0.5 percent povidone-iodine (i.e., the concentration evaluated by the Oral Cavity Panel) is safe as an OTC oral antiseptic for short-term use (not to exceed 7 days).

References

(1) Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(2) Bradley, S. G., "A Review on Some Microbiological Aspects of Povidone-Iodine (PVP-I)," Addendum 20, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(3) Prince, H. N. et al., "Drug Resistance Studies with Topical Antiseptics," *Journal of Pharmaceutical Sciences*, 67:1629–1630, 1973.

(4) Eitzen, H. E., "Efficacy of Povidone-Iodine (PVP-I)," Addendum 22, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(5) Gilmore, O. J. A., and P. J. Sanderson, "Prophylactic Interparietal Povidone-Iodine in Abdominal Surgery," *British Journal of Surgery*, 62:792–799, 1975.

(6) Eitzen, H. E. et al. "A Microbiological In-Use Comparison of Surgical Hand-Washing Agents," *The Journal of Bone and Joint Surgery, Incorporated*, 61–A:403–406, 1979.

(7) Steere, A. C., and G. F. Mallison, "Handwashing Practices for the Prevention of Nosocomial Infections," *Annals of Internal Medicine*, 83:683–690, 1975.

(8) Morgan, W. J., "Povidone-Iodine Spray for Wounds Sutured the Accident Department," Addendum 26, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(9) Carchman, R. A., "The Effects of Povidone-Iodine on Wound Healing," Addendum 27, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(10) Fischer, E., and Z. Paster, "A Study of the Effect of Polydine on Wound Healing," Appendix 10, Comment No. C00019, Docket No. 81N–0033, Dockets Management Branch.

(11) Gilmore, O. J. A., "A Reappraisal of the Use of Antiseptics in Surgical Practice," *Annals of the Royal College of Surgeons of England*, 59:93–103, 1977.

(12) Gilmore, O. J. A., and C. Reid, "A Study of the Effect of Povidone-iodine on Wound Healing," *Postgraduate Medical Journal*, 53:122–125, 1977.

(13) Schwartz, S. L., "Evaluation of the Safety of Povidone and Crospovidone," Addendum 16, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(14) "Studies on Testing of Povidone-Iodine U.S.P. XIX for Mutagenic Effects in Mice and Chinese Hamsters," Comment No. C00019, Docket No. 81N–0033, Dockets Management Branch.

(15) Merkle, J., and H. Zeller, "Absence of Povidone-Iodine-Induced Mutagenicity in Mice and Hamsters," *Journal of Pharmaceutical Sciences*, 68:100–102, 1979.

(16) Kessler, F. K. et al., "Assessment of Somatogenotoxicity of Povidone-Iodine Using Two In Vitro Assays," Addendum 15, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(17) Brusick, D. J., "A Review of the Genotoxic Effects of Povidone-Iodine," Attachment B, Comment No. C00010, Docket No. 81N–0033, Dockets Management Branch.

(18) Attachment A, Comment No. C00010, Docket No. 81N–0033, Dockets Management Branch.

(19) "Serum Fodides and Thyroid Function; Betadine Mouthwash/Gargle (Povidone-Iodine)," Attachment C, Comment No. C00010, Docket No. 81N–0033, Dockets Management Branch.

(20) Borzelleca, J. F., "A Review of the Basic Toxicology of Povidone-Iodine," Addendum 4, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(21) "Toxicology Summary of PVP," Addendum 17, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(22) Blecher, L. et al., "Polyvinylpyrrolidone," Addendum 18, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(23) Digenis, G. A., "Behavior of Povidone-Iodine in the Vaginal Vault of the Rat, Dog, and Sheep," Addendum 11, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(24) Istin, M., "Study of the Urinary, Biliary, and Fecal Excretion of C^{14} by Rats Treated with Labeled Polyvinylpolypyrrolidone (PVPP–C^{14}) by Gastric Intubation," Addendum 12, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(25) Ingbar, S. H., "Studies of the Effects of Surgical Scrubbing with PVP–I," Addendum 13, Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(26) Food and Drug Administration, Center for Drug Evaluation and Research, Adverse Reaction Summary Listing for Povidone-iodine for the years 1970 to August 1993, OTC Vol. 13CTFM, Docket No. 81N–0033, Dockets Management Branch.

16. Two comments objected to the Oral Cavity Panel's conclusion that there is insufficient evidence available to classify povidone-iodine in Category I as an effective oral antiseptic. One comment stated that a commercial mouthwash has been marketed under an approved NDA for a quarter century and that reports of clinical studies involving thousands of patients had been submitted to the Panel.

The comments objected to the Panel's statement that the "* * * slow release [of povidone-iodine] also raises doubts about its effectiveness, since the active ingredient is elemental iodine," (47 FR 22760 at 22883). One comment stated that the Panel's speculation on the release of iodine and its impact on the effectiveness of povidone-iodine is unfounded. The comment added that the effectiveness of povidone-iodine solution as a topical microbicide is proven in the hundreds of studies submitted or referenced to the Panel. The comment contended that the Panel did not develop an independent viewpoint regarding the effectiveness of povidone-iodine but relied upon the Antimicrobial I Panel's evaluation. The comment argued that the issues raised by the Antimicrobial I Panel were fully answered by the data submitted in response to that Panel's report.

Another comment stated that the efficacy of the povidone-iodine complex is independent of the initial content of free iodine and that biocidal effect is determined by iodine liberated from the complex during the reaction with amino acids of the proteins of bacteria, fungi, etc. The comment mentioned that substantial data submissions to the Antimicrobial I Panel and other panels showed that iodine is freely released from the complex and that the rate of iodine release is controlled by tissue demand. The comment submitted data regarding the rate of release and germicidal activity of povidone-iodine (Refs. 1, 2, and 3). The comment stated that the studies established that: (1) The biocidal activity of the complex is independent of the initial free iodine content; (2) the clinical effectiveness of the complex is caused by the amount of available iodine; (3) the iodine becomes effective by oxidation or iodizing reaction of amino acids of the proteins of bacteria, fungi, etc.; (4) the iodine is liberated from the povidone-iodine complex at a rate in the milliseconds time range; and (5) within the acidity levels studied (i.e., those levels relevant to the field of medicine, between pH 3 and 5), no significant change with regard to the rapidity of iodine release from the povidone-iodine complex could be observed. The comment concluded that there are sufficient data available to establish the effectiveness of povidone-iodine for use as an OTC oral antiseptic.

As part of FDA's DESI program, mouthwash products containing povidone-iodine, cetylpyridinium chloride, and other ingredients were reviewed by the NAS-NRC/DESG and found ineffective for claims relating to antimicrobial, antiseptic, germicidal, and analgesic uses (35 FR 12423). In a subsequent notice published in the **Federal Register** of December 2, 1971 (36 FR 23000), the agency stated that because of the implementation of the OTC drug review, mouthwash and gargle products reviewed under the DESI program would now be under the purview of the OTC drug review; thus, final agency action on these products would be deferred pending evaluation of the data and information concerning such products under the OTC drug review.

The agency has reviewed the data submitted regarding the availability of iodine from the povidone-iodine complex and considered the data discussed in the tentative final monograph for OTC topical acne drug products, published in the **Federal Register** of January 15, 1985 (50 FR 2172 at 2173 to 2174) and in the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661). The agency agrees with the comment that the issues regarding the availability of iodine from povidone-iodine complex and the stability of the complex have been resolved for this ingredient. However, the agency has determined that further studies are needed to demonstrate the effectiveness of povidone-iodine for OTC topical use in the oral cavity to help prevent infection.

As discussed in section I.K., comment 27, the agency believes that 0.5 percent povidone-iodine is an effective oral antiseptic for professional use when used for the preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction by a health care professional. However, the data discussed in that comment do not support OTC use of povidone-iodine as an OTC oral antiseptic. The data demonstrate that applying povidone-iodine according to the specialized professional labeling directions proposed in § 356.80(c)(3) of this tentative final monograph results in a decrease of bacteremia after oral surgery or tooth extraction. They did not demonstrate a therapeutic benefit from using povidone-iodine as an OTC oral rinse. Although the gingival mucosa surrounding the operation sites were sampled prior to and immediately after surgery or tooth extraction, the studies did not demonstrate a decrease in the number of oral bacteria over an extended period of time, and the organisms affected by the povidone-iodine treatment were not completely identified. These studies do not demonstrate the effectiveness of povidone-iodine when used as an OTC oral rinse. In addition, the agency is not aware of any data from clinical studies demonstrating a therapeutic benefit from the OTC use of povidone-iodine in the oral cavity.

The agency believes that the Panel's proposed in vitro and in vivo testing guidelines and its discussion of clinical studies represent a good starting point for the design of studies to upgrade a Category II or Category III oral antiseptic ingredient to Category I. (See section I.M., comment 33 for a further discussion of testing guidelines.) However, the agency notes that specific testing guidelines for upgrading ingredients to monograph status are not included in this monograph. (See part II. paragraph A.2.—*Testing of Category II and Category III conditions.*) All such testing should be designed using the most current technology available. The agency will meet with industry representatives or other interested parties at their request to discuss testing protocols.

References

(1) Appendix 2, Comment No. C00019, Docket No. 81N–0033, Dockets Management Branch.

(2) Appendix 3, Comment No. C00019, Docket No. 81N–0033, Dockets Management Branch.

(3) Appendix 4, Comment No. C00019, Docket No. 81N–0033, Dockets Management Branch.

17. One comment objected to the Oral Cavity Panel's statement (47 FR 22760 at 22882) that "There is some disagreement concerning the chemical nature of povidone-iodine. Some believe that it is a specific chemical entity; others claim that it is merely a complex. The prevalent consensus is that povidone-iodine is a complex of povidone and elemental iodine." Maintaining that there is no disagreement among qualified scientists concerning the chemical nature of povidone-iodine, the comment stated that povidone-iodine is a specific chemical entity that is defined in the Official Compendia and the scientific literature. Referring to the "United States Pharmacopeia (U.S.P.) XX" description of povidone-iodine as "* * * a complex of iodine with povidone" (Ref. 1), the comment contended that the fact that povidone-iodine is described as a complex does not contradict its existence as a chemical entity. The comment stated that a "complex" is formed by the "bonding of two or more compounds, resulting in a new chemical entity having properties distinguishable from those of the component parts." According to the comment, data in the public record demonstrate that povidone-iodine is a well-defined chemical entity that retains the full antimicrobial spectrum of iodine without the noxious chemical and physical properties of elemental iodine, thereby providing a stable, essentially nonirritating and nontoxic compound.

Another comment agreed with the Oral Cavity Panel's recognition of the "prevailing consensus" that povidone-iodine is a complex composed of povidone and iodine. However, this comment felt that the Panel may have been unaware of the nature of povidone-iodine, and contended that this lack of awareness may have affected other considerations concerning the source of the complex's effectiveness, the rate of iodine release, and the complex's effect on the rate of healing. The comment included a detailed chemical description of povidone-iodine and of povidone-iodine's activity (Ref. 2).

One comment asserted that the Panel's misunderstanding of the nature of povidone-iodine is indicated by its statement that "Povidone is available as a series of aggregates having mean molecular weights ranging from 10,000 to 700,000 daltons," (47 FR 22760 at 22883). Stating that the U.S.P. XX described povidone as a series of products rather than a series of aggregates (Ref. 1), the comment maintained that the povidone product used in the synthesis of povidone-iodine does not spread over the broad range of molecular weights described by the Panel but has a molecular weight average of less than 40,000. The comment added that this specificity in molecular weight must be recognized when considering the properties of the povidone used to synthesize povidone-iodine.

The agency has reviewed the literature and believes that povidone-iodine is a well-defined chemical. Povidone-iodine is described in "U.S.P. XXII" (Ref. 3) and in "Martindale, The Extra Pharmacopeia" (Ref. 4) as a complex of iodine with povidone (2-pyrrolidinone, 1-ethenyl-, homopolymer or 1-vinyl-2-pyrrolidinone polymer) that contains not less than 9 percent and not more than 12 percent of available iodine calculated on a dried basis. "U.S.P. XXII" (Ref. 3) provides standards for the purity and acceptability of iodine, povidone, and povidone-iodine. Other references describe povidone-iodine as iodine compounded or complexed with povidone (Refs. 5 and 6).

Regarding the Panel's statement that "Povidone is * * * a series of aggregates * * *" (47 FR 22760 at 22883), the agency notes that "U.S.P. XXII" describes povidones as a "synthetic polymer consisting essentially of linear 1-vinyl-2-pyrrolidinone groups, the degree of polymerization of which results in polymers of various molecular weights," (Ref. 3). Povidone is produced commercially as a series of products having mean molecular weights ranging from about 10,000 to about 700,000 (Ref. 6), and the Panel correctly described the range of molecular weights of povidone available. However, it neglected to point out that povidone having an average molecular weight of 40,000 is used in the preparation of povidone-iodine (Ref. 6). For the above reasons, the agency concludes that there is little or no disagreement regarding the chemical nature of povidone-iodine.

References

(1) "The United States Pharmacopeia XX," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 647, 1980.

(2) Comment No. C00020, Docket No. 81N–0033, Dockets Management Branch.

(3) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1118–1119, 1989.

(4) Reynolds, J. E., editor, "Martindale, The Extra Pharmacopoeia," 29th ed., The Pharmaceutical Press, London, p. 1187, 1989.

(5) Gardner, W., E. I. Cooke, and R. W. I. Cooke, "Handbook of Chemical Synonyms and Trade Names," CRC Press, Inc., Cleveland, p. 576, 1978.

(6) Gennaro, A. R., editor, "Remington's Pharmaceutical Sciences," 18th ed., Mack Publishing Co., Easton, PA, pp. 1169 and 1307, 1990.

18. Two comments maintained that several of the Oral Cavity Panel's statements in its discussion of povidone-iodine (47 FR 22760 at 22882 to 22885) showed a basic misunderstanding of the behavior of povidone-iodine in solution. One comment requested that the Panel's introductory discussion of povidone-iodine be rewritten to properly reflect the chemical and physical properties of povidone-iodine and that the information provided should accurately describe the product used in the formulation of OTC oral health care antimicrobial preparations.

The comment asserted that the Panel's statement which reads "The iodine that can be released in its free form from povidone-iodine is approximately 10 percent of the labeled iodine content of the complex" (47 FR 22883) is misleading. The comment noted that povidone-iodine powder contains about 10 percent available iodine and a 10-percent aqueous solution of povidone-iodine provides 1 percent titratable iodine, all of which is available for germicidal use.

The comment indicated that the following statement made by the Panel is in error: "Freshly prepared solutions of povidone-iodine do not give a blue color with starch as do tinctures and other solutions of elemental iodine. Solutions that have been standing for some time do give a blue color" (47 FR 22883). The comment referred to the two identification tests required by the U.S.P. for povidone-iodine solution (Ref. 1) and stated that identification test A requires a blue color upon mixture of a povidone-iodine solution with starch TS (test solution), and test B requires that no blue color be produced. Stating that test B detects the presence of uncomplexed free iodine, the comment asserted that properly manufactured povidone-iodine solutions conform to these U.S.P. standards and do not deteriorate and release free iodine vapor under normal storage conditions, as the Panel's quoted statement implies.

The comment objected to the following statement in the Panel's discussion of povidone-iodine: "The

addition of sodium bicarbonate makes aqueous solutions less acidic, but also less stable," (47 FR 22760 at 22883), and noted that "a current In-Process Revision of the U.S.P." provides for a pH range of 2.0 to 6.5. Citing the "Pharmacopeial Forum" (Ref. 2), the comment stated that this pH range reflects the range of values found in commercial formulations and is consistent with adequate stability, germicidal activity, and dermal safety. Noting that product stability is fully regulated under Current Good Manufacturing Practice (CGMP) regulations found in 21 CFR parts 210 and 211, the comment maintained that its povidone-iodine mouthwash gargle product is stable, has a documented shelf-life stability, and is labeled with an expiration date.

Citing the Panel's statement "When an aqueous solution is applied topically, a slow release of free iodine occurs which exerts antimicrobial action" (47 FR 22760 at 22883), the comment asserted that the activity of povidone-iodine solution is not the result of a slow, "trickle type" of release of free iodine, but occurs because iodine is available in the course of a continuous, dynamic equilibrium reaction. The comment added that the dynamic equilibrium results in the immediate availability of all the iodine present in the solution at virtually the same rate as for tincture of iodine. The comment maintained that data submitted to the Oral Cavity Panel, the Antimicrobial I Panel, and the rulemaking for OTC topical acne drug products demonstrate that all of the iodine present in an aqueous solution of povidone-iodine is instantly (i.e., within milliseconds) available upon application to the tissue site; therefore, the Panel's reference to a "slow release of free iodine" is incorrect.

The second comment maintained that a key factor in the availability of elemental iodine from the povidone-iodine complex is the ability of the complex to keep the antimicrobial iodine in reserve and supply it only on demand. The comment stated that when there is no iodine demand, the level of free iodine is kept quite low, contrary to the Panel's statement regarding the continuous "slow-release" of iodine. The comment contended that at equilibrium the concentration of iodine is low, but as the iodine is depleted from the solution, it is replaced instantaneously from the available pool. Thus, the comment concluded that the rate of release of iodine is not variable, but is always the same and that the germicidal activity of povidone-iodine is not affected until the entire pool is depleted. The comment submitted data describing the structure and the kinetics of iodine release from the povidone-iodine complex (Refs. 3 and 4) and purporting to confirm the in vitro microbiological consequences of the release mechanism (Ref. 5).

The agency considers the following statement made by the Panel in its discussion of povidone-iodine to be unclear and undocumented: "Freshly prepared solutions * * * do not give a blue color * * *" (47 FR 22760 at 22883). The agency agrees with the comments that properly manufactured povidone-iodine solution must comply with the appropriate U.S.P. standards that include two identification tests: one in which the formation of a blue color confirms the presence of available iodine in the povidone-iodine solution, and the other in which the lack of a blue color confirms that free iodine is not being released into the atmosphere (Ref. 6). The absence of free iodine in the atmosphere is indicative that the vapor pressure of povidone-iodine solution is virtually zero in contrast to the high vapor pressure demonstrated by iodine tincture.

Regarding the Panel's statement that "The addition of sodium bicarbonate makes aqueous solutions [pH 2.0] less acidic, but also less stable" (47 FR 22760 at 22883), the agency notes that the U.S.P. specifies a pH range between 1.5 and 6.5 for povidone-iodine topical solutions (Ref. 6). Therefore, a povidone-iodine topical solution should be stable for its shelf life at any pH between 1.5 and 6.5. The agency also agrees with the comment that issues regarding stability would be governed by the CGMP regulations (21 CFR parts 210 and 211). These regulations require a written testing program to assess the stability of finished products and to determine appropriate storage conditions and an expiration date. Section 211.137(a) (21 CFR 211.137(a)) requires that products bear an expiration date supported by appropriate stability testing. However, § 211.137(g) provides that expiration dating requirements are not enforced for human OTC drug products if their labeling does not bear dosage limitations and they have been shown to be stable for at least 3 years by appropriate stability data.

The agency has reviewed the data submitted on the kinetics of iodine released from the povidone-iodine complex in solution (Refs. 3 and 4) and discussed the data in the tentative final monograph for OTC topical acne drug products (50 FR 2172 at 2173 and 2174) and in the tentative final monograph for OTC topical antifungal drug products published in the **Federal Register** of December 12, 1989 (54 FR 51136 at 51143 and 51144). The agency agrees with the comment that all of the iodine in a povidone-iodine solution is immediately available and that the rate of iodine release from the povidone-iodine complex is neither slow nor variable.

Regarding the comment's statement that povidone-iodine powder contains 10 percent available iodine and that a 10-percent solution of povidone-iodine contains 1 percent available iodine, the agency notes that "U.S.P. XXII" states that povidone-iodine powder contains not less than 9 percent and not more than 12 percent available iodine (Ref. 6). Earlier compendia (e.g., "U.S.P. XIX" (Ref. 7)) characterized a 10-percent povidone-iodine solution as equivalent to 1 percent available iodine.

Regarding the data submitted to confirm the in vitro microbiological consequences of the povidone-iodine complex's release mechanism (Ref. 5), the agency discusses the oral antimicrobial effectiveness of povidone-iodine in section I.I., comment 16.

One comment requested that the introductory portion on povidone-iodine in the Panel's report should be rewritten to reflect these corrections. Although the agency acknowledges some ambiguities in the Panel's introductory discussion of povidone-iodine (47 FR 22760 at 22882 to 22885), it does not see a need to rewrite that discussion. The agency believes that the above response should add to and clarify the Panel's discussion of the chemical and physical nature of povidone-iodine in solution.

References

(1) Comment No. C00010, Docket No. 81N-0033, Dockets Management Branch.

(2) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 2343, September and October, 1982.

(3) Schenck, H. U. et al., "Structure of Povidone-Iodine," in "Current Chemotherapy and Infectious Disease," Vol. I, American Society of Microbiology, Washington, pp. 477–478, 1980.

(4) Ditter, W., D. Horn, and E. Luedekke, "Thermodynamic and Kinetic Examinations Concerning the Complex Binding State and the Rate of Liberation of Iodine from Aqueous Iodine-PVP-Solutions," in Comment No. C00020, Docket No. 81N-0033, Dockets Management Branch.

(5) Marcus Research Laboratory Inc., Chemists, "Povidone-Iodine U.S.P., Chemistry, Microbiology, and Toxicology," in Comment No. C00020, Docket No. 81N-0033, Dockets Management Branch.

(6) "United States Pharmacopeia XXII–The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1119, 1989.

(7) "United States Pharmacopeia XIX," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 396, 1975.

J. Comments on Dosages for Oral Antiseptic Ingredients

19. One comment stated that the dosage level of 0.025 percent eucalyptol, as recommended in the Oral Cavity Panel's majority report on antimicrobial agents (47 FR 22760 at 22873), is incomplete. The comment contended that the dosage should read 0.025 to 0.1 percent concentration, the range reviewed by the Panel and correctly listed in the Panel's evaluation of eucalyptol as an anesthetic/analgesic (47 FR 22827).

The agency has reviewed the administrative record regarding the Panel's evaluation of eucalyptol as an antimicrobial agent and notes that one product submitted to the Panel contained eucalyptol at a concentration of 0.025 percent (Ref. 1), while another submitted product contained 0.091 percent eucalyptol (Ref. 2). The Panel also reviewed data on products containing eucalyptol used as an anesthetic/analgesic ingredient in the same dosage range (i.e., 0.025 to 0.091 percent) and apparently rounded off the 0.091 percent dose in the data to 0.1 percent in its report. Therefore, the agency agrees with the comment that the proposed dosage range for eucalyptol as an antiseptic agent should also have read 0.025 to 0.1 percent. However, because eucalyptol is classified as Category III as both an oral health care antiseptic and anesthetic/analgesic ingredient in the OTC oral health care drug products rulemaking, the proposed dosage range serves only as a guide to anyone interested in testing eucalyptol for upgrading to Category I. However, data on any concentration of eucalyptol may be submitted.

References

(1) OTC Vol. 130053.
(2) OTC Vol. 130042.

K. Comments on Labeling for Oral Antiseptic Ingredients

20. Three comments objected to the Oral Cavity Panel's recommendation that the term "antiseptic" and any reference to the pharmacologic effects of antimicrobial agents not be included in its recommended monograph. One comment stated that the Panel's position is contrary to the act, which requires a statement of pharmacologic effect or class of drug in OTC labeling. Another comment contended that the term "antiseptic" should be preserved in the statement of identity because, by traditional definition, an antiseptic is a substance that kills or inhibits the growth of microorganisms. Stating that antiseptic activity is synonymous with antimicrobial activity, the comment requested the approval of the following terms as statements of identity for OTC oral antimicrobials: (1) Oral antimicrobial, (2) oral antiseptic, and (3) oral antibacterial. The other comment added that the terms "antiseptic" and "kills germs" should be placed in Category I in the tentative final monograph.

In discussing the use of the terms "antiseptic," "disinfectant," and "antimicrobial agent," the Oral Cavity Panel stated that the term "antimicrobial agent" describes an ingredient in OTC oral health care drug products that kills or interferes with the proliferation and activity of microorganisms, both pathogenic or nonpathogenic, and that a therapeutic benefit may or may not be derived from its use (47 FR 22760 at 22833). The Panel defined the term "antiseptic" as an antimicrobial agent that, when used on living tissue, produces some therapeutic benefit and acts to counteract an infection. A "disinfectant" was defined as an antimicrobial agent used on inanimate objects. Thus, the Panel considered the term "antimicrobial agent" to be a general term that encompasses both antiseptics and disinfectants, disregarding how the ingredient is used. The Panel included the following statement of identity in § 356.51(a) of its recommended monograph (47 FR 22760 at 22928): "oral health care antimicrobial."

The agency disagrees with the Panel's recommendation that the term "antiseptic" not be used as part of the statement of identity for antimicrobial agents contained in OTC oral health care drug products (47 FR 22760 at 22833). The agency believes that the Panel was opposed to the term "antiseptic" because, according to the Panel's definition, this term implies therapeutic benefit and the Panel was not convinced of the effectiveness of OTC antiseptics in providing a therapeutic benefit, i.e., relief of sore mouth and sore throat symptoms. However, the agency believes that the term "oral antiseptic" is appropriate for use in the statement of identity for the active ingredients included in this segment of the oral health care drug products rulemaking. Those found effective could provide a therapeutic benefit. An antiseptic is a substance that can kill or inhibit the growth of microorganisms when applied to living tissues without significant harm to the tissues (Ref. 1). This definition is in keeping with the definition of an antiseptic in section 201(o) of the act (21 U.S.C. 321(o)). If safety and effectiveness data support the inclusion in Category I of any antiseptic active ingredient(s) for OTC use in oral health care drug products, the agency believes that the term "antiseptic" is well recognized by consumers and can appropriately be used in the labeling for such products.

The agency believes that the term "health care," while appropriate for classification purposes and used to identify this rulemaking, is cumbersome and unnecessary in consumer labeling as a statement of identity for an OTC oral antiseptic. Therefore, in this tentative final monograph, the agency is proposing to revise the statement of identity in § 356.51(a) of the Panel's recommended monograph (47 FR 22928) to include the term "antiseptic" instead of the term "health care antimicrobial." The agency is also revising the statement of identity to include dosage forms (see section I.K., comment 21), and is renumbering the statement of identity section as § 356.64(a).

Because the term "antiseptic" is well recognized by consumers and because the agency wishes to minimize consumer confusion about the labeling of similar marketed products, the terms "oral antimicrobial" and "oral antibacterial" are not being included as alternate statements of identity for this class of drug products. However, the agency has no objection to such terms appearing in the labeling as other information provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information.

The agency is not including in this tentative final monograph the Panel's definition for an antimicrobial agent in § 356.3(c) of its recommended monograph (47 FR 22760 at 22927). Instead, the agency is proposing definitions for the terms "antiseptic drug" and "oral antiseptic" in § 356.3 as follows:

Antiseptic drug. In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

Oral antiseptic. An antiseptic-containing drug product applied topically to the oral cavity to help prevent infection in wounds caused by minor oral irritations, cuts,

scrapes, or injury following minor dental procedures.

The agency believes that claims such as "kills germs" could be potentially misleading to the average consumer if directly associated with the term "infection" that is included in the indication. The term "kill germs" may be interpreted to imply elimination of all bacteria in the mouth when, in fact, oral antiseptics used in the mouth only decrease the number of certain bacteria. However, the agency believes this term is familiar to the average consumer and may be useful in describing a product's action or intended effect. Although this term is not included in the monograph, it may be included in labeling of oral antiseptic drug products provided it is not intermingled with labeling established by the monograph and is not used in a false or misleading manner.

Reference

(1) Berkow, R., editor, "The Merck Manual of Diagnosis and Therapy," 14th ed., Merck and Co., Inc., Rahway, NJ, p. 2300, 1982.

21. One comment requested that the agency approve the following statements of identity, and any reasonably synonymous statements, for the combination of 0.045 percent cetylpyridinium chloride and 0.005 percent domiphen bromide: "(1) oral antiseptic, (2) oral antimicrobial, (3) mouthwash, (4) gargle, and (5) mouthwash and gargle."

The statement of identity for oral health care antiseptics is discussed in section I.K., comments 20 and 22. As explained there, the agency believes that the term "oral antiseptic" is appropriate as the statement of identity for these products. Because the term "antiseptic" is well recognized by consumers, and in order to avoid confusion in the marketplace, the term "oral antimicrobial" is not being included in the monograph as an alternate statement of identity. However, the agency has no objection to the term "oral antimicrobial" appearing in the labeling as other information provided it is not intermingled with labeling established by the monograph, and it is not used in a false or misleading manner.

In accord with 21 CFR 201.61, wherever possible, the agency prefers to use the general pharmacological category as the statement of identity for OTC drug products; where this is not appropriate, the principal intended action is used. The terms "mouthwash," "gargle," or "mouthwash and gargle" by themselves do not inform consumers of the pharmacological category or the principal intended action of a drug product. The agency recognizes that oral products have been marketed for years as "mouthwashes," "gargles," and "mouthwashes and gargles." However, many of these products have been marketed for daily long-term use as cosmetics, and the agency believes that consumers associate the term mouthwash with such unlimited cosmetic use. In this document, the agency is proposing to limit the use of oral antiseptic drug products to 7 days or less. The agency believes that use of the term "mouthwash" on such products could be confusing to consumers, who might be led to assume that the product could be used for an unlimited period of time. However, the agency believes that use of the term "rinse" in the statement of identity would be acceptable because the term "rinse" implies a therapeutic use (e.g., fluoride rinse). Also, the agency does not oppose the inclusion of the term "gargle" in the statement of identity, when included in addition to the required pharmacological category. Therefore, in this tentative final monograph, the agency is proposing an alternate statement of identity for oral antiseptics to include a choice of terms describing the appropriate dosage form of the product, i.e., "rinse," "gargle," or "rinse and gargle," as follows: The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral antiseptic," or an "antiseptic" (select one of the following: "rinse," "gargle," or "rinse and gargle"). (See section I.K., comment 20.)

In this tentative final monograph, the agency is classifying cetylpyridinium chloride, domiphen bromide, and a combination of cetylpyridinium chloride and domiphen bromide in Category III for effectiveness as oral health care antiseptics. (See section I.E., comment 9; section I.G., comment 13; and section I.L., comments 30 and 31.) If cetylpyridinium chloride, domiphen bromide, or a combination of these ingredients are upgraded to Category I for OTC oral antiseptic use, the product may be labeled with either statement of identity proposed in § 356.64(a) of this tentative final monograph.

22. Four comments objected to the Oral Cavity Panel's position that antimicrobial agents should not be used for therapeutic purposes in OTC oral health care products. Three of the comments disagreed with the Panel's statement that antiseptics are used in an attempt to sterilize intact cutaneous and mucous surfaces, contaminated or infected wounds, mucosal ulcerations, or other lesions caused by pathogenic microbial activity (47 FR 22760 at 22831). The comments pointed out that topical antimicrobials are used to decrease the number of bacteria present and to help prevent the chance of infection after minor injury to the mouth or gums; they are not used as sterilizing agents. The comments presented excerpts from the advance notice of proposed rulemaking on alcohol drug products for topical antimicrobial OTC human use published in the **Federal Register** of May 21, 1982 (47 FR 22324) and the tentative final monograph on OTC topical antibiotic drug products published in the **Federal Register** of July 9, 1982 (47 FR 29986) which, they stated, show that the Miscellaneous External Panel and the agency, respectively, favor the use of antimicrobial agents to reduce the number of bacteria on the skin and thus help prevent infection. One of the comments also pointed out that the Oral Cavity Panel's position is directly contrary to that of the Dental Panel which found that the use of an oral antimicrobial is rational therapy (47 FR 22712 at 22720).

One comment noted that the Oral Cavity Panel identified and evaluated two categories of products containing antimicrobial active ingredients: (1) Those used on a short-term basis to relieve symptoms of sore mouth or sore throat, or both, due to microbial infections, and (2) those used on a long-term, often day-to-day, basis. The comment contended that the category of products used on a short-term basis should be further divided into two groups: (1) Products used on a short-term basis that are applied locally (i.e., to the affected site of infection to reduce the number of bacteria), and (2) products used on a short-term basis that are applied to the total oral cavity.

Stating that presentations had been made to the Oral Cavity Panel concerning the existence of a target population for locally applied topical antiseptics, the comment felt that the data supplied on the historical use of topical antiseptics to assist in preventing infection were adequate to establish an oral first aid antiseptic category (Ref. 1). The comment stated that the only indication provided by the Panel for any OTC oral antimicrobial ingredient does not address the issue of reducing organisms at the lesion or site of infection to help prevent oral infection, i.e., the "first aid" category. The comment requested that the following indication and other allowable indications be included as Category I labeling:

Indication: First aid and/or antiseptic to help prevent infection in wounds caused by minor oral irritation; cuts, scrapes or injury

such as following minor dental procedures or from dentures and orthodontic appliances.

Other Allowable Indications: (i) "Decreases" or "Helps" reduce the number of bacteria on the treated area.

(ii) Helps "prevent," "guard against," or "protect against" oral infections.

(iii) Helps reduce the "risk" or "chance" of oral infection.

(iv) Helps prevent bacterial contamination in minor injuries or lesions of the mouth.

The comment also requested that, based upon available data, carbamide peroxide in anhydrous glycerin, sodium phenolate and phenol, and povidone-iodine be classified in Category I as topical antiseptics for local application.

Regarding the Oral Cavity Panel's statement that antiseptics are used in an attempt to sterilize surfaces, wounds, and lesions caused by pathogenic microbial activity (47 FR 22760 at 22831), the agency agrees with the comments that most of the antiseptic agents used in OTC health care drug products are not effective as sterilizing agents. For an antiseptic agent to be an effective sterilizing agent, the ingredient must be sporicidal, i.e., must kill bacterial spores. The majority of the antiseptics used in OTC oral health care products will not destroy bacterial spores. However, as the Panel stated, "Topical antimicrobial ingredients are applied to the mucous membranes of the mouth and throat to kill, inhibit the proliferation of, or alter the metabolic activity of all types of microorganisms, both pathogenic and nonpathogenic," (47 FR 22760 at 22831). The antiseptics are used in an "attempt to sterilize" intact surfaces with complete sterilization of the wound site viewed as the ultimate achievement by the drug. In an ideal sense, a drug that could sterilize a wound site would be very beneficial in the treatment of cuts and scratches. The agency believes that is the point the Panel was trying to relate in its description of the effects of these drugs.

The agency notes that the Panel listed nine reasons why it believed that antiseptic ingredients should not be used in OTC oral health care drug products (47 FR 22760 at 22834). Most of the reasons were based on the Panel's belief that: (1) Antiseptics are nonspecific ingredients that would not be effective in treating wounds in the oral cavity and could possibly be harmful, (2) these ingredients do not penetrate deeply into tissue, and (3) the ingredients would be significantly diluted and removed from the wound site by the action of saliva. Therefore, the Panel did not recommend any Category I indications for antiseptics, but instead included a Category III indication, "For the temporary relief of minor sore mouth and sore throat by decreasing the germs in the mouth." However, the agency disagrees with the Panel's position that antiseptic ingredients should not be used for other therapeutic purposes in OTC oral health care drug products. The agency believes that antiseptics may be useful in helping to reduce the chance of infection in minor sore mouth conditions by decreasing the number of bacteria on the mucous membranes of the mouth.

Two of the studies submitted by one comment provide support that there is a target population that would benefit from the availability of an OTC antiseptic drug product to help prevent or reduce the incidence of certain oral conditions (Ref. 1). Addy et al. (Ref. 2) reported that an antibacterial mouthwash (0.2 percent chlorhexidine gluconate) reduced the incidence, duration, and severity of aphthous ulcers (canker sores) as compared to a control and an astringent mouthwash when evaluated subjectively. The mouthwash was used for 1 minute three times daily for a period of 5 weeks. The authors speculated that, in such conditions, oral hygiene is frequently neglected due to oral discomfort that further increases the possibility of infection from bacterial plaque deposits. Thus, attempts to reduce secondary infection of the aphthous ulcers may be of value for the patient. Olsen (Ref. 3) evaluated patients with denture stomatitis. The treatment consisted of each patient sucking placebo, amphotericin B, or chlorhexidine chloride lozenges combined with denture soaking in a 0.2-percent aqueous solution of chlorhexidine digluconate. Olsen concluded that denture disinfection was an essential part in the management of denture stomatitis, finding that denture immersion in 0.2 percent chlorhexidine solution significantly reduced the number of organisms both on the mucous membranes and on the denture. The combination of amphotericin B lozenges and chlorhexidine denture disinfection was the most effective regimen. Although chlorhexidine, a drug available by prescription for oral use, was used in the studies, the agency believes that these studies do support the existence of a target population that would benefit from the use of antiseptic ingredients in helping to alleviate some oral conditions. However, additional data are needed to support the above indications for OTC oral antiseptics.

The Panel identified two categories of products containing antiseptics for oral use: (1) Those used on a short-term basis to relieve symptoms of sore mouth and sore throat, or both, due to microbial infections, and (2) those used on a long-term, often day-to-day, basis for cleansing the mouth, suppressing mouth odors, and other related purposes in which no symptoms of an infectious process are evident but for which antiseptic claims are made (47 FR 22760 at 22890).

The agency does not see a need at this time to follow one comment's request to subdivide the category of OTC oral antiseptic products used on a short-term basis into two groups: (1) Those applied locally, and (2) those applied to the total oral cavity. The agency believes that on a short-term basis antiseptic ingredients can be used for local application or for application to the total oral cavity to help prevent infection in minor sore mouth conditions. Other monographs, e.g., the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33677) and the amendment to the tentative final monograph for OTC oral health care drug products (56 FR 48302 at 48343 to 48346), identify situations where short-term use of a product for minor sore mouth conditions is appropriate for consumer selfmedication (e.g., use in minor oral wounds, accidental injury or irritation of the mouth or gums, or minor wounds resulting from orthodontic appliances or dentures). Accordingly, the agency is proposing the following indication for these products in this tentative final monograph:

"First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "infection" or "bacterial contamination") "in" (select any of the following: "minor cuts," "minor scrapes," or "minor oral irritation") (which may be followed by) "caused by" (select any of the following: "dental procedures," "dentures," "orthodontic appliances," or "accidental injury").

The Panel's Category III indication for oral antiseptics also included use of these ingredients for sore throat by decreasing the number of germs in the mouth. The agency has determined that this part of the indication should remain in Category III because inadequate data have been submitted to support a "relief of sore throat" indication.

The agency notes that the Panel discussed long-term uses of oral antiseptics to cleanse the mouth and suppress mouth odors. The agency considers such uses to be cosmetic in nature. Cosmetic claims are not subject to this rulemaking. (See section I.A., comment 3.) However, antiseptic

mouthwashes used on a long-term basis for plaque reduction are considered drugs. The agency will address the long-term use of antiseptic mouthwash products for plaque reduction in a subsequent segment of the OTC oral health care drug product rulemaking. (See section I.A., comment 1 and section I.M., comment 32.)

In conclusion, the agency agrees with the comment that a first aid claim is appropriate for OTC oral antiseptics and is proposing such a claim in this tentative final monograph. Claims related to "sore throat," "canker sores," and "denture stomatitis" are Category III because additional data are needed to support these claims for OTC oral antiseptics. The agency's evaluations of the ingredients phenol and povidone-iodine, requested by the comment for Category I classification, are discussed in section I.H., comment 14 and section I.I., comment 16. No additional data were submitted to support the efficacy of carbamide peroxide; thus, this ingredient remains in Category III in this tentative final monograph. The agency invites the submission of data to support reclassification of any oral antiseptic ingredient(s) from Category III to Category I.

References

(1) Comment No. LET004 and OTC Vols. 130132 and 130163, Docket No. 81N–0033, Dockets Management Branch.

(2) Addy, M. et al., "Trial of Astringent and Antibacterial Mouthwashes in the Management of Recurrent Aphthous Ulceration," *British Dental Journal*, 136:452–455, 1974.

(3) Olsen, I., "Denture Stomatitis—Effects of Chlorhexidine and Amphotericin B on the Mycotic Flora," *Acta Odontologica Scandinavica*, 33:41–46, 1974.

23. One comment requested that the agency amend the Oral Cavity Panel's Category III indication for oral health care antimicrobials that states "For the temporary relief of minor sore mouth and sore throat by decreasing the germs in the mouth" (47 FR 22760 at 22889). The comment claimed that a portion of the statement, "by decreasing the germs in the mouth," is not an indication for use, but is a statement of mechanism of action and should be deleted from the proposed indication. The comment stated that including a mechanism of action in the indication is not consistent with the labeling of other OTC oral health care products such as anesthetic/analgesic agents, astringents, debriding agents, or demulcents. Another comment requested that the agency place the following labeling claim in Category I for the combination of 0.045 percent cetylpyridinium chloride and 0.005 percent domiphen bromide: "Temporarily reduces bacteria in the mouth and throat."

The agency acknowledges that the Oral Cavity Panel's recommended Category III indication for oral antiseptics contains a phrase denoting a mechanism of action as does the agency's proposed Category I indication (see section I.K., comment 22). However, this type of labeling is not inconsistent with some of the labeling indications proposed by the agency for other oral health care drug products. For example, the agency's proposed indication for debriding agents, which states "aids in the removal of phlegm, mucus * * * associated with occasional sore mouth" (56 FR 48302 at 48345), and the proposed indication for demulcent drugs, which states "* * * protection of irritated areas in sore mouth and sore throat" (56 FR 48346), contain wording denoting a mechanism of action. Thus, although monograph indications do not always include a mechanism of action, at times such labeling is included in a monograph.

The agency does not believe that the labeling claim requested by one comment, "Temporarily reduces bacteria in the mouth and throat," is an appropriate indication for OTC oral health care drug products. The indication does not inform consumers of what benefit might be expected to result from reducing the bacteria in the mouth and throat. Furthermore, the agency is not aware of any data demonstrating that reducing the bacteria in the throat has a therapeutic benefit. However, the agency has no objection to labeling referring to reduction of bacteria in the mouth (e.g., temporarily reduces the number of bacteria in the mouth) appearing in the labeling of OTC oral antiseptic drug products as other information, provided it is not intermixed with labeling established by the monograph and it is not used in a false or misleading manner.

24. One comment objected to the Oral Cavity Panel's Category II classification of the indication that states "Helps provide soothing temporary relief of dryness and minor irritations of the mouth," (47 FR 22760 at 22858) for mouthwash products containing povidone-iodine. The comment mentioned that the Panel concluded that this statement indicates that the product is used for cosmetic purposes but implies that the product exerts a therapeutic effect (47 FR 22857 to 22858). The comment felt that dryness and irritation of the mouth and throat are recognized by the consumer as an abnormal condition and are thought to be synonymous with such statements as "minor irritation, pain, sore mouth, and sore throat," "discomfort," and "irritated areas in sore mouth and sore throat." The comment claimed that these statements should be permitted as an alternate or adjunct to Category I labeling for antimicrobial products, where the effects are documented with substantial evidence.

The comment added that substantial evidence was submitted to show that a povidone-iodine mouthwash provides relief of dryness and minor irritations of the mouth and throat. The comment referred to evidence supporting this indication, approved under NDA 10–290, but the comment did not include any additional data concerning this claim. The comment requested that the following indications be allowed under § 356.51 for antimicrobial drug products containing povidone-iodine: (1) "To help (or Helps) provide soothing temporary relief of dryness and minor irritations of the mouth and throat," and (2) "Aids in the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat." The comment noted that this second indication was recommended by the Oral Cavity Panel for astringent drug products.

A second comment stated that the indications "An aid to daily oral care," and "Provides soothing temporary relief of dryness and minor irritations of the mouth and throat," and any reasonably synonymous statements, should be approved for the combination of cetylpyridinium chloride 0.045 percent and domiphen bromide 0.005 percent. A third comment requested that the following claim be approved for use on products containing cetylpyridinium chloride: "For daily use as an adjunct to good oral hygiene."

In the **Federal Register** of December 2, 1971 (36 FR 23000), as part of the agency's DESI program, the agency stated that mouthwash and gargle products reviewed under the DESI program would now be under the purview of the OTC drug review; thus, final agency action on these products was deferred pending evaluation of the data and information concerning such products under the OTC drug review. However, in the meantime, the agency found the following labeling claims acceptable for mouthwash products, on an interim basis: "To help provide soothing temporary relief of dryness and minor irritations of the mouth and throat," "an aromatic mouth freshener," "an aid to daily care of the mouth," and "for causing the mouth to feel clean." Thus, the comments' requested indication, "To help provide soothing temporary relief of dryness and minor irritations of the mouth and throat," was allowed as a result of that DESI notice.

In this tentative final monograph, the agency is further addressing the claims permitted by that DESI notice and requested by the comments.

The agency believes that the Panel was correct in placing the statement "Helps provide soothing temporary relief of dryness and minor irritations of the mouth" and similar statements in Category II as an indication for the use of drug products containing antiseptic ingredients. However, the agency believes that the Panel erred when it included this statement under the heading of "Statements or phrases that indicate a product is used for cosmetic purposes but imply that the product exerts a therapeutic effect" (47 FR 22760 at 22857 and 22858). Statements containing phrases such as "relief of dryness" and "irritation of the mouth and throat" are more appropriate as indications for drug products containing astringents (47 FR 22904) and demulcents (47 FR 22919). Astringents alleviate irritation of the mouth and throat and demulcents exert therapeutic actions that will alleviate the conditions of "dryness" and "irritation." On the other hand, the agency does not have adequate evidence showing that antiseptic ingredients are effective in alleviating dryness or irritation of the mouth. These ingredients act by destroying microorganisms that may be present, and there is no proof that the destruction of microorganisms alleviates dryness or irritation.

Regarding the substantial evidence supporting the claim of "relief of dryness and minor irritations of the mouth and throat" mentioned by the first comment, the agency notes that no data were submitted to show that consumers associate the therapeutic activity of an antiseptic agent with the relief of dryness and minor irritations, nor were adequately controlled studies substantiating the claim included in NDA 10–290. Therefore, the agency is not proposing such claims for any antiseptic products.

The agency has already proposed a "relief of dryness" claim for demulcent ingredients as part of this rulemaking in § 356.58 of the amendment to the tentative final monograph for OTC oral health care drug products (56 FR 48302 at 48346). That claim states: "For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat." As mentioned by one comment, the proposed indications for oral health care astringent ingredients presently include a claim for "relief of minor irritation." (See proposed § 356.54 in the amendment to the tentative final monograph for OTC oral health care drug products (56 FR 48345).)

With regard to the other labeling claims permitted in the December 2, 1971 DESI notice and the labeling claims suggested by the second and third comments, i.e., "An aid to daily oral care" and "For daily use as an adjunct to good oral hygiene," the agency now considers these types of claims to be cosmetic claims that are not subject to this rulemaking. (See section I.A., comment 3.)

25. One comment stated that the 2-day duration of treatment recommended by the Oral Cavity Panel for antimicrobial drug products (47 FR 22760 at 22928) is insufficient "to address normal healing time." Stating that the Topical Antimicrobial Drug Products Panel provided a 7-day use limit, the comment recommended that a 7-day duration of use be adopted for this monograph.

The Oral Cavity Panel recommended the 2-day use limit for all OTC oral health care drug products because of the risk of serious illness if appropriate treatment of a sore throat is delayed. However, although a sore mouth may denote the presence of a condition that requires diagnosis and treatment by a physician, in most cases it is caused by minor ulcerations and other benign conditions that are self-limited, last only short periods of time, and generally heal spontaneously in 7 to 10 days (47 FR 22760 at 22774 to 22776). As stated in the first segment of the oral health care drug products tentative final monograph (53 FR 2436 at 2448), the agency believes that because symptoms associated with a sore mouth are unlikely to be indicative of a serious health threat, a 7-day use limitation of an OTC oral health care drug product is appropriate for the relief of symptoms of a sore mouth, e.g., pain and minor irritation. Because a sore throat can be the symptom of a serious disease and may require more immediate attention, the agency believes that it is necessary to place a 2-day limit on the use of an OTC oral health care drug product that is used to relieve symptoms of a sore throat.

For these reasons, in an amendment to the first segment of the OTC oral health care drug products tentative final rulemaking (56 FR 48302 at 48343 and 48346), the agency subsequently proposed the following warning for OTC oral health care drug products that are indicated for the relief of sore mouth and sore throat symptoms: "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly." For products labeled for the relief of sore mouth only, the proposed warning reads: "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days, if irritation, pain, or redness persists or worsens, or if swelling, rash, or fever develops, see your dentist or doctor promptly." (See 56 FR 48302 at 48343, 48345, and 48346.)

Likewise, the agency believes that part of this proposed warning may be applicable to OTC oral health care antiseptic drug products. At this time, sore throat claims are Category III for oral antiseptic ingredients. Therefore, in this document, the agency is not proposing the first portion of the above warning for oral health care drug products that are indicated for the relief of sore throat. If sore throat claims for oral antiseptic ingredients are upgraded to Category I, the agency will include the first portion of the above warning in the final monograph for oral antiseptic drug products. The agency is proposing in this amendment to the OTC oral health care tentative final monograph that the second portion of the above warning replace the warnings recommended by the Panel in § 356.51(c)(1)(i) and (c)(1)(ii). The agency believes that this warning fully conveys the intent of the Panel's recommended warnings. This warning is included in § 356.64(c) of this tentative final monograph in case any oral antiseptic ingredients are classified in Category I to help in reducing the chance of infection in minor oral irritations.

26. One comment requested that the agency approve the following wording, as well as reasonable variations thereof, for directions for use for OTC oral antimicrobials/antiseptics: "Rinse or gargle for 20 seconds with one ounce first thing in the morning, after meals, and before social engagements."

In this tentative final monograph, the agency is addressing only the drug use of antiseptic ingredients in oral rinses and gargles. The agency believes that the comment's suggested directions for use apply to the cosmetic use of oral antiseptic products for the suppression of oral malodor (e.g., "first thing in the morning," and "before social engagements") and for oral cleansing (e.g., "after meals"). Such directions are not appropriate for the drug use of these products and therefore are not being included in this tentative final monograph. However, antiseptic

products intended for use only as cosmetics are not subject to this rulemaking and may bear appropriate directions and other labeling for cosmetic uses. (See section I.A., comment 3.)

27. One comment requested that the following professional labeling for povidone-iodine be included in the oral health care drug products monograph: "Professional labeling—for local degerming prior to dental prophylaxis and gingivectomy." Noting that the Antimicrobial I Panel recommended labeling limited to professional use, the comment stated that professional labeling should likewise be allowed for oral health care drug products. The comment explained that the value of local degerming using povidone-iodine mouthwash in dental prophylaxis and gingivectomy procedures was shown in studies presented to the Panel (Ref. 1). The comment added that the studies demonstrated substantial evidence of the effectiveness of povidone-iodine mouthwash/gargle in significantly reducing gingival surface bacteria prior to dental prophylaxis and procedures, thereby reducing the risk of systemic infection.

In the tentative final monograph for OTC health care antiseptic drug products that will be published in a future issue of the **Federal Register**, the agency intends to propose povidone-iodine in Category I for use as a patient preoperative skin preparation, a surgical hand scrub, and a health care personnel handwash. The agency has reevaluated the data submitted to the Oral Cavity Panel (Ref. 1) and believes that some of the submitted data (Refs. 2 and 3) support the requested professional labeling for povidone-iodine in aqueous solution.

The Oral Cavity Panel stated that povidone-iodine's "application on the injection site of the oral mucosa prior to administering local anesthesia virtually eliminates all readily cultivable organisms" (47 FR 22760 at 22884). The Panel cited three studies (Refs. 2, 4, and 5) that indicate that irrigation of the gingival sulcus and rinsing the mouth with povidone-iodine immediately before tooth extraction or gingivectomy markedly reduces the incidence of associated bacteremia (i.e., the presence of bacteria in the blood). However, because two of the cited studies (Refs. 4 and 5) were published only in abstract form, the Panel considered the data insufficient in detail to be properly evaluated (47 FR 22884).

One study cited by the Panel (Ref. 2) is supportive of professional labeling for povidone-iodine solution for use in local degerming prior to dental prophylaxis and gingivectomy. In this study, 52 patients scheduled for gingivectomy were randomly divided into two equal groups. Test patients were administered a 0.5-percent povidone-iodine solution, whereas control patients were administered a placebo solution that was identical in appearance to the povidone-iodine solution but contained no povidone-iodine. Immediately prior to gingivectomy, each patient rinsed for 30 seconds with about 20 mL of the assigned preparations. The solution was then expectorated and, after a 2-minute interval, the rinsing was repeated. The sulci of the teeth in the quadrant scheduled for gingivectomy and the surrounding mucosa were then irrigated for about 1 minute using 20 mL of the assigned liquid delivered by a standard syringe with a blunt, angulated needle. Gingival surface samples were obtained by swabbing the gingiva just prior to rinsing and immediately after irrigation with the assigned preparation. These gingival swabs provided the inoculum for blood agar plates that were incubated aerobically and anaerobically at 36 °C for 48 hours. After incubation, the colonies on the plates were counted. The grading system for estimating the number of bacterial colonies per plate ranged from 1+ (i.e., few) to 4+ (i.e., too-numerous-to-count), and the major genera and/or species were enumerated. About 15 mL of blood were drawn from each patient before rinsing with the assigned preparation and within 3 minutes after the gingivectomy. The samples were cultured aerobically and anaerobically, and subsequent isolates were identified by standard bacteriological procedures.

The use of the povidone-iodine solution significantly reduced the incidence of post-gingivectomy bacteremia ($p < 0.5$). Fifteen control patients developed positive blood cultures, but only six patients in the test group developed positive blood cultures. Virtually all prerinse bacterial cultures resulted in colony count scores of 4+. Use of the test preparation produced an average decrease of 33 to 42 percent in colony count scores (for example, a decrease from a average score of 4+ to a average score of 2.7). Comparable degerming occurred for both aerobic and anaerobic bacteria.

In a double-blind clinical study (Ref. 3), Scopp and Orvieto randomly assigned 64 patients requiring dental extraction into two groups. One group of 32 patients was prepared preoperatively by gingival sulcal irrigation and rinsing with a 0.5-percent povidone-iodine oral rinse; the other 32 patients were prepared preoperatively in the same manner except that a placebo solution (colored, flavored, and packaged to match the active drug) was used for irrigation and rinsing. All patients were instructed to rinse for 30 seconds with 10 to 20 mL of the assigned oral rinse, then wait 2 minutes and repeat the rinse. The gingival sulcus of each tooth to be extracted and the surrounding gingival mucosa were then irrigated for approximately 1 minute with 10 to 20 mL of the assigned solution using a standard syringe and blunt, angulated needle. Prior to rinsing and immediately after irrigation, cultures of the gingival sulcus were obtained. Dental extraction was performed without further antisepsis. Blood samples were obtained for culture before rinsing and within 3 minutes after the dental extraction.

Bacteremia (i.e., positive blood cultures) occurred in 28 percent of the patients using the povidone-iodine oral rinse and in 56 percent of the patients using the placebo solution. The difference between the two groups is statistically significant in favor of povidone-iodine ($p < 0.05$). The gingival sulcus cultures taken immediately after rinsing and irrigation with the povidone-iodine oral rinse showed reduction or elimination of bacteria in 14 patients, no change in 17 patients, and increased growth in 1 patient. For the placebo group, the gingival sulcus cultures showed no growth and reduced growth in 1 patient each, no change in 28 patients, and increased growth in 2 patients. The difference in bacterial reduction of the gingival sac in the two groups is also statistically significant ($p < 0.01$).

The agency believes that these studies demonstrate the effectiveness of a 0.5-percent povidone-iodine aqueous solution for the preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction when used by a health care professional according to the directions proposed in § 356.80(c)(3) of this tentative final monograph. However, these studies do not demonstrate the effectiveness of povidone-iodine when used by consumers as an oral antiseptic. In order for an ingredient to be classified in Category I as an oral antiseptic, the agency believes that, among other things, the ingredient should demonstrate the ability to decrease the number of bacteria in the oral cavity over an extended period of time (e.g., up to 4 hours). In addition, the ingredient should provide clinically significant benefits under OTC conditions of use (e.g., helping to prevent infection in minor wounds in the mouth, or relieving the symptoms of sore throat). (See section I.M., comment 33 for

further discussion of testing procedures.) These data demonstrate that applying povidone-iodine according to the directions proposed in § 356.80(c)(3) of this tentative final monograph results in an immediate decrease of bacteria around the operation or extraction site and a decrease of bacteremia after oral surgery or tooth extraction. Although the studies sampled the gingival mucosa surrounding the operation sites prior to and immediately after surgery or tooth extraction, they did not demonstrate a decrease in the number of oral bacteria over an extended period of time. In addition, the organisms affected by the povidone-iodine treatment were not completely identified. Furthermore, these data do not demonstrate a therapeutic benefit from the OTC use of povidone-iodine. Therefore, the agency is classifying povidone-iodine in Category III for effectiveness as an OTC oral antiseptic in this tentative final monograph. (See section I.I., comment 16.) The agency is placing povidone-iodine in Category I for use as a dental preoperative by health care professionals and is proposing labeling for such products in § 356.80.

References

(1) OTC Vol. 130176.

(2) Brenman, H. S., and E. Randall, "Local Degerming with Povidone-Iodine II. Prior to Gingivectomy," *Journal of Periodontology*, 45:870–872, 1974.

(3) Scopp, I. W., and L. D. Orvieto, "Gingival Degerming by Povidone-Iodine Irrigation: Bacteremia Reduction in Extraction Procedures," *Journal of the American Dental Association*, 83:1294–1296, 1971.

(4) Brenman, H. S., and E. Randall, "Reduction of Gingival Bacteria and Gingivectomy-Related Bacteremia by Povidone-Iodine," *International Association of Dental Research*, (Abstract #211), 1972.

(5) Randall, E., and H. S. Brenman, "Antimicrobial Action of Povidone-Iodine Mouthwash Before and During Dental Prophylaxis," *Journal of Dental Research*, 51:101, 1972.

L. Comments on Combination Oral Antiseptic Drug Products

28. One comment noted that the Dental Panel recognized that the combination of an oral antiseptic (i.e., antimicrobial agent) and an oral wound cleanser (i.e., debriding agent) was rational and should provide additional protection for an oral wound (44 FR 63270 at 63276). The Oral Cavity Panel, however, placed the same combination in Category II because it believed that the antimicrobial agent would be diluted and washed away from the diseased surface (47 FR 22760 at 22792). The comment stated that manufacturer's directions state that these products should remain in contact with the wound site for at least 1 minute. The comment added that there are active ingredients that function as antimicrobial agents as well as debriding agents and that ingredients with both properties are effective when applied locally. The comment explained that because the purpose of an antiseptic is to decrease the number of bacteria and reduce the chance of infection after minor injuries to oral cavity tissues, the combination of a debriding agent and an antiseptic provides logical therapy to reduce chances of infection, while cleansing the wound site.

In the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436), the agency incorporated portions of the OTC oral mucosal injury rulemaking, which includes oral wound cleansers and oral wound healing agents, into the oral health care rulemaking and proposed that debriding agents and oral wound cleansers be treated as a single therapeutic class of ingredients. The agency addressed OTC oral wound healing agents separately in a final rule (51 FR 26112) and deferred consideration of the combination of an oral wound cleanser and an oral antiseptic (as recommended in § 353.20(b) by the Dental Panel) to this antiseptic segment of the rulemaking for OTC oral health care drug products.

Although the Dental Panel recommended that the combination of an oral wound cleanser and an oral antiseptic be classified as Category I, it stated in a parenthetical note that "the advisability of adding an antiseptic for the stated purpose is under review by the OTC Advisory Review Panel on Oral Cavity Drug Products" (44 FR 63270 at 63276). After reviewing both Panels' recommendations, the agency agrees with the Oral Cavity Panel's Category II classification of one or more antiseptic ingredients combined with any debriding agent. The agency is concerned that combining an antiseptic ingredient with a debriding agent/oral wound cleanser would decrease the effectiveness of the antiseptic ingredient. Because debriding agent/oral wound cleansers loosen and remove tissue, debris, mucus, etc., from mucosal surfaces by their chemical and mechanical action (e.g., foaming, lowering surface tension, and reducing viscosity of mucus), the antiseptic ingredient might not be in direct contact with the oral mucosa for a long enough period of time to exert a significant antiseptic effect, even though the manufacturer's directions state that these products should remain in contact with the wound site for at least 1 minute before spitting out. The agency believes that a reasonable time to apply a Category I antiseptic to an oral mucosal wound site or to the site of an oral inflammation is after that site has been cleansed with a debriding agent/oral wound cleanser. Additionally, the agency has surveyed the marketplace and is not aware of any currently available OTC drug product containing a combination of an oral health care antiseptic ingredient and an oral wound cleanser or debriding agent, nor were data on any such products submitted to either the Dental Panel or the Oral Cavity Panel.

The comment mentioned that some debriding agents also function effectively as antiseptic agents. However, there are no Category I debriding agent/oral wound cleansers that are also Category I antiseptic agents in this tentative final monograph.

In conclusion, for the reasons stated above, the agency is classifying the combination of an antiseptic agent and a debriding agent/oral wound cleanser in Category II in this tentative final monograph. Data are needed to show that the two ingredients are effective when used in combination.

29. Several comments pointed out that the Dental Panel had placed the following combinations in Category I in § 354.20(b), (c), and (d), respectively, of its recommended monograph: (1) An oral mucosal protectant and an oral antiseptic, (2) an oral mucosal analgesic and an oral antiseptic, and (3) an oral mucosal protectant, an oral mucosal analgesic, and an oral antiseptic. The comments noted that the Dental Panel had deferred review of the antiseptic ingredients to the Oral Cavity Panel, but that Panel failed to address locally applied antiseptics in the combinations placed in Category I by the Dental Panel. The comments maintained that these combinations are rational because the antiseptic ingredient will help to prevent or reduce possible infection while the oral mucosal analgesic will relieve the pain due to minor irritations or injury to the oral mucosa, and the addition of an oral mucosal protectant provides a coating over the wound for protection and holds the analgesic and antiseptic ingredients in place where they can act most effectively. The comments urged FDA to accept the recommendations of the Dental Panel and permit these combinations in the tentative final monograph for OTC oral health care drug products.

One of the comments added that the labeling in the tentative final monograph for OTC topical

antimicrobial drug products (47 FR 22986 at 29989) is consistent with the rationale expressed by the Dental Panel for its recommendation to place the combination of an oral mucosal analgesic and an oral antiseptic in Category I. The comment contended that the following claims could be used for topically applied oral antiseptics in such combination products:

(1) (Select one of the following: "Decreases" or "Helps reduce") "the number of bacteria on the treated area."

(2) "Helps" (select one of the following: "prevent," "guard against," or "protect against") "* * * infection."

(3) "Helps reduce the" (select one of the following "risk" or "chance") "of * * * infection."

(4) "Helps prevent bacterial contamination in minor cuts, scrapes, and burns."

The agency has reviewed the Dental Panel's discussion regarding combinations (47 FR 22712 at 22720) and, in general, agrees with that Panel that the following combinations are rational: (1) Oral antiseptic and oral anesthetic/analgesic; (2) oral antiseptic and oral mucosal protectant; (3) and oral antiseptic, oral anesthetic/analgesic, and oral mucosal protectant. In addition, the agency has reviewed the Oral Cavity Panel's evaluation of combinations containing oral antiseptic active ingredients (47 FR 22760 at 22790 to 22793) and agrees that the following combinations are reasonable: (1) Oral antiseptic and oral astringent; (2) oral antiseptic and oral demulcent; (3) oral antiseptic, oral anesthetic/analgesic, and oral astringent; and (4) oral antiseptic, oral anesthetic/analgesic, and oral demulcent. Accordingly, the agency is proposing these seven combinations in § 356.26 of this tentative final monograph.

However, this tentative final monograph does not include any Category I oral antiseptic ingredients. Therefore, these combinations will not be included in the final monograph unless at least one oral antiseptic active ingredient achieves monograph status. Further, the agency notes that the seven proposed Category I combinations may not be appropriate for all Category III oral antiseptic ingredients. For example, if hydrogen peroxide were upgraded to Category I as an oral antiseptic, it might not be appropriate to combine hydrogen peroxide with an oral mucosal protectant or an oral demulcent. As each oral antiseptic ingredient achieves monograph status, the agency will evaluate that ingredient specifically as to which combinations are suitable.

In this tentative final monograph, the indication being proposed for oral health care antiseptic drug products is similar in content to those recommended by one of the comments. (See section I.K., comment 22.) Indications for oral anesthetic/analgesic, oral astringent, oral demulcent, and oral mucosal protectant drug products were proposed in §§ 356.52(b), 356.54(b), 356.58(b), and 356.60(b) of the amendment to the tentative final monograph for OTC oral health care drug products (56 FR 48302 at 48343 to 48346).

The agency considers that the indication proposed for oral anesthetic/analgesic ingredients in § 356.52(b)(1) ("For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat,") as not appropriate for a combination product containing an oral antiseptic because "temporary relief of sore throat" is a Category III indication for OTC oral antiseptics. (See section I.K., comment 22.) In addition, the agency considers the indication proposed for oral anesthetic/analgesic ingredients in § 356.52(b)(2) ("For the temporary relief of pain associated with canker sores") as not suitable for a combination product containing an OTC oral antiseptic ingredient because claims related to canker sores are Category III for OTC oral antiseptics. Likewise, the agency does not consider the indication proposed for oral anesthetic/analgesic ingredients in § 356.52(b)(7) for denture adhesive products containing an oral anesthetic/analgesic ("For the temporary relief of pain or discomfort of the mouth and gums due to dentures") as appropriate for products containing an oral antiseptic ingredient because there is no Category I combination that includes an oral antiseptic and a denture adhesive. Therefore, when an oral antiseptic is present in certain combination products (i.e., with: (1) An oral anesthetic/analgesic, (2) an oral anesthetic/analgesic and an oral mucosal protectant, (3) an oral anesthetic/analgesic and an oral astringent, or (4) an oral anesthetic/analgesic and an oral demulcent), the labeling of the product may not contain the indications proposed for oral anesthetic/analgesic ingredients in § 356.52(b)(1), (b)(2), and (b)(7).

Additionally, the Oral Cavity Panel recommended that oral antiseptics should not be used in children under 3 years of age (47 FR 22760 at 22928). In § 356.50(d), § 356.54(d), § 356.56(d), and § 356.58(d) of the tentative final monograph for OTC oral health care drug products, the agency proposed that the lower age limit for OTC oral health care ingredients be 2 years, except for sodium perborate monohydrate (6-year lower age limit), phenol preparations that are intended for ingestion or that could be inadvertently ingested (6-year lower age limit), tooth desensitizers (12-year lower age limit), butacaine sulfate (12-year lower age limit), and teething preparations (4-month lower age limit) (56 FR 48302 at 48343 to 48346). The agency does not believe that oral antiseptics should be used in children under 2 years of age unless done so under a doctor's supervision. Therefore, the agency is not proposing the indication for oral anesthetic/analgesic ingredients in § 356.52(b)(6) for benzocaine or phenol used in products for teething pain ("For the temporary relief of sore gums due to teething in infants and children 4 months of age and older") for a combination product containing an oral antiseptic and an oral anesthetic/analgesic or an oral antiseptic, an oral anesthetic/analgesic, and an oral mucosal protectant.

The agency does not consider the indication proposed for oral astringents in § 356.54 ("For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat") as appropriate for a combination product containing an oral antiseptic and an oral astringent because oral antiseptics are not indicated for use in relieving the discomfort of sore throat. Therefore, when an oral antiseptic is combined with an oral astringent or an oral anesthetic/analgesic and an astringent, the indication proposed for oral astringent drug products in § 356.54 is not appropriate. Instead, the agency is proposing the following indication for a combination product containing an oral antiseptic and an oral astringent: "For temporary relief of occasional minor irritation, pain, and sore mouth." The agency is also proposing that a combination product containing an oral antiseptic, an oral astringent, and an oral anesthetic/analgesic be labeled with any of the applicable indications proposed in § 356.52(b)(3), (b)(4), or (b)(5) or with the indication proposed above for a combination drug product containing an oral antiseptic and an oral astringent.

The agency does not consider the indication proposed for oral demulcents in § 356.58 ("For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat") as appropriate for a combination product containing an oral antiseptic and an oral demulcent because oral antiseptics are not indicated for use in relieving the discomfort of sore throat. Therefore, when an oral antiseptic is combined with an oral demulcent or an oral anesthetic/analgesic and an oral demulcent, the indication proposed for oral demulcent drug products in

§ 356.58 is not appropriate. Instead, the agency is proposing the following indication for a combination product containing an oral antiseptic and an oral demulcent: "For temporary relief of minor discomfort and protection of irritated areas in sore mouth." The agency is also proposing that a combination product containing an oral antiseptic, an oral demulcent, and an oral anesthetic/analgesic be labeled with any of the applicable indications proposed in § 356.52(b)(3), (b)(4), or (b)(5) or with the indication proposed above for a combination product containing an oral antiseptic and an oral demulcent.

The agency has determined that the indication proposed for oral mucosal protectant active ingredients in § 356.60(b)(4) ("For protecting recurring canker sores") should not be used for a combination product containing an oral antiseptic and an oral mucosal protectant because claims related to canker sores are Category III for oral antiseptics. (See section I.K., comment 22.) Therefore, when an oral antiseptic is combined with an oral mucosal protectant, the indication proposed for oral mucosal protectants in § 356.60(b)(4) is not appropriate.

The agency also notes that certain warnings proposed for oral anesthetic/analgesic ingredients in § 356.52(c)(1), (c)(5), and (c)(6), for oral astringents in § 356.54(c), and for oral demulcents in § 356.58(c)(1) would not be applicable to certain combination products containing an oral antiseptic. The warnings in § 356.52(c)(1), § 356.54(c), and § 356.58(c)(1) are partially sore throat warnings that limit use of a product to 2 days if the sore throat is severe or is accompanied by or followed by fever, headache, rash, swelling, nausea, or vomiting. These warnings are not applicable to a combination product containing an antiseptic because an oral antiseptic is not indicated for use to relieve the symptoms of sore throat. In addition, because oral antiseptics may not be used in teething products or denture adhesives, the warnings related to such products in § 356.52(c)(5) and (c)(6) are not applicable to combination drug products containing an oral antiseptic and an oral anesthetic/analgesic or an oral antiseptic, an oral anesthetic/analgesic, and any other oral health care ingredient.

Because this tentative final monograph does not include any Category I antiseptic ingredients, the agency is not proposing any directions for oral antiseptic ingredients. The agency is reserving § 356.64(d) for directions should any oral antiseptic ingredients be included in the final monograph. Likewise, for the same reason, the agency is not proposing any directions for oral health care combination drug products containing antiseptic ingredients.

Based on the above discussion, the agency is proposing to include specific indications and warnings in § 356.66(b) and (c) for the labeling of combination drug products that include an oral antiseptic. This labeling will appear in the final monograph only if at least one oral antiseptic active ingredient achieves monograph status.

30. One comment requested that the agency approve the combination of 0.045 percent cetylpyridinium chloride and 0.005 percent domiphen bromide as a Category I oral antiseptic. The comment contended that the addition of small amounts of domiphen bromide to a formulation containing cetylpyridinium chloride enhances the in vitro activity of the formulation against gram-positive and gram-negative standard bacterial cultures. The comment contended that this performance improvement satisfies even the Oral Cavity Panel's criteria for the combination of two active ingredients from the same therapeutic category having the same pharmacological mechanism of action (47 FR 22760 at 22792). The comment added that in calling for "improvement of safety or enhanced effectiveness or both," the Panel went well beyond the existing regulatory guidelines for OTC combinations in § 330.10(a)(4)(iv), which requires only that each ingredient in the combination make a contribution to the claimed effect.

The comment submitted the results of two in vitro studies designed to justify the combination of 0.045 percent cetylpyridinium chloride and 0.005 percent domiphen bromide (Ref. 1). It also submitted a published article suggesting that this combination was more effective in a clinical study than a formulation containing cetylpyridinium as the sole oral antiseptic ingredient (Ref. 2).

The agency discussed the Oral Cavity Panel's recommendations regarding combination products in the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436 at 2450). The Panel recommended that any Category I oral health care ingredient could be combined with one or more ingredients from the same therapeutic category if each ingredient is present in its full therapeutic dose, or subtherapeutic dose where appropriate, only when there is a clear demonstration that there is an improvement of safety or enhanced effectiveness or both (47 FR 22760 at 22927). However, the agency currently uses the combination policy in § 330.10(a)(4)(iv) and its guidelines for OTC drug combination products (Ref. 3) as the criteria for evaluating all OTC combination drug products.

The combination policy in § 330.10(a)(4)(iv) states that an OTC drug may combine two or more safe and effective (Category I) ingredients when each ingredient makes a contribution to the claimed effect(s); when combining the ingredients does not decrease the safety or effectiveness of any of the individual ingredients; and when the combination, used under adequate directions for use and warnings against unsafe use, provides rational therapy for a significant proportion of the target populations. Paragraph 3 of the agency's guidelines (Ref. 3) requires that, for combinations of ingredients from the same therapeutic category with the same mechanism of action, such combinations should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation. The ingredients may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC combination policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose.

Although the agency believes that the ingredients cetylpyridium chloride and domiphen bromide in the concentrations mentioned by the comment are safe for OTC use as oral antiseptics, neither ingredient has been demonstrated to be an effective oral antiseptic. (See section I.E., comment 9 and section I.G., comment 13.) The data submitted by the comment are not adequate to demonstrate the effectiveness of either ingredient or a combination of the two ingredients. The two in vitro studies tested the ingredients against only two organisms, *Staphylococcus aureus* and *Salmonella typhosa* (Ref. 1). The agency does not believe that demonstrating antiseptic effectiveness against these two microorganisms is relevant to the use of an antiseptic in the oral cavity. The published article reported the results from a study of the effects of two mouthwashes on bacterial plaque (Ref. 2). As stated in section I.M., comment 32, the agency agrees with the Panel that reduction of plaque accumulation is not an appropriate criterion for establishing oral antiseptic effectiveness. (See

section I.M., comment 33 for a discussion of appropriate testing procedures.)

References

(1) Attachment D, C00013, Docket No. 81N–0033, Dockets Management Branch.

(2) Barnes, G. P. et al., "Effects of Two Cetylpyridinium Chloride-Containing Mouthwashes on Bacterial Plaque," C00013, Docket No. 81N–0033, Dockets Management Branch.

(3) FDA, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

31. One comment stated that cetylpyridinium chloride and domiphen bromide are effective OTC oral antiseptics and that an application (NDA 14–598) for a product containing these ingredients had been approved for 18 years, i.e., up to November 17, 1982, the date of the comment. The comment stated that NDA 14–598 established the safety and effectiveness of the active ingredients, cetylpyridinium chloride 0.045 percent and domiphen bromide 0.005 percent, and their combination; and that the same combination is used today. The comment maintained that supplementation of the application and periodic reporting have supported and even strengthened the proof of safety and effectiveness. In addition, the comment stated that extensive tests demonstrating the ability of a product containing cetylpyridinium chloride and domiphen bromide to kill bacteria and viruses in vitro were reported to the Panel (Ref. 1) and are included in NDA 14–598. The comment also stated that NDA 14–598 contains the results of numerous tests showing reduction of bacterial counts after rinsing with the product and that the application contains data showing effectiveness of the product in temporarily relieving minor sore throat. The comment stated that although the bulk of the material in NDA 14–598 is not publicly available, it is in the agency's files and may be used by the agency to support these comments. Moreover, the comment contended that it regards the continuing validity of the application as conclusive evidence of the product's safety and effectiveness for use as an OTC oral antiseptic (Ref. 2).

The agency notes that data contained in an application are confidential information covered by 21 CFR 20.61 and are not publicly available. The sponsor of the application would have to affirmatively submit these data as part of the public administrative record for the agency to consider them in this rulemaking proceeding. As the agency has indicated elsewhere under similar conditions concerning an antitussive drug product containing diphenhydramine hydrochloride (48 FR 48576 at 48582), determination by FDA that a new drug is safe and effective and the approval of an application for the drug are not synonymous with a determination that a drug is generally recognized as safe and effective in the OTC drug review. See *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 651 (1973). In addition, the agency is aware that the commentor requested that approval of NDA 14–598 be withdrawn because the product was no longer being marketed as a drug (Ref. 4).

General recognition of the effectiveness of a drug in the OTC drug review must be based on adequate published or publicly available medical and scientific data. (*United States* v. *41 Cases * * * Naremco*, 420 F.2d 1126 (C.A. 5, 1970); *United States* v. *An Article of Drug * * * Mykocert*, 345 F. Supp. 571 (D.C. 1972); *United States* v. *An Article of Drug * * * Asper Sleep, CCH F.D. and Cosm. L. Rep.* 40,821 Civil No. 70–C–196 (N.D. Ill. 1971); *United States* v. *An Article of Drug * * * (Furestorol Vaginal Suppositories* 294 F. Supp 1307 (N.D. Ga. 1968).) There is not adequate information publicly available at this time to demonstrate that cetylpyridinium chloride, domiphen bromide, or the combination of the two ingredients are generally recognized as effective for the Category I indication proposed in this document. Therefore, the agency is unable to conclude at this time that these ingredients or a combination of these ingredients are generally recognized as effective oral antiseptic agents, and is proposing that they be Category III for effectiveness. (See section I.E., comment 9; section I.G., comment 13; and section I.L., comment 30.)

References

(1) OTC Vols. 130078, 130118, 130134, 130160, and 130187.

(2) Attachment F, Comment No. C00013, Docket No. 81N–0033, Dockets Management Branch.

(3) Attachment G, Comment No. C00013, Docket No. 81N–0033, Dockets Management Branch.

(4) Letter from W. E. Cooley, The Procter & Gamble Co., to the Division of Radiopharmaceutical, Surgical, and Dental Drug Products, FDA, NDA 14–598, dated January 5, 1990, OTC Vol. 130CTFM.

M. Comments on Testing

32. Addressing the Oral Cavity Panel's consideration of protocols for testing antiseptic mouthwashes, two comments stated that the measurement of plaque reduction is a valid technique to assess the antimicrobial activity of oral antiseptics. Noting that dental plaque is largely composed of living bacteria within a polysaccharide matrix, one comment contended that experts recognize that "antiseptic activity may be measured in the mouth by taking counts of unattached organisms before and after treatment, or by measuring plaque differences among subjects receiving either the test substance or a control." The comment mentioned that the Panel's minority report outlines a scheme of reasonable in vitro and in vivo tests that are well accepted and have been shown to be satisfactory in demonstrating the antiseptic activity of mouthwashes (47 FR 22760 at 22893 to 22901). The comment added that, in 1978, the Oral Cavity Panel voted approval of the clinical protocols needed to support Category I status for oral antimicrobials for use in mouthwashes, and that a professional association of manufacturers concurred with that recommendation. The comment urged that these protocols be reinstated as the proof required to obtain Category I status for antimicrobial mouthwashes.

Also citing the Panel's minority report, the second comment stated that the majority of the Panel, at its next-to-last meeting, voted to reject the testing guidelines for demonstrating antiseptic activity that the Panel had recommended to industry over the course of several years and that the firm submitting the comment had relied upon to confirm its product's antiseptic properties. Although pointing out that the majority of the Panel evidently desired an objective test to justify plaque reduction as a criterion for establishing antimicrobial activity (47 FR 22760 at 22841), the comment contended that such an objective test was originally prescribed by the Panel and successfully conducted for the firm's mouthwash product containing a combination of volatile oils. The comment stated that reductions in dental plaque biomass have been shown to correlate with reductions in dental plaque bacteria by objective weight measurement (47 FR 22894 to 22895) and that other equally valid plaque reduction measurements, such as area measurement, were also successfully conducted for the firm's product. The comment concluded that these "state of the art" plaque reduction measurements should be accepted as indices of antiseptic action.

The agency is aware that the majority of the Panel stated that "the rationality of plaque reduction as a criterion of effectiveness of antimicrobial agents for use in the mouth and throat is highly debatable, and evidence of the validity of the method is scant. Plaque

reduction, therefore, is not accepted by this Panel as a criterion for determining effectiveness of antimicrobial agents for oral health care products intended to treat sore mouth or sore throat," (47 FR 22840). The agency agrees with the Panel and believes that plaque reduction has not been established as a valid technique for determining the antiseptic effectiveness of ingredients used for the types of indications being considered in this segment of the tentative final monograph: (1) First aid to help prevent infection in the mouth, or (2) for the temporary relief of minor sore throat symptoms.

The agency believes that the types of tests suggested in the Panel's testing guidelines at 47 FR 22760 at 22890 to 22893 are better suited to demonstrate the effectiveness of antiseptic ingredients in reducing the risk of infection in the oral cavity or in relieving sore mouth and sore throat symptoms. These testing guidelines are further discussed in section I.M., comment 33. However, as discussed in the previous segments of this tentative final monograph (see 53 FR 2436 and 56 FR 48302), in developing this monograph the agency is not addressing specific testing guidelines for upgrading ingredients to Category I. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part II. paragraph A.2.—*Testing of Category II and Category III conditions.*)

The agency wishes to point out that, as discussed in the call-for-data for antiplaque ingredients and claims (55 FR 38560), the Dental Products Panel will evaluate data regarding the safety and effectiveness of active ingredients contained in products displaying antiplaque and antiplaque-related claims. A subsequent segment of the rulemaking for OTC oral health care drug products will cover that Panel's recommendations to the agency regarding drug ingredients used for the reduction of plaque and plaque-related claims. Methods discussed by the comments and by the minority of the Oral Cavity Panel may be appropriate to demonstrate antiseptic activity of ingredients intended to reduce or prevent plaque.

33. Two comments stated that presentations had been made to the Oral Cavity Panel concerning guidelines for in vitro and in vivo testing of topical antiseptics (Refs. 1, 2, and 3) and that these data were not considered or included in that Panel's discussion. The comments contended that the guidelines were adequate to test ingredients for effectiveness and to establish a first aid antiseptic category for oral health care drug products that meet these guidelines. The comments stated that the guidelines provide for a statistically significant reduction in vivo combined with a 95-percent reduction in vitro of the organisms tested and, thus, provide proof of clinically useful antiseptic activity.

One comment paraphrased an agency statement that was published in the tentative final monograph for OTC topical antimicrobial drug products (i.e., first aid antibiotic drug products) (47 FR 29986 at 29991 to 29992) as follows:

> The agency agrees with the comments that minor skin injuries, such as cuts and scrapes, are self-healing and that the body's healing mechanisms can handle some infections that might develop in these injuries. However, as the reply comment pointed out, some minor skin injuries do not heal without treatment and it is impossible to make that distinction at the time of injury. It is well documented that applying topical antibiotics to skin wound lesions reduces the number of bacteria at the site of application and serves as an adjunct to cleansing wounds.

The comment argued that, in view of the agency's medical assessments of topical antibiotics as stated above, clinical testing of each ingredient or product is unnecessary. The comment felt that in vitro data demonstrating that a product's active ingredient is effective against the organism(s) likely to be found at the site should be sufficient to allow classification in Category I. The comment added that such a decision would be consistent with the agency's acceptance of all Category I topical antibiotics for the first aid indication to help prevent infection in minor cuts, scrapes, and burns (47 FR 29986 at 29999).

The Oral Cavity Panel considered the presentations concerning guidelines for in vitro and in vivo testing (Refs. 1, 2, and 3) and made suggestions concerning requirements for conducting such studies designed to obtain data for reclassifying Category III ingredients to Category I for safety and effectiveness or both (47 FR 22760 at 22890 to 22893). The Panel suggested that preliminary, well-designed in vitro studies be required to demonstrate antiseptic effectiveness and that the data obtained from in vitro studies be verified and supported by in vivo animal and human studies. The Panel stated that human model studies should be followed by appropriate clinical trials. The Panel included recommendations for in vitro and in vivo testing procedures to indicate the types of data necessary to upgrade ingredients from Category III to Category I and provided suggestions for obtaining such data.

Clinical Testing of OTC Oral Antiseptics

The agency believes that data from in vitro testing alone are insufficient to establish that an oral antiseptic is generally recognized as effective in: (1) Decreasing the number of microorganisms in the oral cavity and thus helping to prevent or reduce the chance of infection or bacterial contamination in minor oral wounds, or (2) temporarily relieving the symptoms of minor sore throat or mouth. The agency's assessment of the effectiveness of topical antibiotics in helping to prevent infection in minor skin cuts, scrapes, and burns (47 FR 29986 at 29991 to 29992) is not relevant in evaluating the effectiveness of oral antiseptic ingredients in helping to prevent infection in minor wounds in the mouth. Although demonstrated in vitro antiseptic bactericidal or bacteriostatic action is of predictive value in projecting clinical efficacy for antiseptics used on the skin (39 FR 33103 at 33110 and 56 FR 33644 at 33671), the agency believes that such activity alone is not sufficient to allow classification of an ingredient in Category I.

The environment of the oral cavity is very different from that of the skin. The oral cavity supports one of the most concentrated and varied microbial population of the body. The total microscopic count of saliva has been given as anything from 43 million to 5.5 billion per mL with an average of about 750 million. The microbial concentration of the gingival sulcus and in plaque is at least 100 fold greater, or approximately 200 billion cells per gram of sample (Ref. 4). Conversely, the skin, for the most part, is an inhospitable place for most microorganisms because the secretions of the skin are acidic and most of the skin contains little moisture (Ref. 5). The agency believes that, on the fairly dry surface of the skin, a reduction in microorganisms caused by the application of a topical antiseptic will persist for some time and, thus, may help to prevent minor skin infections. However, even if one could demonstrate a reduction of microorganisms on a site in the oral cavity, it is unlikely that this reduction

would result in a therapeutic benefit because the action of saliva would reinoculate the site almost immediately. As the Oral Cavity Panel stated, approximately 0.25 to 1 mL of saliva is excreted per minute in the oral cavity (47 FR 22766). Therefore, oral surfaces are constantly bathed with saliva, and organisms are readily transported from one area of the mouth to another. This may be particularly true of minor oral irritations, cuts, and scraps where there is an almost irresistible urge to probe the site with the tongue. This continuous reinoculation of the site with large numbers of microorganisms is likely to counteract any therapeutic benefit that might result from topical antiseptic action in the oral cavity. Therefore, the agency tentatively concludes that clinical testing is necessary to demonstrate that an antiseptic ingredient truly has a therapeutic effect in the oral cavity.

Clinical trials to demonstrate the effectiveness of an OTC oral antiseptic ingredient should be well-designed and well-controlled. Such trials should be structured to closely approximate the clinical situations for which a product is intended to be used and to substantiate proposed claims. These studies should demonstrate that the topically-applied antiseptic ingredient helps to prevent infection in minor wounds in the mouth better than the vehicle alone.

In Vivo Testing Procedures

Three in vivo studies submitted to the Panel (Ref. 2), and mentioned by the comments, were designed to answer specific questions raised by the Panel during its evaluation of in vivo testing guidelines for oral antiseptics (Ref. 1). The basic method used in the three studies (Ref. 2) involved the use of 10 normal subjects with no medical problems. The subjects were treated with cetylpyridinium chloride (0.1 or 1 percent) and a placebo (distilled or deionized water). In some of the studies, a template was used to define the cheek treatment area, and in other studies, no template was used. Each subject served as his or her own control. The technique consisted of using a swab to sample the cheek before treatment, treating the cheek with the designated agent (i.e., active ingredient or placebo), and sampling again 1 minute later. Samples were mixed, serially diluted, plated, incubated, and visible bacterial colonies counted. A variety of mixing, plating methods, and environmental conditions were used (e.g., drop plate counting method, standard plating procedures, sonication, and incubation under carbon dioxide, aerobic, and anaerobic conditions.) The results of all three studies indicated that cetylpyridinium chloride decreased the number of bacteria within 1 minute after application on the cheek. Individual studies included the following results: (1) Subjects differ from each other by 10 to 100 fold in their normal bacterial counts, but vary little from 1 day to another in their own bacterial counts; (2) a swab sampling procedure and a drop-plate counting method are sensitive, adequate methods to detect small decreases in bacterial counts in a 10-subject panel, and decreases smaller than 2 logs or 100 fold are significant; (3) a template is not necessary to limit the treatment area; (4) successive samples taken before treatment invariably decrease, as do samples taken after treatment with water while samples taken after treatment with cetylpyridinium chloride level off or increase in successive samples, indicating that the antiseptic killed bacteria in the top layer of the oral mucosa but not in the lower layers; (5) sonication of swab samples increases the sensitivity of the method, but does not affect the estimate of antiseptic effectiveness; thus, this method may be used optionally; (6) conventional plating methods and other well-tested plating methods are highly reproducible; and (7) although results for all three incubation environments were essentially the same, the effect of some oral antiseptics could have differing effects against types of bacteria requiring specific gaseous environments; thus, three environments should be used in future studies.

The agency concludes that the techniques of the in vivo testing guidelines presented to the Panel for demonstrating the effectiveness of a locally applied antiseptic ingredient (Refs. 1 and 2) represent a partial guide for helping to assess an ingredient's effectiveness as an OTC oral health care antiseptic, but are not totally adequate for that purpose. The agency believes that in vivo testing methods used to help demonstrate the effectiveness of oral health care antiseptic ingredients should stipulate the specific organisms to be tested, the acceptable decrease in bacterial numbers, and the period of time for which the antiseptic activity should persist. The Panel's discussion of in vivo testing did not include such information (47 FR 22760 at 22891). Such testing methods should also take into account the following: (1) The normal flora of the site to be used in the study, (2) the complexity of the oral flora, (3) the site-to-site variation of the oral flora within the mouth, (4) when tissue is abraded, burned, or punctured, sites may be exposed that allow the binding of oral microorganisms that would not otherwise reside in that particular ecological niche, and (5) what shifts in the balance of the flora and/or colonization by other species are to be expected if the site is abraded or otherwise damaged. A spectrum of activity against a representative battery of organisms should be developed (i.e., *Candida albicans*, representative actinomyces and streptococcal species, and other flora frequently isolated from the site). A thorough review of the literature should identify the appropriate microorganisms.

In addition, the in vivo testing guidelines presented to the Panel (Ref. 1) did not include adequate sampling intervals after treatment with the oral antiseptic. Using the guidelines, a statistically significant difference was obtained between treatment of the cheek with the placebo and treatment with cetylpyridinium chloride; however, the length of time that the antiseptic effect persists past the 1-minute time interval used in the studies was not explored. The transient decrease in the number of bacteria at the 1-minute interval after cetylpyridinium chloride application, as noted in the comment's studies (Ref. 2), is not unexpected. The ability to maintain such a decrease over a reasonable interval of time is more significant and important, especially when one considers the effect of the oral environment. The agency believes that, for demonstrating antiseptic activity in the oral cavity, more appropriate time intervals might be 1 minute, 10 minutes, 30 minutes, 1 hour, 2 hours, and 4 hours.

The agency also believes that it might be useful to use more than one incubation environment because some microniches in the oral cavity (e.g., the gingival crevice) support anaerobic growth, and organisms commonly isolated from the oral cavity include facultative anaerobes as well as strict anaerobes. One approach would be to use a nonselective medium under anaerobic and carbon dioxide conditions and several selective media under appropriate conditions depending upon the microorganism of interest.

In Vitro Testing Procedures

The agency believes that the Panel's proposed in vitro testing guidelines represent a good starting point for the design of in vitro studies to help upgrade a Category II or Category III oral antiseptic ingredient to Category I (47 FR 22760 at 22890 to 22891. However, all such testing should be designed

using the most current technology available.

Although the agency offers the above comments on clinical, in vivo, and in vitro testing as guidance, specific testing guidelines for upgrading ingredients to Category I are not included in this monograph. (See part II. paragraph A.2.—*Testing of Category II and Category III conditions.*) Instead, the agency will meet with industry representatives or other interested parties at their request to discuss testing protocols. Any party interested in conducting studies should request a meeting at its earliest convenience. (See also section I.M., comments 32 and 35.)

The above discussion applies only to the testing required to upgrade OTC oral antiseptic ingredients from Categories II or III to Category I. In addition, the agency has tentatively concluded that final formulation testing of OTC oral antiseptic drug products is necessary. For a further discussion of such testing, see part II. paragraph B.10—Summary of the Agency's Changes.

References

(1) OTC Vol. 130117, Docket No. 81N-0033, Dockets Management Branch.

(2) OTC Vol. 130132, Docket No. 81N-0033, Dockets Management Branch.

(3) OTC Vol. 130163, Docket No. 81N-0033, Dockets Management Branch.

(4) Burnett, G. W., H. W. Scherp, and G. S. Schuster, "Oral Microbiology and Infectious Disease," The Williams and Wilkins Co., Baltimore, 1976, p. 219.

(5) Tortora, G. J., B. R. Funke, and C. L. Case, "Microbiology, An Introduction," The Benjamin Cummings Publishing Co., Inc., Redwood City, CA, 1989, p. 502.

34. Three comments disagreed with the Oral Cavity Panel's discussion concerning chlorhexidene as a standard for testing the effectiveness of oral antimicrobials. One comment stated that the use of chlorhexidene is inappropriate and unnecessary for this class of products and that the proposed guidelines for topically applied antiseptics for use on the skin do not include chlorhexidene as a standard. The second comment stated that the use of chlorhexidene as a standard is unreasonable because its usefulness is currently at issue, and the drug is not yet accepted as a safe and effective oral antiseptic. The third comment stated that chlorhexidine is unproven as a standard reference for pathogens responsible for the production of sore throat and sore mouth.

The agency acknowledges that neither the tentative final monograph for OTC antimicrobial drug products (43 FR 1210) nor the amended tentative final monograph (now called OTC first aid antiseptic drug products) (56 FR 33644) includes chlorhexidene as a standard for topical antiseptics. However, since the comment was submitted, a chlorhexidene antiseptic mouthwash has been approved for oral use in the U.S. (Ref. 1).

The Oral Cavity Panel's minority report recommended an in vitro test utilizing chlorhexidene as a standard and recommended that all antimicrobial oral products be compared to the standard (47 FR 22760 at 22897). However, as discussed in section I.M., comment 32, the testing procedures recommended by the minority of the Panel are not being accepted by the agency for testing the active ingredients that are included in this segment of the oral health care drug products rulemaking.

In its in vitro testing procedure for determining the effectiveness of oral antimicrobials, the majority of the Panel recommended the use of a positive standard control to validate the test procedure by assuring the consistent susceptibility of the test organisms. The Panel's majority report stated that "chlorhexidene digluconate, 0.2 percent in sterile water, is acceptable for this purpose," (47 FR 22891). The agency does not agree with the Panel that chlorhexidine is an appropriate positive control for this purpose. Determining whether or not an organism is susceptible to chlorhexidine does not correlate to whether or not the organism is susceptible to the test ingredient. Furthermore, as discussed in prt II. paragraph B.10—Summary of the Agency's Changes, the agency is suggesting that the active ingredient, in a suitable inactive medium, be used as a positive control.

Reference

(1) "Physician's Desk Reference," 47th ed., Medical Economics Data, Montvale, NJ, 1993, pp. 1867–1868.

35. Two comments stated that the Oral Cavity Panel's guidelines for testing topically applied antimicrobials (47 FR 22760 at 22890 to 22893) should permit variations in the methods used. One comment mentioned that variations should be allowed depending on the ingredient being tested. As an example of an appropriate variation, the other comment suggested that a method that had been submitted to the Panel would provide adequate status of in vivo antimicrobial activity (Ref. 1). The comment described that method as "swabbing of the active ingredient three times using a template and comparing this to a control."

The agency is not including specific guidelines for upgrading active ingredients to Category I in this document. Instead, the agency will meet with industry representatives at their request to discuss testing protocols and, therefore, revisions may be made from time-to-time. (See section I.E., comment 8; section I.G., comment 12; and section I.M., comment 33 for a discussion of appropriate testing procedures.)

The agency notes that the procedure referred to by one comment calls for volunteer subjects with no symptoms of an oral disease state. The agency does not believe this procedure by itself will provide adequate proof of the in vivo effectiveness of an oral antiseptic.

Reference

(1) OTC Vol. 130153.

36. Referring to the Oral Cavity Panel's discussion of in vivo testing, two comments disagreed with the suggested protocol for the determination of an antimicrobial ingredient's adverse effect on wound healing (47 FR 22760 at 22892). The comment felt that the procedure described by the Panel would be impossible to control if there were only one wound in the mouth. Expressing the opinion that, in order to compare the rate of healing, a controlled study would require multiple wounds, of comparable size and depth, in comparable locations in the mouth, and at a comparable stage in the healing process, both comments considered it virtually impossible to find such a situation occurring naturally in human subjects. The comments agreed with the Panel that such a study could be done in animals, but felt that animal studies would be of little value because animals have different microbial populations than humans. One of the comments added that if a product does not have an excessively high degree of substantivity, the risks of retarding wound healing are limited and such tests are unwarranted.

The agency agrees with the comments that it would be almost impossible to find a representative population of human subjects with multiple mouth wounds so that one wound could serve as a test site and another as a control site in the same subject. However, the agency believes that the Panel was referring to a "controlled study" as one in which a population of subjects with comparable wounds is divided into a group that is treated with the test ingredient and a group that receives a control, such as the vehicle lacking the test ingredient. In the Panel's discussion of general considerations applying to the testing for recategorization of Category III oral health care ingredients (47 FR 22760 at 22782 to 22783), the design for a controlled study is described as one in which subjects who have similar conditions are divided into

a treated group and a placebo group. In the discussion cited by the comments (47 FR 22891), the Panel stated that control groups should receive treatment with inert vehicles that are identical in appearance, color, and consistency to the test materials. The agency believes that the general principles stated above can be coordinated so that well-controlled studies to investigate the adverse effects of oral health care antimicrobial ingredients on wound healing could be designed according to the Panel's recommendations.

The agency disagrees with the comments' belief that animal studies are of little value and concurs with the Panel's position on animal studies. Although believing that the final appraisal of an oral antiseptic must be done by clinical trials, the Panel recommended that in vivo testing, including animal and human models, should be performed prior to clinical studies (47 FR 22891). The agency agrees that an initial assessment of safety and effectiveness of a drug should be made using animal models before the test formulation is given to humans in a controlled clinical study.

However, the agency does not believe that further wound healing studies are necessary for OTC oral antiseptic ingredients. As part of the rulemaking for OTC topical antiseptic drug products, the agency has reviewed many studies designed to show the effect of antiseptic ingredients on wound healing. The agency's conclusions on these data are stated in the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33658, 33660, and 33662). Several of the first aid antiseptic ingredients for which wound healing studies were submitted are also classified as Category III oral antiseptic ingredients, i.e., benzalkonium chloride, iodine, and povidone-iodine. The submitted studies show that these antiseptic ingredients do not delay wound healing when used for a short period of time, i.e., 7 days, on limited areas of the body. The agency believes that these wound healing data are also relevant to oral antiseptic ingredients that are limited to a maximum of 7 days of use on the affected area of the mouth and throat. The Panel was concerned about the lack of data on possible adverse effects on the oral mucosa resulting from the use of oral antiseptic drug products on a daily basis for months at a time (47 FR 22760 at 22834). However, the agency is proposing labeling limiting self-medication with these products to a 7-day period for relief of the symptoms of sore mouth. (See section I.K., comment 25.) In addition, the oral antiseptic ingredients are used in lower concentrations than the first aid antiseptic ingredients and are in contact with the affected area for a shorter time period following application. This occurs because the oral antiseptic ingredients are mixed with the saliva of the mouth and then expectorated. Therefore, oral antiseptic ingredients would not be expected to delay wound healing. For the above reasons, the agency concludes that additional studies to demonstrate that oral antiseptic ingredients do not delay wound healing are unnecessary. Further, according to 21 CFR 310.534(b), any OTC drug product that is labeled, represented, or promoted for use as an oral wound healing agent (e.g., "promotes wound healing") is regarded as a new drug, and an approved application is required before marketing.

37. One comment stated that the Oral Cavity Panel's recommended studies to prove that antiseptic mouthwashes aid in the treatment of sore mouth and sore throat are not feasible for the following reasons: (1) It is not feasible to attempt to collect enough data in any reasonable period of time from volunteers who have symptoms of a sore throat or sore mouth due to the unique infection with a single pathogen in order to prove specific activity of an antibacterial agent (47 FR 22760 at 22779); (2) Koch's Postulates would be virtually impossible to fulfill because proof of the presence of the offending etiologic agent specifically responsible for the sore mouth/sore throat, in addition to correlation of relief of symptoms of sore mouth/sore throat with a decrease or elimination of the etiologic agent, could of itself be impossible to achieve; (3) complementary animal studies simulating these symptoms would be difficult to perform without the introduction of a systemic pathogen and, under these circumstances, the natural conditions specified as a prerequisite for proof of efficacy could not be approximated (47 FR 22890); (4) the test organisms originally approved by the Panel to demonstrate antimicrobial activity (the Bahn test), *Streptococcus mutans*, *Actinomyces viscosus*, *C. albicans* and optionally, *Pseudomonas aeruginosa*, have no precedent for use as test organisms for antibacterial activity relating to production of symptoms of sore mouth or sore throat; and (5) such studies must by necessity avoid the use of any systemic antimicrobial agent and would obviously create a situation which is not only medically unsound but also unethical.

In its discussion of the data required for the evaluation of oral antiseptic ingredients (47 FR 22760 at 22890 to 22893), the Oral Cavity Panel recommended general principles applicable to the design of experimental protocols for demonstrating the safety and efficacy of these ingredients. The Panel did not consider its recommendations for testing the effectiveness of these ingredients to be mandatory requirements, but presented its recommendations merely to indicate the types of data it considered necessary and to provide suggestions for obtaining such data. The agency is adopting this approach and treating the Panel's recommendations as guidelines for obtaining data to upgrade Category II or Category III ingredients to Category I. However, in this tentative final monograph, the agency is proposing testing procedures for final formulations containing Category I oral antiseptics. (See section I.M., comments 32 and 35.)

The Panel recognized that it would be impossible to propose a single general protocol because of the diverse etiology of oral inflammation. The Panel recommended that the data obtained in support of Category I status for oral antiseptic ingredients show that preparations applied to the mucous membranes of the mouth and throat act topically and relieve symptoms caused by an infection by reducing pathogenic microbial populations (47 FR 22760 at 22890), but it also recognized that appropriate individual tests must be devised to demonstrate this for a particular ingredient and that the responsibility of selecting or devising reliable methods for procuring acceptable evidence of the effectiveness of an ingredient rests with the manufacturer sponsoring the product.

The agency is, however, proposing testing procedures for OTC oral antiseptic final formulations in § 356.90 of this tentative final monograph. In those testing procedures, the agency is accepting the Panel's recommendations regarding the use of *S. mutans*, *A. viscosus*, and *C. albicans* as test organisms. (See Part II. paragraph B.10—Summary of the Agency's Changes.) These organisms are representative of organisms commonly found in the oral cavity. The agency believes that a decrease in the number of these organisms in the proposed in vitro testing procedures indicates that the final formulation of a product has not decreased the effectiveness of a Category I oral antiseptic.

II. The Agency's Tentative Conclusions and Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of Ingredient Categories.*

The agency has reviewed all claimed active ingredients submitted to the Oral Cavity Panel, as well as other data and information available at this time, and has made one change in the categorization of oral antiseptic ingredients recommended by the Panel. As a convenience to the reader, the following list is included as a summary of the categorization of oral antiseptic ingredients recommended by the Panel and the proposed categorization by the agency.

Antiseptic Active Ingredients	Panel	Agency
Alcohol	III	III
Benzalkonium chloride	III	III
Benzethonium chloride	III	III
Benzoic acid	III	III
Boric acid	II	II
Boroglycerin	II	II
Camphor	II	II
Carbamide peroxide in anhydrous glycerin	III	III
Cetalkonium chloride	III	III
Cetylpyridinium chloride	III	III
Chlorophyllin copper complex	III	III
Cresol	II	II
Dequalinium chloride	III	III
Domiphen bromide	III	III
Eucalyptol	III	III
Ferric chloride	II	II
Gentian violet	III	II
Hydrogen peroxide	III	III
Iodine	III	III
Menthol	III	III
Meralein sodium	II	II
Methyl salicylate	III	III
Nitromerso	III	II
Oxyquinoline	III	III
Phenol preparations (phenol and/or phenolate sodium)	III	III
Potassium chlorate	II	II
Povidone-iodine	III	III
Secondary amyltricresols	III	III
Sodium caprylate	III	III
Sodium dichromate	II	II
Thymol preparations (thymol and thymol iodide)	III	III
Tincture of myrrh	II	II
Tolu balsam	III	III

2. *Testing of Category II and Category III Conditions.*

The Oral Cavity Panel recommended testing guidelines for OTC oral health care antimicrobial drug products (47 FR 22760 at 22890 to 22893). The agency's position regarding these testing guidelines is discussed in Part I, paragraph E of this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any OTC oral antiseptic active ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the antiseptic section of the Oral Cavity Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. In order to be consistent with terminology used in the rulemaking for OTC topical antiseptic drug products, the agency is proposing to replace the Panel's term "antimicrobial" with the term "antiseptic" in this tentative final monograph. (See section I.A., comment 1.)

2. The agency is not including in this tentative final monograph the Panel's definition for an antimicrobial agent in § 356.3(c) of its recommended monograph (47 FR 22760 at 22927). Instead, the agency is proposing to add definitions for the terms "antiseptic drug" and "oral antiseptic" to § 356.3 of this tentative final monograph. (See section I.K., comment 20.)

3. The Oral Cavity Panel concluded that gentian violet was safe for use in the oral cavity, but that there were insufficient data available to permit final classification of its effectiveness as an oral antiseptic (47 FR 22760 at 22873 to 22875). The Panel based its safety determination on several factors: (1) the oral LD_{50} of gentian violet in mice and rats is 1.2 to 10 g/kg; (2) it is nontoxic when applied to the mucous membrane and skin; and (3) gentian violet has been used orally in both children and adults as an anthelmintic. However, the Panel noted that when gentian violet is ingested, it may cause nausea, vomiting, diarrhea, and lassitude, and that intravenous injection of impure preparations may produce a severe shock-like reaction.

Regarding the use of gentian violet as an anthelmintic, in its report on OTC anthelmintic drug products published in the **Federal Register** of September 9, 1980 (45 FR 59540), the Miscellaneous Internal Panel reviewed the information available to it regarding the safety of gentian violet and acknowledged both a scarcity of acute toxicity data and "a high incidence of undesirable side effects associated with its clinical use in children." That Panel also reviewed reports regarding the potential carcinogenicity of gentian violet and recommended "that further testing be performed to resolve the carcinogenic concerns." According to the Miscellaneous Internal Panel, these concerns were not convincing when weighed against the lack of adverse effects reported during the long marketing history of gentian violet. Thus, that Panel concluded that gentian violet was safe when used as directed. FDA, however, reviewed the available data relevant to the genetic toxicity of gentian violet and stated in its preamble to the Panel's report on OTC anthelmintic drug products that a definitive conclusion regarding the carcinogenic activity of gentian violet could not be reached at that time. On the basis of the available evidence, the agency nominated gentian violet for study in the NTP. The agency concluded that the potential risk of using gentian violet as an oral anthelmintic outweighed the benefits and announced its intent to classify gentian violet in Category II in the tentative final monograph for OTC anthelmintic drug products (45 FR 49540).

In that tentative final monograph published in the **Federal Register** of August 24, 1982 (47 FR 37062 at 37063), the agency further discussed the genetic toxicity of gentian violet, and reaffirmed its earlier conclusions regarding the safety of gentian violet. In that proposal, gentian violet was classified in Category II as an oral anthelmintic. In the final rule published in the **Federal Register** of August 1, 1986 (51 FR 27756 at 27758), the agency determined that gentian violet is a nonmonograph drug for OTC anthelmintic use.

In a proposed rule published in the **Federal Register** of February 13, 1990 (55 FR 5194) regarding the safety of gentian violet in animal feed, FDA discussed the National Center for Toxicology Research's (NCTR) series of studies that provide additional new information on the toxicity and carcinogenicity of gentian violet. One lifetime study (chronic study) showed

gentian violet to be a carcinogen in mice. Another lifetime study in rats also resulted in a carcinogenic response. A residue study showed that residues of gentian violet occurred in the edible tissues of chickens after they were administered gentian violet. Reproductive-teratology studies were negative or inconclusive. A multigeneration study in rats showed a lower body weight, a dose-related necrosis in the thymus, and a dose-related effect on the kidneys in females. However, a pairwise statistical evaluation of these parameters was not performed. Metabolism studies in rats and mice showed that orally administered gentian violet is absorbed, with the highest residue levels of the compound and its metabolites occurring in fat and liver. The proposal also discussed the results of an extensive search of the published literature relevant to the safety of gentian violet (55 FR 5194 at 5200).

The agency concluded that even if the chronic studies that had been performed by NCTR did not establish that gentian violet is an animal carcinogen, they did not establish that gentian violet is safe. There is a paucity in the scientific literature of the kind of studies that are needed to support an expert opinion that gentian violet is generally recognized as safe. In fact, FDA's literature survey generally found that gentian violet tends to have mutagenic, genotoxic, and other toxic properties. FDA believes where such incriminating studies exist, experts generally agree that chronic studies must affirmatively show that the substance does not cause cancer before it can be recognized as safe (55 FR 5194 at 5201). The agency concluded that gentian violet is not generally recognized as safe for use in animal feed or as a food additive. The agency also concluded that gentian violet for veterinary drug use in food animals is not generally recognized as safe and effective and is a new animal drug (55 FR 5201).

In the **Federal Register** of August 15, 1991 (56 FR 40502), the agency issued a final rule amending its regulations (21 CFR 500.29) to declare that gentian violet is neither generally recognized as safe nor prior sanctioned and is a food additive when added to animal feed for any nondrug use. The agency also amended its regulations (21 CFR 500.30) to reflect its determination that gentian violet is not generally recognized as safe, not generally recognized as effective, or not "grandfathered" under the Drug Amendments of 1962 (Pub. L. 87–781). Therefore, gentian violet is a new animal drug when used for any veterinary drug purpose in food animals.

Based on the above, the agency concludes that gentian violet is not safe for use as an oral antiseptic. Therefore, in this tentative final monograph, the agency is reclassifying gentian violet from Category III to Category II.

4. The agency believes that the safety data evaluated by the Panel are sufficient to conclude that cetylpyridinium chloride, domiphen bromide, and povidone-iodine are safe for use as OTC oral antiseptics when labeled for short-term use (not to exceed 7 days). However, there are insufficient data to demonstrate the effectiveness of these ingredients, and they are classified in Category III. (See section I.E., comments 8 and 9; section I.G., comments 12 and 13; and section I.I., comments 15 and 16.)

5. The agency is proposing the following combinations in § 356.26 (and labeling for these combinations in § 356.66): (1) oral antiseptic and oral anesthetic/analgesic; (2) oral antiseptic and oral astringent; (3) oral antiseptic and oral demulcent; (4) oral antiseptic and oral mucosal protectant; (5) oral antiseptic, oral anesthetic/analgesic, and oral astringent; (6) oral antiseptic, oral anesthetic/analgesic, and oral demulcent; and (7) oral antiseptic, oral anesthetic/analgesic, and oral mucosal protectant. (See section I.L., comment 29.)

6. The agency is proposing to revise the statement of identity in § 356.51(a) of the Panel's recommended monograph (and including the revised statement in § 356.64(a) of this tentative final monograph) as follows: "The labeling of the product contains the established name of the drug, if any, and identifies the product as an 'oral antiseptic,' or an 'antiseptic' (select one of the following: 'rinse,' 'gargle,' or 'rinse and gargle')." (See section I.K., comments 20 and 21.)

7. The agency is proposing the following indication in § 356.64(b) of this tentative final monograph: "First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "infection" or "bacterial contamination") "in" (select any of the following: "minor cuts," "minor scrapes," or "minor oral irritation") (which may be followed by) "caused by" (select any of the following: "dental procedures," "dentures," "orthodontic appliances," or "accidental injury"). (See section I.K., comment 22.)

8. The agency is proposing to replace the Panel's recommended warnings in § 356.51(c)(1)(i) and (c)(1)(ii) with the following warning found in § 356.64(c) of this document: "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days, if irritation, pain, or redness persists or worsens, or if swelling, rash, or fever develops, see your dentist or doctor promptly." (See section I.K., comment 25.)

9. The agency is proposing professional labeling in § 356.80 for the use of povidone-iodine as a dental preoperative preparation by health care professionals. (See section I.K., comment 27.)

10. The agency has determined that, because the final formulation of an oral antiseptic drug product can affect the effectiveness of the active ingredient, final formulation testing of oral health care antiseptic drug products is necessary. Therefore, the agency is proposing final formulation testing procedures be included in this tentative final monograph. These testing procedures are being put forth for comment in this document.

The Panel recommended that evidence be submitted to verify that each antiseptic ingredient is released from its vehicle when applied to mucous membranes, but it did not include final formulation testing procedures for OTC oral antiseptics in its recommended monograph (47 FR 22760 at 22890). The agency, however, is aware that the final formulation of an oral health care drug product can affect the activity of an antiseptic ingredient included in that product. Therefore, in keeping with the final formulation testing procedures proposed for first aid antiseptic drug products (i.e., those applied to the skin) (56 FR 33644 at 33673) and those that will be proposed for health care antiseptic drug products (e.g., surgical scrubs) in a future issue of the **Federal Register**, the agency is proposing procedures for testing the final formulations of oral health care antiseptic drug products in this tentative final monograph. These testing procedures are based upon the in vitro effectiveness testing procedures recommended by the Oral Cavity Panel (47 FR 22760 at 22890 to 22893) and the first aid antiseptic testing procedures proposed by the agency in § 333.70 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33673). In general, the proposed testing procedures for first aid antiseptic drug products have been modified to account for the different test organisms required for testing the effectiveness of oral antiseptics. The agency has also taken into account all

comments pertaining to the Oral Cavity Panel's recommended in vitro testing guidelines. (See section I.M., comments 34 and 35.)

In the testing procedures included in the tentative final monograph for OTC first aid antiseptic drug products, the agency proposed in § 333.70(b)(2)(i) and (b)(2)(ii) a "neutralizer inactivation of antiseptic test" and a "neutralizer effect on bacterial viability test" (56 FR 33644 at 33678 and 33679). Differences in microbial plate counts greater than 20 percent between test and control cultures require that the overall test results be discarded. Based upon new information, the agency is concerned that a 20-percent difference in microbial plate counts might be too restrictive. There is a relatively large inherent variation in microbial plate counts. In addition, because the criterion for fulfilling the requirements of the overall testing procedures is a 3-$\log_{10}$ reduction in viable organisms (i.e., 99.9 percent), the agency now questions whether a 1-$\log_{10}$ (i.e., 90 percent) difference might not be a more reasonable criterion for the differences in microbial plate counts for the neutralizer tests. Although the agency is proposing the 20-percent criterion in this tentative final monograph for consistency with the OTC first aid antiseptic tentative final monograph, the agency requests comment on this matter.

In addition, in § 333.70(c)(5) of the OTC first aid antiseptic tentative final monograph, the agency proposed a "test organism antiseptic resistance test" in which the test organisms' resistance to phenol is determined in order to ensure that the resistance of each organism to antiseptics has not changed (56 FR 33679). The Oral Cavity Panel recommended that a 0.2-percent chlorhexidine gluconate solution be used as a positive control to assure the consistent susceptibility of the test organisms (47 FR 22760 at 22891). However, the agency believes that determining an organism's resistance or lack of resistance to phenol or chlorhexidine gluconate has no bearing upon whether or not that organism's susceptibility to a particular test ingredient has changed. The mechanism of action of the test antiseptic may be quite different than that of phenol or chlorhexidine gluconate. Because the "test organism antiseptic resistance test" is designed to demonstrate that the active ingredient is still active in the specific formulation under test, and the active ingredient has presumably already been shown to have in vitro and in vivo antiseptic activity by itself, the proper control is the active ingredient alone. Therefore, the agency is suggesting that the active ingredient, in a suitable inactive medium, be used as a positive control.

The complete testing procedures are included in § 356.90 of this tentative final monograph. The agency invites specific comment at this time on the final formulation testing procedures proposed in this document. After reviewing any submitted comments or data, the agency may revise the testing procedures prior to establishing a final monograph. The agency also recognizes that the testing procedures may need to be revised periodically as newer techniques are developed and proven adequate.

11. For an active ingredient to be included in an OTC drug final monograph, in addition to information demonstrating safety and effectiveness, it is necessary to have publicly available sufficient chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products. Only some of the oral antiseptic active ingredients that the Panel evaluated are standardized and characterized for quality and purity and are included in official compendia. Alcohol, benzalkonium chloride, benzethonium chloride, benzoic acid, boric acid, camphor, carbamide peroxide, cetylpyridinium chloride, cresol, gentian violet, hydrogen peroxide, iodine, menthol, methyl salicylate, nitromersol, oxyquinoline sulfate, phenol, povidone-iodine, tolu balsam, and thymol are currently included as articles in the U.S.P. (Ref. 1). The remaining oral antiseptic active ingredients are not adequately characterized and would need to be if data are submitted to upgrade them to monograph status.

The agency believes that it would be appropriate for parties interested in upgrading nonmonograph ingredients to monograph status to develop with the United States Pharmacopoeial Convention appropriate standards for the quality and purity of any of these ingredients that are not already included in official compendia. Should appropriate standards fail to be established, ingredients otherwise eligible for monograph status will not be included in the final monograph.

Reference

(1) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 34, 146, 149, 219–220, 223, 268, 605, 663, 703–703, 821–822, 954, 1061, 1119, 1390, 1904–1905, 1906, 1921–1922, 1947–1948, 1955, 1991, 1989.

The agency has examined the economic consequences of this proposed rulemaking and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC oral antiseptic drug products is not expected to have an impact on small businesses.

This proposed rule does not include any Category I ingredients. Some ingredients are in Category II (not generally recognized as safe and effective), but most are in Category III (more data needed to establish safety and effectiveness). If data are not submitted to upgrade these ingredients to monograph status, OTC products containing oral antiseptics will not bepermitted to display antiseptic drug claims in labeling. However, most of these products could remain in the marketplace. After relabeling, many products could be marketed as cosmetics; others could be marketed as OTC oral wound cleansing drug products. After reformulation and relabeling, a few products could be sold as OTC oral anesthetic/analgesics. Many OTC products containing oral antiseptics are labeled for use to reduce or prevent the accumulation of dental plague. Unless a safety concern arises, such products may remain on the market until the agency's evaluation of antiplaque and antiplaque-related products is completed.

The impact of the proposed rule, if implemented, appears to be minimal. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC oral antiseptic drug products. No comments on economic impacts were received.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC oral antiseptic drug products. Comments regarding the impact of this rulemaking should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess

the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before August 8, 1994, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before August 8, 1994. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before February 9, 1995, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before April 10, 1995. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on (*insert date 14 months after date of publication in the* Federal Register). Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 356

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 356 (as proposed in the Federal Register of May 25, 1982 (47 FR 22760), the Federal Register of January 27, 1988 (53 FR 2436), and the Federal Register of September 24, 1991 (56 FR 48302)) be amended as follows:

PART 356—ORAL HEALTH CARE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 356 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 356.3 is amended by adding new paragraphs (m) and (n) to read as follows:

§ 356.3 Definitions.

* * * * *

(m) *Antiseptic drug.* In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

(n) *Oral antiseptic.* An antiseptic-containing drug product applied topically to the oral cavity to help prevent infection in wounds caused by minor oral irritations, cuts, scrapes, or injury following minor dental procedures.

3. New § 356.11 is added to subpart B to read as follows:

§ 356.11 Antiseptics.

Povidone-Iodine provided to health professionals (but not to the general public).

4. Section 356.26 is amended by adding new paragraphs (i), (j), (k), (l), (m), (n), and (o) to read as follows:

§ 356.26 Permitted combinations of active ingredients.

* * * * *

(i) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.12.

(j) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral astringent active ingredient identified in § 356.14.

(k) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral demulcent active ingredient identified in § 356.18.

(l) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral mucosal protectant active ingredient identified in § 356.20.

(m) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.12 and any single oral astringent active ingredient identified in § 356.14.

(n) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.12 and any single oral demulcent active ingredient identified in § 356.18.

(o) Any single oral antiseptic active ingredient identified in § 356.11 may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.12 and any single oral mucosal protectant active ingredient identified in § 356.20.

5. New § 356.64 is added to subpart C to read as follows:

§ 356.64 Labeling of oral antiseptic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral antiseptic," or an "antiseptic" (select one of the following: "rinse," "gargle," or "rinse and gargle").

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select

one of the following: "infection" or "bacterial contamination") "in" (select any of the following: "minor cuts," "minor scrapes," or "minor oral irritation") (which may be followed by) "caused by" (select any of the following: "dental procedures," "dentures," "orthodontic appliances," or "accidental injury").

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings": "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days, if irritation, pain, or redness persists or worsens, or if swelling, rash, or fever develops, see your dentist or doctor promptly."

(d) *Directions.* [Reserved]

6. Section 356.66 is amended by adding new paragraphs (b)(3), (b)(4), (b)(5), (b)(6), (b)(7), (b)(8), (b)(9), (c)(1), (c)(2), (c)(3), and (c)(4) to read as follows:

§ 356.66 Labeling of combination drug products.

* * * * *

(b) * * *

(3) *For permitted combinations identified in § 356.26(i).* In addition to any or all of the indications in § 356.64(b), any or all of the indications in § 356.52(b)(3), (b)(4), and (b)(5) should be used.

(4) *For permitted combinations identified in § 356.26(j).* In addition to any or all of the indications in § 356.64(b), the following indication for oral astringent active ingredients should be used: "For temporary relief of occasional minor irritation, pain, and sore mouth."

(5) *For permitted combinations identified in § 356.26(k).* In addition to any or all of the indications in § 356.64(b), the following indication for oral demulcent active ingredients should be used: "For temporary relief of minor discomfort and protection of irritated areas in sore mouth."

(6) *For permitted combinations identified in § 356.26(l).* In addition to any or all of the indications in § 356.64(b), any or all of the indications in § 356.60(b)(1), (b)(2), and (b)(3) should be used.

(7) *For permitted combinations identified in § 356.26(m).* In addition to any or all of the indications in § 356.64(b), any or all of the indications in § 356.52(b)(3), (b)(4), and (b)(5) should be used. The following indication for oral astringent active ingredients should be used: "For temporary relief of occasional minor irritation, pain, and sore mouth."

(8) *For permitted combinations identified in § 356.26(n).* In addition to any or all of the indications in § 356.64(b), any or all of the indications in § 356.52(b)(3), (b)(4), and (b)(5) should be used. The following indication for oral demulcent active ingredients should be used: "For temporary relief of minor discomfort and protection of irritated areas in sore mouth."

(9) *For permitted combinations identified in § 356.26(o).* In addition to any or all of the indications in § 356.64(b), any or all of the indications in § 356.52(b)(3), (b)(4), and (b)(5) and in § 356.60(b)(1), (b)(2), and (b)(3) should be used.

(c) * * *

(1) *For permitted combinations identified in § 356.26(i).* In addition to the warnings in § 356.64(c), the warnings in § 356.52(c)(2), (c)(3), and (c)(4), if applicable, should be used.

(2) *For permitted combinations identified in § 356.26(j).* The warnings in § 356.64(c) should be used.

(3) *For permitted combinations identified in § 356.26(k).* The warnings in § 356.64(c) should be used.

(4) *For permitted combinations identified in § 356.26(k).* In addition to the warnings in § 356.64(c), the warnings in § 356.52(c)(2), (c)(3), and (c)(4), if applicable, should be used.

7. Section 356.80 is amended by adding new paragraph (d) to read as follows:

§ 356.80 Professional labeling.

* * * * *

(d) The labeling of aqueous products containing povidone-iodine identified in § 356.11 provided to health professionals (but not to the general public) may contain the following:

(1) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral antiseptic," or an "antiseptic" (select one of the following: "rinse," "gargle," or "rinse and gargle").

(2) *Indications.* The labeling of the product states under the heading "Indications," the following: "For preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction."

(3) *Directions.* The labeling of the product contains the following information under the heading "Directions:" For products containing povidone-iodine identified in § 356.11, the final product to be applied is a 0.5 percent aqueous solution. Manufacturers may also market a more concentrated solution provided that it contains adequate directions to dilute the product to a 0.5 percent aqueous solution. "Apply 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse for 30 seconds and then spit out. Wait 2 minutes, and apply another 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse again for 30 seconds and then spit out. With a standard syringe and a blunt, angulated needle, irrigate the operative site and the surrounding gingival mucosa for 1 minute with 10 to 20 milliliters of the solution. Instruct the patient to spit out the solution after the irrigation procedure."

8. New subpart D consisting of § 356.90 is added to read as follows:

Subpart D—Final Formulation Testing Procedures

§ 356.90 Testing of oral antiseptic drug products.

An oral antiseptic drug product in a form suitable for topical application will be recognized as effective if it contains an active ingredient included in § 356.11 and if, at its lowest recommended use concentration, it decreases the number of bacteria per milliliter in *Streptococcus mutans* (ATCC No. 25175), *Actinomyces viscosus* (ATCC No. 19246), and *Candida albicans* (ATCC No. 18804) cultures (available from American Type Culture Collection (ATCC), 12301 Parklawn Dr., Rockville, MD 20852) by 3 $\log_{10}$ within 10 minutes at 37 °C in the presence of 10 percent serum in vitro. Oral antiseptic drug products must meet the specified requirements when tested in accordance with the following procedures unless a modification is approved as specified in paragraph (e) of this section.

(a) *Laboratory facilities, equipment, and serum reagent—(1) Laboratory facilities.* To prevent the contamination of test microorganism cultures with extraneous microorganisms, perform the test using aseptic techniques in an area as free from contamination as possible. Because test cultures of microorganisms may be adversely affected by exposure to ultraviolet light or chemicals in aerosols, do not test under direct exposure to ultraviolet light or in areas under aerosol treatment. Do environmental tests to assess the suitability of the testing environment frequently enough to assure the validity of test results.

(2) *Equipment.* Use laboratory equipment that is adequate for its intended use. Thoroughly cleanse the equipment after each use to remove any antiseptic residues. Keep the equipment covered when not in use. Sterilize clean

glassware intended for holding and transferring the test organisms in a hot air oven at 200 to 220 °C for 2 hours. Use volumetric flasks, pipets, or accurately calibrated diluting devices when diluting standard and sample solutions. Use plastic or glass Petri dishes having dimensions of 20 X 100 millimeters. Use covers of suitable material.

(3) *Serum Reagent*—Use inactivated fetal bovine serum without added preservatives and/or antiinfective products.

(b) *Culture media and diluting fluids*—(1) Culture media. Use Brain Heart Infusion Medium for culture media and diluting fluids. Prepare the medium as follows:

	Brain Heart Infusion Medium
Calf Brain, Infusion from	200 grams
Beef Heart, Infusion from	250 grams
Peptone	10 grams
Sodium chloride	5 grams
Disodium phosphate	2.5 grams
Dextrose	2 grams
Water, distilled	q.s. to 1,000 milliliters

Mix thoroughly. Heat with frequent agitation and boil for 1 minute. Sterilize by autoclaving at 121 °C for 15 minutes. In lieu of preparing the media from the individual ingredients, the media may be made from dehydrated mixtures which, when reconstituted with distilled water, have the same or equivalent composition as media prepared from individual ingredients. Media prepared from dehydrated mixtures is to have growth-promoting, buffering, and oxygen tension-controlling properties equal to or better than media prepared from individual ingredients. Adjust the pH of each medium with 1 Normal hydrochloric acid or sodium hydroxide before sterilization, if necessary, so that the medium will have a final pH of 7.4 after sterilization.

(i) *Medium A (without neutralizers).* Use Brain Heart Infusion medium corresponding to that described in paragraph (b)(1) of this section.

(ii) *Medium B.* Brain Heart Infusion agar medium. Same as Medium A, except for the addition of 15 grams of agar per liter.

(iii) *Medium C.* Same as diluting fluid 1, except for the addition of 15 grams of agar per liter.

(iv) *Medium D.* Same as diluting fluid 2, except for the addition of 15 grams of agar per liter.

(2) *Diluting fluids*—(i) *Diluting fluid 1.* Diluting medium for neutralizing quaternary ammonium and phenolic antiseptic ingredients. Same as Medium A, except for the addition of 5 grams of lecithin and 40 milliliters of polysorbate 20 per liter.

(ii) *Diluting fluid 2.* Diluting medium for neutralizing iodophor antiseptic ingredients. Same as Medium A, except for the addition of 5 grams of sodium thiosulfate per liter.

(3) *Neutralizers.* When neutralizers are added to culture media and diluting fluid, perform the following tests.

(i) *Neutralizer inactivation of antiseptic test.* Assay the neutralizer efficacy for the test antiseptic as follows: Prewarm the test antiseptic, culture medium, test culture, and serum to 37 °C by incubating appropriate volumes of all solutions in a water bath at 37 °C for 5 minutes. Mix 0.8 milliliter of antiseptic (for controls use 0.8 milliliter of sterile water) with 9.0 milliliters of culture medium containing an appropriate antiseptic neutralizer followed by the addition of 0.2 milliliter of the test culture in 50 percent serum. Incubate the mixture of cells, serum, antiseptic, and neutralizer at 37 °C for 10 minutes. Remove aliquots, dilute, and assay for surviving bacteria by the plate-count assay method using diluting and plating media containing appropriate neutralizers, if required. Results obtained showing differences greater than 20 percent between test and control cultures indicate that the neutralizer used to inactivate the test antiseptic is ineffective. Reject results obtained from tests employing ineffective neutralization procedures.

(ii) *Neutralizer effect on bacteria viability test.* Test the effect of neutralizers used to inactivate antiseptic active ingredients on cell viability by diluting aliquots of each test organism culture in Medium A (without neutralizer), specified in paragraph (b)(1)(i) of this section, and in the appropriate diluting fluid (neutralizing medium), specified in paragraph (b)(2) of this section. Determine the number of bacteria in aliquots of appropriate dilutions by the plate-count assay method utilizing growth agar medium containing the same neutralizer concentration as the diluting medium. Determine neutralizer effects on cell viability by comparing the relative number of microorganisms growing on Medium B, specified in paragraph (b)(1)(ii) of this section, with and without added neutralizers. Results obtained showing differences greater than 20 percent between cultures diluted in medium with and without neutralizers indicate that, at the concentration utilized, the antiseptic neutralizer alters the determination of viable cells in the test cultures. Reject results obtained from tests in which the neutralizer employed alters the determination of viable cell numbers.

(c) *Test organisms*—(1) Use cultures of the following microorganisms:

(i) *Streptococcus mutans* (ATCC No. 25175).

(ii) *Actinomyces viscosus* (ATCC No. 19246).

(iii) *Candida albicans* (ATCC No. 18804).

(2) *Preparation of suspension.* Maintain stock cultures on Medium B agar slants by monthly transfers. Alternatively, cultures may be lyophilized and stored at -70 °C. Incubate new stock transfers 2 days at 37 °C; then store at 2 to 5 °C. Incubate *Streptococcus mutans* and *Actinomyces viscosus* anaerobically. Incubate *Candida albicans* aerobically. From stock culture, inoculate tubes of Medium A and make at least 4 but less than 30 consecutive daily transfers in Medium A, incubating at 37 °C, before using the culture for testing. Use a 16- to 18-hour culture of *Streptococcus mutans* and *Candida albicans* and a 32- to 36-hour culture of *Actinomyces viscosus* grown in Medium A at 37 °C for the test.

(3) *Determination of cell number in broth cultures.* Prepare serial 1:10 dilutions of each culture in Medium A and determine the number of cells per milliliter of culture by the plate-count assay method. Do not use cultures stored at 4 °C for more than 48 hours for assay. Do not use cultures containing less than 109 cells per milliliter.

(4) *Plate-count assay.* For each culture to be assayed, pipet 1.0 milliliter of each prepared dilution into each of two sterile Petri plates. To each plate, add 20 milliliters of sterile Medium B that has been melted and cooled to 45 °C (if neutralizers are required, use the corresponding agar growth medium with the appropriate neutralizer). Mix the sample with the agar by tilting and rotating the plate and allow the contents to solidify at room temperature. Invert the Petri plates and incubate at 37 °C for 48 hours. Following incubation, count the number of developing colonies. Use Petri plates containing between 30 and 300 colonies in calculating the number of bacteria per milliliter of original culture.

(5) *Test organism antiseptic resistance test.* To ensure that antiseptic resistance properties of each organism have not changed substantially, determine the

susceptibility of each organism to the active ingredient(s) being tested, in a suitable inactive medium, using the testing procedures in this section. The organisms are satisfactory if the number of organisms per milliliter are reduced by 3 $\log_{10}$ within 10 minutes at 37 °C in the presence of 10 percent serum.

(d) *Test procedures*—(1) *Method 1*—(i) *Method validation.* This test is valid only for those antiseptics that are water soluble and/or miscible and that can be neutralized by one of the subculture media specified in paragraphs (b)(2)(i) and (b)(2)(ii) of this section or that can be overcome by dilution.

(ii) *Bactericidal assay procedure.* Prewarm all test solutions by incubating appropriate volumes at 37 °C in a water bath for 5 minutes. Pipet 1.0 milliliter of serum, 1.0 milliliter of appropriate bacterial test culture, and 8.0 milliliters of the test antiseptic product at its recommended use concentration into a medication tube and mix well. Incubate at 37 °C for 10 minutes. Remove triplicate 1-milliliter sample aliquots and dilute in Medium A containing appropriate neutralizers. Determine the number of surviving organisms per milliliter of test culture by the plate-count method using plating media containing appropriate neutralizers, if required.

(iii) *Bacteriostatic assay procedure.* Prewarm all test solutions by incubating appropriate volumes at 37 °C in a water bath for 5 minutes. Pipet 1.0 milliliter of serum, 1.0 milliliter of appropriate bacterial test culture, and 8.0 milliliters of the test antiseptic product at its recommended use concentration into a medication tube and mix well. Pipet 1.0 milliliter aliquots of this test mixture into triplicate medication tubes containing 100 milliliters of Medium A without neutralizers and mix well. Incubate at 37 °C for 48 hours and determine the number of organisms per milliliter of culture by the plate-count method.

(2) [Reserved]

(e) *Test modifications.* The formulation or mode of administration of certain products may require modification of the testing procedures in this section. In addition, alternative assay methods (including automated procedures) employing the same basic chemistry or microbiology as the methods described in this section may be used. Any proposed modification or alternative assay method shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative assay method provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

Dated: December 10, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–2262 Filed 2–8–94; 8:45 am]

BILLING CODE 4160–01–F

federal register

Wednesday
February 9, 1994

Part III

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910, et al.
Hazard Communication; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

RIN 1218–AB02

Hazard Communication

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Final rule.

SUMMARY: The HCS requires employers to establish hazard communication programs to transmit information on the hazards of chemicals to their employees by means of labels on containers, material safety data sheets, and training programs. Implementation of these hazard communication programs will ensure all employees have the "right-to-know" the hazards and identities of the chemicals they work with, and will reduce the incidence of chemically-related occupational illnesses and injuries.

This modified final rule includes a number of minor changes and technical amendments to further clarify the requirements, and thereby help ensure full compliance and achieve protection for employees. In particular, the rule adds and clarifies certain exemptions from labeling and other requirements; modifies and clarifies aspects of the written hazard communication program and labeling requirements; clarifies and slightly modifies the duties of distributors, manufacturers, and importers to provide material safety data sheets (MSDSs) to employees; and clarifies certain provisions regarding MSDSs.

EFFECTIVE DATES: The amendments in this document will be effective on March 11, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., room N3647, Washington, DC 20210; telephone (202) 219–8151.

To aid in efforts to comply with the HCS, a single copy of the following documents may be obtained without charge from OSHA's Publications Office, room N3101 at the above address, (202) 219–4667: the Hazard Communication Standard (a **Federal Register** reprint of today's publication); OSHA 3084, Chemical Hazard Communication, a booklet describing the requirements of the rule; OSHA 3117, Informacion Sobre Los Riesgos De Los Productos Quimicos, a Spanish translation of OSHA 3084; OSHA 3111, Hazard Communication Guidelines for Compliance, a booklet which reprints Appendix E of the standard to further help employers comply with the rule; and OSHA 3116, Information Sobre Riegos Normas De Cumplimiento, a Spanish translation of OSHA 3111.

OSHA 3104, Hazard Communication—A Compliance Kit (a step-by-step guide to compliance with the standard) is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783–3238; GPO Order No. 929–022–00000–9; $18—domestic; $22.50—foreign.

SUPPLEMENTARY INFORMATION: References to the rulemaking record are made in the text of this preamble. The Hazard Communication Standard docket, No. H–022, contains eight sub-dockets—H–022A, H–022B, H–022C, H–022D, H–022E, H–022F, H–022G, and H–022H. All of these docket files are part of the rulemaking record. However, in this document, no specific references are made to either Docket H–022C or H–022E (these files deal exclusively with the issue of trade secrets), or H–022F, H–022G, and H–022H. The following abbreviations have been used for citations to the other record files:

H–022, Ex.: Exhibit numbers in Docket H–022, which includes H–022A and H–022B, for exhibits collected for the original 1983 HCS for manufacturing.

Ex.: Exhibit numbers in H–022D for exhibits collected since the 1985 Court remand related to the expansion of the scope of industries covered. This docket includes the comments received in response to the August 8, 1988 proposal.

Tr.: Public hearing transcript page numbers. The hearing transcript pages from the December 1988 hearing are not numbered consecutively, *i.e.*, each day begins again with page 1. Transcript references will thus include a reference to the day, and the page number for that day's testimony. The days are numbered as follows: December 6 is Day 1; December 7 is Day 2; December 8 is Day 3; December 9 is Day 4; December 12 is Day 5; December 13 is Day 6; and December 14 is Day 7. As an example, a reference to testimony which appears on page 65 of the transcript for December 8 will be indicated as "Tr. 3–65." Transcript references to hearings held between June 15 and July 31, 1982, are consecutively numbered, and will not have a prefix number identifying the day.

I. Background

A. Review of the Need for the Standard

The HCS was promulgated to provide workers with the right to know the hazards and identities of the chemicals they are exposed to while working, as well as the measures they can take to protect themselves. OSHA has estimated that there are over 32 million workers exposed to hazardous chemicals in over 3.5 million workplaces (48 FR 53282, 53323; 52 FR 31871). According to the National Institute for Occupational Safety and Health (NIOSH), there are as many as 575,000 hazardous chemical products in these workplaces (48 FR 53323). Based on the growth rate of the chemical industry with regard to new products, this number may now be as high as 650,000. Chemical exposures occur in every type of industry (52 FR 31858). (See also Exs. 4–1 and 4–2.) In fact, workers typically experience multiple exposures to numerous industrial chemicals at one point of time or over a long period of employment. 48 FR 53323.

Besides having what OSHA considers to be an inherent right to know about hazardous chemicals in their workplaces, exposed employees have a need to know this information as they are at significant risk of experiencing adverse health or physical effects in the absence of such knowledge. Chemicals pose a myriad of hazards to exposed workers, from mild health effects, such as irritation, to death. Some chemicals cause or contribute to chronic diseases, such as heart disease, kidney disease, sterility, or cancer. Many chemicals cause acute injuries or illnesses such as rashes, burns, and poisoning. Numerous chemicals pose physical hazards to workers by contributing to accidents like fires and explosions.

During the HCS rulemaking, data collected about chemical illness and injury rates in manufacturing sectors showed that some 40–50,000 manufacturing workers experienced chemical source illnesses a year, and an average 10,000 worker compensation claims were filed annually in connection with chemical illness or injury in manufacturing (48 FR 53285). Employees in non-manufacturing industries were estimated to experience acute chemical illness and injury at the rate of 13,671 injuries, 38,248 illnesses, and 102 fatalities per year. 52 FR 31868. The chronic disease rate was 17,153 chronic illnesses, 25,388 cancer cases, and 12,890 cancer deaths per year. *Id.* (Compare with, Ex. 4–77 (NIOSH data indicating 136,212 work-related chemical injuries treated in emergency rooms in 1986)).

OSHA believes that the reported data understate the extent of the health and safety problems caused by chemicals in the workplace. Lack of knowledge about health effects associated with chemical exposures contributes to the chronic underreporting of occupational illnesses (Exs. 4–44; 41). As the effects caused are diseases or physical manifestations that may also occur in workers as a result of non-chemical or non-occupational factors, it is often difficult to identify such ailments as being caused by occupational exposures. Misdiagnosis is a problem and often symptoms are treated without realizing that the cause is an occupational chemical exposure. See, e.g., 53 FR 25973 (Ex. 4–178).

Worker turnover in many industries also increases the likelihood that the link between a workplace chemical exposure and subsequent illness will be overlooked and will not be reported. This is particularly true for long-term health effects which develop over time, or after repeated exposures. Many chronic diseases are characterized by long latency periods of 20–30 years or longer.

In addition, health effects of some chemicals may contribute to the occurrence of injuries that are reported but are not causatively linked to chemical exposures. For example, central nervous system depression due to solvent exposure may cause a painter to become dizzy and fall off a ladder. The subsequent injury may be reported, but the solvent exposure is not identified as the cause. (See Exs. 67 for studies on neurobehavioral changes in painters due to solvent exposures; 4–161 for case of injury to cosmetologist resulting from solvent exposure causing dizziness, loss of balance, and a fall.)

B. Overview of Standard

The purpose of the HCS is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. In broad outline, the HCS achieves its purpose by an integrated three-pronged system. First, chemical manufacturers and importers must review available scientific evidence concerning the physical and health hazards of the chemicals they produce or import to determine if they are hazardous. (Paragraph (d)). Second, for every chemical found to be hazardous, the chemical manufacturer or importer must develop comprehensive material safety data sheets (MSDSs) and warning labels for containers and send both downstream along with the chemicals. (Paragraphs (f), (g)). Third, all employers must develop a written hazard communication program and provide information and training to employees about the hazardous chemicals in their workplace. (Paragraphs (e), (h)).

The three information components in this system—labels, material safety data sheets, and worker training—are all essential to the effective functioning of the program. The MSDSs provide comprehensive technical information, and serve as a reference document for exposed workers as well as health professionals providing services to those workers. The labels provide a brief synopsis of the hazards of the chemicals at the site where the chemical is used in the work area. Training ensures that workers understand the information on both MSDSs and labels, know how to access this information when needed, and are aware of the proper protective procedures to follow. Each component effectuates the others. See *General Carbon Co.* v. *OSHRC*, 860 F.2d 479, 481 (DC Cir. 1988).

The provision of information under the HCS about these effects and protective measures will reduce the incidence of chemical source illnesses and injuries in the workplace. 48 FR 53281–83. An effective hazard communication program will accomplish this purpose through modifying the behavior of both employers and employees. Employers, many of whom have not been aware of the potential hazards of the chemicals they purchase to use in their workplaces, will be able to use the information provided under the HCS to design better protective programs. Complete information about chemicals may allow an employer to choose a less hazardous product, thus preventing dangerous exposures from occurring. Exs. 4–194, 71–40. Accurate information is also needed to properly design engineering controls, select appropriate protective clothing, and choose an effective respirator for exposed employees. Ex. 71–40. Improved understanding of chemical hazards by supervisory personnel results in safer day-to-day handling of hazardous substances, and proper storage and clean-up. See *e.g.*, Exs. 4–61, 4–75, 71–40.

Workers provided the necessary hazard information will more fully participate in, and support, the protective measures instituted in their workplaces. The presence of labels and material safety data sheets in the workplace will provide each worker with the hazards of the chemicals, as well as the means to protect themselves. The training of workers will teach them how to use the available information effectively. Properly trained workers will know how to read and use labels and material safety data sheets, will know what protection is required to work safely with the chemicals in the workplace and will use it, and will be able to determine what actions are necessary if an emergency occurs. (E.g., Exs. 4–75, 4–174.) Information on chronic effects of exposure to hazardous chemicals will help workers recognize such symptoms and seek early treatment of chronic disease.

The information provided under hazard communication will also enable health and safety professionals to provide better services to exposed employees. (E.g., Exs. 4–153, 71–37.) Medical surveillance, exposure monitoring, and other such services will be enhanced by the ready availability of health and safety information.

As OSHA has noted in Appendix E of the rule: "For any safety and health program, success depends on commitment at every level of the organization. This is particularly true for hazard communication, where success requires a change in behavior. This will only occur if employers understand the program, and are committed to its success, and if employees are motivated by the people presenting the information to them."

It is in these ways that the HCS addresses the significant risks posed to workers handling hazardous chemicals and not knowing their hazards or the proper methods of handling and using them. This rulemaking is intended to promulgate minor changes and technical amendments to the existing HCS to enhance its effectiveness.

C. History of the Rulemaking

The development of OSHA's Hazard Communication Standard (HCS) was initiated in 1974. The process has been lengthy and is discussed in detail in the preambles to both the original and revised final rules (see 48 FR 53280–81 and 52 FR 31852–54), and in the August 1988 NPRM (53 FR 29822–25). This discussion will focus on the sequence of events which has occurred since the original final rule was published in the **Federal Register** on November 25, 1983, and in particular, those which have occurred since the NPRM was published.

The original rule, which was promulgated on November 25, 1983 (48 FR 53280), covered employees in the manufacturing sector of industry. That rule was modified on August 24, 1987 (52 FR 31852) to expand the coverage to all industries where employees are exposed to hazardous chemicals. Complete implementation of the standard's requirements in the non-

manufacturing sector was subsequently delayed by various court and administrative actions. However, the August 24, 1987, rule is now fully effective and has been so since January 24, 1989, and is being enforced in all industries. (See Notice of Enforcement, 54 FR 6886, Feb. 15, 1989).

Petitions for judicial review of the original 1983 rule covering manufacturing were filed in the U.S. Court of Appeals for the Third Circuit (hereinafter referred to as "the Court" or "the Third Circuit") by the United Steelworkers of America, AFL–CIO–CLC, and by Public Citizen, Inc., representing itself and a number of labor groups. Motions to intervene in these cases were received from the Chemical Manufacturers Association, the American Petroleum Institute, the National Paint and Coatings Association, and the States of New York, Connecticut, and New Jersey. In addition, petitions for review of the standard were filed by the State of Massachusetts in the First Circuit; the State of New York in the Second Circuit; the State of Illinois in the Seventh Circuit; the Flavor and Extract Manufacturers' Association in the Fourth Circuit; and the Fragrance Materials Association in the District of Columbia Circuit. These cases were subsequently transferred to the Third Circuit and consolidated into one proceeding. The cases brought by the Flavor and Extract Manufacturers' Association and the Fragrance Materials Association were withdrawn prior to filing briefs.

The Court issued its initial decision on the challenges to the rule on May 24, 1985 *United Steelworkers of America* v. *Auchter*, 763 F.2d 728 (3d Cir. 1985)(Ex. 4–21.) The standard was upheld in most respects, but three issues were remanded to the Agency for reconsideration. The decision was not appealed.

First, the Court concluded that the definition of trade secrets incorporated by OSHA included chemical identity information that was readily discoverable through reverse engineering and, therefore, was "broader than the protection afforded trade secrets by state law." The Court directed the Secretary of Labor to reconsider a trade secret definition which would not include chemical identity information that is readily discoverable through reverse engineering. Secondly, the Court held the trade secret access rule in the standard invalid insofar as it limited access to health professionals, but found the access rule otherwise valid. The Secretary was directed to adopt a rule permitting access by employees and their collective bargaining representatives to trade secret chemical identities. OSHA complied with the Court orders regarding the two trade secret issues in a separate rule, published in final form on September 30, 1986 (51 FR 34590). The revised trade secret provisions were incorporated into the text of the final rule published on August 24, 1987.

The third issue remanded to OSHA involved the scope of industries covered by the standard. The original HCS applied to employers and employees in the manufacturing sector. The Court directed the Secretary of Labor to reconsider the standard's application to employees in other industry sectors, and "to order its application in those sectors unless he can state reasons why such application would not be feasible." 763 F.2d at 739, 743.

OSHA subsequently published an advance notice of proposed rulemaking (ANPR) to collect comments and information on the expansion of the scope to cover these additional sectors (50 FR 48795; November 27, 1985). In particular, the Agency sought information on the extent employers in non-manufacturing industries had already implemented various aspects of a hazard communication program. In addition, OSHA wanted to obtain data regarding the applicability of the provisions as written in the original rule to these other sectors. A total of 226 responses were received. (See Ex. 2.) OSHA also commissioned a study of the economic impact of extending the HCS to the fifty major non-manufacturing industry groups within its jurisdiction. (See Exs. 4–1 and 4–2.) Based on this newly acquired evidence, as well as the previous rulemaking record, OSHA was in the process of drafting a proposed rule.

On January 27, 1987, however, the United Steelworkers of America, AFL-CIO-CLC and Public Citizen, Inc., petitioners in the 1985 challenge, filed a Motion For An Order Enforcing the Court's Judgment and Holding Respondent in Civil Contempt. Petitioners claimed that the Court's 1985 order had not authorized OSHA to embark on further fact gathering, and that OSHA should have made a feasibility determination based upon the 1985 rulemaking record. Petitioners also argued that even if further fact gathering had been allowed by the Court's order, OSHA's pace was unduly slow.

In response, OSHA noted that the Court's 1985 order did not specify that OSHA should act on the then-existing record. OSHA believed that seeking further evidence on feasibility in non-manufacturing was appropriate in light of its statutory obligation to issue rules that are well grounded in a factual record. OSHA also asserted that, consistent with Supreme Court precedent, the Agency should be permitted to exercise its discretion in determining the appropriate rulemaking procedures for complying with the Court's remand order. Lastly, the Agency argued that its schedule to complete the rulemaking was reasonable and did not constitute undue delay.

On May 29, 1987, the Court issued a decision holding that the Court's 1985 remand order required consideration of the feasibility of an expanded standard without further rulemaking. *United Steelworkers of America, AFL–CIO–CLC* v. *Pendergrass*, 819 F.2d 1263 (3d Cir. 1987) (Ex. 4–20.) The Court declared that adequate notice had been provided to non-manufacturers during the original rulemaking that they might be covered by the HCS, *id.* at 1265–1266, 1269, that the answers to the remaining questions OSHA may have had regarding feasibility were "self-evident" or "readily ascertainable" from the original record, *id.* at 1268–69, and that further fact finding was "unnecessary", *id.* at 1268. The Court ordered the Agency to issue, within 60 days of its order, "a hazard communication standard applicable to all workers covered by the OSHA Act, including those which have not been covered in the hazard communication standard as presently written, or a statement of reasons why, on the basis of the present administrative record, a hazard communication standard is not feasible." *Id.* at 1270.

OSHA subsequently re-evaluated the evidence in the record and determined that a modified final rule covering all employers subject to the Act (*i.e.*, both manufacturing and nonmanufacturing) was both necessary (the Agency had determined in 1983 that all employees exposed to hazardous chemicals without having adequate information about them were at significant risk of experiencing adverse effects) and feasible (both technologically and economically). The Agency therefore issued the revised rule on Hazard Communication which was published in the **Federal Register** on August 24, 1987 (52 FR 31852).

The only modifications OSHA made to the original rule in the 1987 revision were those that were related to expansion of the scope. Publication of a final rule precluded any actions other than those specifically required by the expansion, particularly since the Court determined that the record it reviewed (exhibits collected through November

1983) was a sufficient basis for the final rule. Thus evidence collected subsequent to that time was merely cited as additional substantiation for the expansion.

The revised final rule expanded the scope of industries covered from just the manufacturing sector to all industries where employees are exposed to hazardous chemicals. As OSHA stated at that time, the Agency has evidence to indicate that there is chemical exposure in every type of industry, lack of knowledge about those hazardous chemicals puts employees at a significant risk of experiencing material impairment of health, and thus employees in all industries must have protection under the rule. (See 52 FR 31858.)

Although the standard was issued as a final rule, OSHA invited interested parties to submit information, data or evidence regarding the feasibility or practicality of the provisions as written when applied to the non-manufacturing sector, as well as any recommendations for further modification. A 60-day period was established for such comments, and it ended on October 23, 1987. A total of 137 comments were received (40 of them were received after the deadline), and entered into Docket H-022D (Ex. 5). A variety of opinions was expressed in the comments regarding a number of issues; however, most of the comments did not contain data or evidence concerning either feasibility or practicality. Many of the comments were questions or requests for clarification of the provisions.

In addition to the comments submitted to OSHA, the Office of Management and Budget (OMB) convened a public meeting under the Paperwork Reduction Act (44 U.S.C. 35) to address the information collection requirements of the expanded rule. The transcript of the OMB public meeting (which was held on October 16, 1987) is entered in the docket as Ex. 5–76, and other relevant documents (*e.g.*, copies of statements, etc.) are entered in Exhibit 6. (In addition, the transcript of an April 2, 1987, public meeting on the information collection requirements for the manufacturing sector is Ex. 4–3.) The majority of the participants in OMB's October 16 meeting submitted written comments to OSHA as well, so there is considerable duplication in Exhibit 6 of opinions that had already been expressed by the same parties in other parts of the rulemaking record.

In a letter sent to the Department of Labor on October 28, 1987, and subsequently published by OSHA in the Federal Register on December 4, 1987 (52 FR 46075) (Ex. 4–67), OMB, under the authority of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), disapproved certain information collection requirements in the expanded scope rule, as of the rule's effective date (May 23, 1988). These were based upon the record of the October 16 public meeting and the previous meeting on April 2, 1987 regarding the information collection requirements for the manufacturing sector, as well as OSHA's preamble to its August 24 rule and its justification submitted formally under the Paperwork Reduction Act. The October 28 letter stated that OMB disapproved: (1) The requirement that material safety data sheets be provided on multi-employer worksites; (2) coverage of any consumer product that falls within the "consumer products" exemption included in Section 311(e)(3) of the Superfund Amendments and Reauthorization Act of 1986; and (3) coverage of any drugs regulated by the Food and Drug Administration in the non-manufacturing sector. In addition, OMB determined that OSHA should reopen the rulemaking on the HCS to consider alternatives to the definition of "article" which was included in both the original and revised final rules. Lastly, OMB conditioned paperwork approval upon OSHA's consulting with the U.S. Small Business Administration and the Department of Commerce in order to develop a plan for a Federal administrative effort that will provide assistance to the regulated industries to alleviate paperwork burdens and costs. For a complete description of OMB's rationale for these determinations, see the Federal Register notice of December 4, 1987 (52 FR 46075).

On April 13, 1988, OMB extended its approval of all information collection requirements in the HCS through April 1991, except that OMB continued to disapprove the three provisions previously disapproved. 53 FR 15033. OMB's approval of the existing definition of "article" was limited to the clarification included in a January 14, 1988, letter from Assistant Secretary for Occupational Safety and Health John Pendergrass to OMB, which stated that "absent evidence that releases of such very small quantities could present a health hazard to employees, the article exception to the rule's requirements would apply." In response to commenters who requested that OMB not extend approval to any requirements in the non-manufacturing sector, OMB also stated:

> The concerns of these commenters are largely based on the possibility that the standard and OMB's decision under the PRA will change dramatically as a result of the rulemaking. Although change is always possible, any such change would be fully considered during the rulemaking process. Of course, in order for OMB to grant PRA approvals, any changes must offer sufficient practical utility to justify any incremental paperwork burden they impose, including the burden of revising already-developed written programs. Moreover, as stated above, we are continuing to disapprove the previously-disapproved provisions; the rulemaking should of course conform the rule to these disapprovals.

On August 8, 1988, OSHA published a notice of proposed rulemaking (NPRM) to modify its Hazard Communication Standard (HCS) (53 FR 29822).

In the NPRM, OSHA reopened the rule on all of the issues raised by OMB in its letter in order to have an opportunity to fully discuss the complete current record on each item, as well as to collect additional data from the public.

The initial deadline for receipt of comments on the NPRM was October 7, 1988. This date was later extended to October 28, 1988. OSHA received 167 comments.

An informal public hearing was convened in Washington, DC on December 6, 1988, and was adjourned on December 14, 1988. Over 1300 pages of oral testimony were received. Sixty days were provided for post-hearing submissions of new information by hearing participants (ending February 13, 1989), and an additional thirty days were allowed for submission of summary briefs. A total of thirty-four post-hearing exhibits have been entered into the record.

Administrative Law Judge George Fath certified and closed the hearing record on November 9, 1990.

OSHA published two requests for comments and information subsequent to the 1988 NPRM. On January 22, 1990 (55 FR 2166), the Agency solicited public input related to international harmonization of chemical safety and health information, and a proposed convention and recommendation of the International Labor Organization (ILO). OSHA received 52 comments in response to this notice which were used by United States' representatives to prepare for participation in the ILO meetings on these documents.

On May 17, 1990 (55 FR 20580), OSHA published a request for comments on improving the effectiveness of information generated in accordance with the HCS, and subsequently disseminated on labels and MSDSs. Nearly 600 comments were received during the 90 day comment period. Many commenters supported standardization of the format or order of information on the MSDSs, and of the

presentation of information on labels. The Agency has decided that administrative or regulatory changes to be made in response to these comments will be done separately from this final rule.

D. Court Challenges to the Revised Final Rule

The revised final rule was challenged in the U.S. Court of Appeals by the Associated Builders and Contractors, National Grain and Feed Association, Associated General Contractors of Virginia, Associated General Contractors of America, and United Technologies Corporation. A number of interested parties intervened in the cases as well. The challenges generally involved the appropriateness of OSHA's publishing a final rule in response to the Third Circuit's order.

Although these cases were originally consolidated in the U.S. Court of Appeals for the District of Columbia Circuit, they were transferred to the U.S. Court of Appeals for the Third Circuit on May 20, 1988. The cases were transferred to the Third Circuit because the "revised [HCS] was promulgated in response to orders by the Third Circuit * * * and petitioners have raised issues similar to those already considered by that court."

On June 24, 1988, the Third Circuit granted a stay of the standard as it applied to the construction industry (29 CFR 1926.59) pending the outcome of the litigation challenging the rule. OSHA published a notice in the **Federal Register** on July 22, 1988 (53 FR 27679) to provide the public further information regarding the applicability of the stay to construction employers and enforcement of the rule in the other industries

After considering the merits of the challenges to the standard which were filed by employer representatives, the U.S. Court of Appeals for the Third Circuit issued a decision on November 25, 1988 that denied the petitions for review. The Court stated: "None of the substantive or procedural challenges to the application of the hazard communication standard to the construction or grain processing and storage industries have merit. The petitions for review of ABC (Associated Builders and Contractors, Inc.), AGC (The Associated General Contractors), NGFA (The National Grain and Feed Association, Inc.) and UTC (United Technologies Corporation) will therefore be denied. The stay of those standards granted by a panel of this court on June 24, 1988, shall be vacated." *Associated Builders and Contractors, Inc.* v. *Brock*, 862 F.2d 63, 69 (3d Cir. 1988) (Ex. 15). Further requests from the AGC and the ABC for a continuation of the stay were denied by the Third Circuit and by the United States Supreme Court (Nos. 88–1070; 88–1075). The Supreme Court also declined to review the Third Circuit's decision (November 29, 1988). The Third Circuit's ruling became fully effective on January 30, 1989. The standard, therefore, is effective in all industries. 54 FR 6886.

E. Litigation Involving Provisions Disapproved With Regard to Information Collection Requirements

As described above, on October 28, 1987, the Office of Management and Budget (OMB), citing authority of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), disapproved certain information collection requirements in the expanded scope rule, as of the rule's effective date. On December 4, 1987 (52 FR 46075), OSHA published OMB's letter describing its determination in a notice in the **Federal Register**. (See also 53 FR 15033 (Apr. 27, 1988) (OMB letter to Department of Labor dated April 13, 1988)).

The provisions that OMB disapproved were: (1) The requirement that material safety data sheets be provided on multi-employer worksites; (2) coverage of any consumer product that falls within the "consumer products" exemption included in section 311(e)(3) of the Superfund Amendments and Reauthorization Act of 1986; and (3) coverage of any drugs regulated by the Food and Drug Administration in the non-manufacturing sector. In accordance with OMB's decision, OSHA did not enforce these three disapproved requirements.

OMB's disapproval of the HCS provisions was challenged in the U.S. Court of Appeals for the Third Circuit. On August 19, 1988, the Court of Appeals invalidated OMB's actions as being outside OMB's authority under the Paperwork Reduction Act. *United Steelworkers of America* v. *Pendergrass*, 855 F.2d 108 (3d Cir. 1988)(Ex. 4–190). The Court held that the three disapproved HCS provisions did not require "collection of information" under the Paperwork Reduction Act and embodied substantive policy decisionmaking entrusted to OSHA. *Id.* at 112. The Court ordered that: "The Secretary [of Labor] shall publish in the **Federal Register** a notice that those parts of the August 24, 1987 hazard communication standard which were disapproved by OMB are now effective." *Id.* at 114.

On September 2, 1988, the U.S. Department of Justice filed a petition with the Third Circuit requesting a rehearing and suggesting a rehearing *en banc*, which automatically stayed the effect of the Court's order. The Court denied the petition for rehearing (November 29, 1988), as well as requests for stay of the decision. In addition, a further motion by industry representatives for a stay of the decision was denied by U.S. Supreme Court Justice Brennan (January 24, 1989), and by the full Court upon reconsideration (February 21, 1989).

The Third Circuit's decision became effective January 30, 1989. As ordered by the Third Circuit, OSHA published a notice in the **Federal Register** on February 15, 1989 (54 FR 6886) to inform affected employers and employees that all provisions of the HCS were in effect in all industries. As a matter of enforcement policy, OSHA did not check for compliance with the three provisions in programmed inspections until March 17, 1989.

To implement the court order, technical amendments were made to the HCS to delete from notes following the headings of the standard, and from the parentheticals following the text of the standard, statements that any provisions of the HCS are disapproved by OMB. The OMB-assigned control number for the approved collection of information requirements of the HCS remain following the text of the standard. The Paperwork Reduction Act requires display of OMB control numbers with all information collection provisions.

Following the decision in *United Steelworkers*, the Solicitor General requested the Supreme Court on behalf of the United States government to review the case, and the Court granted its request. In *Dole* v. *United Steelworkers of America*, the Supreme Court affirmed the judgment of the Third Circuit. 110 S.Ct. 929 (1990). The Court held that the term "collection of information" in the Paperwork Reduction Act refers solely to the collection of information by or for the use of a federal agency, and does not cover rules mandating disclosure of information to a third party. *Id.* at 937. Thus, the OMB-disapproved provisions reinstated by the Third Circuit continue to be in effect.

The primary purpose for the 1988 HCS NPRM was to address the issues related to the OMB disapproval. As the Third Circuit has invalidated OMB's disapproval, and that decision was upheld by the Supreme Court, those provisions are no longer considered to be information collection requirements subject to OMB review and approval. The modifications in this final rule are based upon OSHA's determination that

clarifications would enhance compliance and thus protection of workers. The only information collection burdens for the rule involve access by OSHA during inspections to records maintained by the employer. These were approved by OMB on June 24, 1991 until April 1994 (control number 1218–0072). As this final rule does not affect the access burden, OSHA is not submitting this rule for further consideration under the authority of the Paperwork Reduction Act.

F. Advisory Committee on Construction Safety and Health (ACCSH)

As discussed in the preamble to the August 1987 final rule (52 FR 31858–59), the ACCSH reviewed a draft notice of proposed rulemaking to expand the scope of the HCS to construction on June 23, 1987. The ACCSH went through the NPRM line-by-line, making recommendations to adapt it to the construction industry, *i.e.*, the document with the recommended changes constituted an ACCSH recommended standard for hazard communication (Ex. 4–186). A number of the recommendations were adopted (*e.g.*, the definition of workplace was modified to include job sites or projects; the written hazard communication program requirements were amended to state more clearly that the programs are to be maintained at the site).

As the 1988 NPRM addressed issues that affect construction, OSHA transmitted a draft of it to the ACCSH for review and comment. In a meeting on March 30, 1988, the ACCSH did not provide specific recommendations on the NPRM. The ACCSH reiterated its desire to have a separate standard for construction, and appointed a subcommittee to make further recommendations to the Assistant Secretary. However, the ACCSH also reaffirmed that the standard as written should be implemented on May 23, 1988 as originally scheduled.

The ACCSH-appointed subcommittee reviewed the standard again and prepared new recommendations. The full committee voted to submit the subcommittee's recommendations to OSHA at their meeting on November 30, 1988. Their recommendations are in the record as Exs. 14–1, 14–2, and 14–3.

The focus of their recommendations was to reorganize the requirements of the rule by removing any provisions that apply primarily to chemical manufacturers and importers. Their proposed draft rule either deleted the requirements or moved them to an appendix. OSHA does not agree that these requirements should be removed from the rule. It is important for construction employers to be aware of what information they are entitled to, and the distribution mechanisms. Reorganization as suggested by the ACCSH detracts from the logical presentation of the requirements, and makes the rule more difficult to understand. OSHA believes that the addition of non-mandatory Appendix E provides sufficient guidance for construction employers, as well as all other employers using chemicals, to guide them to the applicable provisions of the rule.

In addition, the ACCSH subcommittee suggested that a definition be added for a "competent person," and that such individuals be given certain duties under the rule. OSHA does not believe that this is a provision that would add to the protections of the rule. The HCS is intended to train all workers about the hazards of chemicals and appropriate protective measures. It is not clear what additional training a worker would have to have to be designated a "competent person." The intent of the rule is to ensure that all workers are trained to be "competent." In addition, it was suggested that the "competent person" would have the authority to stop the job or correct the hazards. This type of action is beyond the information transmittal requirements of the HCS.

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (the Act) (29 U.S.C. 651 *et seq.*) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and the authority vested in, the Secretary of Labor to set mandatory safety and health standards.

Authority for issuance of this standard is found primarily in sections 6(b), 8(c)(1), and 8(g)(2) of the Act. 29 U.S.C. 655(b), 657(c)(1), 657(g)(2). Section 6(b), and in particular Section 6(b)(5), governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 8(c)(1) of the Act empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act and to make such records available to the Secretary. Section 8(g)(2) of the Act empowers the Secretary to "prescribe such rules and regulations as [she] may deem necessary to carry out [her] responsibilities under this Act * * *."

Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as follows:

> [A] standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide a safe or healthful employment and places of employment.

In addition, Congress specifically stated in section 6(b)(5) that:

> The Secretary, in promulgating standards dealing with toxic materials, or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

The Supreme Court has said that section 3(8) applies to all permanent standards promulgated under the Act and requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment. *Industrial Union Dep't* v. *American Petroleum Institute*, 448 U.S. 607 (1980). The "significant risk" determination constitutes a finding that, absent the change in practices mandated by the standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm. *Id.* at 642. This finding, however, does not require mathematical precision or anything approaching scientific certainty if the "best available evidence" does not warrant that degree of proof. Id. at 655–656; 29 U.S.C. 655 (b)(5). Rather, the Agency may base its findings largely on policy considerations and has considerable leeway with the kinds of assumptions it applies in interpreting the data supporting it. 448 U.S. at 656.

Moreover, under the authority of Section 6(b)(7), 29 U.S.C. 655(b)(7), any standard issued by the Secretary shall contain requirements that are essentially "information-gathering" in function, including:

* * * prescrib[ing] the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure.

These requirements may be imposed at levels of risk below what would be necessary for the setting of exposure limits because they serve the purpose of "keep[ing] a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary base for decreasing the limit if it was initially set too high." *Id.* at 658 (footnote omitted). They also provide basic protections for workers in the absence of specific permissible exposure limits, particularly by providing employers with guidance for designing protective programs.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by a proposed standard, it must set a standard "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employee will suffer material impairment of health * * *." 29 U.S.C. 655(b)(5). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacturers Institute, Inc.* v. *Donovan* (*ATMI*), 452 U.S. 490 (1981). The "feasibility" constraint has also been described simply as limiting standards to requiring only what is "capable of being done" or "achievable." *Id.* at 508–509. The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." *Id.* at 509. The Court stated that the Agency could use cost-effectiveness analysis and choose the less costly of two equally effective standards. *Id.* at 531 n.32.

A. Finding of Significant Risk

In *United Steelworkers of America* v. *Auchter*, 763 F.2d 728, 735 (3d Cir. 1985), the U.S. Court of Appeals for the Third Circuit concluded, as a threshold matter, that the hazard communication rule is a section 6 standard under the Act which is aimed at correcting a particular "significant risk" in the workplace. The HCS is not "merely an enforcement or detection procedure designed to further the goals of the Act generally." *Id.* (quoting test for distinguishing standards from regulations first explained in *Louisiana Chemical Ass'n* v. *Bingham*, 657 F.2d 777, 782 (5th Cir. 1981)). See also *Associated Builders & Contractors* v. *Brock*, 862 F.2d at 67.

The practices mandated by the standard—hazard evaluations, written hazard communication programs, labels and other forms of warning, material safety data sheets, and information and training—are, at bottom, directed not merely at the identification of workplace chemicals, but more significantly at the correction of their hazards as well. This correction will occur largely as a result of employee compliance with instructions on how to protect themselves when exposed to hazardous chemicals that are an integral part of any hazard communication program, as well as by other hazard-reducing strategies adopted by employers when they become more aware of the hazards in their workplaces (*e.g.*, chemical substitution). And because the record clearly indicates that inadequate communication about serious chemical hazards endangers workers, and that the practices required by this standard are necessary and appropriate to the elimination or mitigation of these hazards, the Secretary is able to make the threshold "significant risk" determination that is an essential attribute of all permanent standards. The Third Circuit Court of Appeals agreed that "inadequate communication is itself a hazard, which the standard can eliminate or mitigate." *United Steelworkers* v. *Auchter*, 763 F.2d at 735.

A number of commenters have questioned OSHA's general finding of significant risk. These commenters argue that OSHA needed to find significant risk: (1) For each industry covered (*e.g.*, Ex. 84 (construction)); (2) for each chemical covered (*e.g.*, Ex. 11–129 (grain dust)); and (3) for each exposure situation (*e.g.*, Ex. 85 (mixtures, articles)). Although these comments are addressed in more detail in Part III of this preamble where the rule is summarized, briefly, it is clear from the relevant court decisions that these specific findings are not required for a standard such as this, where the risk of inadequate knowledge is the same in every application of the standard.

In *Associated Builders & Contractors* v. *Brock*, 862 F.2d 63 (1988), the Third Circuit responded to the first two complaints against OSHA's significant risk finding. The Court noted that the general significant risk finding for the original 1983 rule was appropriate for the entire manufacturing sector, even though OSHA did not make individual findings for each of the twenty major Standard Industrial Classification (SIC) Code manufacturing subdivisions. *Id.* at 67. The Court concluded that "[t]here is no more obvious need for industry specific significant risk determinations for the [non-manufacturing] industries than for subdivisions of the manufacturing sector." *Id.* at 67–68. The Court held that for this "performance-oriented information disclosure standard covering thousands of chemical substances used in numerous industries * * * the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries. A requirement that the Secretary assess risk to workers and the need for disclosure with respect to each substance in each industry would effectively cripple OSHA's performance of the duty imposed on it by 29 U.S.C. 655(b)(5); a duty to protect all employees, to the maximum extent feasible." *Id.* at 68. OSHA was not required to assess individually the significant risk that would be alleviated by the HCS's application to each of the seventy major business classifications, much less for each of the hazardous substances used in those industries.

As for arguments that OSHA should only apply the HCS where chemical exposures pose known significant risks (*e.g.*, Ex. 85), the Agency concludes that neither the record evidence nor policy considerations support such an approach. The record shows that although chemical manufacturers or importers may know, in principle, the use to which their product will be put, they generally do not know enough about downstream operations to make reliable predictions about downstream exposure levels. Therefore, information must be provided for all hazardous chemicals to which employees may be exposed, regardless of any judgments by the chemical manufacturer or importer about possible levels of risk. 48 FR 53295, 53296, 53307. Furthermore, to allow chemical manufacturers or importers to edit hazard information based on their predictions of the extent of downstream exposures is to deprive downstream employers and employees an opportunity to make an effective assessment of potential hazards based on complete information on the individual chemical and in light of any possible additive or synergistic effects that may be posed by the presence of other hazardous chemicals in the workplace. *Id.* at 53295, 53323. OSHA finds that workers would be threatened with a significant risk of harm if chemical manufacturers or importers are

allowed to delete hazard information based on a presumption of downstream risks, thus depriving downstream employees and employers from having complete information on which to base their decisions regarding control measures. See, *General Carbon Co.* v. *OSHRC*, 860 F.2d 479 (DC Cir. 1988).

In addition, in light of § 6(b)(7) of the Act requiring OSHA to "insure that employees are apprised of all hazards to which they are exposed," the Agency concludes that employees must be informed about all potential hazards before the worker is exposed to them and not only when there is overexposure. Linking HCS applicability to downstream exposures posing a significant risk is contrary to the standard's very purpose: to change downstream employer and employee behavior before adverse health effects occur. 48 FR 53296. OSHA has concluded that imposing informational requirements is necessary and appropriate to protect workers even when OSHA has not determined that the level of risk at a particular worksite warrants a substance-specific standard that would employ more elaborate types of controls. *Cf. Associated Builders & Contractors*, 862 F.2d at 67–68; *United Steelworkers*, 819 F.2d at 1269–70.

B. Finding of Feasibility

OSHA originally chose to direct the HCS to employers in manufacturing, based on what were believed at that time to be relevant policy considerations. The Third Circuit held that "[o]nce a standard has been promulgated, however, the Secretary may exclude a particular industry only if he informs the reviewing court, not merely that the sector selected for coverage presents greater hazards, but also why it is not feasible for the same standard to be applied in other sectors where workers are exposed to similar hazards." *United Steelworkers*, 763 F.2d at 738. Therefore, because inadequate communication of chemical hazards is itself a significant risk, *id.* at 735, OSHA was required by the Court order to apply the HCS to all workplaces where employees are exposed to chemical hazards, to the extent feasible.

The feasibility question raised by the HCS is not difficult to resolve. This standard does not relate to activities on the frontiers of scientific knowledge; the requirements are not the sorts of obligations that approach the limits of feasibility. *Associated Builders & Contractors*, 862 F.2d at 68. The record on which the original and expanded HCS's were based did not contain credible evidence that the HCS would be technologically or economically infeasible for any industrial sector, *id.*, and there was substantial evidence of feasibility, 52 FR 31855–58.

Part III of this preamble addresses in more detail the comments which argue that individual requirements of the rule are infeasible (*e.g.*, Exs. 29 (distribution of MSDSs by wholesalers); 32 (provision of MSDSs at construction sites)). As a general matter, however, OSHA concludes that there is substantial evidence in the record that the performance-oriented, informational provisions of the HCS are capable of being done, and will not threaten any industry's "long-term profitability," *ATMI*, 452 U.S. at 531 n.55.

Certainly, the technical expertise needed to develop the chemical hazard information is feasible for producers of the hazardous chemicals. See, *e.g.*, 48 FR 53296–99. Likewise, there are no technological barriers preventing implementation of the other HCS requirements, in that they are conventional and common business practices that are administrative in nature. 52 FR 31855.

Moreover, OSHA concludes that the HCS administrative requirements can be economically incorporated into present practices. OSHA believes all businesses that produce, distribute, and use chemicals can ensure that their containers are maintained with proper hazard warnings just as these businesses would maintain labels or markings on containers to ensure that downstream purchasers and workers handling or using the chemicals comprehend the containers' contents and intended uses. Hazard information can be sent from supplier to user just as suppliers are able to send the chemical product itself to the user. All employers are able to acquire and maintain up-to-date MSDSs for hazardous chemicals just as they are able to acquire and maintain up-to-date cost information and performance specifications on those very same products. OSHA also concludes it is feasible for employers to inform and train workers regarding chemical hazards present in the workplace just as employers are capable of instructing and training their workers to perform their jobs in an efficient and speedy manner. 52 FR 31856–57. OSHA concludes that the record contains substantial evidence of the economic feasibility of the HCS, including such evidence as: (1) The numerous examples of compliance in all industries (see, *e.g.*, *id.*, Ex. 4–169 (71% of the 42,779 manufacturing facilities inspected by OSHA from the initial compliance date to Feb. 1988 in full compliance; of those cited for violating the HCS, majority had a hazard communication program although it was deficient in some respect)); (2) the similar implementation of other Federal communication laws and of state laws (see, *e.g.*, Ex. 4–183 (some 1000 employers inspected by Maryland Apr. 1, 1987 to Mar. 31, 1988, in total compliance with state law; over 1100 non-manufacturing workplaces inspected by Tennessee Oct. 1, 1987 to June 30, 1988, in total compliance), 4–184 (over 16,000 establishments inspected by Washington Jan. 1, 1987 to Dec. 31, 1987, in total compliance)); (3) the detailed regulatory impact and regulatory flexibility analyses which concluded that the costs associated with the HCS were negligible in relation to revenues and profits of affected industries (Ex. 4–1, 4–2. See also 52 FR 31867–76, 53 FR 29846–49); and (4) the development of numerous guidelines and consultative services offered by the Federal Government, States, trade associations, unions, professional organizations, and private consultants (see *e.g.*, 52 FR 31857, 53 FR 29848; Exs. 4–116, 4–118, 4–121, 4–122, 4–123, 4–128, 4–129, 4–130, 4–137, 4–138, 4–139, 4–144, 4–147, 4–148, 4–149, 4–150, 4–151, 4–154, 4–157, 4–158, 4–159, 4–160, 71–16, 71–55, 71–58, 71–61.)

OSHA has tailored the standard for a number of manufacturing and non-manufacturing operations to ensure that its requirements are feasible and effective in protecting all workers. See 52 FR 31858. *Cf.* 452 U.S. at 531, n.32 (OSHA can choose the less costly of two equally effective standards.) Modifications adopted in this final rule also act to tailor the rule to be more effective by incorporating language which clarifies the requirements.

III. Summary and Explanation of the Issues and the Provisions of the Final Rule

The regulatory text presented in this document reprints the entire final rule with the adopted modifications incorporated into the existing provisions. However, the discussion which follows is limited to the adopted changes and related issues raised in the record. It does not provide a complete summary and explanation of all of the provisions of the rule—for such information interested parties should refer to the preambles of the original (48 FR 53334–40) and revised (52 FR 31860–67) final rules.

While the primary purpose of publishing the NPRM was to resolve the issues raised by OMB and presented in the proposed and alternative provisions, OSHA also invited comment on other related issues. (As described in the background section above, due to a decision issued by the U.S. Court of

Appeals for the Third Circuit, subsequently upheld by the U.S. Supreme Court, the OMB disapproval has been invalidated.) In reopening the record, OSHA recognized that it was not operating "on a clean slate." In developing the revised final rule in 1987, OSHA had the benefit of an extensive evidentiary record. In addition, the Agency's experience gained under the original standard, as well as under state standards, some of which already applied to the nonmanufacturing sector, further supported OSHA's regulatory approach. OSHA continues to believe that the record substantially justifies the Agency's regulatory choices, and the information presented to OSHA since the standard was issued in 1987 has not convinced OSHA that significant changes are warranted to comply with the OSH Act. This final rule reflects that position. There are no substantial changes in the requirements, and OSHA is simply promulgating clarifications and modifications to enhance compliance.

As noted in the NPRM, OSHA retains "almost unlimited discretion to devise means to achieve the Congressionally mandated goal." *United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1230 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981). *Accord, Building and Construction Trades Dept., AFL-CIO* v. *Brock*, 838 F.2d 1258, 1271 (DC Cir. 1988). As the Agency determined at the time of the original final rule in 1983 that all employees exposed to hazardous chemicals are at significant risk of experiencing adverse health effects without the protections of the HCS, OSHA is statutorily required to extend those protections to those employees unless it can be shown that the requirements are not feasible (*i.e.*, they are not capable of being done). In the 1987 revised final rule, OSHA determined that the provisions are feasible in all industries. The rule's requirements had thus been determined by OSHA to be both necessary for the protection of all workers exposed to hazardous chemicals (*i.e.*, they would mitigate a significant risk of exposure), as well as capable of being done (*i.e.*, are technologically and economically feasible). As a result of these determinations, OSHA published the NPRM with the stated expectation that the standard would not be changed significantly in this final rule unless the Agency received substantial evidence during the rulemaking that a regulatory modification was clearly necessary. This necessity would have to be based on evidence that the 1987 standard is demonstrably infeasible in a specific respect, or that the proposed alternative would significantly increase the standard's intended safety and health benefit or significantly improve its cost-effectiveness.

As will be discussed in detail below, the information submitted during this rulemaking proceeding has convinced OSHA that its regulatory choices are supported by substantial evidence and that significant changes to the rule are unnecessary. However, some of the comments do reflect a lack of understanding of the requirements and of what is necessary for proper implementation of an acceptable program. Hence OSHA is taking the opportunity in this final rule to incorporate modifications to clarify such provisions and enhance compliance.

The discussion of the record which follows is organized in the order the subjects are addressed in the standard for ease of reference.

Scope and Application

Coverage of all industries. As OSHA described in the preamble to the revised final rule (52 FR 31855–59), expansion of the protections afforded by the HCS to all nonmanufacturing industries is supported by the rulemaking record. Evidence collected by OSHA indicates that there is chemical exposure occurring in every type of industry covered (although every employee may not be exposed), and that employees exposed to hazardous chemicals without knowledge of their identities, hazards, and appropriate protective measures are at a significant risk of experiencing adverse effects from such exposures. Furthermore, it is the Agency's position that all such employees are entitled to information regarding the chemical hazards they are exposed to in the workplace (*i.e.*, that they have a fundamental right to know this information), and that a uniform Federal hazard communication standard is the best method to ensure that it is provided. OSHA's regulatory requirements in this regard are consistent with the mandate of the Act (to protect all employees to the extent feasible), as well as with the Court's decisions upon review of the rule.

Despite these explicit determinations by OSHA in 1983 and 1987, as well as by the Third Circuit in its decisions (subsequently upheld by the Supreme Court), and a subsequent reiteration of this determination in the NPRM, there were still some comments submitted which suggested that certain industrial sectors should be exempted from the rule, or only covered by limited provisions. The majority of these were from representatives of the construction industry, and from distributors of hazardous chemicals. The arguments generally involved the degree of risk encountered in the industry, and the feasibility of the requirements. OSHA has not found the arguments regarding infeasibility to be persuasive, nor is there any justification for lessening the protections afforded employees in the industries in question.

Coverage of the Construction Industry

Significant risk—industry perspective. As was described in the preamble to the NPRM, representatives of the construction industry submitted comments objecting to coverage under the revised final rule (53 FR 29827). They argued that the rule's protections were not required in their industry as exposures to hazardous chemicals did not present a significant risk to workers, and construction employees are already required to be trained under the existing construction training standard, 29 CFR 1926.21. Therefore, according to these commenters, whatever risk there is has already been mitigated by the existing training, and any incremental risk remaining is not significant enough to warrant coverage under the HCS.

The comments and testimony received subsequent to the publication of the NPRM reiterate and expand upon this position. For example, a number of commenters opposed the rule in its entirety, suggesting that it is too burdensome, construction is already adequately covered, and the requirements are not appropriate for construction. See, *e.g.*, Exs. 11–9, 11–24, 11–29, 11–114, and 11–142. "We believe an extension of the Hazard Communication Standard to the non-manufacturing sector is unwarranted and burdensome. Construction workers simply do not face a significant risk of material harm from exposure to chemicals, and the standard is infeasible for the construction industry to implement." Ex. 11–114.

A number of commenters suggested that construction should not be covered since workers in this industry only use hazardous chemicals for short periods of time, the quantities they use are small, and they usually work outdoors (see, *e.g.*, Exs. 11–1, 11–73, 11–84, and 11–97).

Similarly, other commenters suggested that only a few chemicals used in construction are hazardous, and thus may warrant providing the protections of hazard communication to exposed workers (Ex. 11–4, asbestos is hazardous and employees should be trained regarding its hazards). It was

also suggested that the definition of what constitutes a hazardous chemical be limited under the rule (Ex. 11–6), and that OSHA cannot cover the only chemicals that pose a true hazard to workers on the construction job site (Ex. 11–114, natural gas seepage).

The majority of the construction industry commenters stated that there is no significant risk in the industry that requires coverage by the HCS. The Associated General Contractors of America (AGC) (Ex. 11–135) suggested to its members that comments submitted to OSHA in response to the NPRM address whether the company believes construction workers face a significant risk of material harm from exposure to chemicals; whether the standard would reduce whatever risks from hazardous chemicals do exist; and whether the rule is feasible. These commenters uniformly responded to AGC's request for this information to be submitted to the record by stating that there is no significant risk in construction, the rule would not reduce whatever risks there are, and the burdens are substantial (see, *e.g.*, Exs. 11–12, 11–18, 11–20, 11–26, 11–36, 11–83, 11–97, 11–135, and 11–157). (The AGC surveyed its membership to collect information regarding their opinions on the HCS and associated burdens. At the time their comments were submitted, only 102 responses had been received from the 8,000 members that are general contractors. Ex. 11–135.)

Most did not provide any specific comments on provisions of the rule, or suggestions for solutions to the problems they identified, other than exempting the construction industry from coverage. Providing no evidence or substantiation for their opinions, they simply stated that there is no significant risk, the risk would not be alleviated by implementation of the rule, and the burden would not be feasible. For example, at least six of this type of response were received from officers of Charlie's Acoustical Systems, Inc. (Exs. 11–16, 11–18, 11–19, 11–20, 11–26, 11–27, and 11–28). "Chemicals on the construction site are not a significant risk and the manufacturing standard is an infeasible program to implement." Ex. 11–26.

The conclusions of some of the commenters on the issue of significant risk are apparently based on their own organizations' reports of illnesses and injuries caused by chemical exposures. According to these industry representatives, the number of injuries reported that are due to chemical exposures is small, and those which do occur are caused by well known hazards (such as burns caused by handling wet concrete). They further contend that the HCS would not alleviate any of those injuries caused by well-known hazards since no new information would be presented to workers. "[T]he majority of chemical injuries were the result of exposure to concrete. This work is done by union workers with years of experience in this field. It is highly unlikely that training and MSDSs would reduce concrete burns or rashes. Most of which are an allergic reaction." Ex. 11–73.

An additional argument is that chemicals are already handled safely on construction sites (Exs. 11–9, 11–83, and 11–142), and in particular, that compliance with existing training requirements in 29 CFR 1926.21 results in adequate information being given to workers about hazardous chemicals. "With regard to regulating the few chemically related injuries that do occur, OSHA's existing standards regarding employee training (1926.21(b) 2 through 6) address these sufficiently." Ex. 11–83.

In its brief summarizing the record, the AGC cites the testimony of various construction contractors indicating that training is already conducted as proof that no additional information is necessary (Ex. 84). They further discount reports of incidents of chemical injuries occurring: "AGC does not contend that there are no chemical hazards in construction. Rather, AGC maintains that the hazards which exist are well known to employers and employees alike, and that those hazards do not occur with a frequency or intensity which merit the elaborate mechanisms of the revised HCS."

The AGC also argues that the degree of safety and health training unions have in their apprenticeship training programs also indicates how significant workers consider the risk to be in their particular industry (Ex. 84). "During the hearing, AGC sought to ascertain from the Building and Construction Trades Department, AFL–CIO (BCTD), how seriously its members take the risk of chemical exposure in construction, by inquiring whether this issue is covered in construction union apprenticeship programs. Unfortunately, BCTD refused to provide any such information, and even objected that the question was irrelevant. Tr. 12/13/88 pp. 134–136. It would appear, however, that if BCTD truly believes that chemical hazard exposure is a major risk to workers, it would readily have introduced evidence showing the emphasis placed on these concerns in apprenticeship training. The failure to produce any such evidence, coupled with an objection to its relevance, speaks volumes." (Quoted without footnotes.)

Construction industry representatives also contend that statistics cited by OSHA regarding the incidence of chemical source illnesses and injuries verify that the risk in construction is not significant (see, *e.g.*, Ex. 11–142). By their interpretation, the number of illnesses and injuries is too low to warrant the coverage of the HCS.

Significant risk—employee perspective. Representatives of construction workers participating in the rulemaking do not appear to agree with the AGC's contention that the hazards they face are well known to them, and do not warrant coverage under the HCS. In its brief summarizing the record (Ex. 89), the Building and Construction Trades Department (BCTD) of the AFL–CIO states that "although the skin rashes and other chemical incidents these employers report are certainly of concern, there are a myriad of other, far more serious illnesses which our members suffer as a result of exposures on the job." The BCTD further elaborates by citing scientific studies in the record (Ex. 67, submitted by the Sheet Metal Workers' International Association) which give epidemiological evidence of illnesses occurring in construction workers due to workplace exposures: "For example, welders suffer from acute and chronic respiratory disease, and show increased rates of lung cancer of up to 74% after 20 years in the trade. Painters, plumbers and floor-layers experience skin conditions, as well as serious central nervous system problems from exposures to solvents. Employees working with man-made mineral insulation suffer from bronchitis; roofers have skin and eye problems, in addition to increased cancers; and masons suffer from silicosis and lung cancer. Indeed, some of these problems, rather than being minimized by outdoor work, are exacerbated by exposures to sunlight." (Quoted from Ex. 89 without footnote cites.)

In response to questions raised during their oral testimony, the BCTD also addressed the issue of underreporting of illnesses and injuries in construction by reference to the National Academy of Sciences study on reporting of illnesses and injuries (Ex. 41): "That National Academy of Sciences study did dramatically find an under-reporting of illnesses in the construction industry." Tr. 6–97. Another report on recordkeeping prepared by the Keystone Center was also referred to: "And it was agreed upon by that Keystone Center, in their report, that there are serious under-reporting of illnesses in the

construction industry. Actually, across all industries, but more notably the construction industry, because of the latency of most of the illnesses." Tr. 6–97–98.

The Sheet Metal Workers stated in their testimony: "We, in the Sheet Metals Workers', our contractors, and others in construction unions, know that many more health hazards exist on a construction site than is generally believed." (Tr. 5–100.) The testimony further pointed out that products that were once considered to be fairly safe (*e.g.*, asbestos) were later found to be highly hazardous. "As we attempt to cope with the problems of our members with asbestos disease, we are also watching closely research which is unfolding around man-made mineral fibers. Within the past year, Johns-Manville and Owens-Corning have modified their material safety data sheets to recommend the use of respirators for those working around its fiberglass products." (Tr. 5–101–2.) Other substances of concern include those in welding fumes, and propellents in adhesives used in asbestos removal work (such as methylene chloride)(Tr. 5–102). "We want to share in the same protections from those and other health hazards that OSHA offers to our union sisters and brothers, and those in other walks of life. For many obvious reasons, we can't allow the same, or similar kinds of exposures to happen to yet another generation of sheet metal workers." (Tr. 5–102)

Another employee representative asked the Coalition panel to comment on the conclusion of the NAS report, which was read into the record as follows (Tr. 5–87–9): "The only illness data from the BLS annual survey that might be useful for any purpose, may be those on occupational skin diseases, all other illnesses included on the annual survey form are under-reported and can be used only with great caution." The conclusion of the report was further quoted as reading: "For all of these reasons, data on occupational illnesses in the annual survey, other than those for skin diseases, are understated to the point that they are more misleading than useful." The panel declined to comment on this conclusion. The study was entered into the record (Ex. 41).

The AFL–CIO also addressed the issue of significant risk in construction in their oral testimony: "Contrary to the OMB and industry claims, it is clear that chemicals do pose a significant risk to construction workers and to workers at multi-employer worksites—paints, solvents, heavy metals, adhesives, put painters, iron workers, and roofers at serious risk of disease. And these workers, like other workers, exposed to toxic chemicals, should receive the full protections of the standard." Tr. 7–44.

Significant risk—OSHA's findings. As has been discussed previously in this preamble, as well as in the preambles to the final rules in 1983 and 1987 and the Third Circuit litigation on the HCS, OSHA has determined that there is a significant risk to all workers exposed to hazardous chemicals without benefit of information regarding those hazards, the identities of the chemicals, and associated protective measures.

This finding of significant risk applies to construction employment as well as to every other type of industry regulated by OSHA. The sole difference in construction is that those employers in complete compliance with the existing construction training standard (29 CFR 1926.21) will have already done most of the training required under the HCS. Therefore, the burden of compliance is less for construction than for any other of the nonmanufacturing industries.

Although the AGC claims in its post-hearing brief that "the rulemaking record as a whole does not support the finding that the standard is reasonably necessary to reduce significant risk" in the construction industry (Ex. 84), OSHA does not agree. The AGC cites as its primary evidence the statements made by its own representatives and those of other industry sources that the rule is not needed. OSHA believes that the record accumulated since the 1987 rule was published amply demonstrates that the majority of the participating representatives of the construction industry do not want the rule to apply to them. That, however, is quite different than demonstrating that the rule is neither necessary nor feasible in the construction industry. OSHA does not believe that the record evidence supports either of those conclusions.

As OSHA established in the 1983 final rule (48 FR 53284–86), thousands of chemical source illnesses and injuries are reported annually in the construction industry. The numbers are substantial, and yet all scientific indications are that the illnesses are probably grossly underreported (47 FR 12094–95; 48 FR 53284–86; Ex. H–022: 17; Exs. 4–1 and 4–2; Ex. 4–70; Ex. 4–44; and Ex. 41).

The Coalition of Construction Trade Industry Associations (hereinafter referred to as "the Coalition")(Ex. 11–142) claims that the reported incidence rate of chemically-related illness is too low to be considered significant. This is not true. In fact, construction is third after agriculture and manufacturing in terms of incidence rates, and thus exceeds the rates of all other nonmanufacturing industries (48 FR 53285).

This has occurred despite the fact that in construction there are a number of factors which tend to contribute to the underestimation of chemical source illnesses and injuries. The transient nature of the workforce minimizes the likelihood that any illness or injury that does not produce an immediate, acute effect (such as concrete burns) is identified and reported. Since a worker may not report back to the same workplace the day after an exposure, even a number of acute effects would be unreported. Thus any effect which has a latency period of more than one day will generally not be included in the illness and injury log and linked to occupational exposures. This is aptly demonstrated by the anecdotal reports of injuries being limited to concrete burns and similar ailments (Ex. 11–135; Tr. 6–20, 21; Tr. 6–28), while the scientific epidemiological data based on studies of exposed construction workers whose health status was followed over longer periods of time reveal the incidence of serious, chronic health effects (Ex. 67).

The ability of employers to identify occupational illnesses with chemical exposures is always a concern, particularly since the effects of exposure are effects which may also be caused by other factors. As cited in the original NPRM preamble (47 FR 12094), the Bureau of Labor Statistics (BLS) noted this reporting disparity in its annual report. "The recording and reporting of illness continue to present some measuring problem since employers (and even doctors) are often unable to recognize some illnesses as being work related. The annual survey includes data on only current and visible illnesses of workers; it does not include data on illnesses which might surface later."

So if workers being exposed to solvents have headaches and feel nauseous, this may not be identified as being caused by their chemical exposures when in fact they are experiencing central nervous system depression. Part of the purpose of the HCS is to increase awareness regarding these potential effects. In fact, improved reporting of occupational illnesses and injuries caused by chemical exposures is expected to be one of the positive effects of the HCS.

The comments and testimony submitted by the construction industry suggest that some construction employers are either unaware of the extent of potential hazardous effects in their industry, or are attempting to minimize the evidence of the

seriousness of the types of effects which may occur as a result of employee exposure. For example, Trio Construction Services, Inc. (Ex. 11–100) supports an exemption for the construction industry "because the construction industry is not a user of today's highly toxic materials, chemicals, carcinogens, explosives, etc." And yet Trio indicates further that their company uses "gasoline, kerosene, fuel oil, WD–40, paints, lacquers, thinners, adhesives, concrete, oxygen and acetylene to name a few." By the definitions of hazard in the rule, the types of chemicals cited do indeed include "highly toxic materials, chemicals, carcinogens * * *."

Similarly, the Ruhlin Company (Ex. 11–97) argues that "many chemicals utilized by Construction Contractors such as water repellents, form release agents, concrete sealers, solvents, adhesives, bonding agents, epoxy resins, linseed oil and curing compounds are non toxic * * *" This too reveals a lack of information regarding the hazardous properties of chemicals as these types of products commonly include numerous hazardous chemicals.

The AGC itself admitted in a newsletter to its members that there are 82 hazardous chemicals employees involved in concrete work may be exposed to, including such potential carcinogens as benzene and vinyl chloride (Ex. 4–98). In addition, an AGC representative submitted about 400 MSDSs with his notice of intent to appear at the public hearing (Ex. 13–39), including MSDSs for a number of the chemicals listed by Trio and Ruhlin above. The hazards of the chemicals covered by those MSDSs cover a full range of health effects, as well as physical hazards.

Clearly, these comments and references indicate that chemical exposures in the construction industry are extensive, and that the hazards are not apparently as "well known" as the AGC has indicated (Ex. 84).

The industry representatives argue that the transient nature of the work force must result in unique treatment of the industry from a regulatory standpoint, yet they do not seem to recognize that the same industry characteristic results in an underestimation of the magnitude of the problem with respect to chemical exposures.

For example, they argue that exposures are, in essence, relatively isolated instances of brief duration. There is no recognition in their comments that painters exposed on one site today and another tomorrow throughout their working careers have a significant cumulative dose of chemical exposures. In the industry's perspective, viewing exposures as a finite occurrence, the need for the standard is limited and the possibility of disease occurring as a result is remote. In fact, professional trade workers generally use the same types of chemicals from job to job (although the specific constituents may vary) and their potential for long-term substantial exposure is significant. (The industry representatives use the similarity of job exposures to argue for "portability" of training, yet do not seem to recognize that it contributes to the occurrence of chronic disease that is not reported.)

The arguments that the work is completed outdoors and is therefore insignificant are also not persuasive. (See, *e.g.*, Ex. 11–91.) Much construction work is finish or repair work that is conducted indoors, and significant exposures can occur. Outdoor exposures are not guaranteed to be low. A recent article describing exposure to lead at an outdoor site found that the measured levels far exceeded legal limits (Ex. 71–31). No industry representatives submitted exposure data to support their contentions, and it is highly likely that such data do not exist as many of these employers do not generally measure for exposures.

In fact, according to the Coalition, employers don't need permissible exposure limit information on MSDSs because they don't understand it anyway and apparently aren't interested in learning about it (Ex. 11–142). "Nearly all MSDSs provide PELs or TLVs (Threshold Limit Values); none of the labels do. Neither employees nor employers are trained chemists. Since they are incapable of quantifying job-site exposures, PELs and TLVs are useless to them." Of course, PELs are legally established exposure limits that must not be exceeded. The purpose of including them on an MSDS is to ensure the downstream employers and employees are alerted to the fact that the product contains a chemical that is regulated, and thus proper protective measures must be implemented.

AGC's argument that the significance workers attach to the risks of chemical exposures can be determined by the number of hours included in union apprenticeship training programs is spurious at best (Ex. 84). And despite AGC's claims to the contrary, the BCTD's refusal to respond to AGC's inquiries regarding such programs does not indicate that its members do not consider the issue to be important (Tr. 6–134–36). As counsel for the BCTD indicated, "the employer has the responsibility to ensure safety on the work site, and that includes the safety training and hazard communication identification." (Tr. 6–135.) Nevertheless, a member of the BCTD panel had already addressed knowledge gained in apprenticeship programs (Tr. 6–91–3), and in response to similar inquiries from the AGC, both the Sheet Metal Workers (Tr. 5–113–14; Ex. 81) and the AFL–CIO (Tr. 7–77–78) confirmed that such training is in fact included in union programs, and that the emphasis on such information has increased in recent years.

There were suggestions in the record that unions be required to assume some of the compliance burden. The Flat Glass Marketing Association indicated that unions should be held responsible for training since the contractors frequently hire employees from union halls (Ex. 11–152). "There is no reason why OSHA should not require the unions to include in their apprenticeship training programs courses on hazardous chemical identification, detection, and treatment. The unions should be required to cooperate with the employers in developing and conducting such programs insofar as they deal with communicating the hazards of chemicals on the job site."

The reason that this is not a viable option for the HCS is that OSHA has no authority under the Act to compel employees or their representatives to provide training. Although section 5(b) of the Act requires "[e]ach employee comply with all occupational safety and health standards and all rules, regulations and orders issued under the Act" that are applicable, Congress "[did] not intend the employee-duty * * * to diminish in any way the employer's compliance responsibilities or his responsibility to assure compliance by his own employees. Final Responsibility for compliance with the requirements of this [A]ct remains with the employer." S. Rep. No. 1282, 91st Cong. 2d Sess. 1–11 (1970). OSHA cannot sanction employees or their representatives for failure to provide training. *Atlantic & Gulf Stevedores* v. *OSHRC*, 534 F.2d 541 (3d Cir. 1976).

In addition, since the majority of employees working in this country are not members of unions, such an approach would be ineffective for the great majority of worksites in any event. However, as OSHA has stated a number of times with regard to the training requirements of this rule, the HCS only requires each employer to ensure that training has been provided to employees. If employers and employee representatives in a particular area agree

to some sort of centralized training program so that training on the jobsite will be minimal (limited to the information that is specific to that site), the rule is flexible enough to permit that type of approach. Indeed, OSHA encourages joint efforts where possible because such partnerships result in better and more efficient information transfer. (See, *e.g.*, Exs. 4–63, 4–75.) Employers will be held accountable for the adequacy of the training provided, but need not present all of the information themselves.

Reduction of Risk Through Current Training Requirements. Although, as has been described herein, the construction industry representatives claim that the risk of exposure to chemicals in construction is not "significant," this conclusion is coupled with the contention that the existing training requirements (29 CFR 1926.21) alleviate whatever risk there may be (see, *e.g.*, Exs. 11–135, 11–142 and 84).

The construction training requirements that apply to chemicals may be summarized as follows:

(b)(2) The employer shall instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to this work environment to control or eliminate any hazards or other exposure to illness or injury.

(b)(3) Employees required to handle or use poisons, caustics, and other harmful substances shall be instructed regarding the safe handling and use, and be made aware of the potential hazards, personal hygiene, and personal protective measures required * * *.

(b)(5) Employees required to handle or use flammable liquids, gases, or toxic materials shall be instructed in the safe handling and use of these materials and made aware of the specific requirements contained in subparts D, F, and other applicable subparts of this part * * *.

(6)(i) All employees required to enter into confined or enclosed spaces shall be instructed as to the nature of the hazards involved, the necessary precautions to be taken, and in the use of protective and emergency equipment required. The employer shall comply with any specific regulations that apply to work in dangerous or potentially dangerous areas.

(ii) For purposes of paragraph (b)(6)(i) of this section, "confined or enclosed space" means any space having a limited means of egress, which is subject to the accumulation of toxic or flammable contaminants or has an oxygen deficient atmosphere * * *.

As OSHA has indicated in its regulatory impact analysis (Ex. 4–1) and in response to questions in the public hearing (Tr. 1–45), the Agency estimated that approximately 75–80% of the training required under the HCS is also required under the construction training standards described above. Thus if a construction contractor was in full compliance with § 1926.21, the incremental training required to complete compliance with the HCS would primarily be limited to the requirements for explanation of the MSDSs, labels, and other features of the employer's hazard communication program.

The primary difference between the two rules is that the § 1926.21 standard is very general and does not provide employers with sufficient guidance to establish an adequate training program for hazard communication. OSHA testified to this point in response to questions raised at the public hearing, Tr. 1–47–8. This has been pointed out repeatedly by members of the Advisory Committee on Construction Safety and Health (ACCSH) (Tr. 6–78–9), and the Agency has attempted to somewhat rectify the problems by providing additional guidance in a compliance directive (Ex. 4–152). However, there are still problems with enforcement due to the way the provisions were drafted when adopted.

The AGC claims that its analysis of the enforcement statistics OSHA entered into the record (Ex. 4–199) indicates that § 1926.21 is one of the most cited Agency rules (Ex. 84). As described in their post-hearing brief, between fiscal year 1982 and fiscal year 1987, OSHA issued 4,205 citations for violations of § 1926.21(b), "3,814 of which were for § 1926.21(b)(2) governing hazard training." A review of the subparagraphs included in paragraph (b) raises questions regarding the AGC's analysis. Subparagraph (b)(2) is a general one which covers all types of hazards, including safety hazards such as trenching, etc. The subparagraphs of primary relevance to chemical hazard training are (b)(3) and (b)(5). When 90% of the citations that have been issued for paragraph (b) involve subparagraph (b)(2), there are clearly very few citations issued for subparagraphs (b)(3) and (b)(5). In fact, in the 6 year period included in the statistics, only 156 citations were issued for violations of (b)(3) and (b)(5). (As a point of reference, in 1990 OSHA issued over 5600 citations for violations of the HCS training requirements. Over 4300 of those violations were cited as being serious, and 32 were considered to be willful.)

There is evidence in the rulemaking record that complete training on chemical hazards is not widespread in the construction industry despite the long-established requirements. As cited in the NPRM preamble (53 FR 29827), the most compelling evidence is a BLS study which indicated that only 23% of construction workers had been trained regarding such hazards. The BLS report was based on a survey administered to construction workers who had been injured on the job.

AGC cites the testimony of employer representatives during the hearing as substantiating that sufficient training is occurring. In OSHA's view, many of the submissions in the testimony and comments support the Agency's position that the current state of chemical hazard training in construction is not sufficient to protect employees. Therefore, the additional training requirements of the HCS are necessary.

Four employer representatives testified on behalf of the Coalition. As a primary argument of construction industry representatives was that current training sufficiently mitigates any risk of exposure that may occur in construction, OSHA questioned these employers on present practices. Specifically, the OSHA panelist asked each employer to "tell me what kind of training you provide for your workers in accordance with 1926.21, when you do it, and how you get the information in order to do it."

The first contractor initially indicated that his homebuilding firm did not do any training (Tr. 5–43). He then modified his response to indicate that the superintendents on the job were responsible for training, and he didn't know what was included in the training program (Tr. 5–44).

The second employer representative described in detail training regarding scaffolding and other related safety issues for workers in the masonry industries. When further questioned as to whether the training included any information on chemical hazards as required under § 1926.21, he replied (Tr. 5–46): "Not at this time. We have conducted one session. We were cited on a Maryland job site through the Maryland OSHA for not having, by their standards, a hazardous communication program in place." He also did not appear to be aware that in Delaware, where his firm is located, a state right-to-know law was implemented prior to expansion of the HCS, and it covered construction (Tr. 5–46, 5–60). It is likely his firm would have been in substantial compliance with the HCS if it had complied with the preexisting state law in Delaware. He further indicated later in his testimony that he interpreted the current standard (§ 1926.21) as covering

safety hazards, and not training regarding chemical hazards (Tr. 5–59–60).

The third employer was an electrical contractor, and he stated that safety hazards related to electrical work are addressed in worker training. Coverage of chemical hazards in current training was less clear since he indicated there aren't many products of concern in the electrical industry, and the employers are not sure what is a hazard (Tr. 5–47). Apparently, employers are receiving MSDSs for many products they use that are not actually hazardous chemicals covered by the HCS (*e.g.*, flashlight batteries). Products such as flashlight batteries are exempted as articles under the rule, and thus do not have to be included in training.

Only the fourth contractor employer on the Coalition panel, whose business involved painting, appeared to have clearly included training regarding chemical hazards in his program (Tr. 5–48).

The participants on the AGC's panel described chemical training programs in their organization. The two contractor employers were from states with pre-existing right-to-know laws (Vermont and Wisconsin), and had apparently instituted training programs to comply with those rules. Although they referenced training conducted prior to the right-to-know requirements, it appeared to be safety training. There was no description of chemical hazard training done in compliance with § 1926.21. Ex. 44.

As cited before, there are numerous indications in the comments and testimony of the participants that the hazards in the construction industry are not recognized by the employer representatives, thus it is unlikely that adequate training is being done. (See, *e.g.*, Exs. 11–97 and 11–100.) Comments submitted in response to the revised final rule, for example, clearly indicate that companies were estimating compliance burdens based on analyses that assumed no training had been done to date (see, *e.g.*, Exs. 5–10, 5–65, and 5–117).

As the ACCSH indicated in its 1980 report to OSHA regarding occupational health standards for the construction industry (Ex. 4–4), the construction industry's implementation of § 1926.21 has been hampered by lack of information regarding the hazards of the chemicals in use. As OSHA noted in the preamble to the 1987 final rule (52 FR 31858–59): "Of particular concern to the Committee at that time was that construction employers do not have access to the necessary information upon which to develop appropriate signs and labels or material safety data sheets, and therefore must depend upon suppliers for such information. '[C]onstruction employers may not always be aware of the hazard associated with a particular product or device if the items are not accompanied upon purchase by appropriate labels and data sheets * * *.' OSHA agrees that this lack of information has been a problem for all downstream users of chemicals, and thus developed the approach incorporated into the HCS—producers or importers of chemicals are responsible for evaluating the hazards and transmitting that information to downstream employers or users of the materials. Under the expanded rule, construction employers would be the recipients in this downstream flow of information." The ACCSH further noted that "such information was fundamental to the preparation of warning signs, labels, training programs, and other important job safety and health activities."

OSHA's current rule is thus completely consistent with the ACCSH's recommendations in this area. In fact, although the AGC (Ex. 84) and the Coalition (Ex. 11–142) have repeatedly stated that the OSHA rule "ignores" the advice of the ACCSH, the record demonstrates that the Agency has not only consulted the Committee but has also incorporated their advice in a number of respects. The requirements of the rule for labels, MSDSs available to employees on-site, and amplified training programs are entirely consistent with substantive recommendations made by the ACCSH in 1980, as well as when they reviewed the rule line by line in 1987 (Exs. 4–6 and 4–186). Ex. 4–186 is an OSHA-prepared working document in which the Agency took the ACCSH transcript from the June 23, 1987 meeting that was a detailed review of the HCS, and incorporated the suggested changes into the text of the rule to most efficiently address the ACCSH comments. As noted in the preamble to the 1987 rule, a number of the suggestions made by the ACCSH were incorporated into the regulatory text (52 FR 31858). At subsequent meetings in 1987 (Ex. 4–74) and 1988 (Ex. 4–108), they further reiterated their view that the rule as written be implemented.

Despite claims to the contrary, the record clearly shows that OSHA has consulted the ACCSH repeatedly on this issue. And on the substantive requirements, the Agency's rule has been entirely consistent with the recommendations of the Committee. The only difference of opinion in approach has been that the Committee would like a separate standard to be promulgated, and the Agency has maintained that such an approach is not appropriate on this particular issue. A difference of opinion does not mean that the Agency has ignored the advice of the Committee.

The AGC and the Coalition have not substantively addressed the specific recommendations of the ACCSH, and have implied that OSHA has not given the Committee an opportunity to present recommendations. Close examination of the documents cited above that are related to specific ACCSH reviews will reveal that the ACCSH's opinions have been addressed by OSHA in the rule's requirements, and that these opinions are quite different than those put forth by the industry representatives who claim the ACCSH has not been properly consulted. From the 1980 report to the most recent recommendations in November of 1988, the Committee has endorsed the need for a standard; confirmed that such a standard is feasible; recognized that availability of information on multi-employer worksites must be specifically addressed; supported requirements for MSDSs, including their availability on site; and emphasized the need for further training requirements. Thus it appears clear that, unlike the AGC and the Coalition, the ACCSH's recommendations for a vertical standard for construction did not mean a rule that is less protective for construction workers than the rules covering workers in other industries.

Employee representatives in the construction industry have also consistently indicated that training is either not being done, or is inadequate (see, *e.g.*, Tr. 6–91–3). In response to a question, the Sheet Metal Workers' representative indicated that the rule would provide information about chemical hazards that they do not currently have under existing regulations: "Yes, there are adhesives that we are not sure about, that are being used in ventilating systems for coatings. And we are not necessarily sure what they are, except that people will complain about noxious, or obnoxious gases on the job, for example. And we don't know what they are." Tr. 5–115–16.

Thus the rulemaking record clearly indicates that the requirements of the HCS are needed to supplement the provisions of § 1926.21. As has been discussed at length in the preamble to the original final rule (see in particular 48 FR 53301, 53305–06, 53310), in order to ensure that the information is effectively communicated, a hazard communication program must include

three components—labels, material safety data sheets, and training. These provisions are interdependent, serving different purposes and communicating the information in a different way, thus improving the effectiveness of the program. (See also H–022, Exs. 3 and 4; 52 FR 31855.) As indicated by the ACCSH, the construction industry employers will benefit from the acquisition of this information as it will enable them to enhance compliance with the training provisions in § 1926.21. As a result of the improved programs, construction employees' significant risk of experiencing adverse effects due to chemical exposures will be reduced. *Associated Builders & Contractors*, 862 F. 2d at 68 ("We reject * * * the contention by ABC and AGC that because the construction industry already provides training in hazardous materials handling, there is no significant risk in that industry. At best that argument establishes the existence of risks, and the requirement for maintenance on the jobsite of information on those risks can only make the existing training more effective.")

The training requirements of the HCS are more complete, and more specific in terms of what is required. The additional requirements to maintain labels and MSDSs supplied by the producers and distributors of the products used will provide the employer with more information regarding the hazards of the chemicals, identities, and appropriate protective measures. Such information will enable the employer to better protect workers from chemical hazards, as well as improve existing training programs. They will also serve as a reference source for workers to ensure that they truly have access to all applicable information regarding that chemical. As discussed previously, this standard is based primarily on the premise that all workers exposed to hazardous chemicals have a right, and need, to know this basic information.

Feasibility of the rule in the construction industry. In addition to contending that there is no significant risk of exposure in the construction industry, and that the pre-existing training rule mitigates that risk sufficiently, industry representatives claim that the rule as written is infeasible. See, *e.g.*, 11–36, 11–97, 11–98, 11–114, 11–135, and 11–142. But see also Ex. 71–16: "Compliance with the OSHA Hazard Communication Standard will not be as difficult as it first appears if you start now and follow an organized approach—in fact, you may already have some procedures in place that comply with the standard." (From compliance guidance manual prepared by AGC counsel.)

It is clear that these commenters sought to indicate the rule is infeasible because the Court order to OSHA stated that the rule was to be expanded unless the Secretary of Labor found it would be infeasible to do so. OSHA explicitly determined that the rule is both technologically and economically feasible to implement in all industries. 52 FR 31855–58. Of course, as the Court has recognized, the Agency had already determined that there was a significant risk to employees in all industries where they are exposed to hazardous chemicals without benefit of the information provided under the requirements of the HCS.

Clearly, the HCS does not include any requirements that can be considered to be "technology-forcing." It simply requires the development of information regarding hazardous chemicals, and the transmittal of that information to exposed employees as well as to downstream employers using the materials. For the construction industry, where some training was required prior to the expansion of the rule, the requirements simply involve the preparation of a written program, maintenance of labels on containers within the workplace, obtaining and maintaining material safety data sheets prepared by chemical suppliers, and some incremental additional training of workers. There simply are no issues of technological feasibility in these types of requirements. 52 FR 31856–57.

OSHA completed a regulatory impact analysis prior to promulgation of the 1987 final rule, and found that the standard is economically feasible in all industries (Exs. 4–1 and 4–2; 52 FR 31867–76). The analysis for this rulemaking is limited to the changes that were proposed in the NPRM. OSHA concluded that the changes are not significant or major, and therefore a regulatory impact analysis was not required.

As the BCTD has pointed out (Ex. 89), employers' claims of economic infeasibility are based on cost analyses that use inaccurate assumptions about requirements of the rule. "While showing that the employer will incur some economic cost in complying with the standard, industry representatives have fallen far short of demonstrating that the cost they project will cause economic dislocation in the industry. But even their projected costs are greatly inflated." The BCTD then analyzed projections by the Coalition that a general contractor with ten employees would have to spend $15,197.50 to comply the first year. Without questioning the unit costs used, the BCTD deleted costs assessed for activities that are not required by the rule. As a result, using the Coalition's own figures, the costs would be reduced to $5,053. OSHA believes that even that figure is an overestimation of the actual costs, but in any event, the BCTD's analysis aptly illustrates what OSHA itself has found to be true—that the construction industry's statements regarding feasibility are based on inaccurate and inflated assessments of activities that are not required by the rule.

In fact, statements from the industry representatives themselves conflict on this issue. For example, although the AGC (Ex. 11–135, Ex. 84) and various members of the AGC have indicated that the rule is not feasible, the AGC Dallas (Ex. 11–24) stated: "All members have been complying with the standard since 23 May, 1988 * * *." If the 600 members of the Dallas AGC were able to comply with the rule by May 1988, it cannot be considered to be infeasible. The Dallas AGC is opposed to the HCS, and yet indicate that "our members have always trained and monitored the safe work practices of their workers which they feel covers nearly 100% of the Hazard Communication training i.e. safety goggles, protective gloves, respirators, etc. and believe the regulation as it now stands is near impossible to comply with." It is difficult to understand how the members could have accomplished "nearly 100%" of the HCS training prior to the implementation of the rule, and yet have determined that it is "near impossible to comply with."

Similarly, the Coalition has argued that the training requirements of the rule are technologically infeasible (Ex. 11–142). And yet the employer representatives testifying on behalf of the Coalition did not indicate that this is the case. In response to a question from OSHA as to whether training of workers before they actually go out on a site is done, and is therefore feasible, the answer was yes (Tr. 5–48–9).

It is somewhat inexplicable to OSHA that the industry representatives can claim that it is feasible to comply with the existing training standards, and yet not with the HCS requirements. Some of the discrepancy can be explained by the inaccurate interpretations regarding training that persist in the industry despite numerous clarifications and corrections by OSHA. On other issues, however, the different positions on the rule are less clear.

For example, the § 1926.21 rule does not address the so-called "portability"

of training. There is no specific provision in that rule for allowing employers to rely on training provided by some other source, yet employers claim that compliance with that rule is feasible and is being done. On the other hand, the HCS has been criticized for not including such provisions. Ex. 84.

However, OSHA has already provided employers with guidance on this issue in Appendix E to the rule (included in the NPRM at 53 FR 29855, and published separately as a booklet, OSHA 3111). "An employer can provide employees information and training through whatever means found appropriate and protective. Although there would always have to be some training on-site (such as informing employees of the location and availability of the written program and MSDSs), employee training may be satisfied in part by general training about the requirements of the HCS and about chemical hazards on the job which is provided by, for example, trade associations, unions, colleges, and professional schools. In addition, previous training, education and experience of a worker may relieve the employer of some of the burdens of informing and training that worker. Regardless of the method relied upon, however, the employer is always ultimately responsible for ensuring that employees are adequately trained. If the compliance officer finds that the training is deficient, the employer will be cited for the deficiency regardless of who actually provided the training on behalf of the employer."

In addition to this guidance in the appendix to the rule, OSHA has also addressed this issue in its instructions to compliance officers enforcing the rule. These instructions are publicly available, and are included in the record at Ex. 4–170. "Complete retraining of an employee does not automatically have to be conducted when an employer hires a new employee, if the employee has received prior training by a past employer, an employee union, or any other entity." It continues: "An employer, therefore, has a responsibility when hiring a new employee who has been previously trained by someone other than the current employer to evaluate the employee's level of knowledge against the training, information requirements of the standard, and the employer's own program."

Both of these written interpretations were publicly available in August 1988, and thus the construction industry representatives had access to them prior to submitting comments or oral testimony. In any event, they are also entirely consistent with all previous interpretations of the rule on this issue provided by the Agency since it was first promulgated in 1983. As discussed later in this preamble in the discussion of the information and training provisions, OSHA is clarifying the regulatory text to address this misinterpretation of the rule's requirements. However, OSHA does not find that these claims of infeasibility based on an apparent disregard for current interpretations of the rule to be valid.

If employers in an area choose to establish a centralized training program, perhaps in conjunction with local unions, the rule does not prohibit such an arrangement. If the employers can assure themselves that a worker has been properly trained, re-training is not required.

Another misinterpretation that persists in the industry comments also involves training. Many of the claims of both economic and technological infeasibility in the comments (see, *e.g.*, Exs. 11–135, 11–142, and 84) are based on the misconception that the rule requires training on each chemical, and subsequently each MSDS.

The 1987 HCS (as well as the 1983 rule), stated in paragraph (h)(1): "Employers shall provide employees with information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area." The training may be done in whatever way employers find appropriate for their particular work operations, as long as all of the elements addressed in the rule are included.

When OSHA published the 1987 rule, the re-training issue was discussed in the preamble (52 FR 31866–67): "One question that does arise regarding training is whether it needs to be done specifically on each chemical, or whether employers can train regarding categories of hazards. Either method would be acceptable. See 48 FR 53312, 53338. If employees are exposed to a small number of chemicals, the employer may wish to discuss the particular hazards of each one. Where there are large numbers of chemicals, the training regarding hazards could be done on categories (*e.g.*, flammable liquids; carcinogens), with employees being referred to substance-specific information on the labels and the MSDSs. Similarly, the re-training occurs when the hazard changes, not just when a new chemical is introduced into the workplace. If the new chemical has hazards which employees have been trained about, no re-training occurs. If the chemical has a hazard they have not been trained about, re-training would be limited to that hazard."

This issue was also addressed in Appendix E to the proposed rule (53 FR 29855): "Information and training may be done either by individual chemical, or by categories of hazards (such as flammability or carcinogenicity). If there are only a few chemicals in the workplace, then you may want to discuss each one individually. Where there are large numbers of chemicals, or the chemicals change frequently, you will probably want to train generally based on the hazard categories (*e.g.*, flammable liquids, corrosive materials, carcinogens). Employees will have access to the substance-specific information on the labels and MSDSs."

The compliance directive included this topic as well (Ex. 4–170): "Additional training is to be done whenever a new hazard is introduced into the work area, not a new chemical. For example, if a new solvent is brought into the workplace, and it has hazards similar to existing chemicals for which training has already been conducted, then no new training is required. Of course, the substance-specific data sheet must be available, and the product must be properly labeled. If the newly introduced solvent is a suspect carcinogen, and there has never been a carcinogenic hazard in the workplace before, then new training for carcinogen hazards must be conducted in the work areas where employees will be exposed to it."

Thus if an employer trains regarding all possible hazards (and there are a total of 23 types of physical and health hazards covered under the rule), there is no re-training required. If the employer chooses to limit the initial training to some subset of the 23 hazards, and a chemical is introduced into the workplace that has a hazard which has not been addressed in the initial training, then re-training must occur.

The construction industry's interpretation of this requirement is not supported by available documentation. The plain reading of the text indicates that re-training is to be done when the hazard changes, and the hazards covered by the rule are defined, yet the industry representatives interpret the requirement as being chemical-specific. See, *e.g.*, Exs. 11–6, 11–15, 11–24, 11–73, 11–84, 11–98, 11–142, and 11–152. (But see Ex. 4–106, Hazard Communication Guide for California Construction by the Safety and Health Committee of AGC of California, at p. 7. ("Training can be for each individual substance, chemical families (solvents, metals), or categories of hazards.") See

also Ex. 71–16, a manual providing compliance guidance that was prepared by AGC's counsel: "Depending upon the types of hazardous chemicals used, you may organize the subject matter by specific chemical, by categories of hazard or by work area.") The cost analyses they present to demonstrate infeasibility are also based on this perception of the rule's requirements (see, *e.g.*, Ex. 11–142).

As will be discussed in the section of this preamble dealing with information and training, OSHA is further clarifying the regulatory text to deal with this issue. In terms of feasibility, however, the Agency finds no evidence to indicate that the rule is infeasible with respect to training, and particularly training of employees who will be working on multi-employer worksites. OSHA has provided substantial guidance to employers regarding these provisions, and such guidance was available prior to, or at the time of, publication of the NPRM. Infeasibility cannot be established through analyses based on misinterpretations of the rule.

OSHA maintains that the rule is both economically and technologically feasible. Industry claims to the contrary are based primarily on inaccurate statements regarding the requirements of the rule, and on assessments that do not account for training that should have been done to comply with s1926.21 or programs that are required under preexisting state standards. There is a cost associated with compliance with this rule as with any other regulation. The cost is justified by the protections that will be afforded employees as a result of implementation of the requirements.

With regard to state requirements, OSHA included in the rulemaking record enforcement data from a number of state plan states that expanded the scope to construction prior to promulgation of the Federal rule (Exs. 4–183, 4–184). As can be seen from these statistics, construction employers in these states are found to be in compliance in the majority of inspections. This evidence indicates that the rule is feasible. For example, the state of Tennessee has a provision for exchanging MSDSs on multi-employer worksites. Yet two-thirds of the employers inspected were found to be in complete compliance with the rule, indicating that they must be able to comply with the requirements for exchanging MSDSs. This is confirmation that the industry arguments discussed above are not substantiated in practice.

In summary, OSHA concludes that there is substantial evidence in the record indicating that there is a significant risk in the construction industry that warrants coverage under the HCS; the current requirements for training under § 1926.21 do not mitigate that risk sufficiently; and the requirements of the rule can feasibly be implemented in the construction workplace.

Coverage of small businesses and "low hazard" industries. As discussed in the preamble to the NPRM, OSHA does not consider it to be appropriate to determine the extent of protection afforded an employee by the size of business he/she is employed in (53 FR 29826). Although the Agency does have enforcement policies that take into consideration the size of the business, as well as free consultation services that are primarily intended for small employers without on-staff safety and health capability (see Exs. 4–38 and 4–39), such small businesses must still comply with regulations and ensure that their employees are protected to the same extent as employees of larger businesses.

Several responses to the NPRM again argued that the rule is not feasible for small businesses, and is too costly to implement (see, *e.g.*, Exs. 11–3, 11–39, 11–123, and 11–132). "The HCS was enacted for all the right reasons but has placed an unreasonable burden on small businesses." Ex. 11–39. OSHA recognizes that there are costs involved in achieving compliance, but our analyses indicate that these costs are feasible, and the requirements are necessary to achieve employee protection.

Congressional hearings on the impact of the HCS on small business were convened in both the Senate and the House of Representatives under the auspices of their small business committees. Testimony and statements from the House hearing appear in the record in Ex. 4–198. The Senate hearing took place in June 1989, after completion of the rulemaking comment periods and public hearings.

Following these congressional hearings, the General Accounting Office (GAO) was requested to conduct a study of the HCS with regard to small business by the committee chairs, Senator Dale Bumpers and Congressman Norman Sisisky. The GAO recently completed their investigation, and issued two reports. While these studies are not part of the rulemaking record on this final rule, they contain information that is relevant to these discussions. A single copy of each report may be received free of charge from the GAO. The first, issued in November 1991, is entitled OSHA Action Needed to Improve Compliance With Hazard Communication Standard (GAO/HRD–92–8), and the second, issued in May 1992 is Employers' Experiences in Complying With the Hazard Communication Standard (GAO/HRD–92–63BR). Copies may be obtained by calling the GAO at (202) 275–6241, or writing to them at U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20877.

In the course of preparing these studies, the GAO conducted a national survey of approximately 2,000 employers in construction, manufacturing, and personal services. Thus the burdens and benefits described by the GAO were self-reported by the employers surveyed. They also collected information through other means, such as OSHA's compliance data, and interviews with affected employers.

The congressional request for GAO to investigate had particularly focussed on the MSDS provisions of the rule. However, GAO found that 70% of those small employers (fewer than 20 employees) who had attempted to comply had little difficulty with the MSDS requirements. Furthermore, while there were costs associated with compliance, the burden was reported to be "great" or "very great" in fewer than one-fifth of the survey responses.

In addition to assessing burdens, GAO solicited information on the benefits of the HCS. Over 56% reported a "great" or "very great" improvement in the availability of hazard information in the workplace and in management's awareness of workplace hazards. In addition, about 45% of all employers appearing to comply believed that the rule had been beneficial for workers. And about 30% reported that they replaced hazardous chemicals used in their workplaces with less hazardous ones because of information they received on an MSDS.

Other findings of the GAO will be discussed in this preamble where appropriate. On the whole, however, OSHA is encouraged by the results of their study. While the GAO has suggested improvements in the enforcement and implementation of the rule, the findings are supportive overall of hazard communication and indicate that when employers comply, the expected benefits do occur. Furthermore, employers themselves reported that compliance is achievable.

Similar to the suggestions to exempt or limit coverage for small businesses, there were suggestions that certain "low hazard" industries be exempted from the rule as well (see, *e.g.*, Ex. 11–118). OSHA believes that the rule already includes accommodations for many

types of operations that are less hazardous (for example, limited coverage where chemicals are handled in sealed containers), but the rule's protections are necessary for all workers exposed to hazardous chemicals.

Coverage of pesticides. In the NPRM (53 FR 29827–28), OSHA invited comment on an area of potential conflict that had been raised in the comments on the 1987 rule (see, *e.g.*, Exs. 5–6, 5–44, 5–50, and 5–66), involving employees exposed to pesticides. Commenters maintained that OSHA cannot cover pesticide exposures outside the manufacturing sector as these are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) administered by the Environmental Protection Agency (EPA). EPA requires pesticides to be labeled, approves the specific label language, and requires the pesticides to be applied in accordance with the labeling instructions.

EPA also has some specific requirements to protect farmworkers exposed to pesticides (40 CFR part 1970), and proposed modifications to provide additional protection on July 8, 1988 (53 FR 25971) (Ex. 4–178).

OSHA invited comment in the NPRM on the relationship of the jurisdictions of EPA and OSHA with regard to the protection of workers exposed to pesticides. For purposes of this discussion, OSHA suggested that its own jurisdiction could be seen to vary with the degree of protection afforded workers under the EPA rules. (53 FR 29827–28.)

The majority of the comments received stated that EPA should retain sole jurisdiction for farmworker exposure to pesticides (see, *e.g.*, 11–14, 11–30, 11–41, 11–55, 11–87, 11–96, 11–101, 11–112, 11–159). Many of these were from state cooperative extension agents. Other commenters indicated that OSHA and EPA should coordinate to have consistent approaches, or that the jurisdictions need to be clarified (Exs. 11–14, 11–32, 11–102, 11–121). Worker representatives tended to believe that OSHA coverage is needed to provide adequate protection (see, *e.g.*, Exs. 11–21, 11–49, 11–144).

EPA and OSHA worked together to coordinate regulations in this area. EPA issued its final Worker Protection Standard for Agricultural Pesticides on August 21, 1992 (57 FR 38102). OSHA has agreed not to cite employers who are covered under EPA's final rule with regard to hazard communication requirements for pesticides. This policy is already in effect. Agricultural employers who are otherwise covered by OSHA will still be responsible for having a hazard communication program for hazardous chemicals that are not pesticides.

Coverage of the agriculture industry. Representatives of the agriculture industry (Exs. 5–6, 5–50) were also concerned that the revised final rule did not mention the Congressional appropriations rider under which OSHA is prohibited from promulgating or enforcing any OSHA standards on farms with 10 or fewer employees unless the farm has a temporary labor camp. As long as this rider is added annually to OSHA's appropriations bill, the protections of the HCS will not apply on those farms. However, farms with 11 or more employees, as well as those with temporary labor camps, are covered by the rule, except coverage of pesticides as discussed above.

Commenters on the NPRM reiterated that they believed the appropriations rider should be specifically referenced in the rule, rather than simply discussed in the preamble (Exs. 11–34, 11–67, 11–78, 11–87, 11–99, and 11– 101). OSHA does not agree. An appropriations rider may change from year-to-year, and is not a determination by the Agency that coverage of such employers is not necessary. Thus it does not belong in the regulatory text of a rule.

Other comments related to the agriculture industry included a suggestion that OSHA should not cite farmers until jurisdictional problems with EPA are resolved (Ex. 11–34). OSHA is not currently issuing citations for violations of the rule with regard to pesticide application in the fields. All other provisions of the rule are being enforced in the agriculture industry. As this same commenter noted, approximately 100,000 farms will have to have programs for chemicals other than pesticides as they have more than 10 employees.

It was also suggested that the HCS is not needed in agriculture as exposures are limited (Ex. 11–67). OSHA does not agree. (See, *e.g.*, 52 FR 16059–61 (Ex. 4–91); Exs. 4–28; 4–102). As discussed in the preamble to the NPRM (53 FR 29826), the HCS is a right-to-know standard, and employees have the right to know as long as the potential for exposure exists in the work operation, and the chemical has been demonstrated to be hazardous. It is also not sufficient to simply tell a worker that a chemical is hazardous, without telling them what the hazard is (Ex. 11–67). The appropriate response to the information presented about the hazard will vary with the type of hazard. A chemical that is flammable requires a different protective response than one that causes skin burns.

Coverage of distributors. A constant feature of the HCS has been the downstream flow of information from suppliers of chemicals to the ultimate users. When the HCS was originally proposed in 1982, it did not explicitly cover importers or distributors. OSHA invited comment on coverage of these suppliers in addition to the coverage of chemical manufacturers that was already included in the NPRM. The Agency stated that explicit coverage may not be necessary because marketplace pressure exerted by manufacturers needing the hazard information would, in fact, ensure that the importers and distributors make it available to their customers.

Rulemaking participants did not agree that this "marketplace pressure" approach would work, and overwhelmingly supported explicit inclusion of importers and distributors in the final rule (48 FR 53287–88). As a result of those comments, OSHA required these suppliers to ensure that containers they shipped were labeled, and under the original rule, material safety data sheets were supplied with the initial shipment of a chemical to a manufacturing employer.

A regulatory impact analysis of this requirement indicated clearly that this automatic provision of information to downstream customers was the most efficient and cost-effective way of ensuring that the employers using the chemicals had the information before exposing employees. OSHA considered requiring such suppliers to provide the information on request, but information presented by employers in the rulemaking record indicated that this approach was more costly than the automatic transmittal, as well as being less effective. 48 FR 53330. H–022, Ex. 184. When the rule was expanded to cover nonmanufacturing, importers and distributors were required to provide MSDSs in accordance with the rule to all downstream employers.

A number of representatives of distributors to the non-manufacturing sector have requested that the rule be modified to either exclude them from the requirements of the rule (*i.e.*, require employers to request MSDSs directly from the original chemical manufacturer), or allow them to simply respond to requests rather than affirmatively sending the MSDSs with the first shipment of a chemical to a downstream employer. (See, *e.g.*, Exs. 25, 28, 29, 31, 32, 60, and 62.) "[T]he intent of the law to provide meaningful and timely notice to employees using hazardous materials can best be fulfilled through the implementation of an as-needed and on-request responsibility for

transmission of MSDS's." (Ex. 62; Beauty and Barber Supply Institute, Inc.)

Although OSHA recognizes that complying with this requirement does present a burden to distributors, the rulemaking record indicates that such an approach is the most cost-effective way to ensure that the downstream employees are properly protected. The costs of the distribution of the MSDSs are ultimately borne by the downstream user obtaining the information. The recommendations of these distributors that they either be exempted, or allowed to respond to requests only, simply shift the burdens of compliance to other employers and create a less efficient system of information transmittal. In particular, OSHA believes that the distributors who wish to simply respond to requests are assuming that the number of requests will be minimal. As all downstream employers are now covered by the rule, this is not a realistic assumption. Every customer they have to which hazardous chemicals are supplied is required to have the MSDSs. If a distributor has to respond to multiple requests from, as one commenter testified (Tr. 3–43), 10,000 customers, the burden on both the requestors and the distributor will be significant.

OSHA specifically recalculated the costs for distributors to the nonmanufacturing sector to consider an "on request" system (Ex. 71–70). These cost figures reiterated the findings of the original cost analysis, *i.e.*, this is a more costly and less efficient way to distribute the information. Furthermore, as the downstream employers are not supposed to use a chemical without having the MSDS, it will cause them a delay in use of the product, or increase the probability that employees will be inadequately protected because employers will use the product without the MSDS. Clearly, downstream users are not as knowledgeable about the hazards of the chemical products as the manufacturers of those products. The best way to protect downstream employees is for OSHA to assure that complete hazard information is provided to the downstream employers and employees by the time they receive the chemical.

Other comments from these employers related to ideas for information to be included on more detailed labels, instead of MSDSs (Ex. 28), or other specific suggestions for modification of the distributor's duties (Ex. 22). These will be dealt with in the sections of the preamble covering labels and material safety data sheets.

Laboratory coverage. The current HCS limits coverage of laboratories (paragraph (b)(3)), simply requiring that labels be kept on containers that are received labeled; that material safety data sheets which are received be kept, and employees be given access to them; and that employees be trained in accordance with paragraph (h) of the rule. Paragraph(h)(2)(iii) states, among other things, that employees are to be informed of the location and availability of the written hazard communication program. Since laboratories are not required to have written hazard communication programs, this part of the information and training program would not apply to these types of facilities. Although this would appear to be evident, OSHA has received a number of questions regarding this, so the provision has been modified to clarify that the location and availability of the written hazard communication program does not have to be addressed in the laboratory training program. The location and availability of material safety data sheets, which is also currently addressed under paragraph (h)(2)(iii), would still have to be included in the training program.

Two other technical amendments have been made to clarify the laboratory provisions. In paragraph (b)(3)(iii), the current rule states that employees are to be "apprised of the hazards of the chemicals in their workplaces in accordance with paragraph (h) of this section". Paragraph (h) requires employers to provide employees with both information, (h)(2), and training, (h)(3), on hazardous chemicals in their work area. Some employers have misinterpreted the use of the word "apprised" in (b)(3)(iii) as only requiring hazard information transmittal and not training. Clearly the intent of referencing paragraph (h) in paragraph (b)(3)(iii) was to require employers to "fully implement the training provisions of the hazard communication standard for laboratory employees." 48 FR 53288. Paragraph (b)(3)(iii), therefore, has been clarified to indicate that laboratory employees must be provided both information and training in accordance with paragraph (h).

Another recurring question involves a laboratory's responsibilities as a chemical manufacturer or distributor. The limited provisions of paragraph (b)(3) are directed to an employer's duties to laboratory employees. They do not, in current form, affect such an employer's duties once the material is being packaged and shipped elsewhere. At that point, the parts of the standard that deal with distribution of chemicals apply. In order to reiterate those requirements, OSHA has adopted a technical amendment to clarify a laboratory's duties when shipping or transferring a chemical out of the laboratory. In this situation, a laboratory would be a chemical manufacturer or distributor, and would have to evaluate the chemical's hazards under paragraph (d) and label containers and provide material safety data sheets in accordance with the rule if the chemical is determined to be hazardous. This would include samples sent to another laboratory. It must be reemphasized, however, that the HCS is based upon currently available information. If a new chemical is developed, and it has not been tested to determine its hazardous effects, then there is no information to transmit. The rule does not require testing of chemicals to be performed.

One commenter has suggested that laboratories be treated the same as any other workplace in terms of protection (Ex. 11–125). OSHA believes that the feasibility and practicality concerns of laboratories warrant the approach taken (see 52 FR 31861; 48 FR 53287–89 for further discussion).

With regard to laboratories, it should also be noted that OSHA has finalized a specific rulemaking to address Occupational Exposure to Toxic Substances in Laboratories (29 CFR 1910.1450). Some interested commenters in both rulemakings were concerned about potential duplication or conflict in the requirements of the HCS versus the laboratory standard. The Agency drafted the final laboratory standard in a manner that does not conflict with or duplicate the requirements of the HCS.

Coverage of operations involving sealed containers. The 1987 rule included limited coverage for work operations where employees only handle chemicals in sealed containers, *i.e.*, they are not opened in the workplace under normal conditions of use (paragraph (b)(4)). No changes were proposed for the provision when the NPRM was published. However, OSHA is making a minor technical amendment in this final rule. The provision as promulgated requires employers to request an MSDS for chemicals received without one when employees want to have access to the MSDS. There was no time frame included in the rule for this request process. In this final rule, OSHA has clarified that the request is to be made as soon as possible. OSHA has generally interpreted this to mean within 24 hours. This is consistent with the requirement in (g)(6)(iii) for an employer or distributor to obtain an MSDS as soon as possible when one has

not been provided with a shipment of a hazardous chemical.

There were comments received which asked for clarifications of the sealed container exemption. In particular, commenters questioned whether the training requirements of the sealed container provisions apply to retail establishments selling consumer products. Exs. 11–11 and 11–93. For those consumer products that are not otherwise completely exempted (*i.e.*, food, drugs, cosmetics packaged for sale to consumers in a retail establishment), training would apply under the rule. OSHA believes that the limited nature of the requirements are minimally burdensome to these types of employers, but that workers need to be told what to do in the event of a spill or leak in this situation. The large quantities of materials present pose a different potential exposure situation than there would be in a home where consumers generally have smaller quantities stored. The training can be directed to the various types of hazards, and need not be on the specific chemicals.

Labeling exemptions. Following publication of the 1987 final rule, the Department of Agriculture (Ex. 5–28) and the Animal Health Institute (Ex. 5–37) requested that a specific exemption be included for labeling of veterinary biological products. Although these materials are considered to be drugs, the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 392(b) "defers" regulation of some veterinary biologics to the Department of Agriculture when the biologics are subject to the Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151 *et seq.*

To the extent that the hazards of these materials are biological hazards, the HCS would not apply in any event. However, there are apparently some chemicals used in the materials that would potentially be covered by the HCS (in particular, formaldehyde). OSHA has added an exemption for labeling of these items when they are subject to the labeling requirements of either the Food and Drug Administration or the Department of Agriculture. A number of commenters supported this clarification (Exs. 11–48, 11–60, 11–76, 11–89, 11–101, and 11–134), and no one objected. It should be noted, however, that this exemption is just for labeling, and to the extent chemical hazards are present in these materials, the other provisions of the HCS would apply in terms of employee protection.

An additional comment (Ex. 11–119) suggested that a similar labeling exemption be incorporated for seeds that are labeled in accordance with the Federal Seed Act administered by the U.S. Department of Agriculture. OSHA agrees, and has added such an exemption to this final rule.

OSHA has also added an exemption for additional labeling of chemical substances or mixtures that are labeled in accordance with the requirements of EPA under the Toxic Substances Control Act (TSCA). EPA has labeling authority for such products under TSCA, and has adopted some labeling requirements for specific substances. These specific labeling requirements would apply.

Other Exemptions

Hazardous waste. The existing HCS includes a total exemption for hazardous waste when regulated by EPA under the Resource Conservation and Recovery Act (RCRA). However, the rule does not mention hazardous waste regulated by EPA under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). In order to ensure that coverage of the rule is consistently applied, this exemption has been modified to include hazardous substances regulated by EPA under CERCLA.

Wood dust. In the preamble to the revised final rule, OSHA clarified that the wood and wood products exemption did not apply to "wood dust." Wood dust is not generally a wood "product," but is created as a byproduct during manufacturing operations involving sawing, sanding, and shaping of wood. Wood dust does not share solid wood products' "self-evident" hazard characteristics that supported the exemption of wood products from the HCS' coverage. Except for the chemical additives present in the wood, products such as lumber, plywood, and paper are easily recognizable in the workplace and pose a risk of fire that is obvious and well-known to the employees working with them. The potential for exposure to wood dust within the workplace, especially with regard to respirable particles, is not self-evident, nor are its hazards through inhalation so well-known that hazard communication programs are unnecessary.

OSHA is technically amending the rule to clarify that the wood and wood products exemption, paragraph (b)(6)(iv), only applies to wood or wood products for which the chemical manufacturer or importer can show that the hazard potential is limited to its flammability or combustibility, and therefore the other hazards of wood dust or other chemicals that may be emitted from treated wood would be covered. Lumber which will not be processed is exempted. Although this has been the Agency's enforcement policy, there have been commenters who suggested that the rule itself should be clarified (Exs. 2–104 and 2–105).

OSHA recognizes that there are some practical questions regarding the appropriate application of the HCS requirements to wood dust. First, it is obvious that exposure can only occur when the dust is generated in airborne concentrations, in a particle size that can be inhaled by people working in the area, such as sanding, sawing, or grinding operations. (See, *e.g.*, Ex. 2–211). The rule should not be interpreted as requiring hazard communication programs for wood mulch, which is typically made up of rather large pieces of wood, and not processed downstream, or trace quantities of wood dust on boards that have been cut. Secondly, it is also obvious that wood dust cannot be labeled in these work situations since it is not "contained." Work areas could be placarded with the hazard information to provide an immediate visual warning for workers involved in these types of operations. The inability to label in some situations, however, does not negate the need for a material safety data sheet and training on the hazards and the available means of protection, and these, and all other HCS requirements, would still apply.

The question of who should be responsible for generation of the material safety data sheet is one which is more difficult to answer. Several commenters suggested that the generator of the dust in a particular operation (*e.g.*, furniture manufacturing) should be responsible, not the producer of the wood product (*e.g.*, a logging company) (Exs. 2–68, 2–104, 2–138, and 2–211). In this situation, as well as similar situations with grain and other products which are grown rather than produced, OSHA believes it is appropriate to place the responsibility for development of the MSDS on the first employer who handles or processes the raw material in such a way that the hazardous chemical is "produced" and released into the work environment. For wood, although some dust would be produced when the tree is felled, it appears that the duty would most appropriately fall on the sawmill, which is a manufacturing operation (SIC Codes 24 and 26). For grain dust, it would be the grain elevator. Data sheets would thus have to be provided to the workers in these facilities exposed to the hazards, and where these types of operations distribute the product in a form where the hazard will be generated under further processing (*e.g.* the sawmill sells

boards to a furniture manufacturing facility), then the material safety data sheet must be transmitted downstream as well.

Articles. As discussed at length in the NPRM preamble (53 FR 29828–33), OSHA believes that the definition of an exempted "article" which was promulgated under the original final rule in 1983 is still appropriate, but proposed a minor modification to clarify the definition to be consistent with Agency interpretations.

The current definition of "article" is as follows:

"Article" means a manufactured item: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use.

The new definition will read as follows:

"Article" means a manufactured item, other than a fluid or a particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts, of a hazardous chemical (as determined under paragraph (d) of this section) and does not pose a physical hazard or health risk to employees.

The new definition differs from the current one in that it includes as articles items which release not more than very small quantities—e.g., minute or trace amounts—of a hazardous chemical, as long as these items do not pose a physical hazard or health risk to employees. This definition gives manufacturers and importers more latitude in determining whether an item is covered under the HCS, as the current definition requires that to be considered an article, an item not release any amount of a hazardous chemical. The proposed definition also makes clear that fluids and particles are not articles; this is not a change in the definition, but simply articulates this fact for the sake of clarity.

Many of the commenters on the proposed revision supported the changes (see, *e.g.*, Exs. 11–1, 11–11, 11–40, 11–48, 11–50, 11–51, 11–54, 11–86, 11–90, 11–111, and 11–133). Some commenters did not believe that a revision was necessary in any event: "* * * [W]e believe that the definition of the term 'article' is in danger of overelaboration. The extant definition is sufficient. The proposed version, while becoming wordier, would still be acceptable." Ex. 11–10. See also Ex. 11–136. OSHA has concluded that the additional language as proposed is necessary in order to give employers more complete information on what an exempted article is, and is adopting the proposed modifications in this final rule.

As the Agency indicated in the NPRM discussion, the definition has been in place since 1983, and chemical manufacturers and importers have been successfully applying it to their products since that time. There appear to have been few citations issued regarding inappropriate application of the article exemption. The rulemaking participants objecting to the definition have couched their objections in terms of difficulties in applying the requirements of the rule. However, OSHA believes, and the record accumulated since the NPRM was published continues to support this belief, that the true objection is to the coverage of specific products, not to whether the definition can be applied as written. Producers of these types of products clearly can determine that they are not articles under the HCS, and thus the requirements of the rule apply. Their objections, therefore, are to coverage under the rule.

OSHA discussed this issue at length in the NPRM. As indicated at that time, the primary participants regarding this issue are The Formaldehyde Institute (Ex. 11–37, 11–140, Ex. 86), and representatives of other organizations associated with formaldehyde-treated products (see, *e.g.*, National Particleboard Association (Ex. 11–137, Ex. 74); National Cotton Council (Ex. 58, Tr. 7–183–91, Ex. 91)). It should be noted that both the Formaldehyde Institute and the National Particleboard Association submitted notices of intent to appear at the informal public hearings, but withdrew prior to presenting their testimony. Furthermore, although their post-hearing exhibits have been entered into the record, as a procedural matter, organizations not participating in the hearing are not allowed to file post-hearing exhibits. In addition, the National Cotton Council was permitted to testify the last day of the hearing, but had not submitted a notice of intent to appear. Consequently, testimony was not available prior to the hearing to enable OSHA and other interested parties to prepare questions on it. The National Cotton Council submitted a post-hearing exhibit March 23 (8 days after the period for submission of briefs was concluded). Since this submission was not a brief, it should have been submitted by February 13, the date for hearing participants to present additional information.

OSHA is not going to repeat all of the discussion regarding the Agency's interpretation of the rule's requirements. (*See* 53 FR 29828–33.) The formaldehyde-related commenters have attempted to use that discussion to argue that OSHA's position on articles is inconsistent with other parts of the rule or with Agency interpretations. This simply is not the case, and the discussion stands as the Agency's position.

The rule cannot credibly be interpreted as not covering the products these commenters are discussing. In particular, in the original final rule, OSHA indicated that the definition of article was specifically worded in the fashion it was to address problems with such products as these commenters are concerned about: "For example, the ACTWU (Ex. 111) described a situation involving fabrics in common use which are treated with permanent press resins which release formaldehyde when handled. Workers engaged in making clothing from such fabrics should be informed about the nature and identity of their formaldehyde exposures * * *. Therefore, the definition has been modified to ensure that in this type of situation, hazard information is transmitted to employees and downstream employers." 48 FR 53293. Commenters' arguments that their professional judgment allowed them to determine that downstream risks are negligible are completely contrary to the rule as written. Professional judgment comes into play only with regard to the weight of the evidence substantiating a hazard, not with regard to predicting downstream exposures.

As OSHA noted in the NPRM, the definition of an article and application of that definition to determine whether an item is exempted, is an issue for chemical manufacturers and importers, not non-manufacturers. Non-manufacturers have no responsibility for applying the definition, and can rely on the evaluations performed by their suppliers. One commenter took issue with this statement (Ex. 11–111), and indicated that non-manufacturing is concerned about articles as well. Some of these commenters supported the position that the article definition should be narrowed so as to result in fewer products being covered in non-manufacturing workplaces (see, e.g., Ex. 11–135, 11–142). That is a different issue than claiming that the definition itself is unworkable, and OSHA is reiterating that application of the definition to manufactured items is an issue that is solely the concern of

manufacturers. Therefore, opinions expressed by these non-manufacturers who have no experience applying the definition, and have no responsibility to do so, are irrelevant as to whether the definition should be revised.

The primary alternative suggested by representatives of the formaldehyde industry commenters is that OSHA exempt *de minimis* releases so that a manufactured item which releases "small" amounts of a hazardous chemical during normal conditions of use is still considered an article and not covered by the HCS. (See, *e.g.*, Exs. 11–37, 11–107, 11–122, 11–127, 11–135, 11–137, 11–140, 11–142, 11–146, and 11–154) (six of these commenters are formaldehyde-related organizations; two are construction representatives who do not have to apply the definition; one is a mining industry representative that is not covered by OSHA). Several commenters indicated that the changes were a step in the right direction, but did not go far enough (Exs. 11–38, 11–137, and 11–147).

As indicated in the NPRM, this alternative simply does not provide sufficient protection for employees, and does not address the true issue of concern—the exposure of employees. Manufacturers and importers often cannot accurately predict downstream exposures to a hazardous chemical, and individual reactions to an exposure vary. The purpose of this standard, therefore, is to provide information on all hazardous chemicals to which employees could be exposed.

No new arguments have been presented by these rulemaking participants, and as discussed in the NPRM, the existing arguments are not persuasive. As a result of comments these same participants and others have made in the formaldehyde docket, the hazard communication provisions of the formaldehyde rule were stayed repeatedly, and the HCS was applied to those products. As OSHA had indicated in the NPRM, the 0.1 ppm cut-off that applied in the formaldehyde standard was a de-regulatory provision—it resulted in the hazard communication provisions of that rule applying to fewer products than would be covered under the HCS. As far as OSHA is concerned, the specific formaldehyde rulemaking addressed the concerns of the industry producing such products by establishing a substance-specific *de minimis* cut-off for formaldehyde. That cut-off was then stayed at the request of the industry representatives. The Agency does not believe it is appropriate to revise the generic HCS rule to address the specific situation with regard to formaldehyde.

OSHA recently published a new final rule on formaldehyde which revised the substance-specific hazard communication provisions (57 FR 22290; May 27, 1992). The requirements of this specific standard with regard to hazard communication now supercede the generic HCS provisions. As these new provisions address the unique concerns of the formaldehyde-related industries, OSHA does not believe those industries' concerns need be dealt with further in this rulemaking proceeding with regard to the article definition. As noted in the formaldehyde preamble (57 FR 22297–98), nothing in the formaldehyde rule should be considered to be precedent-setting with regard to hazard communication. It was a unique situation that was handled on an individual basis and does not apply to the generic provisions of the HCS.

Several commenters suggested that the mixture rule should be applied to the entire article, including the chemicals that are bound inextricably and to which employees are not exposed (Exs. 11–122, 11–127, 11–137, and 11–140). As OSHA described in the NPRM, this is inappropriate and irrelevant to employee exposures. The weight or volume of a gas present in a solid material is totally unrelated to what is released—in the situation of the formaldehyde-contaminated products, the gas is 100% of the release even though the relative weight or volume would be far less than the percentages indicated. Two other commenters indicated they did not agree with the discussion regarding mixtures (Exs. 11–86, 11–137)—however, the discussion merely describes what the standard already requires. One commenter suggested that the definition be clarified to indicate that the hazard determination is to be done on the release. Ex. 11–147. The definition already refers to paragraph (d) with regard to the release, and the overall scope of the standard is limited to exposures which occur when chemicals are released.

Other commenters indicated that OSHA should emphasize that manufacturers do not have to consider misuse when determining if their product is an article. Exs. 11–11, 11–111. (Another commenter indicated that the definition should cover abnormal conditions of use as well as normal. Ex. 11–125.) The definition does not mention misuse, and certainly that is not a factor in the manufacturer's decision. It also does not apply to the ultimate destruction of the product, *e.g.*, materials emitted when plastics are incinerated. Chemical manufacturers and importers do have to consider any intermediate uses prior to the final use, *i.e.*, whether installation or finishing of the item results in employee exposures (Ex. 11–21). The ACCSH recommendations suggested that the definition list some of these types of operations that would be covered (such as welding). OSHA does not think that is necessary, and as has already been stated, the definition is in danger of becoming too detailed. Therefore, we reiterate again that the exemption applies to the end use of the product only—if intermediate uses result in exposures, they are covered under the rule.

A number of other comments were also received. One suggestion (Ex. 11–51) was that further consideration should be given to exempting those amounts not known to cause adverse health effects. Similar to the arguments regarding *de minimis* cut-offs, this suggestion presumes a "bright line" determination of when risks will occur and knowledge of downstream exposures. This approach is not consistent with the intent of the HCS to prevent effects from occurring by providing information prior to putting the employee at risk.

It was also suggested that for polymers, the primary concern should be what employees are exposed to, not simply the constituents (Ex. 11–51). This is true for all articles, and is the approach OSHA has adopted.

One commenter indicated that most medical devices are articles (Ex. 11–107)—OSHA agrees that this is probably true, since medical devices include such items as crutches, etc. Where this is not true and hazardous chemicals are not completely bound up in the medical device, it would not be an article. It was also noted that trace amounts will be difficult to determine (Ex. 11–122).

Another commenter stated that adding the exemption for fluids and particles confused the issue, and it should be deleted (Ex. 11–108). OSHA does not agree. Fluids and particles never met the definition in the exemption anyway, and stating that explicitly ensures the definition is interpreted correctly and is consistent with EPA's definition of an article.

However, as has been discussed previously, it is not appropriate to adopt all of EPA's definition since it does not adequately address worker exposures (Ex. 11–135), nor is it appropriate to exempt exposures below the PEL (many chemicals do not have PELs, and the manufacturers cannot predict what downstream exposures will be (Ex. 11–122)). Similarly, an action level or percentage of PEL as a trigger is not appropriate for an information

transmittal standard, and will not work as the majority of chemicals do not have PELs (Exs. 11–127, 11–131).

One commenter was under the impression that the change in definition would result in hundreds of products in the printing industry being covered that weren't covered under the original rule (Ex. 11–162). This is inexplicable to OSHA since the revised definition was simply a clarification of the requirements, not a change in the provision.

The National Electrical Manufacturers Association (Ex. 24) submitted examples of electrical brushes to the record, and was concerned about a court decision involving such products. It should be noted that decisions concerning the applicability of the rule to items such as electrical brushes are to be made on a case-by-case basis by the chemical manufacturer or importer in the hazard determination process. It is entirely possible that electrical brushes from different manufacturers would be treated differently under the rule, depending upon their specific characteristics. The brushes of concern in the court case released copper and graphite dust as a result of handling, and employees were exposed. It is conceivable that other brushes would not be capable of releasing such materials when handled, and thus would not be covered.

OSHA concludes that no further change in the definition is warranted based on the information submitted to the record. In fact, the information is not new, and simply repeats the arguments previously presented and rejected by OSHA in the NPRM.

Food, drugs, cosmetics, and alcoholic beverages. For ease of reference, OSHA has reorganized these exemptions in this final rule and separated them by topic (*i.e.*, there is a specific subparagraph dealing with food and alcoholic beverages, another with drugs, and a third with cosmetics).

In the 1987 revised final rule, OSHA included an exemption for food, drugs, cosmetics, or alcoholic beverages in a retail establishment which are packaged for sale to consumers (paragraph (b)(6)(v)). This exemption recognized that even where these chemicals are hazardous (and many are not, particularly in the area of food items), they present little or no hazard to employees when they are in final packaged form for sale to consumers. This exemption effectively limited coverage of many retail establishments which only have hazardous chemicals in this form, *i.e.*, packaged for sale to consumers. But it did not exempt these products when they are being used in a retail establishment and thus exposing employees.

As previously stated in the preamble to the revised final rule, if a product is exempted downstream, a distributor has no responsibility for providing a MSDS on that product to the retail distributor. "In addition, since these products are exempted, employers which package them for retail sale would not have to furnish material safety data sheets to distributors receiving the products." 52 FR 31862. Several commenters suggested that wholesale distributors be exempted (Ex. 11–39), or that the packaged materials be exempted at the wholesale level as well (Exs. 11–111, 11–117, 11–158). OSHA disagrees. The large volume of chemicals handled in these types of workplaces, and the fact that they may readily spill or leak, poses a risk to the distributors' employees. Their coverage, however, is already limited by the sealed container provisions (paragraph (b)(4)) of the rule to maintaining information received, and training workers with particular emphasis on handling spills and leaks. This approach minimizes the burdens of coverage, while providing adequate protection for employees who only handle these chemicals in sealed containers.

Food. OSHA proposed a further modification to this exemption to both clarify and extend it to other food and alcoholic beverage products in retail establishments that are being prepared for consumption by consumers. Thus food used for cooking meals to be sold to customers would be exempt, as would alcoholic beverages which are sold by the glass and thus prepared for consumption rather than "packaged" for consumer use. Although OSHA believes that most such products in terms of food items would not be hazardous under the rule in any event, it appears that some manufacturers are nevertheless providing material safety data sheets for such items as aflatoxin in peanut butter used in a restaurant. To ensure such interpretations are not made, and that material safety data sheets are not unnecessarily being provided for such items, OSHA proposed this modification to the exemption and invited comment on the proposed language.

Comments supporting this exemption were received (Exs. 11–25, 11–88, 11–113, and 11–117), although it was suggested that no differentiation be made between packaged and unpackaged food in this exemption (*e.g.*, bulk food shipments) (Exs. 11–25 and 11–115). No comments were received that objected to the proposed exemption. One commenter suggested that food be totally exempted (11–115), but food can be a hazardous chemical at some stages of production (*e.g.*, flour dust causes baker's asthma). It was also suggested that it be clarified that beverages other than those that are alcoholic are considered to be food. This appears to OSHA to be self-evident.

To accommodate the concerns raised, OSHA has re-drafted the exemption pertaining to food and alcoholic beverages as follows:

"Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees."

Drugs. The original HCS covered the manufacture and formulation of drugs in the manufacturing sector. The rule included a labeling exemption for such products when they were labeled in accordance with the regulations of the Food and Drug Administration (FDA), but all other aspects of the program were applicable to the drug products as well as those chemicals used to make them. In preparing the revised final rule, OSHA determined that it is not necessary to cover such drugs in the non-manufacturing sector when they are in a form that is not likely to result in exposure to employees. Thus the rule totally exempted drugs when they are in a retail establishment (*i.e.*, a drug store or a pharmacy) and are pre-packaged for sale to a consumer (paragraph (b)(6)(v)). Therefore all over-the-counter drugs were exempted at the retail level (thus wholesale distributors did not have to send MSDSs to the retail facilities), and many prescription drugs were exempted at the retail level as well since they are packaged prior to reaching the retail establishment. In addition, OSHA included an exemption for drugs in solid, final form (*e.g.*, pills, tablets, capsules) for direct administration to a patient. As mentioned previously, this was based on the Agency's determination that the potential for exposure is minimal from drugs in these forms.

However, in recognition of the fact that there are various types of workers who may be exposed to drugs in hospitals or pharmacies (*e.g.*, nurses, nurses' aides, pharmacy aides, janitors, or technicians), OSHA did not exempt those drugs that are not solid or are not pre-packaged for sale to consumers (a pharmacy in a hospital would be considered to be a retail sale establishment for purposes of the exemption as written). What remains under this approach are primarily powder, aerosol, or liquid prescription drugs. (An industry representative

admitted in response to questions during the hearing that these exemptions eliminated coverage of 75% of drug products and that industry estimates of cost did not take these exemptions into account (Tr. 3–94–95)). Thus nurses required to mix anti-neoplastic drugs, for example, or janitors cleaning up spills, would be entitled to a material safety data sheet and training under the revised final rule.

There was little discussion of the drug issue in the record prior to the revised final rule (see, *e.g.*, Ex. 2–176). However, since drugs are designed to be biologically active, OSHA wants to ensure that employees will be properly protected. As an example of potential problems, OSHA cited a report in the American Industrial Hygiene Association Journal (Ex. 4–59) that described one hospital's experience with a drug that is generated as an aerosol in a tent for administration to children. Nurses, respiratory therapists, doctors, and other employees are directly exposed when they enter the tent to care for the patients. Information on the drug indicates that such occupational exposure may result in carcinogenesis, fertility impairment, and fetotoxicity. In addition, however, employees who were exposed also complained of experiencing acute effects such as headaches, burning and dryness of the eyes, coughing and dryness of the upper respiratory tract. The hospital eventually devised a protective program for exposed employees based upon its experiences. A MSDS with recommendations for protective measures may have helped them resolve the situation prior to employees being exposed.

In response to the approach taken in the revised final rule, the National Wholesale Druggists' Association (NWDA) (Ex. 5–85) recommended that OSHA recognize package inserts approved under FDA regulations as an acceptable alternative to material safety data sheets required under the rule. Additionally, the NWDA suggested that the Physicians' Desk Reference, a privately developed reference regarding drugs, also be considered to be an alternative to requiring MSDSs for drugs approved by FDA. Other commenters recommended that all prescription drugs be exempted since they are adequately covered by FDA labels, other available resources, and the medical training of persons handling or supervising handling of the drugs (Exs. 5–77 and 5–102).

Although the purpose of the Federal Food, Drug, and Cosmetic Act administered by the FDA is to protect consumers of such products and the general public (see, *e.g.*, *Pharmaceutical Mfrs* v. *FDA*, 484 F. Supp. 1179, 1183 (D.Del. 1980)), the product data inserts that accompany pharmaceuticals do contain some information that is analogous to that found on MSDSs and would provide some protection for employees. In particular, at 21 CFR 201.100(d)(1), FDA requires that inserts for prescription drugs for human use must contain the following information:

> Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended * * * [in] the same [ ] language and emphasis as labeling approved or permitted * * *

This would be useful chemical hazard information for employees involved in administering the products even though employee protection is not the primary purpose of the information presented.

In addition to publication of such information in the package inserts themselves, the FDA regulations also state that (21 CFR 202.1(l)(2)):

> [R]eferences published (*for example*, the "Physicians' Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined [by] the Act."

According to the Physicians' Desk Reference (PDR) in its Forward (40th ed. 1986), "drug information" in the PDR is "prepared by manufacturers, edited and approved by their medical department and/or medical consultant." PDR publishes the information verbatim. *Id.*

OSHA proposed to modify the definition of "material safety data sheet" under the rule to indicate that a package insert approved by FDA, or an entry in the PDR prepared in accordance with FDA's requirements, be considered in compliance with the HCS requirements for a MSDS for these products. In addition, the exemption regarding solid drugs was corrected to read "*e.g.*, tablets or pills" rather than "*i.e.*" as is currently indicated in the revised final rule (see, *e.g.*, Exs. 5–77, 5–85, and 5–102).

The Agency invited comment on this issue, particularly from employees who would be affected by the modification to ensure that they agree that this information is adequate for their protection. The existing exemption for labeling would remain in effect, employers would still have to have hazard communication programs where covered, and training would have to be given to those employees who have not previously been trained regarding the hazards and protective measures.

Industry representatives consistently supported the use of alternatives to MSDSs for drugs (see, *e.g.*, Ex. 11–42, 11–60, 11–108, 11–115, and 11–153), or further thought that a full exemption from all requirements was warranted (*e.g.*, Exs. 11–54, 11–59, 11–75, 11–120, and 11–138) or that drugs should be exempted when handled by wholesalers (Ex. 11–158). "Applying the Hazard Communication Standard to drugs that are either aerosol, mist, or liquid and for patient use seems both impractical and questionable. To begin with, if these drugs are being handled by nurses or doctors, they are being handled by professionals trained to dispense medication." Ex. 11–120. It was also suggested that the exemption be further extended to manufacturing (Ex. 11–48), and that other alternative information sources be permitted in addition to those indicated in the proposal (Exs. 11–92, 11–108, and 11–138).

Additionally, some of these commenters suggested that other items regulated by FDA (such as medical and dental devices) should also be allowed to be accompanied by package inserts instead of MSDSs (Exs. 11–48, 11–96, and 11–108).

It was also suggested that other information comparable to the PDR should be permitted (Exs. 11–92, 11–108, and 11–138), and it was noted that FDA does not actually approve package inserts, they are just issued in compliance with the law, and therefore the OSHA rule should not refer to approved inserts (Ex. 11–48).

Another commenter suggested that the PDR be permitted to be used, but that the entries be modified to include safety information for workers (Ex. 11–62). It was also confirmed that training needs to be provided for proper handling of drugs (Ex. 11–92), so a total exemption would not be appropriate. However, one commenter suggested that OSHA could rely on "voluntary" training (Ex. 11–120).

On the other hand, a number of commenters indicated that package inserts and PDR entries are not acceptable alternatives to MSDSs (Exs. 11–7, 11–21, 11–69, 11–103, 11–125, and 11–144). Concerns expressed by these commenters included the fact that the information on the package inserts and PDR entries is not clear or easily understood, and the information is not comparable to that included on MSDSs.

For example, the American Nurses' Association and the American Association of Critical-Care Nurses (Ex. 11–69) objected to allowing alternatives to MSDSs for drugs. "The use of such inserts or entries has not historically been for occupational exposure alerts * * * Additionally, they are usually in minute print and contain voluminous patient response and safety information. This would negate the effect of a hazard alert to employees." The ANA and AACN indicated that nurses are experiencing significant exposure potentials to many different types of drugs: "Increasingly, nurses have to mix patients' intravenous medications on holidays, evening, night and weekend shifts because there is no pharmacist in the facility. Likewise, nurses have had to perform housekeeping duties, cleaning equipment, and disinfecting patient areas after waste spills * * * Technological advances in pharmaceuticals used to medicate patients and for medical treatment could increase nurse exposures to drugs that are harmful outside of the pharmacy preparation area."

Similarly, the American Federation of State, County and Municipal Employees (Ex. 11–144) stated: "Workers may receive significant and hazardous exposure to drugs in the course of manufacturing, preparing, or administering those drugs. For example, hospital personnel who prepare and administer cytotoxic drugs have been shown to experience both short-term health effects (such as dizziness, nausea, headache, lightheadedness, allergic reactions), and chronic effects (including cancer, leukemia, birth defects, miscarriages, and chromosomal damage). Waste anesthetic gases, such as nitrous oxide, have caused nausea, dizziness, headaches, fatigue, and irritability, as well as sterility, miscarriages, birth defects, cancer, and liver and kidney disease, among operating room staff and/or their spouses (in the case of miscarriages and birth defects)." AFSCME also noted that PDR entries and package inserts do not include the following information that MSDSs would: Exposure limits, physical hazards, routes of exposure, health hazard data related to worker exposure, control measures, and procedures for safe handling and use.

OSHA has decided not to adopt the proposed modification in the final rule. It is clear from the comments of worker representatives and others that the proposed alternative does not provide adequate information, and is not as effective as having MSDSs.

Although the National Wholesale Druggists Association has provided estimates of extensive burdens that would be caused by coverage of the non-solid, prescription drugs in the non-manufacturing industries, their numbers are not credible. As mentioned previously, even assuming that their unit costs are correct, their burden estimates do not take into account the existing exemptions in the rule. For example, at a Congressional hearing (Ex. 4–198) the NWDA distributed two MSDSs for toothpaste and an over-the-counter stomach remedy to illustrate the types of information they had to distribute. In fact, the MSDS for the toothpaste clearly indicated that the chemical was not hazardous under the HCS—so it was not covered and distribution of the MSDS was not necessary. The stomach remedy was combustible—a concern in the manufacturing facility. However, it too is exempt in terms of MSDS distribution once it is packaged for sale to a consumer. Thus NWDA members are not required to send MSDSs downstream for either of these products.

NWDA estimated that compliance with the rule would cost their industry $59 trillion dollars (Exs. 5–76 at p. 175), although at the same time they reported total sales of pharmaceutical products to be about $13 billion a year. More recent estimates varied from $1.8 million per facility to $16 million per facility (Tr. 3–94–95; Ex. 82). These figures are grossly exaggerated, and are based on incorrect assumptions such as having an MSDS included with every package instead of provided once with the initial shipment, or providing copies of every MSDS in a product line to every customer whether they purchase the product or not. OSHA does not find NWDA's arguments to be credible, nor do we believe that it is infeasible to distribute MSDSs for drugs that are not already exempted elsewhere. Proper protection of the workers exposed to these chemicals warrants the burdens imposed.

OSHA also raised another issue of concern regarding labeling of drugs dispensed by a pharmacist to a nurse who gives it to the patient. It is our understanding that these dispensed drugs may not be marked in any way, and since the nurse doesn't transfer the material from the labeled container, the portable container exemption for labeling would not apply. OSHA invited comment on suggestions for dealing with this issue for non-solid drugs. One commenter suggested that each facility should develop an appropriate method for dealing with the issue in conjunction with a training program (Ex. 11–92). The other indicated that dispensed drugs do not need to be labeled (Ex. 11–96). A third suggested that although the commenting organization supported such labeling, it appeared to be more beneficial to the patient than to health care workers (Ex. 11–69). OSHA has decided that the containers of drugs dispensed by a pharmacist to a health care provider to give to a patient will be considered to be exempted under the portable container provisions of the rule. This exemption has been added to paragraph (f)(7). Although the employee administering the drugs may not be the person performing the transfer, it appears that the necessary information is readily accessible to them, and that labeling the individual containers is not necessary in this situation.

Cosmetics. OSHA has separated the exemptions applying to cosmetics and placed them in a new subparagraph, but has not changed the substance of the requirements. Cosmetics are exempt when packaged for sale to consumers in a retail establishment, and when brought into the workplace for employee consumption. Otherwise, they are covered by the rule when they contain hazardous chemicals.

Consumer products. As described in the NPRM (53 FR 29834–38), one of the fundamental principles upon which the HCS is built is that employees are entitled to information regarding any chemical which is hazardous and to which they are potentially exposed. The type of use a hazardous chemical is intended for is irrelevant—the risk being addressed is exposure to a chemical without knowing what the hazards and appropriate protective measures are. That being the case, the 1982 NPRM contained no exemptions for any "types" of chemicals. The exemptions which were in the original final rule were based upon comments submitted to the rulemaking record after that proposal. OSHA limited the exemptions to situations where other regulatory programs addressed the problems involved (*e.g.*, labeling exemptions for those products labeled in accordance with another Federal agency's requirements), or where the hazards did not result from workplace exposure.

In the area of consumer products, the original final rule included an exemption for additional labels on such products when they are labeled in accordance with the requirements of the Consumer Product Safety Commission (CPSC). CPSC's requirements for labeling of hazardous substances are for the purpose of protecting consumers when such products are used in the home, the school, and recreational facilities (15 U.S.C. 2052(a)(1)). The Federal Hazardous Substances Act, 15 U.S.C. 1261 *et seq.*, and regulations issued under that Act by CPSC are not

designed to protect workers. See *American Petroleum Institute* v. *OSHA*, 581 F.2d 493, 510 (5th Cir. 1978), *aff'd on other grounds sub. nom. Industrial Union Dep't.* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

Consumer products generally do not include the type of specific hazard information OSHA would require on the labels of containers of hazardous chemicals which are shipped. Although some consideration is given to chronic hazards, the basic emphasis is on acute effects. In addition, the labels focus on precautionary statements and routes of exposure rather than informing the user of the specific hazards. For example, a label for lead solder purchased in a hardware store indicates that it is "fatal if swallowed" and "causes severe burns," but gives no indication of the fact that lead causes not only acute lead poisoning but also has severe effects on a number of body systems, including damage to blood-forming, nervous, and reproductive systems (see, OSHA's lead standard, 29 CFR 1910.1025). Furthermore, the primary route of entry for occupational exposure to lead would normally be inhalation—the consumer label does not indicate that inhalation of fumes generated when soldering is of concern. Ex. 4–71. Conversely, a properly prepared MSDS for the same material will indicate the full range of health effects, the appropriate protective measures, the fact that there is an OSHA standard for the material with a permissible exposure limit, and other useful information for both the employer and the employee being exposed.

Upon considering what information is necessary for the protection of workers exposed to these so-called consumer products in the workplace, OSHA decided that protection of workers would be served by allowing the CPSC labels to suffice, but requiring MSDSs and training as for any other hazardous chemicals. There appears to be some misconception that by virtue of being permitted to be marketed to consumers, consumer products are inherently safe and don't require any additional information be given to workers using them. This certainly is not the case.

As OSHA described at length in the NPRM preamble, the Consumer Product Safety Commission (CPSC), in its National Electronic Injury Surveillance System (NEISS), compiles estimates of product-associated injuries based on a statistically significant sample of incidents reported to institutions with emergency treatment departments. Information regarding work-related injuries treated in emergency rooms has subsequently been provided by CPSC to the National Institute for Occupational Safety and Health (NIOSH). See Ex. 4–77.

The NIOSH data indicate that a total of 136,212 work-related chemical injuries were estimated to have been treated in emergency rooms in 1986. As examples of the types of exposures responsible for these injuries, included in this total were chemicals and chemical compounds (solids, liquids, gases): 102,428; coal and petroleum products: 23,532; and soaps, detergents, cleaning compounds not classified elsewhere: 10,252. Thus OSHA has concluded that workers exposed to hazardous chemicals in consumer products are at a significant risk of experiencing adverse health effects. In particular, OSHA has determined that workers exposed to such chemicals by using the products in a manner not anticipated by the chemical manufacturer or importer, or using them in such a way that exposures are more substantial than those consumers would normally experience, need the protections of the HCS. For example, as NIOSH indicated in its comments, many paint thinners and paint removers available as consumer products contain organic solvents with toxic properties which could produce a hazard if used in large quantities and over an extended time period (Ex. 11–124).

Many products used industrially are also sold and used as consumer products. Thus exempting such products would be in essence exempting them because of the method of distribution for them, *i.e.*, that they are generally sold in retail establishments, rather than through wholesale distribution systems. This is not an appropriate rationale for such an exemption since it does not consider either workplace exposure potential or the hazardous nature of the chemical.

OSHA did not exempt consumer products from any provisions of the original final rule other than labeling. During the implementation of the original final rule, OSHA determined that its enforcement policy regarding consumer products would focus on the type and extent of usage (see, OSHA's instructions to compliance officers for enforcement of the HCS, Ex. 4–24):

> A common sense approach must be employed whenever a product is used in a manner similar to which it could be used by a consumer, thus resulting in levels of exposure comparable to consumer exposure. The frequency and duration of use should be considered. For example, it may not be necessary to have a data sheet for a can of cleanser used to clean the sink in an employee restroom. However, if such cleanser is used in large quantities to clean process equipment, it should be addressed in the Hazard Communication Program.

This appeared to OSHA to be a reasonable accommodation for employers who use consumer products in the manner intended, and with the same frequency and duration of exposure as would be experienced as consumers. The State of Maryland has implemented a similar exemption in its right-to-know law since 1985 (Ex. 11–21). They commented that the coverage of consumer products in this manner is necessary for the proper protection of employees, and employers in Maryland have been able to comply with the provision.

OSHA recognized that many more non-manufacturers would use consumer products than would be found in manufacturing facilities, and that the method of obtaining them might more likely be from retail distributors than wholesale. Thus the ANPR included questions regarding the use of such products, and the means of obtaining them. Relatively few responses were received. However, the responses did confirm that in many cases the use of consumer products in workplace operations has the potential to result in significant exposures that warrant more information being available than that which appears on a consumer product label (see, *e.g.*, Exs. 2–59, 2–83). OSHA decided to incorporate into the revised final rule its existing enforcement policy which was tied to type and extent of exposure (52 FR 31878; paragraph (b)(6)(vii)):

> Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and the Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can demonstrate it is used in the workplace in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not greater than exposures experienced by consumers * * *.

OSHA further stated that this exemption "strikes a balance between the practical considerations of acquiring and maintaining material safety data sheets on CPSC regulated products which employees are exposed to at home as well as at work, and the worker's need for more hazard information than a CPSC label when exposures are greater or more frequent than typical public use of the chemical would generate." 52 FR 31863.

There were some comments submitted on the coverage of consumer products following the publication of the revised final rule. A number of them felt that they could not define what

exposures in the workplace would be comparable to consumer exposure, and that the rule should exempt such exposures unless they are "significantly" greater than consumer exposure or that such products should be completely exempted (Exs. 5–53, 5–72, 5–88, 5–93, 5–94, and 5–97). As we have stated earlier, a common sense approach is required in making these determinations, and most employers we have dealt with clearly know whether the use of such products is unusual, of longer duration, or more frequent than home use. However, in the NPRM we invited further comment on the issue of adding the word "significantly" to the consumer product exemption to modify "greater." A number of commenters supported this suggestion (see, *e.g.*, Exs. 11–51, 11–93, 11–104, 11–111, 11–115, 11–140, and 11–158). In some cases, however, this support was only endorsed as an alternative if the Agency did not agree to a broader exemption (see, *e.g.*, 11–111, 11–115).

Another suggestion submitted (Exs. 5–84, 5–93), and endorsed by OMB in its paperwork decision (Ex. 4–67), was to use the same consumer product exemption adopted by Congress in the community right-to-know provisions of the Superfund Amendments and Reauthorization Act (SARA) of 1986, Public Law 99–499 (Ex. 4–16), which is being implemented by the Environmental Protection Agency (EPA). The exemption would then be for "any substance to the extent that it is used for personal, family, or household purposes, or is present in the same form and concentration as a product packaged for distribution and use by the general public." As OSHA noted in the NPRM, this exemption is not related to the extent of employee exposure to chemicals that are hazardous—which is the concern of OSHA in the HCS—and it is not appropriate for this rule. NIOSH also noted that "consumer products" are defined by EPA and OSHA for different purposes, and should not be summarily grouped together (Ex. 11–124).

The legislative history for SARA does not discuss the household or consumer product exemption. OSHA's rule preceded the SARA legislation, and it can be presumed that the exemptions in SARA were intended by Congress to address the different needs of community right-to-know versus worker right-to-know. Community right-to-know under SARA entails informing the general public and emergency response facilities about chemicals in their neighborhoods that could cause hazardous conditions during emergency situations. The HCS involves informing employees about the chemicals they are potentially exposed to on a day-to-day basis as a result of their work. The SARA exemption of consumer products was not a determination by Congress that such coverage is unnecessary in the workplace.

Nevertheless, a number of employer representatives supported such an exemption as appropriate for inclusion in the HCS (see, *e.g.*, Exs. 11–11, 11–74, 11–106, 11–127, 11–142, and 11–156), or simply suggested that consumer products not be covered (Ex. 11–9), or that CPSC labels provide enough protection (Exs. 11–82, 11–95). The arguments presented involve the desire for consistency with SARA (although the HCS provisions preceded SARA's), the perceived lack of need for additional information on such products, and concerns about interpreting the exemption as written. For example, the Texas Eastern Gas Pipeline Company (Ex. 11–128) stated: "The significant difference between these two is that SARA III is a blanket consumer product exemption, whereas OSHA requires an employer demonstration to exempt an item. Our concern is the potential adverse interpretations of OSHA Field Compliance Officers and the required extent of any such demonstration by the employer."

Obviously, a complete exemption is easier to comply with and enforce than a partial exemption. (Likewise, another option that would be easier to comply with and enforce would be to totally cover the products, rather than exempting any of them.) However, the issue of concern here is whether employees have sufficient information to be protected, not whether it would be less burdensome to completely exempt the products. A total exemption for consumer products would not adequately protect employees, and since the Agency has determined that these employees are at significant risk of experiencing adverse health effects if the workplace use of consumer products is not covered, then OSHA would not be meeting its statutory mandate.

Consistency with SARA requirements is not a persuasive argument either. Since EPA has adopted a permanent reporting threshold of 10,000 pounds for most hazardous chemicals (55 FR 30632), there will be many products covered in the workplace under the HCS that will not be reported under SARA. In fact, there will be many workplaces that will not be required to report anything under SARA that will nevertheless be covered under the HCS. In addition, although the Agencies have attempted to be consistent where possible, they nevertheless have different statutory mandates and purposes for regulation. OSHA's intent is to protect workers and provide them the right to know about the hazardous chemicals in their workplaces. This is quite different from reporting the presence of chemicals to local authorities for the purpose of emergency planning.

A number of commenters, particularly those who represented workers, were concerned about employee access to information about consumer products (see, *e.g.*, Exs. 11–51, 11–125, and 11–144). Some questioned whether the CPSC label should be permitted even when the product has an MSDS and there is training. For example, the National Institute for Occupational Safety and Health (NIOSH) (Ex. 11–124) stated: "[M]any paint thinners and paint removers available as 'consumer products' contain organic solvents with toxic properties which could produce a hazard if used in large quantities and over an extended time period. The information reported for 'consumer products' does not offer the type of information needed to prevent hazardous exposure if used as an industrial chemical when extended exposure times are likely."

Similarly, at testimony during the hearing representatives of workers in the construction industry expressed concern about coverage of consumer products: "Now, the typical label says 'Use with adequate ventilation and don't ingest it', you know, don't eat it. That we do not think is adequate information for the use of a material on a construction site. Because, number one, we are not using it as Harry Homeowner, where he may be fixing one trap underneath the kitchen sink. Our people are using it every day, over a seven or eight hour period for 40 hours a week, for 52 weeks a year. That's a little bit different use." Tr. 6–106–7.

Other employee representatives addressed the appropriateness of the SARA exemption in a worker right-to-know standard: "In our view, exclusion of consumer products as done under Title 3 really isn't appropriate under OSHA. Under OSHA the concern should be is the chemical hazardous, and what do we need to do with respect to information, not what is the source—does it come off a shelf of a retail distributor, or does it come directly from the manufacturer? And so we think OSHA's treatment in this area is really the appropriate one of looking at the hazardous nature of the chemical, and stemming from that, the information that must be provided to the employer and to the worker. So, we think that the

OSHA definition should be maintained." Tr. 7–47.

Representatives of the Chemical Manufacturers Association also agreed that consumer products should not be completely exempted (Tr. 7–24–6). Their members are producers of such products, and are required to prepare the MSDSs and distribute them.

OSHA believes that the record does not support excluding consumer products that are used in a manner different from normal consumer use, or are used more frequently, resulting in greater employee exposures. These chemicals present a hazard to workers that is not sufficiently mitigated by the CPSC-required labels. MSDSs and training are necessary to protect exposed employees. OSHA also does not believe that adding the word "significantly" to modify "greater" in the exemption resolves the problems employers have suggested will occur as a result of the exemption. In particular, if these employers believe they cannot determine when exposures are "greater" than that experienced by consumers (*i.e.*, it's too subjective), it's unclear how these same employers would be able to determine when the exposures are "significantly" greater.

We also believe that some of the employer objections were based on interpretations of the requirements that were more onerous than intended. For example, as was quoted above, there were some employers who felt that the employer would have to go to some great length to "demonstrate" that the use was a true consumer-type usage. To come within the exemption of this provision, an employer need only show that employee use of a consumer product containing hazardous chemicals is of a duration and frequency that clearly does not exceed what a reasonable person would concede to be normal consumer use in a home environment. (Generally, these types of objections were based on an assumption that OSHA's enforcement of the provision would be unreasonable. This certainly has not been the case in the manufacturing sector, and in any event, if a citation is issued unreasonably, existing options are available in the form of employer contest to the citation.)

In order to address the concerns about how the exemption was worded, and therefore would be interpreted, OSHA has modified the language in the final rule. The exemption is now worded as follows:

> Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended.

We believe these changes make the exemption clearer, and yet do not diminish the protections that are necessary for workers exposed to the chemicals involved.

There were a few other comments received regarding this issue as well. One was that training could still be done, based on the labels, rather than totally exempting the products from coverage (Ex. 11–141). As has been fully described in both the NPRM preamble and this document, MSDSs provide information that is necessary for the protection of exposed workers. Training cannot be done adequately without the information on the MSDS for the product. Others suggested that OSHA provide guidance on what it considers to be a consumer product (Exs. 11–38, 11–104). As OSHA stated in the preamble to the NPRM, a consumer product is anything that can be purchased in a retail store and is therefore available to the general public for personal or household use. One commenter also suggested that the exemption from the Maine right-to-know standard that was quoted in the NPRM was a better alternative (Ex. 11–93). We do not agree, and believe the changes incorporated herein address the situation appropriately.

Consumer products which meet the definition in paragraph (b)(6)(ix) are totally exempted from the requirements of the rule. Those which do not meet this exemption are exempted from further labeling under (b)(5)(v). Employers must still provide MSDSs and training on these products.

Nuisance particulates. In the 1985 ANPR, OSHA requested comments on the coverage of nuisance particulates. Under the HCS, all chemicals for which OSHA has a standard, or which are listed in the latest edition of the American Conference on Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values and Biological Exposure Indices annual publication, are to be considered hazardous for purposes of the HCS (paragraphs (d)(3)(i) and (ii)). At that time, OSHA had a generic permissible exposure limit (PEL) for all nuisance dust. There were also a number of substances listed in the threshold limit value (TLV) publication which are specifically identified as nuisance particulates. These substances were listed by name in the main table of the TLVs and in Appendix D, entitled "Some Nuisance Particulates." The HCS covers any chemicals listed in the TLV publication, so these nuisance particulates were in fact part of the "floor" of chemicals covered by the HCS.

However, since any dust or particulate can potentially be a "nuisance," OSHA decided as a matter of interpretation to limit coverage of this part of the rule to those nuisance particulates that were specifically listed at that time in Appendix D of the TLV booklet. OSHA further determined that if a substance listed in Appendix D was not included in an employer's hazard communication program, a *de minimis* notification would be issued as long as the substance did not pose a covered physical or health hazard other than its nuisance characteristics. A *de minimis* violation is one involving a technical violation of a rule, but which bears no relationship to safety or health. A *de minimis* violation has no penalties associated with it, and the employer has no duty to abate the condition.

The majority of those commenting in response to the 1985 ANPR stated that nuisance dust should not be covered (see, *e.g.*, Exs. 2–12, 2–23, 2–64, 2–77, 2–90, 2–107, 2–128, 2–144, 2–167, 2–193, 2–211). Additional comments recommending exclusion of nuisance dusts were received after the final rule as well (Exs. 5–84, 5–86, and 5–93). Edison Electric Institute's argument is an example of the comments received (Ex. 2–107):

> The purposes of the standard can be well-served even with the omission of nuisance dusts. Any solid (powder, flake, granules) can produce nuisance dusts. Requiring MSDSs on nuisance dusts would be impractical in some cases (*e.g.*, floor sweeping dusts), and of little use in others because those do not present a significant health hazard.

There were also a few comments which supported continued coverage of nuisance dust (Exs. 2–30, 2–59, 2–88, and 2–105), and others which addressed specific dusts such as flour (particularly with regard to baker's asthma) (Exs. 2–88, 2–153, and 2–166), and grain (Exs. 2–97, 2–125, and 2–160).

In the 1988 NPRM, OSHA proposed to exempt nuisance particulates which did not meet any of the definitions of health or physical hazards under the rule. Most participants who commented on this change supported the exemption (see, *e.g.*, Exs. 11–40, 11–50, 11–56, 11–90, 11–100, 11–147, and 11–160). However, it was suggested that the exemption was too limited (Ex. 11–135). This does not appear to OSHA to be true since the

dusts are being treated in the same manner as any other type of chemical would be.

There were concerns raised about the potential irritant effects of the dusts still being covered (Exs. 11–7, 11–51). If a properly conducted hazard evaluation indicates the potential to cause eye irritation, that is a covered hazard and the chemical would not be exempted as a nuisance particulate. Similarly, one commenter said that dusts which exhibit effects at high concentrations should not be exempted (Ex. 11–124). The hazard evaluation process for nuisance particulates is not any different than for any other chemical. If the dust does not meet the definition of hazard (at any concentration), it is not covered. Evaluation of the hazards of the dusts is to be done by the producer of the material. Again, dusts are not different from any other material under the rule in terms of hazard evaluation (Ex. 11–133). One commenter also stated that the exemption will discourage rigorous testing (Ex. 11–58). OSHA is not sure why this would be the case, particularly since it has been our understanding that many companies have undertaken more testing since the HCS was promulgated to help ensure that better information is available.

It was also suggested that physical hazards should not be considered to trigger coverage as the HCS was designed to address health effects, not physical hazards (Ex. 11–129). This statement is simply not true. The HCS has always covered all types of health and physical hazards. (See definition of "hazardous chemical" in 29 CFR 1910.1200 (c)).

Another suggestion was to extend the exemption to include nuisance "droplets" (Ex. 11–126). Mineral oil mist was the concern in this comment. Mineral oil mist has a specific PEL and is thus a hazardous chemical under the rule. OSHA does not agree that it would be appropriate to exempt any such chemical that is specifically regulated. Therefore, chemical manufacturers or importers must develop and transmit an MSDS and label for any substance with a specific OSHA PEL.

The ACGIH no longer lists a separate nuisance particulate appendix, although there is still a general recommended TLV for nuisance particulates. These would be exempt unless there is evidence they present a physical or health hazard separate from their nuisance characteristics.

OSHA is also clarifying that the burden of proof for this exemption belongs to the manufacturer or importer. The language in the NPRM was "nuisance particulates for which * * * no evidence is found to indicate that they pose any covered physical or health hazard," and in the final rule reads "nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard * * *" This is consistent with the provision on wood dust. It also complies with Executive Order 12778 which, in order to reduce unnecessary litigation, requires each agency formulating proposed regulations to try to ensure that the regulations provide a clear and certain legal standard for affected conduct. Exec. Order No. 12778, 3 CFR 359 (1992).

Coverage of grain dust. Following promulgation of the revised final rule, a number of commenters objected to grain dust being considered a hazardous chemical under the rule, and to OSHA "adopting" the ACGIH TLV for grain dust (see, *e.g.*, Exs. 5–2, 5–16, 5–21, 5–32, 5–43, 5–57, 5–104, and 5–124). The majority of the comments on this subject submitted in response to the NPRM still objected to coverage of grain dust (see, *e.g.*, Exs. 11–43, 11–53, 11–63, 11–77, 11–109, and 11–151). Some indicated that OSHA's rule on grain handling already adequately covers training of workers (Exs. 11–67 and 11–109). OSHA's position on this issue remains the same—grain dust meets the definition of a hazardous chemical under the HCS, and is fully covered by the rule. To the extent that workers are already trained, this merely minimizes the burden of compliance.

Since publication of the NPRM, OSHA adopted a PEL of 10 mg/m^3 for grain dust under its 1989 Air Contaminants final rule (54 FR 2332). The Eleventh Circuit Court of Appeals vacated the final exposure limits designated in that standard on July 7, 1992. However, the AFL–CIO and the National Grain and Feed Association which had reached a settlement with OSHA on the new grain dust limit moved the appeals court to rule that its decision did not disturb this settlement. The court granted the motion on February 1, 1993, and stated that the agreement remains in effect. Consequently, OSHA will continue to enforce the 1989 limit (58 FR 35339). Information regarding this PEL must now appear on MSDSs for grain. Information regarding this PEL must now appear on MSDSs for grain.

As explained in the NPRM preamble (53 FR 29840–41), under the provisions of the original final rule, as well as the revised final, OSHA established a "floor" of chemicals which are always considered to be hazardous under the rule. These include chemicals which OSHA regulates, and chemicals which appear in the latest edition of Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, an annual publication of the American Conference of Governmental Industrial Hygienists (ACGIH) (now entitled Threshold Limit Values and Biological Exposure Indices)(paragraph (d)(3)). ACGIH is a professional society which is widely recognized as an authority in evaluation of the hazards of materials in the workplace, and establishment of recommended permissible exposure levels for those materials. During the rulemaking on the original rule, participants confirmed that if ACGIH finds a material to be hazardous, and thus establishes a permissible level for it, this is important information to be considered in the hazard determination process. (See, *e.g.*, 48 FR 53298–99.) Therefore, OSHA included this conclusion in the hazard determination process by stating that if the material appears on the ACGIH list, it is, by definition under the rule, a hazardous chemical. Chemicals listed by ACGIH (or regulated by OSHA), however, are not the only substances covered under the scope of the rule. If there is evidence to indicate a material presents a physical hazard in the workplace (*e.g*, flammability or combustibility) or if there is one statistically significant study that indicates a potential adverse health effect may occur upon exposure, the chemical is covered by the rule (paragraph (d)(2)).

OSHA has not "adopted" the threshold limit value (TLV) for any of the substances on the TLV list. It has simply stated that the fact that this recognized authority has found a substance to be hazardous is important information for exposed employees and users of a product to be aware of, as well as being aware of the level of exposure that authority has recommended. Where OSHA has specific exposure levels, this information must also be indicated on a MSDS, and if the producer has a recommended level—as many larger manufacturers do—this information must also appear. Thus the downstream employers will have the benefit of knowing that such recommendations and requirements exist, and this will help them design appropriate protective measures for their employees.

Whether these materials appeared on the TLV list or not is somewhat immaterial in terms of whether they are covered by the rule since, if they are not listed, an evaluation still has to be made of the available hazard data to determine if they meet the definition of "hazardous chemical" under the

standard. (See Ex. 11–124, comments from NIOSH specifically supporting the finding of hazard for grain dust.) For grain dust, there is evidence that it presents both a physical hazard (potential for explosion) and a health hazard (there is evidence that respiratory effects result from exposure). (See, *e.g.*, OSHA Final Rule for Grain Handling Facilities, 52 FR 49542; Ex. 4–29 (MSDS for grain); Ex. 4–30 (ACGIH documentation for the TLV for grain dust); Ex. 4–43 (OSHA Grain Elevator Industry Hazard Alert, 1/5/78); and Ex. 4–49 (U.S. General Accounting Office report on grain fumigation, 1981). Thus grain dust would be covered by the rule regardless of whether the TLV list is referenced or not. The additional TLV reference merely ensures that the downstream employers are provided the necessary information about available recommendations for control of the exposures to the material.

OSHA does not agree that it has "delegated" its authority to ACGIH under the rule, and the Agency certainly has not "adopted" the TLV under this rulemaking process. The HCS requires employers to disclose complete and current information on hazardous materials employees are potentially exposed to, and employees are entitled to receive available information on grain dust. It is not necessary for the Agency to make individual judgments about the hazards of each chemical under the HCS to determine if it is covered—the HCS is a generic rule which establishes criteria by which these judgments can be made by producers of substances, subject to review by OSHA through its enforcement procedures.

It should also be noted that the National Grain and Feed Association (NGFA) challenged the requirements of the revised final rule in the litigation described in the background section of this preamble. *Associated Builders and Contractors, Inc.* v. *Brock*, 862 F.2d 63 (3d Cir. 1988). The Third Circuit rejected the NGFA's arguments as having no merit. *Id.* at 69. NGFA petitioned the Supreme Court for a writ of certiorari, but their request was denied (November 29, 1988).

Radiation and biological hazards. Although OSHA has never considered either radioactivity or biological hazards to be covered by the HCS, we have received inquiries regarding such coverage, and therefore added specific exemptions for these types of hazards in the NPRM. These specific exemptions are being adopted in this final rule. If, however, another type of hazard is presented along with the material (e.g., a container with a biological sample packed in a hazardous solvent), then the container would be subject to the requirement of the HCS for the other hazardous chemical.

Several commenters supported the clarification regarding these types of hazards (Exs. 11–21, 11–48, and 11–50). Others suggested that biohazards should be included (Exs. 11–103; 37), and that the Centers for Disease Control could be responsible for generating MSDSs for such hazards (Ex. 11–103). OSHA believes that this particular rulemaking is more appropriately limited to chemical hazards, although we do not discourage employers from including coverage of such agents in their hazard communication programs. A separate rulemaking on occupational exposure to bloodborne pathogens (29 CFR 1910.1030) was recently completed, and should address some of the concerns of these commenters.

Suggestions for other exemptions. Several commenters suggested additional exemptions for the rule. One indicated that non-food products used by the food service industry (such as cleaners) should be exempt (Ex. 11–117). This obviously would not provide adequate protection for employees in that industry required to use such products, and no such exemption has been included.

Other commenters indicated that the HCS should only cover chemicals for which the Agency has made specific hazard determinations (Ex. 11–78), or initiated notice and comment on whether or not the chemical should be covered (Ex. 11–145). Such a substance-specific approach is essentially the system that was in place prior to the promulgation of the HCS, and only directly covered a few chemicals. As has been demonstrated, employees exposed to hazardous chemicals without benefit of information about the hazards and protective measures are at significant risk of experiencing health effects. This generic standard provides that broad-based protection, although OSHA will continue to use a substance-specific approach when necessary.

There was also a suggestion that the rule specifically exempt kitchen cabinets (Exs. 11–51 and 11–54). OSHA has made no explicit determination regarding kitchen cabinets in terms of coverage. If employees are exposed to hazardous chemicals during installation of such cabinets, they would be covered. It is the responsibility of the manufacturer of the products to do a proper hazard determination to decide whether or not they are covered under the rule.

Definitions

Article. The issues involving the article definition and exemption have already been described in detail in the preceding section. The modified definition for "article" being adopted is "a manufactured item, other than a fluid or particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities (e.g., minute or trace amounts) of a hazardous chemical (as determined under paragraph (d) of this section) and does not pose a physical hazard or a health risk to employees."

Commercial account. OSHA proposed a definition for "commercial account" to help clarify which retail distributors need to maintain MSDSs for their customers, and is adopting it as part of the final rule. The rationale for this is discussed further under the section of the preamble dealing with material safety data sheets.

The definition proposed was: "commercial account" means "an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and at costs that are below the regular retail price." One commenter (Ex. 11–21) suggested that discounts are not always given, even to those who purchase large quantities over time. Therefore, to accommodate this concern, the final rule language indicates they generally purchase large quantities over time "and/or at costs that are below the regular retail price."

Exposure or exposed. An additional clarification has been made to the definition for "exposure" or "exposed." The definition in the final rule referred to employees being "subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes potential (e.g. accidental or possible) exposure." This was interpreted by a few people as meaning that if a chemical only poses a physical hazard (i.e. it is flammable but does not have any health effects), it would not be covered by the rule because the employee would not be "exposed" to it. This was certainly not the intent, as the employee would be "subjected" to the hazardous chemical by virtue of it being present in the workplace with the potential for burning, and thus injuring the employee. In order to ensure that such an interpretation is not erroneously

made, the clarified definition in this final rule refers to both physical and health hazards, rather than just a "hazardous chemical".

Hazard warning. The 1983 and 1987 final rules included a definition for "hazard warning" which states that it means "any words, pictures, symbols, or combination thereof which convey the hazard(s) of the chemical(s) in the container(s)." "Appropriate hazard warnings" are to be put on container labels. Since the rule covers "physical" and "health" *hazards*, specific information regarding these would be required on a label to comply and be considered appropriate. OSHA provided clarification regarding the Agency's interpretations of these requirements in the preamble to the revised final rule (see, 52 FR 31864). In the NPRM, the Agency proposed to incorporate these clarifications into the text of the rule. Thus the new definition proposed was that "hazard warning" means "any words, pictures, symbols, or combination thereof appearing on a label or other appropriate forms of warning which convey the specific physical and health hazard(s), including target organ effects, of the chemical(s) in the container(s). (See the definitions for "physical hazard" and "health hazard" to determine the hazards which must be conveyed.) This modification is being adopted in this final rule. The Agency's interpretation of the rule in requiring health effects information, including information on target organ effects, was challenged and upheld in *Martin* v. *American Cyanamid*, on No. 92–3321 (6th Circuit September 15, 1993.)

In the development of the 1983 final rule, the Agency sought to require on labels that information that it considered to be necessary to employee protection, and which did not appear on many of the labels in use in industry at that time. It appeared to OSHA, based on the information available at that time, that labels frequently included precautionary information but infrequently enumerated the actual hazards of the chemical. In addition, the labels often lacked identity information. Thus OSHA chose to require that this limited information—the identity and hazards—be included on the label, while not precluding the addition of other types of information thought to be appropriate by the chemical industry. The rule also took a performance-oriented approach to the presentation of information, allowing various formats to be used as long as the information required by the HCS was included. OSHA did not endorse or support any particular existing labeling system as being in compliance with the requirements as drawn. In fact, it was thought likely that many existing labels, regardless of what system was used, would have to be revised to meet the new requirements.

Unfortunately, some have interpreted this performance-oriented approach to label format as allowing any label to suffice. This was not the intent of the rule, and OSHA has not enforced it in that manner. Furthermore, the rule does not permit label preparers to make judgments about the information to be included based on assumptions about downstream exposure situations. If the chemical is present in the quantities required to be considered a health hazard under the mixture provisions of the rule, and it is there in a form where employees can be exposed (i.e., it is available for exposure), then the demonstrated hazards must be included on the label. There is some professional judgment involved in assessing the weight of the evidence available to indicate that the hazard exists. Therefore, if there is one animal study as the only evidence of a particular adverse effect, it is likely that this generally would not be included on a label as part of an appropriate hazard warning, although it would have to be on the MSDS. Where there are multiple studies, or human evidence, professional judgment would result in a warning statement.

For products that are being shipped, the label is at certain points the only information available to people handling the container. Therefore, complete information must be available, and accessible in a fashion that does not require special training to use. Whether it's on a loading dock, or in a warehouse where only sealed containers are handled, it is necessary to have the complete hazard information for employees who may not have access to an MSDS.

For in-plant systems, OSHA has allowed some leeway with respect to the nature of the hazard information required on the label, so long as the employer can establish that its entire Hazard Communication Program is effective. Some of the labeling systems that pre-dated the HCS and which are used in-plant highlight the type and severity of the hazard and the personal protective equipment needed. These alternative in-plant labeling systems typically make use of a numerical and/or color coding to indicate the type and severity of a particular hazard (e.g., a "health hazard" rated at 4 would be a particularly serious "health" hazard). The labels are often supplemented by specific health effect information, but are sometimes limited to the generalized rankings.

These systems tend to be used in plants where there are large number of chemicals used, and the chemicals change frequently. These types of labels give the workers a quick snapshot assessment of the hazards. The labels also provide workers with information about the particular protective equipment needed in their work areas so they can properly and quickly protect themselves.

OSHA has permitted these types of systems to be used for in-plant labeling when the three-part Hazard Communication system is proven to be effective despite the potential absence of target organ effect information on the container labels. It is reasonable to allow this limited flexibility for in-plant labeling systems (as opposed to shipping labels) because in the in-plant context, the employer retains control over the entire hazard communication program within the workplace. In this limited circumstance, the employer can assure—through more intensified training—that its own employees are fully aware of the hazards of the chemicals being used. When these types of systems are used, the health effects information on the label may therefore be somewhat streamlined (in comparison to a shipping label for the same chemical) only because worker training—including training on the specific health effects of chemicals used—is proportionately intensified. Employers must ensure that their workers are aware of all information required to be conveyed under the HCS, and OSHA will make a plant-specific determination of the effectiveness of the complete program when an inspection is conducted. Any employer who chooses to rely on one of these types of alternative labeling systems instead of using labels which contain complete health effects information will—in any enforcement action alleging the inadequacy of the information conveyed through labeling—bear the burden of establishing that its overall hazard communication program has achieved a level of awareness among its employees which equals or exceeds the level of awareness that would have been achieved if the employer had used labels containing complete health effects information.

As will be discussed under labeling requirements, OSHA is incorporating this long-standing interpretive distinction into the requirements of the rule. Based on our implementation experiences, we believe that target organ information can be made readily accessible to workers in-plant through

all three components of the program. On shipped containers, however, it must be addressed on the label since the label will be standing alone in some situations, and workers may not have the training to understand every different type of labeling system they may encounter in these situations.

Hazard Determination

Mixtures. OSHA made one minor correction to the mixture provisions in the NPRM. Paragraph (d)(5)(iv) indicates that hazardous chemical components of a mixture in concentrations less than one percent (or in the case of carcinogens, less than 0.1 percent) are covered by the HCS if they can be released in concentrations which may exceed an OSHA exposure limit or ACGIH Threshold Limit Value, or could present a health "hazard" to employees in the concentrations released. OSHA incorrectly used the term "hazard" in this provision. A hazard is an inherent property of the chemical, and would exist no matter what quantity was present. OSHA intended to refer to the presence of a health risk to employees exposed to the chemical. The risk is a function of the inherent hazard and the amount of exposure. Therefore, in accordance with these scientific principles, OSHA corrected paragraph (d)(5)(iv) to state that such concentrations of hazardous chemicals are always covered by the HCS when they present a health risk to employees even if they are present in a mixture in amounts below the cut-offs.

Written Hazard Communication Program

Mobile worksites. Under the revised final rule, OSHA included what it termed a mobile worksite provision which permitted employers of employees who travel between workplaces during a work shift to maintain MSDSs at the primary workplace as long as the information is available to employees immediately in the event of an emergency (paragraph (g)(9)). Such employees would also have access to the MSDSs at the primary workplace prior to departing for the other sites, and when they return to the primary workplace. This appeared to OSHA to be a reasonable accommodation for such a work operation, but one which would still provide employees with immediate access to necessary information in an emergency and daily access to all information as a reference source.

Several commenters requested that OSHA clarify that in this situation the written hazard communication programs may also be maintained at the central workplace (Exs. 5–46, 5–67, 5–79, and 5–110). Therefore OSHA proposed to add the following paragraph to the written hazard communication program requirements (paragraph (e)(5)):

> Where employees must travel between workplaces during a workshift, *i.e.*, their work is carried out at more than one geographical location, the written hazard communication program may be kept at a central location at the primary workplace facility.

It should be noted that as in the situation with MSDSs, this exception is limited to work operations where employees are dispatched from a primary workplace each day, thus making it impractical to either carry a written program with them, or to have a duplicate copy at each site serviced (such as oil wells).

Few comments were received on this modification, but those that were submitted generally supported the approach proposed (Exs. 11–67, 11–90, and 11–101). OSHA has incorporated it into the final rule, but removed the phrase "at a central location." The written program must be available at the primary workplace upon request, consistent with existing requirements in paragraph (e)(4).

Multi-employer worksite provision. When OSHA promulgated the original final HCS, there was a requirement in the written hazard communication program that employers include in the plan and implement "the methods the employer will use to inform any contractor employers with employees working in the employer's workplace of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures." 48 FR 53343, paragraph (e)(1)(iii). As described in the preamble to the NPRM (53 FR 29842–45), OSHA found substantial evidence in the record to indicate that the rule needed to address the issue of employers on multi-employer worksites exposing the other employer(s)' employees to hazardous chemicals.

In preparing the revised final rule, OSHA took the comments of rulemaking participants into consideration and included a multi-employer worksite provision in the written hazard communication program requirements (52 FR 31880; paragraph (e)(2)):

> Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:
>
> * * * The methods the employer will use to provide the other employer(s) with a copy of the material safety data sheet, or to make it available at a central location in the workplace, for each hazardous chemical the other employer(s)' employees may be exposed to while working;
>
> * * * The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,
>
> * * * The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

As described in the preamble to the final rule (52 FR 31865), this type of provision is necessary to ensure that all employees have sufficient information to protect themselves in the workplace, regardless of which employer uses the hazardous chemical. It also ensures that employers have the necessary information to adequately conduct training, and to select appropriate protective measures for the work operation.

It should be noted that the multi-employer worksite provision does not create the duty for each employer to have MSDSs on-site. That duty appears in paragraphs (g)(1) and (g)(8), which were not new requirements in the revised final rule. The multi-employer worksite provisions simply require that employers describe methods in their written HCS programs to make those already-present MSDSs available to the other employers on the site when the other employers' employees are being exposed.

Initial industry comments objecting to the multi-employer worksite provisions appeared to envision a situation where every contractor on a site duplicates every MSDS in his possession for every other contractor on-site. As has been discussed by OSHA repeatedly, the provisions of the rule simply do not require such an activity. First of all, the only time MSDSs must be shared is if the contractors are working in the same area of a site at the same time and thus exposing each other's employees. Secondly, the MSDSs can be made available in any way the employers on a site deem to be appropriate, *i.e.*, they can be made available in an office trailer on-site, they can be kept in the employer's truck, or they can be made available to both employees and other employers through electronic access.

The issue became somewhat confused when OMB disapproved the requirement to "provide" MSDSs on a multi-employer worksite (Ex. 4–67), as opposed to the multi-employer worksite

provision to have methods that would make the already-present MSDSs available to the other employers. OMB's action effectively removed the employee protections of paragraph (g). Furthermore, there appears to be some misunderstanding about what a multi-employer worksite is (Ex. 11–116). Such a site is not limited to construction. Any type of workplace where there are employees of more than one employer working is a multi-employer site. It is likely that every worksite is a multi-employer worksite at some point.

A number of the comments received subsequent to OMB's actions favor keeping the MSDSs in a central office location and providing them on request (Exs. 11–1, 11–141, 11–142, and 11–155). Others simply object to MSDSs on every site, and support OMB's approach (Exs. 11–13, 11–110, 11–114, 11–135, and 11–154). These employers claim that employees are not interested in the MSDSs (Ex. 11–6); there are too many of them to keep them at the site (Ex. 11–24); and there is no place to keep them on the site (Ex. 11–142).

Other commenters, however, emphasized the importance of maintaining MSDSs on-site, for the benefit of employees as well as for making them available to other employers. "U S WEST supports the basic requirements regarding provision of material safety data sheets (MSDS) at multi-employer work places. In fact, U S WEST would be supportive of stronger language to emphasize the responsibility of employers who produce, use or store hazardous chemicals at a workplace to adequately communicate potential hazards to the employees of other employers." Ex. 11–50. See also Exs. 11–51, 11–54, 11–90, and 11–124. And as another commenter indicated (Ex. 11–40): "Common sense should serve as the linchpin for establishing the presence of material safety data sheets (MSDS) on multi-employer work sites. Very simply, some provision must be made to advise workers of any actual or potential hazardous exposure while on the work site."

The ACCSH subcommittee which recommended a change to this provision also appeared to be confused. They recommended that the provision address an employer's duty to obtain MSDSs for chemicals his/her employees are exposed to that are generated by other contractors. The duty to obtain MSDSs appears in paragraph (g)—the multi-employer worksite provision's only purpose is to ensure that the other employer's written program describes the methods that will be used to provide the MSDSs. The ACCSH-recommended change does not accomplish that purpose.

As was discussed in the history section of this preamble, OMB's disapproval has been invalidated by the Third Circuit decision which was subsequently upheld by the Supreme Court. Therefore, all of the requirements are currently being enforced.

The current rulemaking activity has not provided any substantial evidence that the requirements are unnecessary or inappropriate.

Without MSDSs the hazard communication program will not be effective. The consensus of the participants in the rulemaking on the original final rule was that labels can only provide limited information—the MSDS provides the detailed source of information. Most concurred with OSHA's conclusion that a program cannot be effective without all of the major components currently in the OSHA rule—including MSDSs being available to employees and employers at the job site (see, *e.g.*, H–022 Exs. 19–62, 19–91, 19–124, 19–156, 19–185, and 19–199.) As will be discussed further below, comments objecting to the use of MSDSs have been received in this rulemaking. However, these participants have not provided evidence that has persuaded OSHA that employees can be protected appropriately without the information available on the MSDSs.

The argument that there may be large numbers of MSDSs on multi-employer worksites does not mean that employees should not be protected from those chemicals. Although cumulative numbers are large (Ex. 11–142, the Coalition indicates that on a particular homebuilding site there were 302 MSDSs required), the fact remains that for most individual contractors the number per site is much smaller and quite manageable (those 302 MSDSs were accumulated by 38 subcontractors, for an average of 8 MSDSs per subcontractor.)

Many of these same employers would have OSHA believe that there are no trailers or offices on these sites, and no vehicles, so they have no place to keep the MSDSs (Tr. 5–50; 54; 57). As has been stated in the record before (53 FR 29845), every job site has a significant amount of paper associated with it, including blueprints, building specifications, building permits, etc. See, *e.g.*, Ex. 4–162. We believe that employers can keep the MSDSs in the same location as these other papers.

By removing the MSDSs from the site, employers are creating a barrier to access, *i.e.*, it is far less likely that employees will request MSDSs from a remote site. If an employee is on the site for one day only, as these employers indicate is often the case, it is unlikely that a request will be made for the MSDS to be delivered at some later time. (Similarly, experiences under state laws that allow extended periods of time for delivery of the MSDS (such as 15 days), are not analogous. In 15 days, the construction employee's exposure would likely have long since ended, and he/she would probably be at another job site. Provision of MSDSs under these conditions does not serve the purpose of being available prior to exposure to prevent adverse health effects from occurring.) And although construction employers maintain that employees are not interested in MSDSs, evidence from other industries indicates that employees do use MSDSs when they are readily accessible (Ex. 4–75).

OSHA has costed out the alternative of providing MSDSs on request through delivery from a central office location, although this would not be an acceptable alternative to the current requirement because it is not at least as protective and therefore does not protect employees to the extent feasible. The costs were calculated using the percentage of employees reported to be using data sheets in the study referenced above (Ex. 4–75), and assuming a short and a long distance request for the information, and thus the time for delivering the MSDS. Ex. 71–70. This analysis reveals that it is less costly to maintain the MSDSs on-site as currently required, rather than responding to requests from employees and delivering the MSDSs to the site upon request.

Therefore, the alternative suggested to maintain MSDSs at the office, and provide them on request, is not only less effective but also more costly. OSHA is maintaining the current requirement for MSDSs to be available on-site for employee access and to be accessible to other employers when necessary due to exposure of their employees.

We have modified the language of the provision to address some of the misinterpretations discussed in the comments. The applicable provision will now read: "[T]he methods the employer will use to provide the other employer(s) on-site access to material safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working." This removes the language that employers have been interpreting as meaning they had to physically give each employer a copy of every MSDS, or create an office to deposit them. Whatever means the employers find appropriate for the on-site access on a particular job will be acceptable. Thus

a repository in the trailer may be used; they may be accessible electronically; or each subcontractor could keep his/her own MSDSs in the company vehicle on the site. The key to ascertaining compliance is whether the MSDSs are readily accessible (i.e., there are no barriers to accessing the information) to exposed workers as well as other employers.

Labels and Other Forms of Warning

As noted above under the discussion of the definition of "hazard warning", OSHA proposed to modify the language in paragraph (f)(5)(ii) regarding in-plant labeling requirements to clarify that employers may, as an alternative to specific hazard warnings, provide more general hazard information on the labels as long as the specific physical and health hazards of the chemicals are effectively conveyed through implementation of the other aspects of the hazard communication program (*i.e.*, provision and explanation of data sheets and more extensive training). For example, some labeling systems indicate the presence of an acute "health hazard" and rate the severity of that "hazard" using a number system. The specific health hazard is not on the label under this system, but is available on the MSDS. Employers using this type of hazard rating system must ensure that the worker has the required immediate access to the data sheet, and understands the labeling system used and how to obtain and use the information provided. The training program will generally need to be more detailed to address these aspects of the employer's hazard communication program. An employer relying on one of these labeling systems will have to augment his training program to specifically address target organ effects that may not be readily discerned from a numerical or symbol warning system. Precautionary statements alone are not considered to be general hazard information under this provision.

The proposed modification was not a change in Agency policy or interpretation of this requirement. Since 1985, OSHA's instructions to its compliance staff have included allowances for these types of systems in a facility. For example, the current directive, CPL 2–2.38C, states:

> OSHA recognizes that the degree of detail on a label needed to convey a hazard may be different within a workplace where other information is readily available compared to labels required on shipped containers, where the label may be the only information available.

Several commenters indicated that the proposed distinctions are helpful (Exs. 11–10, 11–51, and 11–139), and supported the change to the definition of "hazard warning" (Exs. 11–21, 11–86). There was a suggestion that the acceptance of specific labeling systems be indicated (Ex. 11–10). OSHA does not agree with that approach. In keeping with the performance-oriented approach of the rule, whatever in-plant labeling system is used will be judged during a compliance inspection in the context of the effectiveness of the entire program.

There were also suggestions that the language be modified to indicate that only "significant" hazards need to be warned about (Exs. 11–48, 11–90). OSHA does not agree with that suggestion. The HCS requires warnings on all well-substantiated hazards. If the weight of the evidence demonstrates that a hazard is "well-substantiated", the hazard must be warned about regardless of its perceived severity.

One commenter noted that Department of Transportation (DOT) placards on cargo will generally not indicate target organs (Ex. 11–68). This is true, but the actual containers being shipped are the ones that would be labeled in accordance with OSHA's requirements, rather than the shipping containers. The only time this would be a problem is when there is a bulk shipment, and the shipping container is the only container. OSHA has already addressed this by allowing the additional label information to be with the shipping papers, rather than on the outside of the shipping container.

There were objections to this modification from representatives concerned about information available to workers (Exs. 11–21, 11–125). OSHA believes that its compliance policy to assess the effectiveness of the entire program will ensure that complete information is available to workers in all situations.

One commenter (Ex. 11–86) thought in-plant labels should only have the name of the chemical, not the hazards. OSHA does not agree with this—the label must provide hazard information to be an effective reminder of the more detailed data available elsewhere on MSDSs and in training. Additionally, MSDSs cannot be substituted for labels—they serve different purposes and contain information presented in a different fashion. "Hazard warnings" provide a brief summary of the hazards in a highlighted form. The MSDS provides more detailed information.

The current HCS did not address the issue of updating labels when new information becomes available regarding the hazards of the chemical. OSHA is clarifying this situation by adding a provision which is consistent with the updating requirements for material safety data sheets, *i.e.*, the new information is to be added to the label within three months of becoming aware of significant new information regarding the hazards of the chemical.

ANSI Standard for Precautionary Labeling. As noted in the preamble to the NPRM (53 FR 29542), the American National Standards Institute (ANSI) revised its standard for precautionary labeling of industrial chemicals (Z129.1–1988) to include, among other things, guidance for target organ effect labeling. A copy of the final document has been available in the record (Ex. 49). OSHA invited comment on whether the Agency should recognize (either in the final rule or in a compliance directive) that the ANSI standard provides employers with useful guidance to produce an acceptable label for compliance with the HCS. In other words, if the employer follows the guidance provided by ANSI, that would be one way to comply with the requirements of the HCS. Employers would still be free to use other labeling systems or approaches to labeling, where appropriate, as long as they meet the requirements of the HCS. But those employers who wish to have more specific guidance to follow would be able to use the ANSI standard to assist them in complying. OSHA indicated that it was particularly interested in comments about the extent of target organ information that would be on a label under the ANSI scheme, and whether this would provide enough information to comply with the HCS.

A number of comments were submitted which supported the use of the ANSI standard as compliance assistance (see, *e.g.*, 11–51, 11–57, 11–106, 11–143, 11–147, and 11–156). Many of these also emphasized that it should not be considered to be the only way to comply, just one method that could be used. There were also related suggestions that a uniform labeling approach would be helpful (Exs. 11–124 and 11–155).

An objection was raised about the public's opportunity to comment on the final ANSI standard before addressing it in the HCS (Ex. 11–125). The ANSI standard was finalized prior to the publication of the HCS NPRM, and was available in the docket as Ex. 4–110. As OSHA specifically solicited comments on this issue in the NPRM, the public was given an opportunity to provide input.

OSHA believes that the ANSI standard provides much useful information for employers required to prepare product labels. The standard has been revised significantly since the

previous version was issued in 1982, and provides helpful guidance in new areas, such as classification of carcinogens, mutagens, and teratogens for purposes of labeling, and the addition of phrases to be used to report target organ effects. All of this information would assist employers in complying with the HCS.

OSHA does have one concern, however, regarding the health hazard evaluation process. As the Agency has stated from the outset of this rulemaking, the HCS is based on the premise that chemicals have inherent characteristics that pose potential hazards, and workers have the right to know what those potential hazards are. Risk of exposure is to be addressed in training, not in the process of deciding what information will be provided on labels and MSDSs. Any well-substantiated hazard must appear on the label where there is a potential for exposure.

The ANSI standard, on the other hand, specifically states that the labeling recommendations are not based only on the inherent properties of the chemical, but are directed to the avoidance of hazardous exposures resulting from customary and reasonably foreseeable occupational use, misuse, handling and storage. The health hazard evaluation also refers to an exposure assessment being performed.

It is possible for someone following the guidance in the ANSI standard to construct a label that is complete enough to satisfy the requirements of the HCS. OSHA's concern is that information may be eliminated from some labels based on the "exposure assessment" factor, and employers will not be in compliance with the HCS. The inability of the producer or importer to accurately predict downstream exposures, and thus the need for complete disclosure of hazards, was discussed in the original final rule (48 FR 53296), and is still applicable.

Therefore, employers must be advised that while following the ANSI standard would provide useful assistance to them when preparing labels, it does not guarantee compliance. Employers must also be aware of the requirements of the HCS, which, among other things, may be interpreted to have a lower threshold than ANSI for reporting hazard information. OSHA believes that the use of the ANSI standard will generally be very helpful to employers when complying with the HCS, and that labels will be improved through the availability of this voluntary consensus standard. A reference to it will be included in the Agency's instructions to its compliance officers.

Labeling limitation for certain shipments. In the revised final rule, OSHA made a change to the labeling requirements for shipments of solid metal. Solid metal is often considered to be an "article" under the rule, and thus exempt. Where the metal is not an "article" since its downstream use results in hazardous chemical exposure to employees working with it, a provision was added which allows shippers of this type of material to send the label information once, similar to material safety data sheet transmittal, as long as the material is the same and it is being shipped to the same customer. In these situations, there should be no hazard to anyone handling the metal from the time it is produced in solid form until the time someone works on it in a way that releases a chemical hazard. Since the label information transmitted would only reflect the chemical hazards released when it is later worked on, the label would not provide any hazard information that is needed by those handling the material in transit. The label information does serve a different purpose than the MSDS as the label is an immediate visual warning, a "snapshot picture" of the hazards, whereas the MSDS provides detailed hazard information. Thus both information transmittal sources are necessary. It was emphasized in the preamble that this exception is only for the solid metal itself—any hazardous chemicals present in conjunction with the metal in such a form that employees may be exposed when handling the material (*e.g.*, cutting fluids, lubricants, and greases), would require labels with each shipment.

OSHA proposed to further modify this exception to include wood, plastic, and whole grain. The Agency believes the situation involving wood and plastic is analogous to solid metal in that the hazard potential is in the downstream use and does not involve employees involved in transit. For whole grain, OSHA recognized that some dust may be generated during the transportation process, but believed that the repetitive nature of the shipments and the relatively small amount of dust generated due to the handling at this stage makes such an exemption appropriate. (See, *e.g.*, Ex. 5–13, 5–15, 5–21, 5–52, and 5–92.) The Agency invited comment on this extended exception. Supporting comments were received (see, *e.g.*, Exs. 11–51, 11–54, and 11–90). The modifications are being adopted in this final rule as proposed.

One commenter suggested that it be clarified that only containers are required to be labeled, not pieces of wood, etc. Ex. 11–137. This is true. However, ultimately these items are in some sort of container for purposes of shipment, from shrink-wrapped pallets to the truck itself. Thus labels are still required for the shipment in this situation, unless the items are covered by the one-time labeling approach incorporated into the final rule.

With regard to this change in requirement for shipments of whole grain, most of the comments from the grain industry were concerned with totally exempting grain dust rather than the specific labeling limitation. Several objected to any labels for shipments of whole grain (Exs. 11–94, 11–109, 11–129, and 11–160), also indicating that all facilities already have both labels and MSDSs. If this is the case, they are already in compliance with the rule so there should be no problem with this provision. The exemption was also supported (Ex. 11–67).

The American Iron and Steel Institute (AISI) testified that the exemption for solid metal should be extended to include the coatings on the metals (Ex. 70). They suggested that employees involved in the transport of large steel items in particular would not be exposed to potential hazards due to the manner in which the items are handled. OSHA does not agree. There is still a risk of contact dermatitis, and thus workers need to be warned regarded these hazards.

Other comments on labeling. A number of comments were received suggesting that the labeling requirements be changed. In particular, it was suggested that the information on the labels be expanded in lieu of requiring material safety data sheets (see, *e.g*, 11–8, 11–75, 11–104, 11–118, 11–132, 11–147, and 11–156). "For non-manufacturers, it is more efficient for workers to obtain their warnings from the labels on containers of chemical products. The labels accompany each product and are always readily available to the user. Labels are required to contain all significant dangers." Ex. 11–104.

Specific suggestions for labels included precautionary statements (11–17, 11–57, and 11–125), and the telephone number of the supplier (11–38, 11–115, and 11–150). In terms of precautionary statements, employers are free to include such information. However, as discussed at length in the original final rule (48 FR 53300–05), the purpose of the label is to provide an immediate visual warning of the hazards. Label warnings tend to be the same from product to product (*e.g.*, nearly everything is harmful if inhaled).

This type of information does not tell the worker what the hazard is. Furthermore, most producers already include such information on their labels—the missing elements generally involve what the hazards actually are. With regard to the telephone number, OSHA originally proposed the number be included on labels (47 FR 12121). There were numerous objections from producers to this requirement. Thus OSHA limited the telephone number provision to the MSDS, rather than the label. The information is available through the MSDS to all employers, as well as to health professionals providing services to exposed employees.

Material Safety Data Sheets

An issue that is related to the coverage of consumer products, and is undoubtedly the genesis of some of the recommendations to eliminate such products from coverage, is the distribution of consumer products in commerce. It is important to point out that the vast majority of consumer products are not covered by this rule. Only those which are hazardous are potentially covered, and within that group, only those which are used in the workplace. Producers of the materials which, while marketed to consumers, are also likely to be sold to employers and used in the workplace are well aware of that potential market. (See, *e.g.*, Ex. 2–148.) Thus manufacturers of materials used in construction, graphic arts, and cleaning operations, are aware that their products have industrial applications even when sold as consumer products. MSDSs have already been prepared and distributed for many, if not most, of these products. Manufacturers are required to have MSDSs for their own workers, and have already been required to distribute such MSDSs to non-manufacturing customers in a significant number of states with right-to-know rules. Furthermore, most manufacturers have and make available MSDSs because of product liability concerns separate and apart from any regulatory requirements. This was certainly demonstrated in the record by the large number of manufacturers that produced MSDSs in the absence of such requirements prior to promulgation of the original HCS. The sealed container provision also eliminates many consumer products from full coverage in workplaces where employees may handle such materials, but do not open the containers to use them. Employees may, however, request data sheets for the chemicals they only handle in sealed containers.

The record for the original final rule strongly supported the need for automatic transmittal of MSDSs from producers to users through the supply chain. The cost analyses of the rule demonstrated that a system that relies on users requesting a copy of a MSDS will be more costly, and less protective (48 FR 53327). However, in the revised final rule, OSHA determined that where retail distributors are involved in the distribution chain it was necessary to slightly revise this position. Therefore, the revised final rule stated (52 FR 31882, paragraph (g)(7)):

> Retail distributors which sell hazardous chemicals to commercial customers shall provide a material safety data sheet upon request, and shall post a sign or otherwise inform them that a material safety data sheet is available. Chemical manufacturers, importers, and distributors need not provide material safety data sheets to retail distributors which have informed them that the retail distributor does not sell the product to commercial customers or open the sealed container to use it in their own workplaces.

OSHA provided the following rationale for this departure from the automatic provision approach found to be necessary in the original final rule (52 FR 31866):

> Retail distributors, however, often sell to businesses and the general public and frequently have no way of knowing who a particular purchaser is. Under the current rule, retail distributors might have to give material safety data sheets to each customer to ensure that commercial customers get the information they need under the HCS. A specific statement regarding retail distributors is, therefore, included in paragraph (g)(7) to address this practical problem. Those retail distributors who sell hazardous chemicals to employers must provide a material safety data sheet upon request, and must post a sign or otherwise inform the employers that an MSDS is available.

OSHA recognizes that although it is possible for an employer to incidentally purchase a hazardous chemical from any type of retail establishment, it is not reasonable to expect every retail store that happens to carry such materials to keep a file of MSDSs in case an employer decides to make a random purchase at the store. We further recognize that such random purchases would normally be of small amounts that would generally be used as a consumer uses them, and thus would be exempt under the rule anyway. However, even in those cases where they are used in greater quantities, it appears more reasonable to place the burden on the user in that situation to obtain the MSDS than to have every retail establishment keep large numbers of them on file. This provision also limits the number of establishments to which distributors of such products have to transmit MSDSs.

The National Retail Merchants Association (NRMA) (Ex. 5–74) indicated that the revised final rule "* * * has struck a good balance between the obvious problem of requiring retailers to train all employees about every product which may appear on retailers' shelves, and the real need for employee training for emergency spillage of packaged products." They did think, however, that the definition of "consumer product" as stated by CPSC might be confusing to retailers, particularly small businesses, since "retailers would have to go through the process of examining all goods sold in their stores to determine if they are or are not consumer products." In fact, if retailers are selling the products, they are considered to be "consumer" products, and there is no determination to be made by the retailer in this respect. In this situation, deciding whether a product is a consumer product or not is a determination made by the producer in developing the appropriate label for the material based upon its intended use.

With regard to the issue of making MSDSs available at the retail distribution level, NRMA suggested that OSHA define the term "commercial account" to ensure it is being properly interpreted and applied. They further suggested that this definition be related to selling items in large quantities and below the regular retail price. "Such accounts can be identified, and it would be less burdensome to notify such customers that MSDSs are available upon request. In fact, many retail firms have already done this under many state right-to-know laws." (Ex. 5–74).

The United Brotherhood of Carpenters and Joiners of America (UBCJA) similarly noted that with regard to MSDSs being available from retail distributors (Ex. 2–105):

> [T]hose contractors who do purchase materials from retail outlets generally buy them from a building-supply house that sells such materials in larger quantities, and may give them a volume discount. These stores would have no problem supplying MSDSs to customers * * *.

OSHA agreed with the NRMA that adding such a definition would clarify that many retail distributors have no need to maintain MSDSs because they do not generally supply hazardous chemicals to commercial customers (*e.g.*, grocery stores, clothing stores). Therefore, we proposed a definition for the term "commercial account" based upon NRMA's recommended criteria, and invited comment on the appropriateness of this approach. In

addition, we proposed to further modify the language in paragraph (g)(7). The language regarding the general duty for distributors to provide MSDSs was modified to track the language in paragraph (g)(6) immediately preceding it regarding the duty of chemical manufacturers and importers to transmit such information with their initial shipment and with the first shipment after a material safety data sheet is updated. Previously, the rule simply stated that "distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and employers." This slight modification clarifies that distributors are required to provide MSDSs in the same manner that chemical manufacturers and importers do.

Proposed paragraphs (g)(7) (iii) and (iv) further indicated that retail distributors only need to provide MSDSs if they have commercial accounts for employers purchasing hazardous chemicals. If an employer incidentally purchases a hazardous chemical from them, and they are not required to have an MSDS available since they don't use the chemical or have commercial accounts, then the retail distributor's duty is limited to providing that employer with the name, address, and telephone number of the supplier from which the MSDS can be obtained.

As discussed earlier in this preamble, a number of distributors suggested that they be deleted from the coverage of the rule in terms of MSDSs, either by eliminating them from the chain of distribution for the information or by dropping requirements for MSDSs. The record does not support either of these approaches as being a viable alternative for the HCS.

In general, the commenters on the proposed modifications supported the changes (see, *e.g.*, Exs. 11–11, 11–93, 11–106, 11–111, 11–117, and 11–147). "[W]e agree with the modifications made to the definition of commercial account, and the requirement that retail establishments would only have to make MSDSs available upon request to these customers only." Ex. 11–11. Some thought the approach was better but still needed further revision (Exs. 11–115, 11–132). "The proposed modifications of the Standard enunciated in the notice of proposed rulemaking are a step in the right direction. We urge further modifications * * *." Ex. 11–115.

The State of Maryland pointed out that with the proposed modifications, a gap was created in the distribution chain with regard to MSDSs since there was no explicit requirement for manufacturers, importers, and distributors to provide MSDSs in response to requests from downstream employers purchasing products from a retail distributor without having a commercial account. "There is no requirement (here or elsewhere) that the manufacturer, importer, or distributor supply that employer with an MSDS, effectively leaving a hole in the previously closed 'loop'." Ex. 11–21.

Other commenters noted that wholesale distributors that have over-the-counter sales should be permitted to provide MSDSs on request as their operations are similar to those of concern in retail establishments. "The fact is that wholesaler-distributors, like retail businesses, sell products to employers that do not have a commercial account and do not use the product itself. Additionally, wholesaler-distributors, like retail establishments, sell products in walk-in, over-the-counter transactions." Ex. 11–111.

There were also a few comments that did not support the modifications. In particular, worker representatives were concerned that employees would be required to use the chemical immediately, without benefit of the MSDS information (see, *e.g.*, Ex. 125).

OSHA is adopting the modifications in the final rule. In addition, the Agency has changed paragraph (g)(6) to break it down into subparagraphs similar to the changes being made to paragraph (g)(7). As suggested by the State of Maryland, a specific requirement for chemical manufacturers, importers, and distributors to respond to requests has been added. In addition, OSHA has added a provision to paragraph (g)(7) that would allow wholesale distributors to provide MSDSs on request in over-the-counter sales operations.

These provisions, in summary, are intended to clarify the obligations of chemical manufacturers and importers to provide MSDSs to downstream distributors and employers. OSHA especially means for these requirements to apply in three situations: Where a distributor or employer does not receive an MSDS from the manufacturer or importer; where a distributor or employer who has purchased a hazardous chemical in the normal course of business needs a replacement MSDS; and where an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have MSDSs on file.

A number of other comments were received regarding the distributor requirements of the rule. One noted that distributors would not have MSDSs to protect their own employees if they have commercial accounts (Ex. 11–21). However, many of these employers already come under the sealed container provisions of the rule and only have to obtain MSDSs if their employees request them. If they use the chemicals, they will have to have one as well. Another thought the retailer should have to ask the employee making a purchase if an MSDS is needed (Ex. 11–133). This seems to defeat the purpose of allowing the on-request system to alleviate the burden in over-the-counter operations.

The National Welding Supply Association (Ex. 54) appeared to be under the impression that the rule previously allowed distributors to provide MSDSs at some time after the shipment, when it was convenient for them. They thus viewed the clarification as a change in duties. In fact, the distributors were always required to provide MSDSs at the time of the initial shipment, just as the chemical manufacturers and importers were required to do so. Sending it at some undetermined later time would not provide timely protection for workers.

There was also a suggestion that the term "retail" distributor be defined. Ex. 11–103. This does not appear to be necessary as the Standard Industrial Classification (SIC) Codes already define and delineate between retail and wholesale distribution. The commenter was particularly concerned about dental product distributors defining themselves as "retail" distributors to avoid the automatic provision of MSDSs. Dental product distributors are not retail establishments. Retail establishments primarily sell to the general public for personal or household use. Distributors, such as those providing dental products to dental offices, that sell primarily to businesses institutions, professional offices, etc., are considered to be wholesale distributors. They are thus required to provide MSDSs automatically with their first shipment of a hazardous chemical to the dental office, and also with the first shipment after the MSDS for a product is updated.

Several commenters also suggested that retailers be required to request MSDSs, rather than requiring upstream distributors to ascertain the need of the retailers for the information. Exs. 11–106, 11–150, and 11–158. As discussed previously, this "on request" system is not as efficient, and is in fact more costly, than the automatic transmittal.

One concern raised was that chemical manufacturers should not have to keep track of the employers they provide MSDSs to on request, where the chemicals were purchased from a retail distributor (Ex. 11–156). In other words,

these requestors are not actually customers of the chemical manufacturer and when the MSDS is updated, it should not have to be routinely provided to these employers. In fact, the standard does not require such an approach. Updated MSDSs only have to be provided with the next shipment to a customer after being updated. If the shipment is going to a distributor, the MSDS is sent there. It would be up to the employer making the purchase from a retail distributor to ask for the current MSDS.

A number of commenters discussed the widespread distribution of MSDSs for products that do not require them (see, *e.g.*, Ex. 11–158; Exs. 22, 25, and 30). Many chemical manufacturers and importers are preparing MSDSs for all of their products, whether they are hazardous or not, and whether they are required by the HCS or not. This is apparently being done because some customers request MSDSs for all products, not just those that are hazardous. In addition, it is intended to provide adequate warning in light of product liability concerns.

OSHA certainly cannot prevent anyone from providing MSDSs for products that are not covered by the rule. In fact, it is often useful to know that there is no hazard associated with the product, and MSDSs are often being requested so customers can assure themselves that the hazards have been evaluated.

It does present a problem, however, for distributors. In particular, distributors of products that are considered to be articles are receiving numerous data sheets for these items, and are thus having to either distribute them or determine whether they have to be distributed. (See, *e.g.*, testimony of the National Association of Electrical Distributors, Tr. 2–121–161.)

Distributors do not have to provide the MSDSs to downstream customers for products that are not hazardous under the rule. OSHA is aware that many of the MSDSs provided for articles and other exempted products indicate on them that the MSDS is not required under the HCS. We encourage all producers of such items to include that information on the MSDS. One commenter suggested that the rule require that the MSDS indicate whether the chemical is within the scope of the HCS. Ex. 11–117. Others made this same suggestion in response to the request for comments and information OSHA published in May 1990. It will be considered if the rule is reopened to address improvements to MSDSs. It would help both the distributor, and the ultimate user of the material, to have a clear indication as to whether the product is actually hazardous within the requirements of the rule. (For example, construction contractors testified that they have received MSDSs for items such as flashlight batteries, and were thus confused regarding whether or not these items had to be addressed in their hazard communication program. See, *e.g.*, Tr. 5–47.)

There were also suggestions that chemical manufacturers be required to provide MSDSs in each carton or unit they ship (Exs. 11–117, 11–158). This would result in the proliferation of many more MSDSs than are required to satisfy the purposes of the rule.

Additionally, one commenter suggested that manufacturers be required to compile relevant MSDSs into a "unitary reference source" and periodically revise it (Ex. 11–158). It appears that this means that manufacturers should include all MSDSs for their product line in one book, and send all of them to each customer. Although some manufacturers have chosen this way to comply, and it would be acceptable, this alternative also results in the proliferation of many more MSDSs than the rule requires. A similar suggestion for shifting the burden is to require the chemical manufacturers to supply customers with the MSDSs directly. This is less cost-efficient, the chemical manufacturers frequently don't even know who the customers are, and it increases the possibility that chemicals will be used without information.

As discussed previously, OSHA recognizes that there are burdens associated with complying with the rule (*e.g.*, Ex. 11–132). However, these burdens are necessary to protect employees, and are ultimately borne by the downstream users of the chemicals as the costs will be reflected in the costs of the products. The automatic provision of the MSDSs is far less burdensome than the alternative "on request" system suggested by some of the commenters (see Ex. 71–70).

A number of other comments were received regarding MSDSs. One commenter noted that the MSDS requirements are not sufficient to protect producers against product liability (Ex. 11–7). As far as OSHA is concerned, this is irrelevant to the rulemaking. The purpose of the HCS is to provide appropriate information to employees and employers. If producers want to provide additional data to satisfy product liability concerns, that's their prerogative.

Inclusion of SARA Title III hazard categories on the MSDSs was also suggested (Exs. 11–38, 11–52). OSHA is aware that some producers are including such information, and encourages others to do so. However, since that information is not required to protect workers, OSHA does not have the authority to require it or prohibit its being on the MSDSs.

Another comment was that manufacturers should not be allowed to provide only component information on the MSDSs for mixtures (Ex. 11–50). The HCS requires data available on mixtures tested as a whole to determine its hazards to be utilized first before data on the hazards of its components. Component information is only permitted when there is no information on the mixture as a whole. The HCS does not require testing of a mixture in any way—chemical manufacturers and importers are allowed to rely on currently available information for components of the whole mixture where no information exists for the mixture as a whole.

This same commenter also said that OSHA should not permit chemical manufacturers and importers to put "worst case" recommendations on MSDSs rather than realistic recommendations (Ex. 11–50). MSDS preparers are required to provide accurate information on MSDSs. If a recommendation is not accurate, the chemical manufacturer or importer could be cited. OSHA is aware that there are MSDSs that have information on them that is not accurate in this regard. For example, the MSDS may indicate the material is not hazardous, yet under precautionary measures it is suggested that if the material gets on the skin, it must be washed off immediately. The precautionary measures must be consistent with the hazards of the chemical, not simply written to protect the liability of the manufacturer by suggesting more protective measures than are necessary.

It was also suggested that MSDSs should only be updated when changes are significant (Ex. 11–60). In fact, this is what the standard already requires. Chemical manufacturers and importers may be updating them more frequently to meet their internal requirements, but the rule simply requires updating when there is "significant" information of concern. Paragraph (g)(5).

A request was also received to clarify who is responsible for ensuring the MSDS is with the shipment and available in marine cargo handling operations. Ex. 11–68. The MSDS does not have to be "with" the shipment—it only has to be provided at the time of the first shipment. Marine cargo handling operations would generally come under the limited sealed container

provisions of the rule, in which case MSDSs only have to be obtained by the employer when an employee requests it.

Other commenters suggested that the format for the MSDSs should be standardized (Exs. 11–103, 11–124). OSHA has provided a non-mandatory format (OSHA 174) for those chemical manufacturers and importers that choose to use it. As described earlier in this preamble, subsequent to this rulemaking, OSHA published a request for comments and information on ways to improve the information presented on labels and MSDSs. OSHA is also aware that the Chemical Manufacturers Association has prepared guidelines for the preparation of MSDSs (Ex. 11–90 and Ex. 49), and that an ANSI standard is being developed. International activities regarding harmonization of formats and information are underway as well (Exs. 75 and 71–12), and there is research being conducted regarding MSDS variability, appropriate format, etc. OSHA is evaluating available information, and expects to take regulatory action to improve the presentation of information on MSDSs at a later date.

OSHA believes that the quality of available MSDSs needs to be improved. Although implementation of the HCS has resulted in the creation of many more data sheets than were provided voluntarily, and most of these sheets are of better quality than were available prior to promulgation of the standard, there are still many which need to be improved. The accuracy and sufficiency of the information provided is one concern. Some employers have generated MSDSs to comply with the rule, but have not ensured that the information provided is adequate.

The second issue with regard to the quality of the MSDSs has to do with the presentation of the information. MSDSs now serve a multitude of purposes, being directed to employees as well as to health professionals and the community. In some cases, the language is too technical to properly communicate the necessary information. The format of the MSDSs often "buries" the information that is of most concern to workers (such as hazard information and protective measures).

Chemical manufacturers and importers should be carefully reviewing their MSDSs to ensure they provide accurate and useful information, and to consider whether or not they are presented in the most communicative manner. We are aware that many employers are already considering these factors. For example, many word processing programs will reveal the reading level required to understand the information presented. For those parts of the MSDS or label that are intended for workers, the reading level should be directed to a level that is appropriate for the workforce (generally sixth to eighth grade). It would also be helpful to place information intended for workers at the beginning of the sheet.

As mentioned previously, the GAO has prepared two studies of the HCS, and has made recommendations concerning MSDS requirements in a recent report (GAO/HRD–92–8). It found that MSDSs are seen by employers as being too complicated, and that OSHA's system of reviewing the accuracy of the sheets is not likely to detect systemic problems. As a result, they recommended that the standard be revised to:

> Specify that developers of MSDSs include on each data sheet a brief description of employer responsibilities under the standard, and
>
> Address the problem of employers' and employees' inability to understand the MSDSs by clearly specifying the language and presentation of information to be used on MSDSs.

The description of the standard is intended to address concerns that small businesses in particular are not aware of the requirements of the rule. OSHA will solicit comment on these suggestions at such time as the rulemaking is opened to consider changing the MSDS requirements. In addition, strategies for reviewing MSDS accuracy in compliance inspections will be reviewed.

Related to this issue regarding comprehensibility were the comments received objecting to the use of MSDSs under the rule (see, *e.g.*, Exs. 11–74, 11–78, 11–108, 11–118, 11–142). Many of these employer comments indicated that employees are not interested in the information on MSDSs, or that it is not useful to them. "The information contained on these sheets is written by chemists and for chemists. They are much too technical for everyday use. The average employee on a home improvement job site already knows not to drink paint and not to apply hot tar to his skin." Ex. 11–74.

Proper implementation of the HCS results in both employers and employees being educated about the hazards of chemicals in their workplaces. Statements such as these trivialize the importance of the information conveyed. For example, many paints contain solvents that are neurotoxins. Application can generate vapors that can impair a worker's ability to function and may lead to accidents such as falling off ladders. Unfortunately, some of the comments indicate that the employers do not want more information about the chemicals they use. For example, the Coalition submitted an analysis of label information versus MSDS information for the same chemical products. Their conclusion was that MSDSs include more information, but they don't want or need it (Ex. 11–142).

This simply perpetuates the situation which necessitated the promulgation of the rule, *i.e.*, that employers do not know about the chemicals in use in their workplaces, and therefore workers are not able to learn about these materials either.

The effectiveness of a hazard communication program is directly related to the attitude and ability of the person presenting the information to the workers (see Ex. 4–75). If the trainer conveys the impression that the information is trivial, or the message is unnecessary, then the program will not be effective. (For example, a trainer for the AGC testified that: "You need to understand that the interest level is low, the attention span is limited, and in some cases, people showed up for class, shall we just say 'under the influence'." Tr. 6–33. OSHA recognizes that not every employee is going to be interested in all of the information presented. However, it appears to OSHA that approaching a class with the attitude that the workers aren't interested and won't understand the information will not result in an effective program.)

Employee representatives did not indicate that employees are not interested in having access to MSDSs. In fact, the testimony and comments were quite the opposite—employee representatives emphasized that access to MSDSs is considered to be necessary. See, *e.g.*, BCTD testimony: "* * * [L]et us repeat that the worksite is exactly where the MSDS is needed, and it is used by our members."

OSHA believes that the fact that MSDSs need to be improved is not an indication that they should be discarded in favor of the limited information on labels. The appropriate response to the problem is to improve the MSDSs, not to remove protections from employees by limiting the information that is available to them. Furthermore, labels simply cannot provide all of the information that is required to be disclosed. The label format is limited by size, and the effectiveness of a label in serving its primary purpose—to provide an immediate visual warning—will be impeded by information overload if all possible information is required to be included on a label. Participants arguing that MSDSs have information overload have missed the key difference in the

roles of labels and MSDSs. Labels are subject to the overload argument because they are intended to provide an immediate warning—a purpose that research has shown cannot be met if there is too much information on the label. On the other hand, MSDSs are reference documents, not an immediate warning mechanism.

Some of the comments on the role of labels versus data sheets revealed a lack of information on the part of the participants regarding available research on the role of labeling. For example, one commenter indicated that there are "hundreds" of studies that indicate labels are effective, and thus the preferred means of transmitting information (Ex. 11–108). When asked during the hearing to provide a bibliography of these studies (Tr. 3–182), the American Dental Trade Association suggested that OSHA consult the ANSI labeling standard for such a bibliography.

The ANSI labeling standard does not contain any such information. The one study referenced is one on symbols that was conducted in conjunction with the development of the standard. That study concluded that many commonly used symbols are not well-recognized, and thus are not effectively transmitting hazard information. Based on that study, the ANSI committee decided not to include requirements for symbols in the standard. Ex. 49.

The chairman of the ANSI committee testified on behalf of the Chemical Manufacturers Association (Tr. 6–6–39). He is also chairman of the Board of a professional society (formerly the American Conference on Chemical Labeling but now the Society for Chemical Hazard Communication) of experts on labeling and material safety data sheets. OSHA asked him if he or the ANSI committee were aware of "hundreds" of studies regarding the effectiveness of labels, and he replied: "No, I am not aware of any studies of that nature." Tr. 6–29. Mr. Talcott further indicated that "a full hazard communication program really includes the label, a properly constructed label, but it has other parts. And the data sheet, as well as the hazard determination and training programs serve very vital parts in that full hazard communication program. And I think OSHA has properly recognized that there are multiple parts, and a label alone is not going to be a full hazard communication program." Tr. 6–28–29.

In fact, although there have been various labeling requirements and practices for many years, there is little evidence that labeling results in a change in behavior without the availability of other information and communication mechanisms. See Ex. 71–23A, Handbook of Chemical Industry Labeling: "[T]he editors have found no published research which clearly isolates the effect of a given label on a specific chemical product from the effects of other factors including inserts, training, general media information, advertising and promotion or consumerist activities."

It should also be noted that it was suggested that the labeling requirements of the ANSI standard result in enough information for workers. Yet the ANSI committee specifically addressed this issue in the preamble to the standard: "Precautionary labels are not intended to include all information on the properties of a chemical nor the complete details of its handling under all conditions. Such information is more appropriately provided through other means, such as material safety data sheets, technical bulletins, training, or other communications intended to enhance and supplement the label." Ex. 49.

Clearly, the genesis of many of the comments received opposing the MSDS requirements is simply that these commenters do not want to deal with them, rather than any objective evidence that they are not necessary. As has been discussed at length in previous HCS **Federal Register** documents (see preambles to original NPRM and final rule), the effectiveness of a hazard communication program relies on the three-pronged approach in the HCS (labels, MSDSs, and training). Each serves a different purpose, and they are all interdependent on each other. No information provided during this rulemaking proceeding has altered that finding.

Comments that MSDSs are intended for manufacturing and are only useful there are not supported by evidence either (Ex. 11–104). MSDSs were first created many years ago, and were used in many different types of operations. (See Ex. 71–33, a paper on the history of the development of data sheets: "[B]y the middle of the nineteenth century manufacturers were supplying their customers with some sort of data sheet, either along with their product or on demand * * *. The earliest example of an MSDS that I have ever seen is one by Valentine and Company of 1906." The first Federal requirements for MSDSs were in the maritime industries, ship building, breaking and repairing operations, and were promulgated in 1968. MSDSs have been required by various state laws in all industries for some years. International activities in the area of hazard communication also indicate that there is widespread recognition of the need for MSDS information to supplement labels (Ex. 71–12).

Thus MSDSs remain a key aspect of the regulatory approach in the HCS. Activities to improve them will be encouraged by OSHA, and further regulatory action may be taken to update the requirements at a later date.

Some minor modifications have been made to the requirements to clarify the provisions. It has come to OSHA's attention that the requirement for MSDSs to be readily available to workers when they are in their work areas during the workshift has been interpreted as meaning the MSDSs can be located elsewhere, as long as they are available through some means such as by telephone. This is not permissible under the rule. The provisions in paragraph (g)(8) state that "the employer shall maintain copies of the required material safety data sheets for each hazardous chemical in the workplace, and shall ensure that they are readily accessible during each work shift to employees when they are in their work areas." The incorrect interpretations are apparently being reached by reading the phrase "in the workplace" as a modifier to "hazardous chemical", rather than as a designation as to where the MSDSs must be. In order to ensure that such misinterpretations are not perpetuated, the phrase has been reworded to indicate that "the employer shall maintain in the workplace copies of the required material safety data sheets for each hazardous chemical * * *." In addition, paragraph (g)(1) which requires an employer to have MSDSs has been modified to include the phrase "in the workplace."

Paragraph (g)(8) has been further modified to indicate that "electronic access, microfiche, and other alternatives to maintaining paper copies of the material safety data sheets are permitted as long as no barriers to ready employee access in each workplace are created by such options." OSHA has always permitted such alternatives for purposes of compliance, but did receive comments that indicated not all employers were aware of these options (see, *e.g.*, Ex. 35). (See also Ex. 11–50: "In keeping with the performance-oriented intent of the HCS U S WEST expects OSHA to allow employers flexibility in meeting the requirements of this section (e.g. allow the use of telefaxing or other data transmission means for providing access to MSDS). A particular need for flexibility must be recognized for service industries where there is frequent and varied association with multi-employer workplaces on a

daily basis.") This modification should help ensure that employers know they can achieve compliance using these methods.

The MSDS requirements have always indicated that the documents must be in English, paragraph (g)(2). However, this was to ensure that MSDSs for imported products are not simply provided in the language of the country of origin. It was not intended to prevent translation of MSDSs into other appropriate languages. Thus this provision has been modified to indicate that the MSDSs may be available in other languages as well.

One commenter noted that the change in the hazard determination provisions regarding mixtures (changing "hazard" to "risk"), needed to be made in the MSDS requirements for disclosure of chemical identity as well. Ex. 11–137. OSHA agrees, and the change has been made in paragraph (g)(2)(i)(C)(*2*). In addition, paragraph (g)(2)(i)(C)(*1*) is being technically amended to delete an inappropriate reference to paragraph (d)(4) regarding carcinogenicity. All of the hazard determination provisions apply to carcinogens, and the reference should simply be to paragraph (d).

The mobile worksite provision, paragraph (g)(9) is also being modified to take out the reference to a central location at the primary workplace facility. The MSDSs may be kept wherever the employer deems appropriate and accessible at that facility.

Employee Information and Training

OSHA did not propose to modify the information and training requirements. However, a number of comments which have been received regarding training, particularly in the construction industry, reveal a continuing lack of understanding of the requirements. OSHA has corrected these misperceptions in a number of forums, but the misinterpretations persist. Thus the Agency is modifying the requirements to ensure they are better understood.

Since 1983, the HCS has included the following provision: "Employers shall provide employees with information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area." The provisions of the paragraph further elaborate the specific information the employees must receive, and the elements to be addressed in the training program.

A substantial portion of the comments received from the construction industry maintain that the training is infeasible in their industry. This claim of infeasibility is based upon their interpretation that the employer must train each worker on the MSDS on each chemical, and thus would have to stop the work on the job each time a new contractor comes on the site with new chemicals to re-train all employees on those chemicals. (See, *e.g.*, Exs. 11–6, 11–15, 11–73, 11–98, 11–142.)

In fact, the information and training requirements are flexible, and do not specify how the training is to be accomplished. If an employer only has a few chemicals, it may be most useful to individually review each one in the workplace. However, where there are many chemicals, and the chemicals change frequently, it would be more appropriate to train workers regarding all types of hazards, by categories, rather than addressing each individual substance. The chemical-specific information will always be available to the workers on the labels and the data sheets.

The re-training required by the rule is when a new hazard is brought into the workplace, not a new chemical. If a new chemical is flammable, and the employer has already trained regarding flammability, there is no re-training required. If a new chemical is carcinogenic, and that type of hazard was not addressed in the employee's training, then re-training is required.

As was noted in the NPRM, the construction industry is unique among the non-manufacturing industries because there are long-standing requirements for regular training regarding hazardous chemicals. Relevant paragraphs of 29 CFR 1926.21 state that:

> The employer shall instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his work environment to control or eliminate any hazards or other exposure to illness or injury.
>
> Employees required to handle or use poisons, caustics, and other harmful substances shall be instructed regarding the safe handling and use, and be made aware of the potential hazards, personal hygiene, and personal protective measures required * * *.
>
> Employees required to handle or use flammable liquids, gases, or toxic materials shall be instructed in the safe handling and use of these materials and made aware of the specific requirements contained in subparts D, F, and other applicable subparts of this part.

OSHA would like to reiterate that employers who are in compliance with these provisions as required are substantially in compliance with the HCS training provisions as well. The HCS simply requires that construction employers supplement these already established training programs with the additional information required by the HCS, such as the existence of the rule and the use and availability of labels and MSDSs.

Coverage of construction employers under the HCS will enable them to provide more effective training under the construction rules because the HCS will ensure they are provided with necessary substance-specific information upon which to base an appropriate training program. It will also enable them to select more appropriate protective measures for the hazardous chemicals on their sites. As has been previously cited, the Advisory Committee on Construction Safety and Health has long recognized the construction employers' decreased ability to properly transmit hazard information and design appropriate protective measures without the labels and MSDSs for the specific products (Ex. 4–4).

Effective date. The changes being promulgated in this final rule are minor, and do not require any additional employer actions to comply. Therefore, there is no need for an extended period for compliance, and the changes will become effective 30 days after publication of the rule.

Appendix A. This appendix has only been modified in one respect to clarify the intent. The specific definitions of hazards which are included in this appendix were never intended to be a categorization scheme for hazards. If a substance meets one of these definitions, it is definitely covered by the rule. However, if it does not, the employer is still required to evaluate the validity of any other available data in accordance with the requirements of the rule. This is now stated in Appendix A as a clarification.

Appendix B. A statement regarding the need to evaluate all data on carcinogenicity, besides the referenced sources, has also been added for clarification to Appendix B. In addition, a statement regarding short-term tests has been added. Short-term tests (i.e., *in vitro* studies) were not specifically addressed in the final rule, but it is OSHA's determination that they generally would not provide results which can be analyzed for statistical significance, and thus would not meet the requirements of the rule for such a finding.

Addition of Appendix E. OSHA published a new nonmandatory appendix in the NPRM to provide additional guidance to employers complying with the HCS, and is adopting it in this final rule. The appendix suggests the steps an

employer using chemicals should follow to achieve compliance, and provides some information regarding how OSHA will be enforcing the requirements of the HCS. A reference to Appendix E has also been added to the scope and application (paragraph (b)(1)) to direct employers to the guidance it provides. OSHA believes this appendix will assist employers to design and implement effective programs.

Although a number of comments received after the revised final rule was published in 1987 stressed the need for guidance or outreach materials (see, *e.g.*, 11–74, 11–104, 11–123, 11–141), few of those previously interested parties commented on the new appendix or its contents. Those who did comment were generally supportive, and believed it would be helpful to employers (Exs. 11–10, 11–34, 11–38, 11–40, and 11–90).

One chemical manufacturer suggested that OSHA should not encourage employers to discard any MSDSs, whether the chemical is hazardous or not (Ex. 11–10). Although OSHA agrees in a general sense that having information regarding the absence of hazards is useful, the rule's coverage is limited to hazardous chemicals to which employees are potentially exposed. The proliferation of MSDSs on products for which they are clearly not necessary (such as floor mats and hard hats) dilutes the attention that should properly be paid to those products that are covered.

There were suggestions that a reference to the American National Standards Institute (ANSI) standard for labeling be included in Appendix E (Exs. 11–51 and 11–90). As this appendix is intended for employers who use chemicals, rather than employers who evaluate hazards and prepare labels, this suggestion does not appear to be appropriate.

There was also a suggestion that a specific appendix is needed for agriculture (Ex. 11–67). OSHA believes that the generic guidance can be successfully used to assist all types of industries.

In order to make Appendix E more widely available, OSHA has published it in a separate booklet, OSHA 3111, Hazard Communication Guidelines for Compliance. A single copy may be obtained from OSHA's Publications Office, (202) 523–9667.

IV. Analyses of Regulatory Impact, Regulatory Flexibility, and Environmental Impact

Executive Order 12866 (58 FR 51735, Sept. 30, 1993) requires that a regulatory impact analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) similarly requires the Occupational Safety and Health Administration (OSHA) to consider the impact of a regulation on small entities.

The current final rule is merely a minor revision of the HCS which already applies to all industrial sectors where workers are exposed to hazardous chemicals. This revision is not a major or significant rule, thus no additional regulatory impact analysis is necessary. As noted in the NPRM (53 FR 29846–49), the analyses performed prior to publication of the 1987 final rule, which is currently being enforced, are not being revised. However, as comments were submitted concerning the costs of the current provisions, OSHA is taking this opportunity to briefly discuss some of the issues that have been raised.

As was the case with comments submitted subsequent to the publication of the 1987 final rule, most of these comments either provided no specific data or evidence regarding either the costs or the analysis, or rather simply provided cost summaries with no indication of methodology or substantiation of unit assumptions. Others provided cost estimates that were clearly unrealistic or based on false premises in terms of the actual requirements of the rule. OSHA maintains that the economic methodology used in the analysis was appropriate, and the costs were based on reasonable assumptions. Information submitted subsequent to that analysis have not persuaded OSHA that the cost analyses were unreasonable.

For example, as noted in the preamble to the NPRM, the Small Business Administration (SBA) and others criticized the estimates of products covered per firm. In particular, the use of the National Occupational Exposures Survey (NOES) data was considered by some to be inappropriate. Although OSHA has already shown that these criticisms were not valid (53 FR 29846–49), a few more points on the subject are in order.

As indicated previously, the data used from the NOES are averages. OSHA expected that some establishments in the nonmanufacturing industries will maintain more MSDSs than the average, just as some establishments will maintain fewer. Consequently, examples of firms with more than the average number of chemicals do not invalidate the survey (see Ex. 5–93). Furthermore, it should be noted that OSHA's estimates are for the number of hazardous chemical products at a facility or site, not for an inventory of all the chemicals a firm may have at multiple sites. The HCS also only requires that a firm maintain one MSDS for a particular chemical—where multiple suppliers are used, the chemical is only counted once.

The construction industry in particular claimed that the number of chemical products used in the estimates was too low. In general, estimates OSHA used varied by the size of the firm and the two-digit SIC code, but were approximately 12 products per firm per site (and an estimate of 3 ongoing sites for each firm at any given time). The Coalition (Ex. 11–142) submitted an actual count of products at a home building site per subcontractor. The average number per contractor per site was 8 (4 less than the OSHA average), although the number varied from 1 to 90. Only 5 of the 38 subcontractors had more than the average of 12 estimated by OSHA. The total number of MSDSs for this site was 302 (763 pages), which could easily fit in one file drawer on the site.

The Coalition still maintains OSHA's numbers are faulty, but could not explain why the data they submitted did not support their own contention in this regard (Tr. 5–56–7).

Similarly, AGC surveyed their members and received responses regarding number of MSDSs required (Ex. 11–135). The numbers varied from 10 to 525. However, it appears that these product counts are for the firm, and not for each job. And some of the commenters admitted that they send MSDSs to the site for chemicals that are not there so they do not have to sort the MSDSs in any fashion. In any event, even the largest reported number (525) for a firm (not a site) is substantially smaller than earlier claims of "thousands" (Ex. 5–76). Although 525 is a substantial number of MSDSs, they will fit in a space less than the size of a file drawer. This is also a quite smaller volume than claims that construction firms would need a separate office building to maintain MSDSs on a site (Ex. 5–76).

Actual community right-to-know reporting data from nonmanufacturing firms in Los Angeles also confirm that OSHA's estimates of products per firm are reasonable (Ex. 4–187).

The cost information submitted to the OSHA docket after the current rule was published does not provide sufficient evidence for OSHA to conclude that the Hazard Communication Standard that is currently being enforced is infeasible in any industry. (In fact, much of it does not include any information about how the costs were calculated.) As described

in the NPRM, there have been claims from the construction industry that costs were underestimated by OSHA and the rule is therefore infeasible for this industry to comply with (see, *e.g.*, Exs. 5–65, 5–83, and 5–86). Additional comments were received in response to the NPRM (see, e.g., 11–135, 11–142). However, many firms in the construction industry have been subject to state hazard communication laws for the last several years. Evidence on enforcement activities in several of those states indicate that construction firms are able to comply. The construction industry has also been subject for many years to the requirements of 29 CFR 1926.21, which establishes the obligation to train construction workers in the recognition and the safe handling of hazardous substances. In this regard the Hazard Communication Standard has added very few additional training responsibilities. OSHA's cost estimates focus only on new duties, not on the burdens of pre-existing standards. So the cost estimate for the expanded rule does not assume the costs for training that should have been conducted to comply with § 1926.21. Employers who were not in compliance with that rule, or with the requirements of the states they are operating in, will have to spend more to comply than has been estimated. However, that is not a cost that is attributable to the HCS.

As the Agency has indicated before, the cost estimates were based on the best available information, and are averages. Firms will be expected to have costs both above and below the figures estimated. As long as estimates are based on reasonable assumptions and cost figures, the Agency has satisfied its analysis requirements to assure the rule is economically feasible. If OSHA were to rely on some or all of the assertions in the record regarding estimates of time involved in complying with the Standard, and estimates of the number of MSDSs which would be generated by the imposition of the Standard, the Standard would still be feasible in every SIC. Consequently, OSHA finds that claims of infeasible costs are not substantiated by any analysis or evidence, and that nothing in the record supports a conclusion of infeasibility in any SIC regulated under the existing rule.

Many of the claimed costs were also based on misinterpretations of the rule. As noted earlier in this preamble, for example, the Coalition cost estimates for a firm were based largely on accomplishment of activities that were not required to comply. Ex. 11–142. The results were therefore unrealistically inflated from what costs might actually be expected to occur.

OSHA expects that the limited modifications being promulgated in this final rule will not eliminate protections of the rule, but may make the standard more cost-effective. OSHA does not consider this NPRM to be either a major or significant rule. In addition, the changes are too subtle for the economic model to be able to reflect the decreases in the costs. However, it is expected that if the proposed changes are implemented the costs will be somewhat reduced.

With regard to criticisms of the cost methodology used by OSHA, the GAO has reviewed it at the request of Congress and concluded that OSHA's general approach to estimating the costs of compliance with the HCS requirements is fundamentally sound. It noted that the cost estimates derived would vary based on differences in assumptions regarding parameters. (GAO/HRD–92–63BR).

Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Assistant Secretary certifies that modifications to the existing HCS contained in this final rule will not have a significant economic impact on a substantial number of small entities. This final rule has not substantively changed the HCS promulgated on August 24, 1987. The changes do not eliminate protections already provided by the rule, but simply clarify the rule to enhance compliance and thereby further improve employee protections. As noted in the discussion above regarding the regulatory impact analysis, the changes are too subtle to be quantified by the economic model used to calculate compliance costs of the HCS. It is expected, however, that if the proposed changes are implemented, the compliance costs would be somewhat reduced for small businesses.

A regulatory impact and regulatory flexibility analysis was prepared by OSHA for the August 1987 revised HCS (Exs. 4–1 and 4–2). See also 52 FR 31867–76 (summary of analyses). OSHA analyzed the impact of expanding the coverage of the HCS from the manufacturing sector to all employers within OSHA's jurisdiction. Economic impacts were analyzed for each provision of the rule; for each of fifty business classifications as indicated by their two-digit Standard Industrial Classification Codes; and for four employment size classes (1–19; 20–99; 100–249; and greater than 250). The majority of non-manufacturers are small businesses with fewer than 20 employees, and the effects of the HCS on small businesses were analyzed. *Id.* at 31869, 75–76 (tables 9 and 10). It should be noted, however, that although a particular workplace may be considered a small business based upon the number of employees at that site, many of these businesses are actually part of large corporations with significant safety and health resources (*e.g.*, fast food franchises, retail store chains). OSHA's analyses indicated that the HCS's compliance costs would be a negligible percentage (less than one-half of one percent) of the typical small business' average annual revenue. *Id.* at 31869, 75 (table 9). In addition, no disproportionate impact was foreseen for small businesses when compared to large businesses. *Id.* at 31870, 75–76 (table 10).

OSHA believes that it has minimized the economic impact of the HCS on small entities in accordance with the Regulatory Flexibility Act, while accomplishing the objectives of the OSH Act. The HCS is a performance-oriented rule which benefits small employers by allowing them to choose compliance methods best suited for their individual workplaces. The HCS is also tailored for some work operations found in small businesses to ensure that the standard is practical and cost-effective in communicating hazards to workers. See, *e.g.*, 29 CFR 1910.1200(b)(3), (laboratories); (b)(4), (handling of sealed containers); (b)(5), (container labeling exemptions); (b)(6), (products totally exempted). See also 52 FR 31858. In addition, OSHA-developed compliance guidelines, such as the new Appendix E to the rule, and the compliance kit available from GPO (OSHA 3104), will directly benefit small businesses by clarifying and simplifying compliance efforts.

Environmental Assessment—Finding of No Significant Impact

In accordance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality guidelines (40 CFR part 1500), and the Department of Labor regulations (29 CFR part 11), the Assistant Secretary for OSHA has determined that this final rule will not have a significant environmental impact. As concluded previously, the current standard will not significantly affect the quality of the human environment outside the workplace. 52 FR 31870; 48 FR 53333–34. Labeling of containers will not have a direct or significant impact on air or water quality, land or energy use, or solid waste disposal outside of the workplace. Similarly, the requirements for preparation of a written compliance

plan, provision and maintenance of MSDSs, and provision of information and training should not have an adverse environmental impact. Accordingly, this document's modifications to the HCS also will not have a significant impact on the environment outside the workplace.

V. Clearance of Information Collection Requirements

On March 31, 1983, the Office of Management and Budget (OMB) published a new 5 CFR part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (48 FR 13666). Part 1320, which became effective on April 30, 1983, sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements.

In accordance with the provisions of the Paperwork Act and the regulations issued pursuant thereto, OSHA certifies that it submitted the information collection requirements contained in the HCS to OMB for review under section 3504(h) of that Act. In June 1991, OMB extended its approval of the information collection requirements through April 1994. There are no changes in this modified final rule which affect those requirements or change the burden of the requirements. The OMB Control No. is 1218–0072.

VI. Federalism and State Plan Applicability

This final standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act, a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan—States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of a final standard. These States include: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

Although a State HCS becomes effective in accordance with State promulgation provisions, and is enforceable upon promulgation, OSHA must also review and approve the standard to assure that it is "at least as effective" as the Federal standard. OSHA intends to closely scrutinize State standards submitted under current or future State plans to assure not only equal or greater effectiveness, but also that any additional requirements do not conflict with, or adversely affect, the effectiveness of the national application of OSHA's standard. Because the HCS is "applicable to products" in that it permits the distribution and use of hazardous chemicals in commerce only if they are in labeled containers accompanied by material safety data sheets, OSHA must determine in its review whether any State plan standard provisions which differ from the Federal are "required by compelling local conditions and do not unduly burden interstate commerce." Section 18(c) of the Act, 29 U.S.C. 667(c).

VII. Authority, Signature, and the Final Rule

This document was prepared under the direction of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

For the reasons set out in the preamble, and under the authority of section 41 of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333), sections 4, 6 and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 8033) as applicable, and 29 CFR part 1911, and 5 U.S.C. 553, the Occupational Safety and Health Administration hereby amends parts 1910, 1915, 1917, 1918, 1926, and 1928 of Title 29 of the Code of Federal Regulations, as set forth below.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

Hazard communication; Occupational safety and health; Right-to-know; Labeling; Material safety data sheets; Employee training.

Signed at Washington, DC, this 26th day of January 1994.

Joseph A. Dear,

Assistant Secretary for Occupational Safety and Health.

OSHA is amending parts 1910, 1915, 1917, 1918, 1926, and 1928 of title 29 of the Code of Federal Regulations as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

PART 1917—MARINE TERMINALS

PART 1918—SAFETY AND HEALTH REGULATIONS FOR LONGSHORING

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

PART 1928—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR AGRICULTURE

PART 1910—[AMENDED]

1. The authority citation for subpart Z of part 1910 continues to read as follows:

Authority: Secs. 6,8 Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Order 12–71 (36 FR 8754), 9–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act,

except those substances which have exposure limits listed in Tables Z–1, Z–2 and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553. Section 1910.1000, Tables Z–1, Z–2 and Z–3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings.

Section 1910.1001 also issued under Sec. 107 of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 333.

Section 1910.1002 not issued under 29 U.S.C 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

Section 1910.1025 also issued under 5 U.S.C. 553.

Section 1910.1043 also issued under 5 U.S.C. 551 *et seq.*

Sections 1910.1200, 1910.1499 and 1910.1500 also issued under 5 U.S.C. 553.

PART 1915—[AMENDED]

2. The authority citation for part 1915 continues to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable; 29 CFR part 1911.

Section 1915.99 also issued under 5 U.S.C. 553.

PART 1917—[AMENDED]

3. The authority citation for part 1917 continues to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable; 29 CFR part 1911.

Section 1917.28 also issued under 5 U.S.C. 553.

PART 1918—[AMENDED]

4. The authority citation for part 1918 continues to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable.

Section 1918.90 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

5. The authority citation for subpart D of part 1926 continues to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable.

Section 1926.59 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

PART 1928—[AMENDED]

6. The authority citation for part 1928 continues to read as follows:

Authority: Secs. 6 and 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable; 29 CFR part 1911.

Section 1928.21 also issued under 5 U.S.C. 553.

7. Parts 1910, 1915, 1917, 1918, and 1926 are amended by revising §§ 1910.1200, 1915.1200, 1917.28 and 1918.90, and 1926.59 to contain the identical text, including Appendices A, B, C, D, and E, to read as follows:

§ _____ Hazard communication.

(a) *Purpose.* (1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of evaluating the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legal requirements of a state, or political subdivision of a state, pertaining to this subject. Evaluating the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of material safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce, through any court or agency, any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.

(b) *Scope and application.* (1) This section requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, material safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers. Appendix E of this section is a general guide for such employers to help them determine their compliance obligations under the rule.)

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;

(iii) Employers shall ensure that laboratory employees are provided information and training in accordance with paragraph (h) of this section, except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section; and,

(iv) Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f)(1) of this section, and that a material safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

(4) In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain copies of any material safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a material safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a material safety data sheet if an employee requests the material safety data sheet, and shall ensure that the material safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and,

(iii) Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

(5) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any chemical substance or mixture as such terms are defined in the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(iii) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (*e.g.* flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 *et seq.*), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

(iv) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, and Firearms;

(v) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission; and,

(vi) Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7 U.S.C. 1551 *et seq.*) and the labeling regulations issued under that Act by the Department of Agriculture.

(6) This section does not apply to: (i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 *et seq.*), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)(42 U.S.C. 9601 *et seq.*), when subject to regulations issued under that Act by the Environmental Protection Agency;

(iii) Tobacco or tobacco products;

(iv) Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

(v) Articles (as that term is defined in paragraph (c) of this section);

(vi) Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;

(vii) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (*e.g.*, tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (*e.g.*, over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (*e.g.*, first aid supplies);

(viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

(ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

(x) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;

(xi) Ionizing and nonionizing radiation; and,

(xii) Biological hazards.

(c) *Definitions.*

Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.*, minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chemical means any element, chemical compound or mixture of elements and/or compounds.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or

the Chemical Abstracts Service (CAS) rules of nomenclature, or a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation.

Combustible liquid means any liquid having a flashpoint at or above 100 °F (37.8 °C), but below 200 °F (93.3 °C), except any mixture having components with flashpoints of 200 °F (93.3 °C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

Compressed gas means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 °F (21.1 °C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 °F (54.4 °C) regardless of the pressure at 70 °F (21.1 °C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100 °F (37.8 °C) as determined by ASTM D–323–72.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

Explosive means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

Exposure or *exposed* means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard, and includes potential (*e.g.* accidental or possible) exposure. "Subjected" in terms of health hazards includes any route of entry (*e.g.* inhalation, ingestion, skin contact or absorption.)

Flammable means a chemical that falls into one of the following categories:

(i) *Aerosol, flammable* means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) *Gas, flammable* means: (A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of thirteen (13) percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than twelve (12) percent by volume, regardless of the lower limit;

(iii) *Liquid, flammable* means any liquid having a flashpoint below 100°F (37.8°C), except any mixture having components with flashpoints of 100°F (37.8°C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) *Solid, flammable* means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

Flashpoint means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24–1979 (ASTM D 56–79)) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100°F (37.8°C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7–1979 (ASTM D 93–79)) for liquids with a viscosity equal to or greater than 45 SUS at 100°F (37.8°C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278–78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Hazardous chemical means any chemical which is a physical hazard or a health hazard.

Hazard warning means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the specific physical or health hazard(s), including target organ effects, of the chemical(s) in the container(s). (See the definitions for "physical hazard" and "health hazard" to determine the hazards which must be covered.)

Health hazard means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be

considered hazardous for purposes of this standard.

Identity means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made among the required list of hazardous chemicals, the label and the MSDS.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.

Label means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals.

Material safety data sheet (MSDS) means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.

Mixture means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

Organic peroxide means an organic compound that contains the bivalent -O-O-structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

Oxidizer means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

Physical hazard means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

Pyrophoric means a chemical that will ignite spontaneously in air at a temperature of 130°F (54.4°C) or below.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix D sets out the criteria to be used in evaluating trade secrets.

Unstable (reactive) means a chemical which in the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks, pressure or temperature.

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

Water-reactive means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

(d) *Hazard determination.* (1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate chemicals unless they choose not to rely on the evaluation performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(3) The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:

(i) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,

(ii) *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment,* American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition). The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of this standard.

(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:

(i) National Toxicology Program (NTP), *Annual Report on Carcinogens* (latest edition);

(ii) International Agency for Research on Cancer (IARC) *Monographs* (latest editions); or

(iii) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

Note: The *Registry of Toxic Effects of Chemical Substances* published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

(5) The chemical manufacturer, importer or employer shall determine the hazards of mixtures of chemicals as follows:

(i) If a mixture has been tested as a whole to determine its hazards, the results of such testing shall be used to determine whether the mixture is hazardous;

(ii) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture shall be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under paragraph (d)(4) of this section;

(iii) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and,

(iv) If the chemical manufacturer, importer, or employer has evidence to

indicate that a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees in those concentrations, the mixture shall be assumed to present the same hazard.

(6) Chemical manufacturers, importers, or employers evaluating chemicals shall describe in writing the procedures they use to determine the hazards of the chemical they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director. The written description may be incorporated into the written hazard communication program required under paragraph (e) of this section.

(e) *Written hazard communication program.* (1) Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

(2) *Multi-employer workplaces.* Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:

(i) The methods the employer will use to provide the other employer(s) on-site access to material safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;

(ii) The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

(iii) The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

(3) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.20 (e).

(5) Where employees must travel between workplaces during a workshift, *i.e.*, their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

(f) *Labels and other forms of warning.* (1) The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s);

(ii) Appropriate hazard warnings; and

(iii) Name and address of the chemical manufacturer, importer, or other responsible party.

(2)(i) For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;

(ii) The label may be transmitted with the initial shipment itself, or with the material safety data sheet that is to be provided prior to or at the time of the first shipment; and,

(iii) This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).

(3) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 *et seq.*) and regulations issued under that Act by the Department of Transportation.

(4) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

(5) Except as provided in paragraphs (f)(6) and (f)(7) of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s) contained therein; and,

(ii) Appropriate hazard warnings, or alternatively, words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

(6) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(5) of this section to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(7) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

(8) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(9) The employer shall ensure that labels or other forms of warning are

legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(10) The chemical manufacturer, importer, distributor or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(11) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within three months of becoming aware of the new information. Labels on containers of hazardous chemicals shipped after that time shall contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importers, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(g) *Material safety data sheets.* (1) Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Employers shall have a material safety data sheet in the workplace for each hazardous chemical which they use.

(2) Each material safety data sheet shall be in English (although the employer may maintain copies in other languages as well), and shall contain at least the following information:

(i) The identity used on the label, and, except as provided for in paragraph (i) of this section on trade secrets:

(A) If the hazardous chemical is a single substance, its chemical and common name(s);

(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,

(C) If the hazardous chemical is a mixture which has not been tested as a whole:

(*1*) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens under paragraph (d) of this section shall be listed if the concentrations are 0.1% or greater; and,

(*2*) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees; and,

(*3*) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;

(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);

(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;

(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;

(v) The primary route(s) of entry;

(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Annual Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions), or by OSHA;

(viii) Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;

(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;

(x) Emergency and first aid procedures;

(xi) The date of preparation of the material safety data sheet or the last change to it; and,

(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

(3) If no relevant information is found for any given category on the material safety data sheet, the chemical manufacturer, importer or employer preparing the material safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer preparing the material safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

(6)(i) Chemical manufacturers or importers shall ensure that distributors and employers are provided an appropriate material safety data sheet with their initial shipment, and with the first shipment after a material safety data sheet is updated;

(ii) The chemical manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;

(iii) If the material safety data sheet is not provided with a shipment that has been labeled as a hazardous chemical, the distributor or employer shall obtain one from the chemical manufacturer or importer as soon as possible; and,

(iv) The chemical manufacturer or importer shall also provide distributors or employers with a material safety data sheet upon request.

(7)(i) Distributors shall ensure that material safety data sheets, and updated

information, are provided to other distributors and employers with their initial shipment and with the first shipment after a material safety data sheet is updated;

(ii) The distributor shall either provide material safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

(iii) Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a material safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a material safety data sheet is available;

(iv) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also, as an alternative to keeping a file of material safety data sheets for all hazardous chemicals they sell, provide material safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a material safety data sheet is available;

(v) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have material safety data sheets on file (*i.e.*, the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a material safety data sheet can be obtained;

(vi) Wholesale distributors shall also provide material safety data sheets to employers or other distributors upon request; and,

(vii) Chemical manufacturers, importers, and distributors need not provide material safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

(8) The employer shall maintain in the workplace copies of the required material safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access, microfiche, and other alternatives to maintaining paper copies of the material safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

(9) Where employees must travel between workplaces during a workshift, *i.e.*, their work is carried out at more than one geographical location, the material safety data sheets may be kept at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

(10) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in in their work area(s).

(11) Material safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.20(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) *Employee information and training.* (1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new physical or health hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (*e.g.*, flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and material safety data sheets.

(2) *Information.* Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

(3) *Training.* Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical and health hazards of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

(i) *Trade secrets.* (1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name and other specific identification of a hazardous chemical, from the material safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the material safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The material safety data sheet indicates that the specific chemical identity is being withheld as a trade secret; and,

(iv) The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph.

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i) (3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, epidemiologist, or occupational health

nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee, or designated representative, within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(8) The health professional, employee, or designated representative whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(10)(i) If OSHA determines that the specific chemical identity requested under paragraph (i)(3) of this section is not a *bona fide* trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If a citation for a failure to release specific chemical identity information is contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation *in camera* or issue appropriate orders to protect the confidentiality of such matters.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure

under any circumstances of process or percentage of mixture information which is a trade secret.

(j) *Effective dates.* Chemical manufacturers, importers, distributors, and employers shall be in compliance with all provisions of this section by March 11, 1994.

Appendix A to § —Health Hazard Definitions (Mandatory)

Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body—such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees—such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be apprised of both the change in body function and the signs and symptoms that may occur to signal that change.

The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. Occasionally, a substance causes an effect that is rarely seen in the population at large, such as angiosarcomas caused by vinyl chloride exposure, thus making it easier to ascertain that the occupational exposure was the primary causative factor. More often, however, the effects are common, such as lung cancer. The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects.

There have been many attempts to categorize effects and to define them in various ways. Generally, the terms "acute" and "chronic" are used to delineate between effects on the basis of severity or duration. "Acute" effects usually occur rapidly as a result of short-term exposures, and are of short duration. "Chronic" effects generally occur as a result of long-term exposure, and are of long duration.

The acute effects referred to most frequently are those defined by the American National Standards Institute (ANSI) standard for Precautionary Labeling of Hazardous Industrial Chemicals (Z129.1–1988)—irritation, corrosivity, sensitization and lethal dose. Although these are important health effects, they do not adequately cover the considerable range of acute effects which may occur as a result of occupational exposure, such as, for example, narcosis.

Similarly, the term chronic effect is often used to cover only carcinogenicity, teratogenicity, and mutagenicity. These effects are obviously a concern in the workplace, but again, do not adequately cover the area of chronic effects, excluding, for example, blood dyscrasias (such as anemia), chronic bronchitis and liver atrophy

The goal of defining precisely, in measurable terms, every possible health effect that may occur in the workplace as a result of chemical exposures cannot realistically be accomplished. This does not negate the need for employees to be informed of such effects and protected from them. Appendix B, which is also mandatory, outlines the principles and procedures of hazard assessment.

For purposes of this section, any chemicals which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards. However, this is not intended to be an exclusive categorization scheme. If there are available scientific data that involve other animal species or test methods, they must also be evaluated to determine the applicability of the HCS.

1. *Carcinogen:* A chemical is considered to be a carcinogen if:

(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or

(b) It is listed as a carcinogen or potential carcinogen in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or,

(c) It is regulated by OSHA as a carcinogen.

2. *Corrosive:* A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in appendix A to 49 CFR part 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. This term shall not refer to action on inanimate surfaces.

3. *Highly toxic:* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD_{50}) of 50 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD_{50}) of 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC_{50}) in air of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter or less of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

4. *Irritant:* A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

5. *Sensitizer:* A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

6. *Toxic.* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD_{50}) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD_{50}) of more than 200 milligrams per kilogram but not more than 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC_{50}) in air of more than 200 parts per million but not more than 2,000 parts per million by volume of gas or vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

7. *Target organ effects.*

The following is a target organ categorization of effects which may occur, including examples of signs and symptoms and chemicals which have been found to cause such effects. These examples are presented to illustrate the range and diversity of effects and hazards found in the workplace, and the broad scope employers must consider in this area, but are not intended to be all-inclusive.

a. Hepatotoxins: Chemicals which produce liver damage
   Signs & Symptoms: Jaundice; liver enlargement
   Chemicals: Carbon tetrachloride; nitrosamines
b. Nephrotoxins: Chemicals which produce kidney damage
   Signs & Symptoms: Edema; proteinuria
   Chemicals: Halogenated hydrocarbons; uranium
c. Neurotoxins: Chemicals which produce their primary toxic effects on the nervous system
   Signs & Symptoms: Narcosis; behavioral changes; decrease in motor functions
   Chemicals: Mercury; carbon disulfide
d. Agents which act on the blood or hematopoietic system: Decrease hemoglobin function; deprive the body tissues of oxygen
   Signs & Symptoms: Cyanosis; loss of consciousness
   Chemicals: Carbon monoxide; cyanides
e. Agents which damage the lung: Chemicals which irritate or damage pulmonary tissue
   Signs & Symptoms: Cough; tightness in chest; shortness of breath

Chemicals: Silica; asbestos

f. Reproductive toxins: Chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis)
Signs & Symptoms: Birth defects; sterility
Chemicals: Lead; DBCP

g. Cutaneous hazards: Chemicals which affect the dermal layer of the body
Signs & Symptoms: Defatting of the skin; rashes; irritation
Chemicals: Ketones; chlorinated compounds

h. Eye hazards: Chemicals which affect the eye or visual capacity
Signs & Symptoms: Conjunctivitis; corneal damage
Chemicals: Organic solvents; acids

Appendix B to § _____—Hazard Determination (*Mandatory*)

The quality of a hazard communication program is largely dependent upon the adequacy and accuracy of the hazard determination. The hazard determination requirement of this standard is performance-oriented. Chemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards, but they must be able to demonstrate that they have adequately ascertained the hazards of the chemicals produced or imported in accordance with the criteria set forth in this Appendix.

Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards. The performance-orientation of the hazard determination does not diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible evaluation. For purposes of this standard, the following criteria shall be used in making hazard determinations that meet the requirements of this standard.

1. *Carcinogenicity:* As described in paragraph (d)(4) of this section and Appendix A of this section, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a chemical is a carcinogen or potential carcinogen will be considered conclusive evidence for purposes of this section. In addition, however, all available scientific data on carcinogenicity must be evaluated in accordance with the provisions of this Appendix and the requirements of the rule.

2. *Human data:* Where available, epidemiological studies and case reports of adverse health effects shall be considered in the evaluation.

3. *Animal data:* Human evidence of health effects in exposed populations is generally not available for the majority of chemicals produced or used in the workplace. Therefore, the available results of toxicological testing in animal populations shall be used to predict the health effects that may be experienced by exposed workers. In particular, the definitions of certain acute hazards refer to specific animal testing results (see Appendix A).

4. *Adequacy and reporting of data.* The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. *In vitro* studies alone generally do not form the basis for a definitive finding of hazard under the HCS since they have a positive or negative result rather than a statistically significant finding.

The chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

Appendix C to § _____—Information Sources (Advisory)

The following is a list of available data sources which the chemical manufacturer, importer, distributor, or employer may wish to consult to evaluate the hazards of chemicals they produce or import:

—Any information in their own company files, such as toxicity testing results or illness experience of company employees.
—Any information obtained from the supplier of the chemical, such as material safety data sheets or product safety bulletins.
—Any pertinent information obtained from the following source list (latest editions should be used):

Condensed Chemical Dictionary

Van Nostrand Reinhold Co., 135 West 50th Street, New York, NY 10020.

The Merck Index: An Encyclopedia of Chemicals and Drugs

Merck and Company, Inc., 126 E. Lincoln Ave., Rahway, NJ 07065.

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man

Geneva: World Health Organization, International Agency for Research on Cancer, 1972–Present. (Multivolume work). Summaries are available in supplement volumes. 49 Sheridan Street, Albany, NY 12210.

Industrial Hygiene and Toxicology, by F.A. Patty

John Wiley & Sons, Inc., New York, NY (Multivolume work).

Clinical Toxicology of Commercial Products

Gleason, Gosselin, and Hodge.

Casarett and Doull's Toxicology; The Basic Science of Poisons

Doull, Klaassen, and Amdur, Macmillan Publishing Co., Inc., New York, NY.

Industrial Toxicology, by Alice Hamilton and Harriet L. Hardy

Publishing Sciences Group, Inc., Acton, MA.

Toxicology of the Eye, by W. Morton Grant

Charles C. Thomas, 301–327 East Lawrence Avenue, Springfield, IL.

Recognition of Health Hazards in Industry

William A. Burgess, John Wiley and Sons, 605 Third Avenue, New York, NY 10158.

Chemical Hazards of the Workplace

Nick H. Proctor and James P. Hughes, J.P. Lipincott Company, 6 Winchester Terrace, New York, NY 10022.

Handbook of Chemistry and Physics

Chemical Rubber Company, 18901 Cranwood Parkway, Cleveland, OH 44128.

Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment and Biological Exposure Indices with Intended Changes

American Conference of Governmental Industrial Hygienists (ACGIH), 6500 Glenway Avenue, Bldg. D–5, Cincinnati, OH 45211.

Information on the physical hazards of chemicals may be found in publications of the National Fire Protection Association, Boston, MA.

Note: The following documents may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Occupational Health Guidelines

NIOSH/OSHA (NIOSH Pub. No. 81–123).

NIOSH Pocket Guide to Chemical Hazards

NIOSH Pub. No. 90–117.

Registry of Toxic Effects of Chemical Substances

(Latest edition)

Miscellaneous Documents published by the National Institute for Occupational Safety and Health:
Criteria documents.
Special Hazard Reviews.
Occupational Hazard Assessments.
Current Intelligence Bulletins.

OSHA's General Industry Standards (29 CFR Part 1910)

NTP Annual Report on Carcinogens and Summary of the Annual Report on Carcinogens.

National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161; (703) 487–4650.

Bibliographic data bases service provider	File name
Bibliographic Retrieval Services (BRS), 1200 Route 7, Latham, NY 12110.	Biosis Previews
	CA Search
	Medlars
	NTIS
	Hazardline
	American Chemical Society
	Journal
	Excerpta Medica
	IRCS Medical Science Journal
	Pre-Med
	Intl Pharmaceutical Abstracts
	Paper Chem
Lockheed-DIALOG Information Service, Inc., 3460 Hillview Avenue, Palo Alto, CA 94304.	Biosis Prev. Files
	CA Search Files
	CAB Abstracts
	Chemical Exposure
	Chemname
	Chemsis Files
	Chemzero
	Embase Files
	Environmental Bibliographies
	Enviroline
	Federal Research in Progress
	IRL Life Science Collection
	NTIS
	Occupational Safety and Health (NIOSH)
	Paper Chem
SDC-ORBIT, SDC Information Service, 2500 Colorado Avenue, Santa Monica, CA 90406.	CAS Files
	Chemdex, 2, 3
	NTIS
National Library of Medicine	Hazardous Substances Data Bank (NSDB)
Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD 20209.	Medline Files
	Toxline Files
	Cancerlit
	RTECS
	Chemline
Pergamon International Information Corp., 1340 Old Chain Bridge Rd., McLean, VA 22101.	Laboratory Hazard Bulletin
Questel, Inc., 1625 Eye Street, NW, Suite 818, Washington, DC 20006	CIS/ILO
	Cancernet
Chemical Information System ICI (ICIS), Bureau of National Affairs, 1133 15th Street, NW, Suite 300, Washington, DC 20005.	Structure and Nomenclature Search System (SANSS)
	Acute Toxicity (RTECS)
	Clinical Toxicology of Commercial Products
	Oil and Hazardous Materials Technical Assistance Data System
	CCRIS
	CESARS
Occupational Health Services, 400 Plaza Drive, Secaucus, NJ 07094	MSDS
	Hazardline

Appendix D to § _____—Definition of "Trade Secret" (Mandatory)

The following is a reprint of the *Restatement of Torts* section 757, comment *b* (1939):

b. Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see s759 of the *Restatement of Torts* which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operations of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy.

Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Appendix E to § _____ (Advisory)—Guidelines for Employer Compliance

The Hazard Communication Standard (HCS) is based on a simple concept—that employees have both a need and a right to know the hazards and identities of the chemicals they are exposed to when working. They also need to know what protective measures are available to prevent adverse effects from occurring. The HCS is designed to provide employees with the information they need.

Knowledge acquired under the HCS will help employers provide safer workplaces for their employees. When employers have information about the chemicals being used, they can take steps to reduce exposures, substitute less hazardous materials, and establish proper work practices. These efforts will help prevent the occurrence of work-related illnesses and injuries caused by chemicals.

The HCS addresses the issues of evaluating and communicating hazards to workers. Evaluation of chemical hazards involves a number of technical concepts, and is a process that requires the professional judgment of experienced experts. That's why the HCS is designed so that employers who simply use chemicals, rather than produce or import them, are not required to evaluate the hazards of those chemicals. Hazard determination is the responsibility of the producers and importers of the materials. Producers and importers of chemicals are then required to provide the hazard information to employers that purchase their products.

Employers that don't produce or import chemicals need only focus on those parts of the rule that deal with establishing a workplace program and communicating information to their workers. This appendix is a general guide for such employers to help them determine what's required under the rule. It does not supplant or substitute for the regulatory provisions, but rather provides a simplified outline of the steps an average employer would follow to meet those requirements.

1. Becoming Familiar With The Rule.

OSHA has provided a simple summary of the HCS in a pamphlet entitled "Chemical Hazard Communication," OSHA Publication Number 3084. Some employers prefer to begin to become familiar with the rule's requirements by reading this pamphlet. A copy may be obtained from your local OSHA Area Office, or by contacting the OSHA Publications Office at (202) 523–9667.

The standard is long, and some parts of it are technical, but the basic concepts are simple. In fact, the requirements reflect what many employers have been doing for years. You may find that you are already largely in compliance with many of the provisions, and will simply have to modify your existing programs somewhat. If you are operating in an OSHA-approved State Plan State, you must comply with the State's requirements, which may be different than those of the Federal rule. Many of the State Plan States had hazard communication or "right-to-know" laws prior to promulgation of the Federal rule. Employers in State Plan States should contact their State OSHA offices for more information regarding applicable requirements.

The HCS requires information to be prepared and transmitted regarding all hazardous chemicals. The HCS covers both physical hazards (such as flammability), and health hazards (such as irritation, lung damage, and cancer). Most chemicals used in the workplace have some hazard potential, and thus will be covered by the rule.

One difference between this rule and many others adopted by OSHA is that this one is performance-oriented. That means that you have the flexibility to adapt the rule to the needs of your workplace, rather than having to follow specific, rigid requirements. It also means that you have to exercise more judgment to implement an appropriate and effective program.

The standard's design is simple. Chemical manufacturers and importers must evaluate the hazards of the chemicals they produce or import. Using that information, they must then prepare labels for containers, and more detailed technical bulletins called material safety data sheets (MSDS).

Chemical manufacturers, importers, and distributors of hazardous chemicals are all required to provide the appropriate labels and material safety data sheets to the employers to which they ship the chemicals. The information is to be provided automatically. Every container of hazardous chemicals you receive must be labeled, tagged, or marked with the required information. Your suppliers must also send you a properly completed material safety data sheet (MSDS) at the time of the first shipment of the chemical, and with the next shipment after the MSDS is updated with new and significant information about the hazards.

You can rely on the information received from your suppliers. You have no independent duty to analyze the chemical or evaluate the hazards of it.

Employers that "use" hazardous chemicals must have a program to ensure the information is provided to exposed employees. "Use" means to package, handle, react, or transfer. This is an intentionally broad scope, and includes any situation where a chemical is present in such a way that employees may be exposed under normal conditions of use or in a foreseeable emergency.

The requirements of the rule that deal specifically with the hazard communication program are found in this section in paragraphs (e), written hazard communication program; (f), labels and other forms of warning; (g), material safety data sheets; and (h), employee information and training. The requirements of these paragraphs should be the focus of your attention. Concentrate on becoming familiar with them, using paragraphs (b), scope and application, and (c), definitions, as references when needed to help explain the provisions.

There are two types of work operations where the coverage of the rule is limited. These are laboratories and operations where chemicals are only handled in sealed containers (*e.g.*, a warehouse). The limited provisions for these workplaces can be found in paragraph (b) of this section, scope and application. Basically, employers having these types of work operations need only keep labels on containers as they are received; maintain material safety data sheets that are received, and give employees access to them; and provide information and training for employees. Employers do not have to have written hazard communication programs and lists of chemicals for these types of operations.

The limited coverage of laboratories and sealed container operations addresses the

obligation of an employer to the workers in the operations involved, and does not affect the employer's duties as a distributor of chemicals. For example, a distributor may have warehouse operations where employees would be protected under the limited sealed container provisions. In this situation, requirements for obtaining and maintaining MSDSs are limited to providing access to those received with containers while the substance is in the workplace, and requesting MSDSs when employees request access for those not received with the containers. However, as a distributor of hazardous chemicals, that employer will still have responsibilities for providing MSDSs to downstream customers at the time of the first shipment and when the MSDS is updated. Therefore, although they may not be required for the employees in the work operation, the distributor may, nevertheless, have to have MSDSs to satisfy other requirements of the rule.

2. Identify Responsible Staff

Hazard communication is going to be a continuing program in your facility. Compliance with the HCS is not a "one shot deal." In order to have a successful program, it will be necessary to assign responsibility for both the initial and ongoing activities that have to be undertaken to comply with the rule. In some cases, these activities may already be part of current job assignments. For example, site supervisors are frequently responsible for on-the-job training sessions. Early identification of the responsible employees, and involvement of them in the development of your plan of action, will result in a more effective program design. Evaluation of the effectiveness of your program will also be enhanced by involvement of affected employees.

For any safety and health program, success depends on commitment at every level of the organization. This is particularly true for hazard communication, where success requires a change in behavior. This will only occur if employers understand the program, and are committed to its success, and if employees are motivated by the people presenting the information to them.

3. Identify Hazardous Chemicals in the Workplace.

The standard requires a list of hazardous chemicals in the workplace as part of the written hazard communication program. The list will eventually serve as an inventory of everything for which an MSDS must be maintained. At this point, however, preparing the list will help you complete the rest of the program since it will give you some idea of the scope of the program required for compliance in your facility.

The best way to prepare a comprehensive list is to survey the workplace. Purchasing records may also help, and certainly employers should establish procedures to ensure that in the future purchasing procedures result in MSDSs being received before a material is used in the workplace.

The broadest possible perspective should be taken when doing the survey. Sometimes people think of "chemicals" as being only liquids in containers. The HCS covers chemicals in all physical forms—liquids, solids, gases, vapors, fumes, and mists—whether they are "contained" or not. The hazardous nature of the chemical and the potential for exposure are the factors which determine whether a chemical is covered. If it's not hazardous, it's not covered. If there is no potential for exposure (e.g., the chemical is inextricably bound and cannot be released), the rule does not cover the chemical.

Look around. Identify chemicals in containers, including pipes, but also think about chemicals generated in the work operations. For example, welding fumes, dusts, and exhaust fumes are all sources of chemical exposures. Read labels provided by suppliers for hazard information. Make a list of all chemicals in the workplace that are potentially hazardous. For your own information and planning, you may also want to note on the list the location(s) of the products within the workplace, and an indication of the hazards as found on the label. This will help you as you prepare the rest of your program.

Paragraph (b) of this section, scope and application, includes exemptions for various chemicals or workplace situations. After compiling the complete list of chemicals, you should review paragraph (b) of this section to determine if any of the items can be eliminated from the list because they are exempted materials. For example, food, drugs, and cosmetics brought into the workplace for employee consumption are exempt. So rubbing alcohol in the first aid kit would not be covered.

Once you have compiled as complete a list as possible of the potentially hazardous chemicals in the workplace, the next step is to determine if you have received material safety data sheets for all of them. Check your files against the inventory you have just compiled. If any are missing, contact your supplier and request one. It is a good idea to document these requests, either by copy of a letter or a note regarding telephone conversations. If you have MSDSs for chemicals that are not on your list, figure out why. Maybe you don't use the chemical anymore. Or maybe you missed it in your survey. Some suppliers do provide MSDSs for products that are not hazardous. These do not have to be maintained by you.

You should not allow employees to use any chemicals for which you have not received an MSDS. The MSDS provides information you need to ensure proper protective measures are implemented prior to exposure.

4. Preparing and Implementing a Hazard Communication Program

All workplaces where employees are exposed to hazardous chemicals must have a written plan which describes how the standard will be implemented in that facility. Preparation of a plan is not just a paper exercise—all of the elements must be implemented in the workplace in order to be in compliance with the rule. See paragraph (e) of this section for the specific requirements regarding written hazard communication programs. The only work operations which do not have to comply with the written plan requirements are laboratories and work operations where employees only handle chemicals in sealed containers. See paragraph (b) of this section, scope and application, for the specific requirements for these two types of workplaces.

The plan does not have to be lengthy or complicated. It is intended to be a blueprint for implementation of your program—an assurance that all aspects of the requirements have been addressed.

Many trade associations and other professional groups have provided sample programs and other assistance materials to affected employers. These have been very helpful to many employers since they tend to be tailored to the particular industry involved. You may wish to investigate whether your industry trade groups have developed such materials.

Although such general guidance may be helpful, you must remember that the written program has to reflect what you are doing in your workplace. Therefore, if you use a generic program it must be adapted to address the facility it covers. For example, the written plan must list the chemicals present at the site, indicate who is to be responsible for the various aspects of the program in your facility, and indicate where written materials will be made available to employees.

If OSHA inspects your workplace for compliance with the HCS, the OSHA compliance officer will ask to see your written plan at the outset of the inspection. In general, the following items will be considered in evaluating your program.

The written program must describe how the requirements for labels and other forms of warning, material safety data sheets, and employee information and training, are going to be met in your facility. The following discussion provides the type of information compliance officers will be looking for to decide whether these elements of the hazard communication program have been properly addressed:

A. Labels and Other Forms of Warning

In-plant containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings. Chemical manufacturers, importers, and distributors are required to ensure that every container of hazardous chemicals they ship is appropriately labeled with such information and with the name and address of the producer or other responsible party. Employers purchasing chemicals can rely on the labels provided by their suppliers. If the material is subsequently transferred by the employer from a labeled container to another container, the employer will have to label that container unless it is subject to the portable container exemption. See paragraph (f) of this section for specific labeling requirements.

The primary information to be obtained from an OSHA-required label is an identity for the material, and appropriate hazard warnings. The identity is any term which appears on the label, the MSDS, and the list of chemicals, and thus links these three sources of information. The identity used by

the supplier may be a common or trade name ("Black Magic Formula"), or a chemical name (1,1,1,-trichloroethane). The hazard warning is a brief statement of the hazardous effects of the chemical ("flammable," "causes lung damage"). Labels frequently contain other information, such as precautionary measures ("do not use near open flame"), but this information is provided voluntarily and is not required by the rule. Labels must be legible, and prominently displayed. There are no specific requirements for size or color, or any specified text.

With these requirements in mind, the compliance officer will be looking for the following types of information to ensure that labeling will be properly implemented in your facility:

1. Designation of person(s) responsible for ensuring labeling of in-plant containers;
2. Designation of person(s) responsible for ensuring labeling of any shipped containers;
3. Description of labeling system(s) used;
4. Description of written alternatives to labeling of in-plant containers (if used); and,
5. Procedures to review and update label information when necessary.

Employers that are purchasing and using hazardous chemicals—rather than producing or distributing them—will primarily be concerned with ensuring that every purchased container is labeled. If materials are transferred into other containers, the employer must ensure that these are labeled as well, unless they fall under the portable container exemption (paragraph (f)(7) of this section). In terms of labeling systems, you can simply choose to use the labels provided by your suppliers on the containers. These will generally be verbal text labels, and do not usually include numerical rating systems or symbols that require special training. The most important thing to remember is that this is a continuing duty—all in-plant containers of hazardous chemicals must always be labeled. Therefore, it is important to designate someone to be responsible for ensuring that the labels are maintained as required on the containers in your facility, and that newly purchased materials are checked for labels prior to use.

B. Material Safety Data Sheets

Chemical manufacturers and importers are required to obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Distributors are responsible for ensuring that their customers are provided a copy of these MSDSs. Employers must have an MSDS for each hazardous chemical which they use. Employers may rely on the information received from their suppliers. The specific requirements for material safety data sheets are in paragraph (g) of this section.

There is no specified format for the MSDS under the rule, although there are specific information requirements. OSHA has developed a non-mandatory format, OSHA Form 174, which may be used by chemical manufacturers and importers to comply with the rule. The MSDS must be in English. You are entitled to receive from your supplier a data sheet which includes all of the information required under the rule. If you do not receive one automatically, you should request one. If you receive one that is obviously inadequate, with, for example, blank spaces that are not completed, you should request an appropriately completed one. If your request for a data sheet or for a corrected data sheet does not produce the information needed, you should contact your local OSHA Area Office for assistance in obtaining the MSDS.

The role of MSDSs under the rule is to provide detailed information on each hazardous chemical, including its potential hazardous effects, its physical and chemical characteristics, and recommendations for appropriate protective measures. This information should be useful to you as the employer responsible for designing protective programs, as well as to the workers. If you are not familiar with material safety data sheets and with chemical terminology, you may need to learn to use them yourself. A glossary of MSDS terms may be helpful in this regard. Generally speaking, most employers using hazardous chemicals will primarily be concerned with MSDS information regarding hazardous effects and recommended protective measures. Focus on the sections of the MSDS that are applicable to your situation.

MSDSs must be readily accessible to employees when they are in their work areas during their workshifts. This may be accomplished in many different ways. You must decide what is appropriate for your particular workplace. Some employers keep the MSDSs in a binder in a central location (*e.g.*, in the pick-up truck on a construction site). Others, particularly in workplaces with large numbers of chemicals, computerize the information and provide access through terminals. As long as employees can get the information when they need it, any approach may be used. The employees must have access to the MSDSs themselves—simply having a system where the information can be read to them over the phone is only permitted under the mobile worksite provision, paragraph (g)(9) of this section, when employees must travel between workplaces during the shift. In this situation, they have access to the MSDSs prior to leaving the primary worksite, and when they return, so the telephone system is simply an emergency arrangement.

In order to ensure that you have a current MSDS for each chemical in the plant as required, and that employee access is provided, the compliance officers will be looking for the following types of information in your written program:

1. Designation of person(s) responsible for obtaining and maintaining the MSDSs;
2. How such sheets are to be maintained in the workplace (*e.g.*, in notebooks in the work area(s) or in a computer with terminal access), and how employees can obtain access to them when they are in their work area during the work shift;
3. Procedures to follow when the MSDS is not received at the time of the first shipment;
4. For producers, procedures to update the MSDS when new and significant health information is found; and,
5. Description of alternatives to actual data sheets in the workplace, if used.

For employers using hazardous chemicals, the most important aspect of the written program in terms of MSDSs is to ensure that someone is responsible for obtaining and maintaining the MSDSs for every hazardous chemical in the workplace. The list of hazardous chemicals required to be maintained as part of the written program will serve as an inventory. As new chemicals are purchased, the list should be updated. Many companies have found it convenient to include on their purchase orders the name and address of the person designated in their company to receive MSDSs.

C. Employee Information and Training

Each employee who may be "exposed" to hazardous chemicals when working must be provided information and trained prior to initial assignment to work with a hazardous chemical, and whenever the hazard changes. "Exposure" or "exposed" under the rule means that "an employee is subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.) and includes potential (*e.g.*, accidental or possible) exposure." See paragraph (h) of this section for specific requirements. Information and training may be done either by individual chemical, or by categories of hazards (such as flammability or carcinogenicity). If there are only a few chemicals in the workplace, then you may want to discuss each one individually. Where there are large numbers of chemicals, or the chemicals change frequently, you will probably want to train generally based on the hazard categories (*e.g.*, flammable liquids, corrosive materials, carcinogens). Employees will have access to the substance-specific information on the labels and MSDSs.

Information and training is a critical part of the hazard communication program. Information regarding hazards and protective measures are provided to workers through written labels and material safety data sheets. However, through effective information and training, workers will learn to read and understand such information, determine how it can be obtained and used in their own workplaces, and understand the risks of exposure to the chemicals in their workplaces as well as the ways to protect themselves. A properly conducted training program will ensure comprehension and understanding. It is not sufficient to either just read material to the workers, or simply hand them material to read. You want to create a climate where workers feel free to ask questions. This will help you to ensure that the information is understood. You must always remember that the underlying purpose of the HCS is to reduce the incidence of chemical source illnesses and injuries. This will be accomplished by modifying behavior through the provision of hazard information and information about protective measures. If your program works, you and your workers will better understand the chemical hazards within the workplace. The procedures you establish regarding, for example, purchasing, storage, and handling of these chemicals will improve, and thereby reduce the risks posed to employees exposed to the chemical hazards involved. Furthermore, your workers' comprehension will also be increased, and proper work practices will be followed in your workplace.

If you are going to do the training yourself, you will have to understand the material and be prepared to motivate the workers to learn. This is not always an easy task, but the benefits are worth the effort. More information regarding appropriate training can be found in OSHA Publication No. 2254 which contains voluntary training guidelines prepared by OSHA's Training Institute. A copy of this document is available from OSHA's Publications Office at (202) 219–4667.

In reviewing your written program with regard to information and training, the following items need to be considered:

1. Designation of person(s) responsible for conducting training;

2. Format of the program to be used (audiovisuals, classroom instruction, etc.);

3. Elements of the training program (should be consistent with the elements in paragraph (h) of this section); and,

4. Procedure to train new employees at the time of their initial assignment to work with a hazardous chemical, and to train employees when a new hazard is introduced into the workplace.

The written program should provide enough details about the employer's plans in this area to assess whether or not a good faith effort is being made to train employees. OSHA does not expect that every worker will be able to recite all of the information about each chemical in the workplace. In general, the most important aspects of training under the HCS are to ensure that employees are aware that they are exposed to hazardous chemicals, that they know how to read and use labels and material safety data sheets, and that, as a consequence of learning this information, they are following the appropriate protective measures established by the employer. OSHA compliance officers will be talking to employees to determine if they have received training, if they know they are exposed to hazardous chemicals, and if they know where to obtain substance-specific information on labels and MSDSs.

The rule does not require employers to maintain records of employee training, but many employers choose to do so. This may help you monitor your own program to ensure that all employees are appropriately trained. If you already have a training program, you may simply have to supplement it with whatever additional information is required under the HCS. For example, construction employers that are already in compliance with the construction training standard (29 CFR 1926.21) will have little extra training to do.

An employer can provide employees information and training through whatever means are found appropriate and protective. Although there would always have to be some training on-site (such as informing employees of the location and availability of the written program and MSDSs), employee training may be satisfied in part by general training about the requirements of the HCS and about chemical hazards on the job which is provided by, for example, trade associations, unions, colleges, and professional schools. In addition, previous training, education and experience of a worker may relieve the employer of some of the burdens of informing and training that worker. Regardless of the method relied upon, however, the employer is always ultimately responsible for ensuring that employees are adequately trained. If the compliance officer finds that the training is deficient, the employer will be cited for the deficiency regardless of who actually provided the training on behalf of the employer.

D. Other Requirements

In addition to these specific items, compliance officers will also be asking the following questions in assessing the adequacy of the program:

Does a list of the hazardous chemicals exist in each work area or at a central location?

Are methods the employer will use to inform employees of the hazards of non-routine tasks outlined?

Are employees informed of the hazards associated with chemicals contained in unlabeled pipes in their work areas?

On multi-employer worksites, has the employer provided other employers with information about labeling systems and precautionary measures where the other employers have employees exposed to the initial employer's chemicals?

Is the written program made available to employees and their designated representatives?

If your program adequately addresses the means of communicating information to employees in your workplace, and provides answers to the basic questions outlined above, it will be found to be in compliance with the rule.

5. Checklist for Compliance

The following checklist will help to ensure you are in compliance with the rule:

Obtained a copy of the rule. _____
Read and understood the requirements. _____
Assigned responsibility for tasks. _____
Prepared an inventory of chemicals. _____
Ensured containers are labeled. _____
Obtained MSDS for each chemical. _____
Prepared written program. _____
Made MSDSs available to workers. _____
Conducted training of workers. _____
Established procedures to maintain current program. _____
Established procedures to evaluate effectiveness. _____

6. Further Assistance

If you have a question regarding compliance with the HCS, you should contact your local OSHA Area Office for assistance. In addition, each OSHA Regional Office has a Hazard Communication Coordinator who can answer your questions. Free consultation services are also available to assist employers, and information regarding these services can be obtained through the Area and Regional offices as well.

The telephone number for the OSHA office closest to you should be listed in your local telephone directory. If you are not able to obtain this information, you may contact OSHA's Office of Information and Consumer Affairs at (202) 219–8151 for further assistance in identifying the appropriate contacts.

8. In § 1928.21, paragraph (a)(5) is republished for the convenience of the user to read as follows:

§ 1928.21 Applicable standards in 29 CFR Part 1910.

(a) * * *

(5) Hazard communication—§ 1910.1200.

* * * * *

[FR Doc. 94–2273 Filed 2–8–94; 8:45 am]

BILLING CODE 4510–26–P

federal register

Wednesday
February 9, 1994

Part IV

Department of Transportation

Research and Special Programs Administration

Michigan Marking Requirements for Vehicles Transporting Hazardous and Liquid Industrial Wastes; Notice

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Preemption Determination No. PD-6(R); Docket No. PDA-8(R)]

Michigan Marking Requirements for Vehicles Transporting Hazardous and Liquid Industrial Wastes

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Administrative determination that Michigan marking requirements for vehicles licensed to carry hazardous and liquid industrial wastes are preempted by the Hazardous Materials Transportation Act.

APPLICANT: Chemical Waste Transportation Institute, on behalf of the National Solid Wastes Management Association.

STATE LAWS AFFECTED: Michigan Compiled Laws § 323.277(1); Michigan Administrative Code 299.9406(6).

APPLICABLE FEDERAL REQUIREMENTS: Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. 1801 *et seq.*, and the Hazardous Materials Regulations (HMR), 49 CFR parts 171–180.

MODE AFFECTED: Highway.

SUMMARY: Michigan Compiled Laws § 323.277(1) and Michigan Administrative Code 299.9406(6), requiring the marking of motor vehicles used to transport, respectively, "liquid industrial waste" and "hazardous waste," are preempted by 49 App. U.S.C. 1811(a)(3). These marking requirements are not "substantively the same as" Federal marking, labeling and placarding requirements. As applied to vehicles used to transport only liquid industrial wastes that are not hazardous materials, the marking requirement at § 323.277(1) is preempted as an obstacle to accomplishing the purposes of the HMTA.

FOR FURTHER INFORMATION CONTACT: Charles B. Holtman, Office of the Chief Counsel, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street SW., Washington DC 20590–0001, telephone number (202) 366–4400.

SUPPLEMENTARY INFORMATION:

I. Application for Preemption Determination

On January 4, 1993, the Chemical Waste Transportation Institute (CWTI), an institute of the National Solid Wastes Management Association, applied for a determination of preemption pursuant to 49 CFR 107.203. The CWTI application seeks an administrative determination that State of Michigan requirements to mark motor vehicles used to transport "hazardous waste" and "liquid industrial waste" are preempted by the HMTA.

On January 26, 1993, RSPA published a Public Notice and Invitation to Comment, providing for comments until March 31, 1993 and rebuttal comments until June 4, 1993. 58 FR 6170. The Michigan Department of Natural Resources (DNR) submitted comments opposing preemption; one waste industry association and two waste transporters submitted comments supporting preemption. CWTI submitted rebuttal comments responding to those of the DNR.

A. Michigan Requirements for Marking Waste-Hauling Vehicles

The two provisions of Michigan law for which CWTI seeks a preemption determination impose marking requirements on motor vehicles used to transport "liquid industrial waste" and "hazardous waste."

Michigan Compiled Laws, §§ 323.271 through 323.280 (cited by CWTI and commenters as Michigan Act 136, Public Acts of 1969), regulates the transportation and disposal of "liquid industrial waste." "Liquid industrial waste" is defined as:

> Any liquid waste, other than unpolluted water, which is produced by or incident to or results from an industrial or commercial activity or the conduct of any enterprise.

Mich. Comp. Laws Ann. § 323.271(b) (West Supp. 1993). The statute requires any person removing liquid industrial waste from the premises of another to be licensed and bonded. Records of waste removal and disposal must be maintained, and vehicle operation and waste disposal must accord with applicable provisions of State law.

The first State requirement for which CWTI seeks a finding of preemption, Michigan Compiled Laws § 323.277(1), requires the marking of motor vehicles used to transport liquid industrial waste. On each side of the vehicle, the words "licensed industrial waste hauling vehicle" must be "painted * * * in letters not less than 2 inches high." These words must be followed by the vehicle license number and a seal furnished by the State designating the year for which the license is issued. Apparently, the lettering is to remain on the truck at all times it is licensed to transport liquid industrial waste, whether or not it actually is carrying the regulated waste.

Hazardous waste transportation within the State of Michigan is governed by Michigan Administrative Code Part 299.9400 (1991), promulgated pursuant to Michigan Compiled Laws, §§ 299.501 through 299.551 (cited by CWTI and commenters as Michigan Act 64, Public Act of 1979).

The definition of "hazardous waste" at § 299.504(3) of the State statute essentially mirrors the definition under the Federal Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 *et seq.* See 42 U.S.C. 6903(5), (27). As under RCRA, see 42 U.S.C. 6921(a), 40 CFR 261.20, 261.30, "hazardous waste" under Michigan law consists of "characteristic" wastes, i.e., those meeting a criterion of ignitability, corrosivity, reactivity or toxicity, Mich. Admin. Code 299.9203(1)(a), 299.9212, and "listed" wastes designated pursuant to an administrative finding of potential hazard, Mich. Admin. Code 299.9203(1)(b), 299.9213, 299.9214. State regulations provide that any federally designated RCRA hazardous waste is a hazardous waste under Michigan law. Mich. Admin. Code 299.9208(1), 299.9209(1). Thus, while the director of the DNR may designate additional hazardous wastes, Mich. Admin. Code 299.9209(2), the regulations in question apply, at a minimum, to all RCRA hazardous wastes.

Michigan Administrative Code part 299.9400 imposes business and vehicle licensing, recordkeeping and operational requirements on hazardous waste transporters. The second State requirement for which CWTI seeks a finding of preemption, § 299.9406(6), requires the following marking on each side of the "waste-hauling portion of the vehicle":

> The words "Hazardous Waste-Hauling Vehicle" followed by the company name, city, and state in clearly legible letters not less than 5 centimeters high. * * * A transporter may remove this lettering for uses other than hazardous waste treatment [sic][1] if such alternate uses are identified in the transporter's business or vehicle license.

Mich. Admin. Code 299.9406(6). The lettering is to remain "visible" while the vehicle is licensed. *Id.*

The two marking requirements apply, respectively, to motor vehicles licensed to haul liquid industrial waste or hazardous waste, as defined under Michigan law. The requirements apply to vehicles used for both bulk and non-bulk transportation, as those terms are defined in the HMR. See 49 CFR 171.8. With the limited exception in § 299.9406(6) quoted above, they apply

[1] CWTI advises that, according to the DNR, "treatment" should read "transportation." 58 FR 6170 n. 6.

both when materials other than waste are being transported in the licensed vehicle and when the vehicle is empty.

B. HMTA Requirements for Motor Vehicle Marking and Placarding

RCRA hazardous wastes, as designated pursuant to 42 U.S.C. 6921 by the Administrator of the U.S. Environmental Protection Agency (EPA), are hazardous materials under the HMR. 49 CFR 171.8 ("Hazardous material"] (as amended at 55 FR 52930, 52935 (Nov. 5, 1992)); see also 49 CFR 171.3(a) ("No person may offer for transportation or transport a hazardous waste * * * in interstate or intrastate commerce except in accordance with the requirements of [the HMR]."). Both interstate and intrastate hazardous waste transporters are subject to the HMR. 49 CFR 171.1(a).

Under the HMR, if a hazardous waste meets the definition of any of the hazard-specific classes 1 through 8, it is subject to the marking, labeling and placarding requirements applicable to that class. 49 CFR 172.101(c)(12), 173.2a. If the waste does not meet the definition of one of those classes, it is designated as a Class 9 hazardous material. 49 CFR 173.140(b). Different vehicle marking and placarding requirements apply depending on the hazard class of the waste, the quantity, and whether it is transported in bulk or non-bulk packagings.

The general marking requirements for bulk packagings in which hazardous waste is transported appear at 49 CFR 172.302. Under this section, only the identification number of the waste need be marked on the packaging; if the packaging is used under the terms of an exemption, the exemption number must be marked as well. 49 CFR 172.302(a), (c); 172.504(f)(9). The packaging must remain marked until it has been cleaned of residue and purged of vapors, or refilled with a material requiring different markings, at which time the markings for the waste must be removed. 49 CFR 172.302(d). If the waste is radioactive, poisonous by inhalation, explosive or an elevated temperature material, additional marking requirements apply. 49 CFR 172.310, 172.313, 172,320, 172.325. Labeling requirements apply to certain smaller bulk packagings. 49 CFR 172.400(a).

A vehicle transporting hazardous waste in bulk must display placards designated in the HMR for the hazard class(es) of the waste. 49 CFR 172.504. The vehicle must remain placarded until it is cleaned of residue and purged of vapors, or refilled with a material requiring different or no placards, at which time the placards for the waste must be removed. 49 CFR 172.514(b). If the waste is a Class 9 hazardous material in domestic transportation, the vehicle need not be placarded. 49 CFR 172.504(f)(9). The required waste identification number may, however, be displayed on a placard rather than as a marking. 49 CFR 172.336(b).

Non-bulk packages of hazardous waste are subject to a number of requirements for marking, 49 CFR 172.301, 172.310, 172.312, 172.313, 172.316, 172.320, 172.324, 172.325, and labeling, *id.*, 172.400, 172.402, 172.403, 172.404. No marking requirements, however, apply to the motor vehicle that transports them. Rather, the vehicle must display placards designated for the hazard class(es) of the waste being transported. 49 CFR 172.504(a). Exceptions from placarding may apply if the waste is an infectious substance, 49 CFR 172.500(b)(1), or if there is less than 454 kilograms (1001 pounds) of it, 49 CFR 172.504(c). Under certain circumstances, a "Dangerous" placard may be used in place of two or more hazard-specific placards. 49 CFR 172.504(b). If the waste is a Class 9 material in domestic transportation, the vehicle need not be placarded. 49 CFR 172.504(f)(9).

II. Preemption Under the HMTA

The HMTA was enacted in 1975 to give the Department of Transportation greater authority "to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce." 49 App. U.S.C. 1801. It "replace[d] a patchwork of state and federal laws and regulations concerning hazardous materials with a scheme of uniform, national regulations." *Southern Pac. Transp. Co.* v. *Public Serv. Comm'n*, 909 F.2d 352, 353 (9th Cir. 1990).

As enacted in 1975, the HMTA preempted "any requirement, of a State or political subdivision thereof, which is inconsistent with any requirement set forth in [the HMTA], or in a regulation issued under [the HMTA]." HMTA, Public Law 93–633, section 112(a), 88 Stat. 2161 (1975). Congress intended this provision "to preclude a multiplicity of State regulations and the potential for varying as well as conflicting regulations in the area of hazardous materials transportation." S. Rep. No. 1192, 93d Cong., 2d Sess. 37 (1974).

Thereafter, DOT's Materials Transportation Bureau (MTB), predecessor of RSPA's Office of Hazardous Materials Safety, implemented HMTA preemption through the issuance of inconsistency rulings. Inconsistency rulings, while advisory in nature, were "an alternative to litigation for a determination of the relationship of Federal and State or local requirements" and also a possible "basis for an application [for] a waiver of preemption pursuant to section 112(b) of the HMTA." Inconsistency Ruling No. 2 (IR–2), 44 FR 75566, 76657 (Dec. 20, 1979).

In the 1990 amendments to the HMTA, Public Law 101–615 (Nov. 16, 1990), preemption under the HMTA was strengthened on the basis of the following Congressional findings:

> (3) Many States and localities have enacted laws and regulations which vary from Federal laws and regulations pertaining to the transportation of hazardous materials, thereby creating the potential for unreasonable hazards in other jurisdictions and confounding shippers and carriers which attempt to comply with multiple and conflicting registration, permitting, routing, notification, and other regulatory requirements,
>
> (4) Because of the potential risks to life, property, and the environment posed by unintentional releases of hazardous materials, consistency in laws and regulations governing the transportation of hazardous materials is necessary and desirable,
>
> (5) In order to achieve greater uniformity and to promote the public health, welfare, and safety at all levels, Federal standards for regulating the transportation of hazardous materials in intrastate, interstate, and foreign commerce are necessary and desirable.

49 App. U.S.C. 1801 note. In amending the HMTA, Congress affirmed that "uniformity was the linchpin" of the statute. *Colorado Pub. Util. Comm'n* v. *Harmon*, 951 F.2d 1571, 1575 (10th Cir. 1991). Unless a waiver of preemption is granted by DOT, the HMTA as amended explicitly preempts "any requirement of a State or political subdivision thereof or Indian tribe" not "otherwise authorized by Federal law" if

> (1) Compliance with both the State or political subdivision or Indian tribe requirement and any requirement of [the HMTA] or of any regulation issued under [the HMTA] is not possible,
>
> (2) The State or political subdivision or Indian tribe requirement as applied or enforced creates an obstacle to the accomplishment and execution of [the HMTA] or the regulations issued under [the HMTA], or
>
> (3) It is preempted under section 105(a)(4) [49 App. U.S.C. 1804(a)(4), concerning "covered subjects"] or section 105(b) [49 U.S.C. 1804(b), concerning highway routing requirements].

49 App. U.S.C. 1811(a).

The first two paragraphs codify the "dual compliance" and "obstacle" criteria that RSPA had applied in

issuing inconsistency rulings prior to the 1990 amendments to the HMTA. These criteria derive from U.S. Supreme Court preemption decisions. *E.g., Ray* v. *Atlantic Richfield, Inc.*, 435 U.S. 151 (1978); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52 (1941).

The third paragraph, 49 App. U.S.C. 1811(a)(3), refers to 49 App. U.S.C. 1804(a)(4), which specifies five "covered subject" areas in which non-Federal requirements are given particular scrutiny:

(i) The designation, description, and classification of hazardous materials.

(ii) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials.

(iii) The preparation, execution, and use of shipping documents pertaining to hazardous materials and requirements respecting the number, content, and placement of such documents.

(iv) The written notification, recording, and reporting of the unintentional release in transportation of hazardous materials.

(v) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold as qualified for use in the transportation of hazardous materials.

In any of these areas, a non-Federal requirement that is "not otherwise authorized by Federal law" is preempted unless it is "substantively the same" as the HMTA or HMR requirement. To be "substantively the same," the non-Federal requirement must "conform[ ] in every significant respect to the Federal requirement. Editorial and other similar *de minimis* changes are permitted." 49 CFR 107.202(d).

HMTA preemption of non-Federal waste transportation regulation is further implemented through 49 CFR 171.3(c):

With regard to hazardous waste subject to [the HMR], any requirement of a state or its political subdivision is inconsistent with [the HMR] if it applies because that material is a waste material and applies differently from or in addition to the requirements of [the HMR] concerning:

(1) Packaging, marking, labeling, or placarding;

(2) Format or contents of discharge reports (except immediate reports for emergency response); and

(3) Format or contents of shipping papers, including hazardous waste manifests.

In place of the prior process for issuing advisory inconsistency rulings, the HMTA authorizes any directly affected person to apply to the Secretary of Transportation for a preemption determination with respect to a requirement of a State, political subdivision or Indian tribe. 49 App. U.S.C. 1811(c)(1). Preemption determinations under authority of the HMTA address preemption only by the HMTA, and not by the Commerce Clause of the Constitution or federal statutes other than the HMTA. Other statutes may be relevant to determining HMTA preemption, for instance in establishing whether a non-Federal requirement is "otherwise authorized by Federal law." 49 App. U.S.C. 1804(a)(4)(A).

The Secretary of Transportation has delegated to RSPA the authority to make preemption determinations, except for those concerning highway routing, which are delegated to the Federal Highway Administration. 49 CFR 1.53(b). Under RSPA's regulations, preemption determinations are issued by RSPA's Associate Administrator for Hazardous Materials Safety. 49 CFR 107.209(a). If a requirement of a State, a political subdivision of a State or an Indian tribe is preempted, that jurisdiction may apply for a waiver of preemption under 49 CFR 107.215 through 107.227. A waiver may be granted if the Associate Administrator finds that the non-Federal requirement affords the public a level of safety equal to or greater than that afforded by the HMR, and that it does not unreasonably burden commerce. Alternatively, the jurisdiction may petition under 49 CFR 106.31 for adoption of a uniform Federal rule.

Preemption determinations under the HMTA are consistent with the principles and policy set forth in Executive Order No. 12,612 ("Federalism"), 52 FR 41685 (Oct. 30, 1987). Section 4(a) of that Executive Order authorizes preemption of State laws only when a statute contains an express preemption provision, there is other clear evidence of Congressional intent to preempt, or the exercise of State authority directly conflicts with the exercise of Federal authority. The HMTA contains an express preemption provision, which RSPA has implemented through its regulations.

III. The CWTI Application and Public Comment

A. The CWTI Application

CWTI states that hazardous materials vehicle marking is a "covered subject" under 49 App. U.S.C. 1804(a)(4)(B)(ii). State regulations pertaining to marking, CWTI continues, must be "substantively the same" as those of the HMR or they are preempted. CWTI then characterizes the Michigan requirements as marking requirements. It contends that they are not substantively the same as the Federal requirements, and therefore are preempted. CWTI supports its argument by citing 49 CFR 171.3(c)(1), quoted in Section II, above. This section prohibits regulation of waste materials as hazardous waste differently than the HMR with respect to, among other categories, marking, labeling and placarding.

CWTI suggests that the required vehicle markings will confuse the public and emergency responders outside of Michigan. It contends that vehicles not carrying hazardous or liquid industrial waste but marked according to Michigan law are more likely to be, and have been, denied entry to non-hazardous waste disposal facilities, resulting either in a *de facto* vehicle dedication or in more trips, more mileage and a correspondingly greater public risk. CWTI asserts that by complying with the Michigan requirement to mark even trucks that are empty, transporters must violate the HMTA prohibition on representing that a hazardous material is present when it is not. See 49 App. U.S.C. 1804(e); see also 49 CFR 171.2(f)(2).

Finally, CWTI asserts that the Michigan requirements are not "otherwise authorized by Federal law," 49 App. U.S.C. 1811(a), by RCRA or any other Federal statute.

B. Comments Supporting Preemption

Comments supporting preemption were received from three additional parties. The Hazardous Materials Advisory Council (HMAC), an organization representing "shippers, carriers of all modes, container manufacturers and reconditioners, emergency response and waste clean-up companies," echoed CWTI's arguments that the Michigan requirements violate both 49 CFR 171.3(c)(1), which prohibits regulation of wastes as wastes in a manner different from the HMR, and 171.2(f)(2), which prohibits representing that hazardous materials are present when they are not.

HMAC also cites 49 App. U.S.C. 1819, which establishes a working group to recommend uniform forms and procedures for State registration and permitting of hazardous materials transporters. The recommendations, when transmitted to the Secretary of Transportation, will form the basis for possible Department of Transportation regulations. After the effective date of any promulgated regulations, no State shall enforce any requirement relating to that subject matter unless it is "the same as" the regulations. 49 App. U.S.C. 1820(e). HMAC states that it is a non-voting member of the working group,

and that the group has not contemplated regulations such as the Michigan marking requirements.

Two private waste haulers, Price Trucking Corporation and Enmanco, state that they have been turned away from, or been delayed at, non-hazardous waste disposal facilities due to the markings on their trucks, and that those markings have caused confusion outside of Michigan. Enmanco suggests that the markings are imprecise and cause confusion as to what the truck is carrying. Price Trucking joins CWTI and HMAC in arguing that compliance with the Michigan requirements brings a vehicle into violation of 49 CFR 171.2(f)(2).

C. Comments Opposing Preemption

The Michigan DNR filed comments opposing preemption of its marking requirements.

The DNR asserts that the application filed by CWTI is procedurally defective, in that it fails adequately to:

1. State how CWTI is affected by the Michigan requirements.
2. Set forth the text of the Michigan requirements for which a finding of preemption is sought.
3. Specify the HMTA or HMR provisions with which the Michigan requirements are to be compared.
4. Explain why the Michigan requirements should be preempted.

See 49 CFR 107.203(b)(2), (3), (4), (5).

On the merits of the determination, the DNR contends that the marking requirements serve important public interests. First, the markings warn emergency responders and the public in the event of an accident. The DNR asserts that its requirements are particularly warranted for vehicles transporting Class 9 hazardous wastes, or hazardous wastes in non-bulk containers. These vehicles are not required to be placarded under the HMR, resulting, according to the DNR, in a situation that is "inimical to the public health, safety and welfare, and the public interest." Without the markings required under Michigan law, the DNR argues, a vehicle transporting Class 9 or non-bulk wastes will inadequately communicate its hazards to those arriving at an accident scene.

The DNR further suggests that the markings will alert the public to the dual activities of those waste transport vehicles that also are used to carry gravel, topsoil, sand, food or other commodities. They will allow those engaging transportation services better to determine the past uses of a vehicle, and will assist sanitary landfills in preventing the receipt of hazardous wastes.

The DNR asserts that there is no conflict between State and Federal regulation, as the Department of Transportation "has chosen not to fill this important regulatory void." It states that the benefits of the Michigan marking requirements outweigh a minimal regulatory burden.

D. Rebuttal Comments

In rebuttal, CWTI responds that Preemption Determination No. 2 (PD–2(R)), 58 FR 11176 (Feb. 23, 1993), has affirmed the CWTI's "standing" to file applications for preemption determinations on behalf of its members. In that ruling, concerning a State of Illinois hazardous waste manifest at variance with the uniform Federal manifest, RSPA, according to CWTI, affirmed its broad reading of the "directly affected" standard for who may apply for a preemption determination. CWTI also states that in its application it cited the State requirements for which it seeks a finding of preemption, that the cited requirements were appended to the application, and that a "plain reading" indicates the HMR provisions to which comparison is to be made, namely, those governing marking, labeling and placarding.

CWTI disputes the DNR claim that the required markings convey accurate hazard warning information. Specifically, it suggests that the information will be inaccurate when the vehicle is empty or contains something other than the wastes indicated by the marking. It notes that while vehicles transporting Class 9 hazardous materials are not required to be placarded under the HMR, not all wastes covered by the marking requirements are Class 9 materials. It states that the DNR's purported concerns about cross-contamination are not relevant to vehicles used to transport hazardous wastes in non-bulk packagings. Finally, CWTI contends that Michigan's, and indeed RSPA's, judgments as to the adequacy of the Federal vehicle marking system are not pertinent to determining preemption in a "covered subject" area. RSPA's determination, CWTI asserts, is limited to "whether the non-federal requirement is 'substantively the same as' the federal standard." Finally, CWTI reiterates its position that neither RCRA nor its implementing regulations "otherwise authorizes" the Michigan requirements at issue.

IV. Discussion

A. Procedural Issues

The DNR asserts that CWTI, contrary to 49 CFR 107.203(b)(5), has not adequately stated how it is affected by the Michigan marking requirements for which it seeks a finding of preemption. In its application, CWTI states that it is

> A not-for-profit association that represents approximately 2,000 waste services companies throughout the United States and Canada. Members of the Institute are commercial firms specializing in the transportation of hazardous waste, by truck and rail, from its point of generation to its management destination. Our members are both private and for hire carriers that operate in interstate and intrastate commerce, including points to and from and through Michigan.

This averment is sufficient to inform RSPA and interested members of the public of how CWTI is affected by the Michigan requirements. Beyond considering simply whether petitioner has stated its interest, however, it is appropriate to address the DNR's implied claim: That CWTI lacks standing to apply for the preemption determination.

The HMTA, as originally enacted, provided for the preemption of non-Federal requirements that were "inconsistent" with the HMTA or the HMR. HMTA, Public Law 93–633, section 112(a), 88 Stat. 2161 (1975). Preemption questions were decided by RSPA, in accordance with its regulations, through a process that resulted in the issuance of inconsistency rulings. The 1990 amendments to the HMTA elevated the advisory inconsistency ruling to that of a "binding administrative process for determining whether State and local requirements are preempted." H.R. Rep. No. 444, 101st Cong., 2d Sess. 1 (1990).

As amended, the HMTA provides:

> Any person, including a State or political subdivision thereof or Indian tribe, directly affected by any requirement of a State or political subdivision or Indian tribe, may apply to the Secretary, in accordance with regulations prescribed by the Secretary, for a determination of whether that requirement is preempted by [the HMTA].

49 App. U.S.C. 1811(c). The HMTA standing test, then, is that a person be "directly affected" by a non-Federal requirement for which it seeks a preemption determination. This provision codified and amended RSPA's prior practice in considering applications for inconsistency rulings, in which RSPA interpreted the standing requirement broadly.

Absent dispute with the facts of CWTI's averment, it is established that CWTI's members include those who transport hazardous waste in or through Michigan by motor vehicle. As CWTI notes, in PD–2(R) RSPA found that CWTI had standing on behalf of its

members to challenge Illinois' enforcement of a requirement to use a State hazardous waste manifest at variance with that countenanced by the HMR. 58 FR at 11181–82. CWTI has standing sufficient for the present application.

The DNR claims that CWTI has not set forth the text of the Michigan requirements for which it seeks a finding of preemption. CWTI's application cites to the two provisions of Michigan law containing the marking requirements at issue, 58 FR at 6170 n. 4 & 5, with the text of those provisions attached. The application as submitted did not include the full text of Michigan statutes and rules (such as definitions and jurisdictional sections) necessary to understand the scope of the two provisions. For RSPA's purposes, this deficiency was remedied by CWTI in response to a July 7, 1993 letter from the RSPA Office of Chief Counsel to CWTI, a copy of which was sent by certified mail to the DNR. Were an interested party prejudiced in its ability to comment by the absence from the docket of these supporting materials, a suitable procedural remedy might be in order. The DNR has not alleged prejudice to itself from CWTI's failure to include these materials with its application, and indeed cannot reasonably claim to lack access to its own statutes and administrative rules. Accordingly, CWTI's compliance with 49 CFR 107.203(b)(2) is adequate.

The DNR argues that the CWTI application did not "specify each requirement" of the HMR with which CWTI seeks the Michigan marking requirements to be compared. See 49 CFR 107.203(b)(3). The application did not include citations to specific HMR provisions. It did, however, state that the HMR requirements at issue were, for instance, those "in certain covered subject areas including the 'marking' of hazardous materials." Marking, labeling and placarding requirements are set forth concisely in the HMR at 49 CFR part 172 subparts D, E and F, respectively. In addition, the non-Federal requirements on their face pertain to motor vehicle marking and placarding. RSPA has been able to identify the HMR provisions relevant to its analysis; the DNR has not suggested that its ability to comment on CWTI's application has been undermined by the application's failure to specify the Federal provisions at issue. Accordingly, compliance with § 107.203(b)(3) is adequate.

Finally, the DNR asserts that CWTI has not sufficiently explained why the Michigan requirements should be preempted. The CWTI application contends that these requirements should be preempted because they concern a covered subject and are not "substantively the same" as HMR requirements. It also argues that the Michigan requirements violate 49 CFR 171.3(c)(1) by regulating waste materials in a manner different from the HMR, and that they conflict with 49 CFR 171.2(f)(2), by requiring a vehicle to represent that a hazardous material is aboard at times when it is not. Finally, the application asserts that the requirements will confuse the public and emergency responders, and either will result in more vehicle mileage and correspondingly greater public risk, or will constitute a burdensome *de facto* vehicle dedication requirement. These arguments meet the procedural requirement of 49 CFR 107.203(b)(4).

B. "Covered Subject" Test

The 1990 amendments to the HMTA strengthened Federal preemption with respect to five "covered subjects." In these five areas, Congress recognized "a compelling need for standardized requirements relating to certain areas of the transportation of hazardous materials." H.R. Rep. No. 444, 101st Cong., 2d Sess. at 33–34. Congress explained its rationale for the 1990 amendments to the HMTA, including broad Federal preemption of requirements concerning "covered subjects," with findings quoted in Section II, above. See 49 App. U.S.C. 1801 note.

If the non-Federal requirement regulates in the area of a covered subject, a strict preemption standard applies: the requirement is preempted unless it is "substantively the same" as applicable requirements under the HMTA and HMR. 49 App. U.S.C. 1804(a)(4)(A). "'Substantively the same' means that the non-Federal requirement conforms in every significant respect to the Federal requirement. Editorial and other similar *de minimis* changes are permitted." 49 CFR 107.202(d). The non-Federal regulations must contain "the same substance" as the Federal regulations. *Colorado Public Utilities Comm'n* v. *Harmon*, above, 951 F.2d at 1578.

In PD–2(R), RSPA considered whether the State of Illinois' Uniform Hazardous Waste Manifest was preempted under the HMTA. 58 FR 11176. The Illinois manifest differed from the Federal manifest in requiring that additional manifests rather than continuation sheets be used, and that the figure for the total quantity of waste documented on the manifest be rounded to the nearest whole number in the units used. 58 FR at 11176–77.

Because the Illinois requirements concerned the number and content of shipping documents, a "covered subject," the question was whether the Illinois manifest was "substantively the same" as the Federal Uniform Hazardous Waste Manifest required by the HMR. 49 App. U.S.C. 1804(a)(4)(B). RSPA concluded that the differences were not *de minimis* and not merely editorial, but "significantly alter[ed]" both the information supplied on the manifest and the manifest format, and therefore were preempted. 58 FR at 11183.

"The packing, repacking, handling, labeling, marking, and placarding of hazardous materials" is a "covered subject" under 49 App. U.S.C. 1804(a)(4)(B). Congress, identifying this area as one in which uniformity is critical, stated:

> [C]onsistency in regulations pertaining to [packing, repacking, handling, labeling, marking and placarding] are [sic] needed to promote safety at all stages of hazardous materials transportation. Conflicting requirements for any of these subjects will confuse all who come into contact with hazardous materials, including shippers, carriers, and other handlers of such materials in transit. Of major importance as well is the need for consistency for those who respond to emergencies involving hazardous materials. Different requirements in these areas would lessen the ability of emergency responders quickly to identify hazardous materials, thus impairing their ability promptly and effectively to respond to any emergency.

H.R. Rep. No. 444, 101st Cong., 2d Sess. at 34.

In designating the marking, labeling and placarding of hazardous materials as an area of particular Federal primacy, the 1990 amendments essentially codified RSPA's long-standing position that this area is one "of exclusive HMTA domain." IR–3, 46 FR 18918, 18924 (Mar. 26, 1981).

RSPA's inconsistency rulings uniformly found hazard warning requirements different from HMR requirements to be preempted. See IR–31, 55 FR 25572 (June 21, 1990) (placard); IR–30, 55 FR 9676 (Mar. 14, 1990) (sign); IR–24, 53 FR 19848 (May 31, 1988) (placard); IR–22, 52 FR 46574 (Dec. 8, 1987) (placard); IR–3, 46 FR 18918 (identification numbers); *cf.* IR–32, 55 FR 36736 (ordinance requiring placarding in accordance with HMR not preempted).

In the present case, the requirements at Michigan Administrative Code 299.9406(6) and Michigan Compiled Laws § 323.277(1) compel trucks used to transport hazardous wastes and liquid industrial wastes to bear on each side "Hazardous Waste-Hauling Vehicle"

and "licensed industrial waste hauling vehicle," respectively. These requirements, according to the DNR, "facilitate safe and proper emergency response activities by providing a hazard warning to the public concerning the content of a vehicle transporting hazardous waste." They are marking requirements within the meaning of 49 App. U.S.C. 1804(a)(4)(B)(ii), because they direct that language regarding the hazards of a material in transportation be marked in a way that is likely to be understood by emergency responders and the public as hazard communication information. *Cf. Colorado Pub. Util. Comm'n* v. *Harmon*, above, 951 F.2d at 1583 (the preemption inquiry turns not on the purpose of the non-Federal requirement, but on its effect).

Markings, when required under the HMR, generally must be placed on the package. 49 CFR 172.301(a), 172.302(a). In bulk highway transport, markings are placed directly on the cargo tank or portable tank, 49 CFR 172.302(a), 172.326; vehicles transporting hazardous materials in non-bulk packagings are not marked, 49 CFR 172.301(a), see generally 49 CFR 172.300–.338. Conversely, markings required by Michigan need not appear on the packaging; they may be placed elsewhere on the waste-hauling vehicle. Mich. Comp. Laws Ann. § 323.277(1), Mich. Admin. Code 299.9406(6). The location of the markings, however, does not in itself determine whether or not they are markings within the meaning of 49 App. U.S.C. 1804(a)(4)(B)(ii). What is important is that they (1) are in a location where they purport to communicate hazards posed by the material in the vehicle; and (2) use language to do so that may be confused with that of HMR-required markings (see 49 CFR 172.101(c)(9)(requiring use of word "waste" in proper shipping name for hazardous wastes). In this instance, the risk of confusion is present even if the markings appear in a location other than that specified in the HMR.

While the director of the DNR is authorized to designate a material as a "hazardous waste" under Michigan law even if it is not a RCRA hazardous waste, the universe of State "hazardous waste" encompasses all RCRA hazardous wastes. Mich. Admin. Code 299.9104(d), 299.9203(1), 299.9209(1), 299.9213(1). All materials subject to EPA manifest requirements at 40 CFR Part 262 are hazardous materials, 49 CFR 171.8 ("Hazardous waste," "Hazardous material"); RCRA hazardous wastes are subject to EPA manifest requirements. 40 CFR 262.20, 263.20. Thus, RCRA hazardous wastes are hazardous materials, and the marking requirement of Michigan Administrative Code 299.9406(6) applies to the transportation of hazardous materials.

Michigan Compiled Law 323.277(1) applies to "any liquid waste, other than unpolluted water, which is produced by or incident to or results from an industrial or commercial activity or the conduct of any enterprise." Mich. Comp. Laws Ann. § 323.271(b). From this broad definition, it may be inferred that many "liquid industrial wastes" are not hazardous materials under the HMTA. At the same time, the term encompasses liquid hazardous wastes, which, as noted above, are hazardous materials. This marking requirement thus applies to a significant number of liquid wastes that are hazardous materials. Therefore, the two requirements concern the "marking * * * of hazardous materials," a covered subject under 49 App. U.S.C. 1804(a)(4)(B)(ii).

The two Michigan provisions require that motor vehicles used to transport certain hazardous materials be marked in a manner different from the HMR. The HMR require only that the vehicle be placarded to communicate the hazard class(es) of the waste(s) being transported and, for bulk transport, that the identification numbers of the waste(s) on board be displayed. 49 CFR 172.302(a), 172.504(a); see Section I.B, above. In some cases, no placarding is required, or the "Dangerous" placard is authorized. 49 CFR 172.500(b)(1), 172.504(b), 172.504(c), 172.504(f)(9). Placards and identification number markings may not be displayed if no hazardous wastes are on board. 49 CFR 171.2(f)(2). The Michigan provisions require vehicles to be marked with descriptions, formulated by the State, intended to communicate that wastes are, or have been, on board; these descriptions must remain on the vehicle even when it is empty. These differences are not *de minimis* or editorial. The Michigan requirements, as applied to materials designated as hazardous materials under the HMTA, are not "substantively the same" as the Federal requirements, and are preempted under 49 App. U.S.C. 1811(a)(3).

C. "Obstacle" Test

"Liquid industrial waste," defined at § 323.271(b), is a broad category that, as indicated by the parties, includes wastes that are not hazardous materials under the HMTA. With respect to the § 323.277(1) marking requirement, the above finding of preemption pertains only to the marking of vehicles in which hazardous materials are transported. In determining whether the HMTA preempts the application of § 323.277(1) to vehicles transporting only liquid industrial wastes that are not hazardous materials, the analysis differs.

The marking requirement of § 323.277(1) here does not concern the "marking * * * of hazardous materials," a covered subject under 49 App. U.S.C. 1804(a)(4)(B), because we are concerned with the situation where the vehicle is used to transport only liquid industrial wastes that are not hazardous materials. If the marking requirement were an adoption or a duplication of an HMR marking requirement, the effect of the requirement would be to treat the regulated materials as hazardous materials. This would constitute, in effect, the "designation * * * and classification of hazardous materials," also a covered subject under § 1804(a)(4)(B). Here, the Michigan marking requirement differs from HMR-specified markings and applies to materials that are not hazardous materials. No covered subject is involved and, accordingly, the "substantively the same" standard is not applicable.

As discussed in Section II, above, application of the marking requirement to vehicles transporting only liquid industrial wastes that are not hazardous materials nevertheless is preempted by the HMTA if:

> (1) Compliance with both the State * * * requirement and any requirement of [the HMTA] or of a regulation issued under [the HMTA] is not possible, [or]
>
> (2) The State * * * requirement as applied or enforced creates an obstacle to the accomplishment and execution of [the HMTA] or the regulations issued under [the HMTA].

49 App. U.S.C. 1811(a).

The marking requirement, as applied to liquid industrial wastes that are not hazardous materials, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the HMTA, *Colorado Pub. Util. Comm'n* v. *Harmon*, above, 951 F.2d at 1580, and therefore is preempted.

The purpose of the HMTA is "to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce." 49 App. U.S.C. 1801. The single, comprehensive body of requirements concerning hazardous materials shipping papers, marking, labeling, and placarding is at the heart of the regulatory framework established in the

HMR to achieve this purpose. Uniformity in this area is critical to ensure that hazardous materials are handled appropriately during transportation and that emergency responders can take efficient and effective response action when an accident occurs. See generally H.R. Rep. No. 444, 101st Cong., 2d Sess. at 34 (quoted above).

For this reason, the Office of Hazardous Materials Safety consistently has expressed the position that the Federal role in designating hazardous materials and applying marking, labeling and placarding requirements to those materials is exclusive. *E.g.*, IR–32, 55 FR 36736; IR–29, 55 FR 9304 (Mar. 12, 1990); IR–28, 55 FR 8884 (Mar. 8, 1990); IR–3, 46 FR 18918 (Mar. 26, 1981); IR–2, 44 FR 75566 (Dec. 20, 1979). This principle has been judicially affirmed. *Missouri Pacific RR Co.* v. *Railroad Comm'n of Texas*, 671 F.Supp. 466, 481–82 (W.D. Tex. 1987), *aff'd* 850 F.2d 264 (5th Cir. 1988), *cert den.* 109 S.Ct. 794 (1989). Congress emphasized the importance of uniformity in 1990, when it amended the HMTA to identify hazardous materials designation and marking, labeling and placarding as "covered subjects" under essentially exclusive Federal jurisdiction.

RSPA has determined that hazardous materials classification by States and localities in a manner different from the HMR undermines the framework of hazard identification the HMR establishes:

> The key to hazardous materials transportation safety is precise communication of risk. The proliferation of differing State and local systems of hazard classification is antithetical to a uniform, comprehensive system of hazardous materials transportation safety regulation. This is precisely the situation which Congress sought to preclude when it enacted the preemption provision of the HMTA.

IR–6, 48 FR 760, 764 (Dec. 29, 1982).

> If every state were to assign additional requirements on the basis of independently created and variously named subgroups of * * * materials, the resulting confusion of regulatory requirements would lead ineluctably to the increased likelihood of reduced compliance with the HMR [a]nd subsequent decrease in public safety.

IR–15, 49 FR 46660, 46660 (Nov. 27, 1984). While these rulings concerned the attempt to apply non-Federal requirements different from the HMR to hazardous materials, the rationale applies equally to marking requirements imposed on materials that are not hazardous materials.

Application of the Michigan marking requirement, even to vehicles transporting only liquid industrial wastes that are not hazardous materials, is detrimental to the purposes of the HMTA. The Michigan statute requires a vehicle marking that announces the potential hazard of an "industrial waste." Under the HMR, the term "waste" is a component of the proper shipping name of any RCRA hazardous waste. 49 CFR 172.101(c)(9). "Liquid industrial waste," however, does not conform to markings specified in the HMR. This is tantamount to the creation of an additional class of hazardous materials with its own marking requirements. A proliferation of vehicles bearing non-conforming markings would undermine efforts to educate hazardous materials employees and emergency responders in the single, uniform nomenclature of hazard communication contained in the HMR. Shippers, consignees, law enforcement officers and emergency responders are familiar with HMR-specified markings, which are referable to a single, national body of regulations. Those encountering vehicles with the "liquid industrial waste" marking may be uncertain as to whether the marking indicates the presence of a hazardous material and, if so, what the material might be. Confusion as to whether the marking is an HMR-prescribed marking introduces ambiguity into the regulatory framework. This ambiguity in the long run tends toward reduced compliance. Finally, requiring the marking of vehicles transporting "any liquid waste * * * produced by * * * the conduct of any enterprise," Mich. Comp. Laws Ann. § 323.271(b), expands the universe of vehicles displaying hazard warnings to include those that pose no or little risk to health, safety or property, diminishing the attention that vehicle hazard warnings under the HMR framework should and do command. In all of these respects, a greater risk to public safety is the result.

When a vehicle marking is required, sufficiently similar to HMR markings that it appears to be a hazard warning, but that does not conform to HMR markings, the purposes of the HMTA are undermined. The marking requirement of § 323.277(1), as applied to vehicles transporting liquid industrial wastes that are not hazardous materials, stands as an obstacle to accomplishing the purposes of the HMTA, and therefore is preempted.

Because we find that the Michigan marking requirement is preempted as an obstacle to the HMTA, we need not address the argument that it fails the "dual compliance" test.

D. Other Arguments

The DNR suggests that there is no conflict between the Michigan requirements and the HMR because the former simply "fill th[e] important regulatory void" that the HMR allegedly do not address. The DNR does not explain the "void" to which it refers. Presumably, it is the absence of language on a vehicle describing the wastes it carries, specifically for vehicles shipping Class 9 or non-bulk wastes not subject to placarding requirements.

The HMR are a comprehensive framework of packaging, hazard communication and transportation controls directed to ensuring the safe and efficient movement of hazardous materials. Subparts A through G of 49 CFR part 172 establish a comprehensive system of hazard communication through hazardous materials nomenclature, shipping paper, marking, labeling, placarding and emergency response requirements reflecting a considered balance among regulatory goals of risk minimization, feasibility of administration and compliance, and regulatory cost.

The structure of the HMR is reflected in the statutory language identifying hazardous materials "packing, repacking, handling, labeling, marking, and placarding" as a covered subject. 49 App. U.S.C. 1804(a)(4)(B)(ii). With respect to this "subject," there is no regulatory void in the HMR; there is an encompassing, integrated framework of regulation.

The fact that the HMR do not require additional descriptive markings on vehicles transporting hazardous wastes simply means "that the Secretary has determined that no regulation is needed on that topic." IR–22, 54 FR 26698, 26703 (June 23, 1989) (decision on appeal). For example, the exception of Class 9 materials from placarding requirements is not an oversight, but the result of a conscious decision implemented by regulation. 49 CFR 172.504(f)(9).

CWTI argues that the Michigan requirements will confuse emergency responders and the public; that they will result in additional mileage for marked trucks and correspondingly greater public risk; or, in the alternative, that they constitute a *de facto* vehicle dedication requirement.

The DNR, conversely, claims that the requirements serve important public interests by informing emergency responders, the public, landfill operators and those seeking transportation services that marked vehicles contain or have contained

wastes. It contends that the public benefits of the requirements outweigh the minimal regulatory burden that they impose.

Whether Michigan's requirements confuse or, to the contrary, inform responders and the public, whether in fact they increase vehicle mileage and public risk, and whether they constitute a significant burden on the regulated community are not relevant to the preemption determination concerning a covered subject. In prescribing the "substantively the same" standard, Congress has concluded as a matter of law that in the area of covered subjects, uniformity is paramount and Federal regulation shall prevail. *Colorado Pub. Util. Comm'n* v. *Harmon*, above, 951 F.2d at 1582–83. This is true as well with respect to marking requirements subject to the "obstacle" test. PD–1(R), 58 FR 32418, 32420 (June 9, 1993) (preemption under the HMTA turns on the effect, not the purpose, of the non-Federal requirement) (denying petition for reconsideration). "The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail." *Colorado Pub. Util. Comm'n* v. *Harmon*, above, 951 F.2d at 1583 (quoting *Free* v. *Bland*, 369 U.S. 663, 666, 8 L.Ed.2d 180 (1962)).

V. Ruling

For the reasons set forth above, RSPA finds that Michigan Compiled Laws § 323.277(1) and Michigan Administrative Code 299.9406(6), requiring the marking of motor vehicles used to transport, respectively, "liquid industrial wastes" and "hazardous wastes," are preempted by 49 App. U.S.C. 1811(a)(3). These marking requirements are not "substantively the same as" Federal marking, labeling and placarding requirements. As applied to vehicles used to transport only liquid industrial wastes that are not hazardous materials, the marking requirement at § 323.277(1) is preempted as an obstacle to accomplishing the purposes of the HMTA.

VI. Petition for Reconsideration/ Judicial Review

In accordance with 49 CFR 107.211(a), "[a]ny person aggrieved" by RSPA's decision on CWTT's application may file a petition for reconsideration within 20 days of service of the decision. Any party to this proceeding may seek review of RSPA's decision "by the appropriate district court of the United States * * * within 60 days after such decision becomes final." 49 App. U.S.C. 1811(e).

This decision will become RSPA's final decision 20 days after service if no petition for reconsideration is filed within that time. The filing of a petition for reconsideration is not a prerequisite to seeking judicial review of this decision under 49 App. U.S.C. 1811(e).

If a petition for reconsideration is filed within 20 days of service, the action by RSPA's Associate Administrator for Hazardous Materials Safety on the petition for reconsideration will constitute final agency action. 49 CFR 107.211(d).

Issued in Washington, DC on February 2, 1994.

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 94–2907 Filed 2–8–94; 8:45 am]

BILLING CODE 4910–60–P

federal register

Wednesday
February 9, 1994

Part V

Corporation for National and Community Service

Community Service—Summer of Safety Youth Corps Program; Notice

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Community Service—Summer of Safety Youth Corps Program

AGENCY: Corporation for National and Community Service.

ACTION: Notice of availability of funds.

SUMMARY: The Corporation for National and Community Service announces the availability of up to $2.5 million for grants to support existing public or private nonprofit summer youth corps programs addressing public safety or environmental needs in local communities. These funds will provide opportunities for approximately 1000 youth to serve their communities on a full-time basis during the summer while earning a limited stipend and a $1000 post-service educational award.

DATES: The deadline for the submission of proposals is Monday, March 21, 1994.

ADDRESSES: All proposals should be submitted to the Corporation for National and Community Service, 1100 Vermont Avenue, NW., Washington DC, 20525.

FOR FURTHER INFORMATION CONTACT: Nathalie Augustin, Senior Program Officer, at the Corporation for National and Community Service, (202) 606–5000, ext. 116.

SUPPLEMENTARY INFORMATION:

Background

On September 21, 1993, the President signed into law the National and Community Service Trust Act (the Act), which created the Corporation for National and Community Service. The Corporation's mission is to engage Americans of all ages and backgrounds in service that addresses the nation's education, public safety, health, and environmental needs to achieve direct and demonstrable results. In doing so, the Corporation will foster civic responsibility, strengthen the ties that bind us as a people, and provide educational opportunity for those who make a substantial commitment to service.

The Corporation is a new Federal agency that encompasses the work and staff of two existing independent agencies, the Commission on National and Community Service and ACTION. The Corporation will fund a new national service initiative called AmeriCorps, service-learning initiatives in elementary and secondary schools and institutions of higher education, and the new National Civilian Community Corps. The Corporation will also engage in efforts to improve the quality of service programs and continue to support the Volunteers In Service To America (VISTA) program and the senior volunteer programs previously sponsored by ACTION.

The Act generally authorizes the Corporation to support summer service programs. Pursuant to this authorization, the Corporation has established a range of Summer of Safety initiatives which will focus on enhancing public safety. These are briefly described in Appendix #1. The youth corps component of the Summer of Safety program will provide an opportunity for school-age youth to make a full-time commitment to addressing the public safety needs of their communities during their summer vacation. Because summer youth corps programs typically concentrate their activities on environmental projects, applicants may propose environmental projects in addition to public safety projects.

Objectives of the Summer of Safety Program

The Summer of Safety Program is being launched to respond to the growing fear of and frustration over the levels of crime and violence in communities in every part of the country. The 1994 Summer of Safety will demonstrate the potential of national service to respond to these urgent needs by tapping the talents and energies of Americans of all ages and backgrounds—especially young adults. Specifically, Summer of Safety will address the public safety needs of communities by achieving the following objectives:

—Making direct, demonstrable impacts on crime, violence and fear by identifying and meeting public safety needs.
—Building new partnerships and collaborations for safety that capitalize on all of the community's resources.
—Demonstrating that every citizen—especially young people—can help make communities safer.
—Providing seed support for innovative service programs that address public safety needs.
—Stimulating public interest in national service as a means to respond to America's problems.

Program Overview

The Corporation will award up to $2.5 million to support existing summer youth corps programs operated by State agencies, Indian tribes, and private nonprofit organizations. Of the available funds, States will be able to compete for $1 million dollars, Indian tribes and private nonprofit organizations will be able to compete for $1.5 million. One million dollars will be reserved in the National Service Trust Fund for educational awards to up to 1,000 participants who successfully complete the summer program.

Funded youth corps programs must engage youth in service projects that address public safety or environmental needs. The term "youth corps program" means a program such as a conservation or youth service corps that:

—Undertakes meaningful service projects with visible public benefits;
—Includes as participants youths and young adults between the ages of 16 and 25, inclusive, including out-of-school youths and other disadvantaged youths (such as youths with limited basic skills, youth in foster care who are becoming too old for foster care, youths of limited English proficiency, homeless youths and youths who are individuals with disabilities) who are between those ages; and
—Provides those participants with: crew-based, highly structured, and adult-supervised work experience, life skills, education career guidance and counseling, employment training, and support services; and the opportunity to develop citizenship values and skills through service to their community and the United States.

Grants will be awarded to operate 10- to 12-week summer youth corps programs. Service activities during the summer must focus on the areas of public safety and the environment. At least one-half of the funds awarded will support public safety-related service activities. Permissible activities include assisting in community policing initiatives, escorting seniors in high-crime neighborhoods, and recreation/activities for children and youth that incorporate violence prevention and safety education. See Appendix #2 for an approach to developing a public safety program and examples of possible public safety activities in which corpsmembers may be engaged.

In addition to public safety activities, youth corps programs may also engage in environmental activities including:

—Revitalizing neighborhoods by creating and maintaining trees, green spaces, and recreation areas;
—Eliminating environmental risks through education, testing, and cleanup;
—Reducing waste through energy efficiency efforts, recycling, and other conservation measures;
—Conserving and restoring public lands, forests, rivers, streams, and wetlands;

—Making parks more accessible through trail maintenance and infrastructure improvements; and
—Sampling, mapping, monitoring, and recording the status and trends of air, water, groundwater, land, plants, and animals.

Programs do not have to address both public safety and environmental needs. Some programs may focus solely on public safety projects, other programs may focus solely on environmental projects; and still others may focus on both issue areas. We note again that at least one half of the funds awarded will be used to support programs engaging in public safety.

Eligibility

States, through a Corporation-approved State Commission, Alternative Administrative Entity (AAE), or Transitional Entity (TE), are eligible to submit applications to support existing State-operated summer youth corps programs pursuant to Subtitle C of the Act (AmeriCorps Grants). If a State has yet to establish a State Commission or AAE, such a State may designate a State agency (including a State Lead Agency that was designated to administer grants awarded by the Commission on National and Community Service) to serve as a TE.

Private nonprofit organizations and Indian Tribes operating existing youth corps programs are also eligible to apply for funds pursuant to Subtitle H of the Act (Investment for Quality and Innovation).

Program Requirements

Funded programs must comply with the following requirements:

(1) Programs must seek to strengthen the ability of the community to utilize community service as a means of responding to problems of crime, violence and fear or environmental problems. In order to respond to such problems, programs must clearly identify the specific needs they seek to address.

(2) Programs must establish specific objectives that reflect demonstrable positive outcomes in the areas of public safety or the environment. These objectives should be directly related to alleviating the identified needs.

While the goal of public safety projects should be the reduction of crime, violence and fear in the communities served, it may be very difficult to document such accomplishments, given the limited time during which a summer program can operate. Accordingly, as well as quantifiable measures of outcome, there may also be intermediate measures of effort and accomplishment which are appropriate as specific objectives.

Examples of such objectives—each of which should address only one activity and include one result—may include reduction in reported crime of XX% (generally or in more limited focus, e.g., robberies of convenience stores, gang-related assaults, attacks against senior citizens, etc.), XX% of neighborhood residents feel safer compared to before program, XX victims of violent crime assisted at court or at home, XX Safe Houses established, XX playgrounds refurbished and supervised, etc.

Examples of demonstrable objectives for environmental projects include XX trees planted, XX low-income homes tested for lead paint and radon, XX% participation in a community recycling project, XX miles of trails built.

(3) Programs proposing to engage in any public safety activities must form collaborative partnerships with organizations within the community that will enhance the capacity of the community to respond to problems of crime, violence, and fear. Given the range of needs that must be met and the variety of possible service activities that may help meet these needs, there are many organizations, institutions and individuals within the community that can meaningfully contribute. Such organizations include: law enforcement, schools, and other public agencies; private nonprofit organizations (including victim assistance and youth-serving organizations); health and welfare programs; senior centers; civic organizations; youth groups; and the business sector.

(4) There are activities that are not appropriate for Summer of Safety youth corps participants. Concern for the physical safety of participants and the specialized training/skill requirements for certain law enforcement/corrections tasks limit the types of service activities which are appropriate. Certain other activities are not appropriate absent a clear link to a broad community public safety effort. Finally, some tasks are not suitable for national service programs at all. Specifically:

—The Corporation will not support programs which place service participants in situations that (i) involve the arrest process, (ii) involve the chain of custody of evidence, (iii) involve witnessing criminal incidents which may result in participants being called as witnesses in adjudicatory proceedings, (iv) result in intentional contact with suspected criminal offenders, (v) involve contact with defendants or convicted offenders without appropriate safeguards in place, or (vi) otherwise pose significant risk to participant safety (e.g., working alone in a high crime neighborhood).
—Grant funds may not be used to support programs that merely provide positive activities for youth (e.g., recreation, field trips, cultural opportunities, social/athletic events, vocational support, academic assistance, mentoring). Although the Corporation recognizes the importance of such activities and their indirect connection to public safety in the long term, grant funds may not be used to support such activities unless they are conducted as components of broad public safety initiatives.
—Activities that do not provide a direct benefit to the community, such as clerical work or research, may be performed if they support direct service, but may not be the primary activity of a national service program.
—Certain activities are prohibited for participants in national service programs. These activities include: (i) Efforts to influence legislation; (ii) organizing protests, petitions, boycotts or strikes; (iii) assisting or deterring union organizing; impairing contracts for services or collective bargaining agreements; (iv) partisan political activity; (v) religious instruction; and (vi) benefiting profitmaking businesses, labor unions, partisan political organizations, or non-profit organizations which fail to comply with Section 501(c) of the Internal Revenue Code. Further information about these prohibited activities may be found in the Corporation's Proposed Regulations, published in the **Federal Register** on January 7, 1994.

(5) Programs must actively seek to include participants from diverse racial, ethnic, economic, and educational backgrounds, and include residents from the community where the program will be conducted.

(6) Programs must provide appropriate training and educational opportunities, including service learning, to participants.

(7) The physical safety of participants must be of paramount concern. Thus, programs must demonstrate their plans for ensuring the physical safety of participants.

(8) Programs must provide a living allowance in an amount not to exceed $170 per week. The Corporation will provide a $1000 post-service educational award to participants who successfully complete the summer

program. The award may be used only for higher educational purposes, including loan repayment, or certain types of vocational training. The educational awards will be administered through the National Service Trust Fund. In order for a participant to receive the educational award, such participant must successfully complete a minimum of 381 hours of service during the course of the summer program. Up to 10 hours per week of classroom training and education activities may be counted toward these service hours.

(9) Programs must agree to (a) begin operations between June 1, and June 20, 1994, (b) officially "launch" summer activities on June 21, 1994, and (c) conclude by August 24, 1994.

(10) Programs must track progress toward achievement of their program objectives. Programs must also monitor the quality of service activities, the satisfaction of both persons served and program participants, and management effectiveness. Internal evaluation and monitoring should be a continuous process allowing for frequent feedback and quick correction of weaknesses. Additionally, programs must cooperate with the Corporation and its evaluators in all Corporation monitoring and evaluation efforts. As part of these efforts, programs must collect and submit to the Corporation certain participant data, including the total number of participants in the program, and the number of participants by race, ethnicity, sex, age, economic background, education level, disability classification, and geographic region. The Corporation will provide forms for collecting participant data.

(11) Programs must comply with a number of match requirements outlined below. The program cost match may be in cash or in-kind services. Other Federal funds may be used as a match for the purpose of this proposal, except as noted below. Programs are encouraged to exceed the required match amounts because evidence of such "over-matching" will be a factor in the selection of programs. Programs must provide a match of at least:

—25% of the cost of operating the program; and

—15% of the cost of the living allowance for participants. This match may not include in-kind services or other Federal funds.

(12) Awards made by the Corporation are Federal Grants, and will be subject to the Corporation's Regulations, applicable Office of Management and Budget Circulars, including Audit Requirements, and other appropriate Federal Statutory requirements. These various requirements will be incorporated into the terms and conditions of the grant award.

The Corporation's proposed program regulations were published in the **Federal Register** (Volume 59, No. 5) on January 7, 1994. The Corporation intends to issue its regulations in final form prior to the application submission deadline.

Proposal Guidelines

Applicants must submit an unbound original and four (4) unbound copies of their applications. Applications must be received by the Corporation by 6:00 p.m. Eastern Daylight Saving time, March 21, 1994. Applications must be mailed or hand-delivered to the Corporation, 1100 Vermont Avenue, NW., Washington, DC 20525. Facsimiles will not be accepted.

Proposals should not exceed twenty-five (25) typewritten, double-spaced pages, including title page, budget, budget narrative, all attachments or appendices, organized and labeled in the following categories.

I. Title Page

The title page should provide the following information: (1) Specification that funds are being requested under the Summer of Safety Youth Corps Programs; (2) the name and address of the legal applicant, and signature of its authorized executive; (3) the amount of Corporation funds requested, and the amount of non-Federal match; (4) the number of participants; and (5) one paragraph describing the proposed activities (including the amount of requested funds which will be used to support public safety projects) and the target community.

II. Program Narrative

A narrative describing the proposed program should be organized in the following manner.

(A) Needs

(1) Discuss the specific needs or problems that exist in the target community/neighborhood(s) which the program will address. Sources of official data (demographic data, crime offense data, etc.), public opinion surveys, expert analysis and other sources of local information are all useful.

(2) Describe specifically how the program will address the identified problem(s). Outcomes must be measurable and direct.

(3) Discuss why the method of addressing needs will be effective in achieving the specified objectives established by the program. This should include discussion of long-term effects (e.g., safe houses established during the summer will continue to operate during the school year, vacant lots will be converted into community gardens or green spaces, neighborhood volunteers will continue activities initiated during the summer, etc.)

(B) Participants

(1) Describe plans to recruit, screen, select, and assign a qualified pool of participants, including individuals from the community served.

(2) Describe the training and education to be provided to participants to ensure successful involvement in the summer program.

(3) Discuss how the entire summer experience for participants—including orientation, training, service activities, etc.—will develop useful skills, teach participants about public safety and environmental issues, promote active citizenship, and strengthen participants' commitment to service.

(4) Describe the policies and practices designed to assure the safety of participants while carrying out service activities.

(5) Describe plans to provide health care and appropriate child care for certain program participants. Preliminary guidance may be found in the Corporation's proposed regulations (See Appendix #3). These plans may be revised prior to grant approval as a result of requirements in this area that will be set forth in the Corporation's final regulations.

(6) Describe the arrangements that will be made to provide for appropriate program and participant liability coverage.

(7) Describe the arrangements that will be made to cover on-the-job injury to participants, such as linkage with State Workers' Compensation or other appropriate accident and injury policies.

(C) Service Activities

(1) Describe the specific service activities that will be conducted by the program.

(2) Identify the number of participants and unstipended volunteers, if appropriate, who will serve in each of the identified activities.

(3) Discuss how participants' background, skills or other factors will influence the assignment of participants to the various service activities.

(4) Describe the training participants will receive to enable them to carry out service assignments.

(5) Describe procedures for the supervision of participants engaged in service activities.

(6) Discuss the process by which the program will ensure that service participants will not displace paid workers, including consultations with appropriate labor unions.

(D) Continuation

(1) While demonstrable impact should be evidenced during the summer, it is not likely that problems will be completely solved during a 10 to 12-week period. Efforts with a longer-term horizon, such as the development of plans for action beyond the scope of the summer effort, may also begin during the summer. It is important to ensure that promising community-based activities are not lost at the end of the summer.

Unless a program will achieve its entire intended impact in the summer only or its impact will be long-term without further program effort, plans to continue the service projects should be addressed in the proposal. Examples of ways in which a program could seek to continue the service projects begun in the summer include the following:

—The service projects could continue to be carried out by an organization—including the applicant or partner organizations—using other resources;
—A combination of local, State and private funds could be secured, thus permitting the continuation of service and volunteer activities; or
—The program partnership could establish (or expand) an effective volunteer cadre to continue its efforts.

(2) Identify priority activities or strategies which will be sustained following the summer. This may be the entire service projects, select components, or efforts begun in the summer that will be brought to fruition.

(3) Describe the resources and approaches that will assure continuation of the program activity.

(4) Programs that will accomplish their objectives by the end of the summer or those that have no need to sustain activity because they will achieve long-term impact as a result of the summer effort need not respond to this section.

(E) Workplan/Timeline

(1) Identify steps and milestones in a program development, implementation and management process that begins April 8 (the date by which successful applicants will receive notice of selection) and ends on August 24.

(2) Incorporate a required national-scope training and technical assistance workshop for the leadership (program director and two key supervisory staff) of programs that will engage in public safety activities in late April.

(3) Absent a compelling reason to do otherwise, establish the week of June 13 for participant orientation and training, use June 21 as the official date to "launch" their efforts, and end the program by August 24.

(F) Applicant Capacity

(1) Describe the applicant's capacity to develop and administer the program; include a description of any experience running pubic safety or environmental programs, or managing the types of partnerships needed for effective public safety projects.

(2) Include brief resumes or other descriptions of the experience and background of proposed or actual program director and key supervisory staff. Please note that such attachments will count towards an applicant's overall 20-page limitation.

(3) For programs engaging in public safety activities, or for programs which have established certain partnerships to carry out environmental projects, describe the working relationships that exist with the appropriate community organizations and public agencies, including the local law enforcement agency.

(4) Certify the applicant's willingness to promote a national identity for the Summer of Safety program, as an AmeriCorps project, through the use of logos and other materials, and participate in activities such as common opening or closing ceremonies and other events.

(G) Partnership

(1) For applicants proposing public safety activities, identify the organizations and agencies (and, if appropriate, individuals) that have committed to participating in the partnership effort, and identify the leader of the partnership.

(2) Describe the commitment each partner has made to carry out specific roles and to contribute specific resources (training, expertise, space, supplies, funds, publicity, etc.) to support the program.

(H) Monitoring and Evaluation

(1) Describe how progress toward program objectives will be monitored.

(2) Describe how the quality of service activity and the satisfaction of both the participants and the individuals or institutions served will be assessed on an on-going basis.

(3) Include sound plans for ensuring that the required descriptive and demographic data is collected.

(4) Include the results from previous evaluations.

(5) Commit to cooperating with the Corporation's national evaluation effort.

III. Budget

(1) The Budget Summary Form included here should be completed. On an attached sheet, please provide brief explanations and/or justifications of each budget item.

(2) "Other Expenses" may include other allowable costs (including such things as local training, equipment, transportation, insurance, etc.), related to the operation of the program. Each component of "other expenses" must be explained.

(3) The Corporation is in the process of determining the advisability of requiring health care coverage for participants (see Appendix #3). For purposes of this budget, please reflect a line item for health care equal to $300 per participants, $255 of which is paid for by the Corporation and $45 of which is paid for by the program.

(4) For those programs proposing public safety projects, include in your budget an estimate of $700 for the cost of travel and per diem for the program director and two key supervisory staff to attend a three day training program that will be held in late April in a location to be determined by the Corporation.

(5) The educational award of $1000 for participants who successfully complete the program will be administered directly by the Corporation and should not be included in the budget submitted for this proposal.

Selection Criteria

The following criteria will be used to select applicants for award. Each criteria will be considered up to the percentage of the total proposal as noted.

(1) Quality (65%)

(a) Plan (30%): The program narrative describes a high quality public safety and/or environmental service initiative with:

—Direct demonstrable outcomes;
—Feasible project implementation plans and realistic timetables, which were developed with input from the community to be served;
—A range of service activities appropriate to community needs and participant backgrounds and skills. Discussion of proposed service activities should include description of specific assignments;
—Recruitment and selection plans that will attract a qualified and diverse group of participants, including community residents;
—Evaluation reports, if available, that support the proposed program; and

—Self-assessment techniques to monitor performance against objectives.

(b) Applicant and Partnership (35%): The applicant organization evidences:

—The existence or selection of a well-qualified project director and supervisors for participants;
—Experience in operating public safety or environmental initiatives;
—Track record demonstrating capacity to organize and facilitate partnership of participating agencies and organizations; and
—Ability to conduct fiscal affairs of program.

In addition, for applicants proposing public safety activities, the proposal identifies a broad-based working partnership of agencies and organizations to carry out public safety-related service activities that:

—Includes appropriate public and private agencies and organizations with track records of operating public safety programs and youth and community efforts. If local law enforcement agencies/organizations are not included, proposal must explain why the participation of law enforcement is not necessary;
—Includes residents of the communities in which the program will be based;
—Evidences specific commitment from participating entities to contribute to and cooperate with activities initiated by community partnership;
—Identifies tasks and roles to be carried out by partnership members during project planning phase (prior to summer) and during operating phase; and
—Defines procedures for the effective operation of a practical working partnership.

(2) Cost Effectiveness (15%)

The proposal evidences a cost effective approach to the use of Corporation and other Federal funds and non-Federal resource (cash, in-kind, and human). Specifically:

—The budget is reasonable for the proposed service activities and the identified community needs;
—The match requirement is achieved. Additional match that enhances the cost effectiveness of the proposal is strongly encouraged;
—The extent and type of matching funds and other resources from other public (including Federal agencies and private sources will be considered; and
—Linkages with other federally-funded programs are encouraged.

(3) Sustainability (10%)

The quality and feasibility of plans to sustain especially effective elements of program activity following the completion of the summer program without additional Corporation funding will be considered.

(4) Innovation and Replication (10%)

The proposal incorporates innovative approaches to partnerships, community involvement, and service, and evidences strategies and activities potentially replicable in other locations.

In addition to the above criteria, the Corporation will give special consideration to: (1) Youth corps programs that previously received funding from the Commission on National and Community Service, under the American Conservation and Youth Service Corps program, to operate summer programs; and (2) programs with creatively designed service projects that meet both environmental and public safety needs, e.g., a project that involves the clean-up and creation of a green space in a vacant lot that has attached much criminal activity.

Moreover, the Corporation will ensure that at least 50% of the funds awarded to States for State-operated corps will support projects that will be conducted in areas of need, as detailed in Appendix #4.

Application Review and Selection Process

The Corporation will evaluate the applications using a panel of reviewers consisting of experts in the field of public safety, youth corps, and the environment. Publication of this announcement does not obligate the Corporation to award any specific number of grants or to obligate the entire amount of funds available.

Notification of tentative selection will be made by April 8, 1994. Selections will be considered tentative until execution of a final grant agreement, which may require discussions between Corporation and program staff to resolve remaining financial or programmatic issues and to refine and/or further develop plans or specific strategies.

Appendix 1

The other components of 1994 Summer of Safety which are sponsored by the Corporation for National and Community Service are briefly described below. For further information about any of these Summer of Safety initiatives, please contact the Corporation.

Summer of Safety Grants Program—The Summer of Safety Grants program will provide opportunities for 1000 participants, at least 17 years of age, to serve full-time in community-based collaborative efforts to respond to public safety needs related to crime, violence and fear. Awards will be made in 10 to 20 locations—both urban and rural—to programs run by partnerships that may include law enforcement, other public agencies, nonprofit and community-based organizations, institutions of higher education, Indian Tribes, and the business community.

VISTA Summer Associates—The VISTA Summer of Safety program will support 1,000 full-time VISTA Summer Associates beginning service between June 1 and June 21, and serving from 8–10 weeks on projects which also have full-year VISTA Volunteers assigned. Participants will receive a living allowance, and those who successfully complete the summer term of service are eligible to receive a $1,000 educational award from the National Service Trust.

VISTA Summer Associate activities will address the issues of crime, violence, and fear in low-income communities by working on efforts such as community policing, crime prevention, and victim assistance. Both new and existing VISTA-sponsoring organizations are eligible to apply for VISTA Summer Associates through ACTION State Offices which will provide technical assistance in developing project applications.

Learn and Serve America—Summer of Safety grants of up to $50,000 will be made through the Corporation's Learn & Serve America program to engage 1500 youth between the ages of five and seventeen in innovative public safety-related community service. Eligible applicants are public or private nonprofit organizations that have experience working with school-age youths, and that have been in existence for at least one year. K–12 Summer of Safety programs must be innovative, and may encompass multiple program sites.

National Senior Volunteer Corps—The National Senior Volunteer Corps will fund 20 grants to existing NSVC sponsors involving the full range of public safety activities. An estimated 2,600 Senior Corps members will be recruited. The Corps will include professionally trained and other seniors interested in serving public safety needs. There will be a targeted recruitment campaign to attract highly skilled senior or retired police officers, sheriff's deputies, correctional officers, military police, social workers, teachers, public defenders and community leaders.

Activities may include: providing administrative support to police departments, conducting neighborhood crime surveys, providing crime prevention education to seniors, assisting domestic violence victims navigate the court system, coordinating neighborhood watch programs, and serving as mentors, tutors and counselors to juveniles under court supervision.

Guidance to existing sponsors will be issued in late January with projects becoming operational in June.

National Civilian Community Corps—Approximately 200 Corps members, ages 14–17, will do public safety-related service projects with schools, local law enforcement agencies, and community-based organizations. Corps members will receive leadership training and a mix of the best military and civilian youth service

programming during their eight weeks at the camp on an underutilized military installation. The site for the NCCC Summer of Safety camp will be selected by March, 1994.

Appendix 2

This Appendix provides suggestions for how you might approach the development of a Summer of Safety program. It is meant to be thought-provoking and is not a required process.

I. Identify the Crime/Violence Problem To Be Addressed

By working directly with local law enforcement, canvassing door-to-door in neighborhoods, attending community meetings, setting up meetings for law enforcement with community groups, contacting and surveying local businesses, public agencies, service organizations, youth groups, senior groups, etc., your organization can identify specific crime problems which confront the community and concern residents. The types of issues most readily identified through this kind of analysis include:

—Specific population needs (e.g., seniors who are afraid to go to the market after dark, or children who can't use a playground because of drug activity, debris or disrepair, or teenagers who get in trouble when a facility—theater, club, etc.—closes for the evening, or targets of hate crimes);
—Physical hazards (e.g., drug houses, vacant structures used for drug trade or other illegal or disorderly purpose, abandoned vehicles, missing street lights, broken fences, dangerous vehicle traffic patterns, open-air drug markets);
—Resident safety concerns (e.g., fear of crime and victimization, need for crime prevention information—locks, etc., lack of information about crime within neighborhood); and
—Unreported or undetected criminal activity (e.g., drug use or sales in a neighborhood location, gang activity, prostitution, victims of crime who have not reported the victimization or who continue to be victimized—especially victims of domestic violence or fraudulent solicitors/practices).

II. Pick The Partners

Think broadly about the range of organizations that are already involved in reducing crime and violence in your community, or that may be interested in joining such an effort. Try to determine which ones have missions, resources or experience comparable to yours. City agencies, especially local law enforcement agencies, should be considered. Other possible partners include:

—Schools (including higher education institutions).
—Private non-profit organizations (particularly those that work to prevent crime and violence or that work with youth or victims of crime).
—Community and neighborhood organizations.
—Senior or neighborhood centers.
—Private businesses.

Please read Program Narrative section 2(g) ("Partnership") carefully regarding the delineation of roles and other aspects of creating a useful partnership. Keep in mind that, while effective partnerships will involve many elements in a community, eligibility to receive funds and parameters of allowable activities are limited. (See sections entitled, "Eligibility" and "Limitations".)

III. Craft a Specific Problem Response

After analyzing the community's needs and picking your partners, you will plan and implement a specific program designed to make a direct and demonstrable difference.

It may help to have various activities linked with a common theme. For example, in a victim's assistance program, participants might be engaged in the following activities:

—Supporting victim services within the court, notify victims of court dates and procedures, meet and accompany victims to courtrooms, staff child care centers, follow-up on restitution orders, etc.:
—Accompanying law enforcement on calls to provide immediate crisis intervention support, accompany victims to hospital or police department, make social service referrals (including to battered women's shelters), arrange lock/home repairs, assist with emergency funds, lost documents, public assistance, etc.;
—Maintaining follow-up contact with victims to help identify longer-term needs; and
—Assisting in operation of a victim service program; i.e., work in a family violence shelter providing child care, tutoring, transportation, vocational help; serve with a sexual assault crisis center/hotline or abused children's center.

It is also possible that, within a Summer of Safety program, there may be a number of different service activities which can positively impact the safety of the community. But make sure that the activities you are contemplating are realistic. Will they make a real difference in your communities within the short time frame of the summer? Clearly, not every problem can be solved in one summer, but appropriate responses can be developed that identify the parties responsible for necessary actions, specify and take initial steps, and evidence impact.

While the range of possible effective activities is potentially limitless, below are additional examples of activities that can be started and have appreciable impact in a short time:

—Involving neighborhood youth in a senior escort service;
—Conducting and disseminating crime prevention surveys and information/advice;
—Undertaking community clean-up efforts, focusing on graffiti, vacant lots, alleys, AND other sites where fear of crime and disorder are evident;
—Identifying and boarding-up abandoned properties in which drug use/trade may be occurring;
—Organizing neighborhood watch-type programs;
—Initiating or enhancing relationships between law enforcement and local youth organizations;
—Developing a network of "Safe Houses" or "safe Corridors" in neighborhood, and training parents and children about the program;
—Developing and conducting anti-violence presentations for youth groups;
—Joining with senior volunteers in intergenerational efforts designed around youth safety themes;
—Developing and supervising youth activities that incorporate age-appropriate personal safety/violence prevention training; e.g., illicit drug use, impaired driving, etc.;
—Establishing conflict resolution programs, including outreach, training, and ongoing activities for youth through schools and community-based youth organizations; and
—Leading public safety-related field trips for youth, with appropriate orientation; e.g., to jails/prisons, police stations, courts, hospitals, family violence shelters, etc.

Appendix 3

The Corporation is in the process of determining the advisability of requiring health care policies for Summer of Safety participants. That determination will be discussed with prospective grantees prior to entering into a final grant agreement.

The Act requires that service programs make child care available or provide an allowance for child care for service participants. The Act further requires the Corporation to issue guidelines for child care and the child care allowance.

Below is the guidance contained in the Corporation's proposed regulations, Section 2522.250, published in the **Federal Register** (Volume 59, No. 5) on January 7, 1994. This guidance is subject to change upon issuance of the Corporation's final regulations.

(a) *Child care.* Grantees must provide child care through an eligible provider or a child care allowance in an amount determined by the Corporation to those full-time participants who need child care in order to participate.

(1) *Need.* A participant is considered to need child care in order to participate in the program if he or she:

(i) Is the parent or legal guardian of, or is acting in loco parentis for, a child under 13 who resides with the participant;

(ii) Has a family income that does not exceed 75 percent of the State's median income for a family of the same size;

(iii) At the time of acceptance into the program, is not currently receiving child care assistance from another source, including a parent or guardian, which would continue to be provided while the participant serves in the program; and

(iv) Certifies that he or she needs child care in order to participate in the program.

(2) *Provider eligibility.* Eligible child care providers are those who are eligible child care providers as defined in the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858n(5)).

(3) *Child care allowance.* The amount of the child care allowance will be determined by the Corporation based on payment rates for the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858c(4)(A)).

(4) *Federal share.* The Corporation will pay 100% of the child care allowance, or if the

program provides child care through an eligible provider, the actual cost of the care of the amount or the allowance, whichever is less.

Appendix 4

The Act requires that, in selecting projects for funding under Subtitle C, the Corporation consider whether the project would be conducted in areas of need, which are:

(1) Communities designated by the Federal government or States as empowerment zones or redevelopment areas, targeted for special economic incentives, or otherwise identifiable as having concentrations of low-income people.

(2) Areas that are environmentally distressed.

(3) Areas adversely affected by Federal actions related to the management of Federal lands that result in significant regional job losses and economic dislocation.

(4) Areas adversely affected by reductions in defense spending or the closure or realignment of military installations.

(5) Areas that have an unemployment rate greater than the national average unemployment rate for the most recent 12 months for which satisfactory data are available.

Dated: February 4, 1994.

Catherine Milton,

Vice President and Director of National and Community Service programs

BILLING CODE 6820-BA-M

BUDGET SUMMARY FORM

1. **Participant Stipends**

_____ x _____ x _____ = $ _____
# of participants living allowance per week # of weeks[1]

2. **Total Salaries**

Project Director _____

Project Staff _____ $ _____

3. **Participant Training** $ _____

4. **Other Expenses**[2] _____

_____

_____ $ _____

5. **National Training & Travel** $ _____

TOTAL PROJECT COSTS $ _____

6. **NON-CORPORATION CONTRIBUTIONS:**

Matching Funds _____

In-kind contributions _____

Other Federal Funds _____ Total $ _____

7. **FUNDS REQUESTED FROM THE CORPORATION:** $ _____

1. There must be a minimum of 8 weeks of service including local training.

2. Any other expenses should be included and briefly explained.

[FR Doc. 94–2993 Filed 2–8–94; 8:45 am]
BILLING CODE 6820–BA–C

federal register

Wednesday
February 9, 1994

Part VI

Corporation for National and Community Service

Community Service—Summer of Safety Learn and Serve America Program; Notice

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Community Service—Summer of Safety Learn and Serve America Program

AGENCY: Corporation for National and Community Service.

ACTION: Notice of availability of funds.

SUMMARY: The Corporation for National and Community Service announces the availability of up to $400,000 for grants to support innovative summer service-learning initiatives that address public needs. These funds will provide service opportunities for more than 1,000 youth to serve their communities. Operating grants will be awarded on a competitive basis to qualified public or private nonprofit organizations for the purpose of implementing exceptionally innovative, high-quality community-based service-learning programs.

DATES: The deadline for the submission of proposals is Monday, March 21, 1994.

ADDRESSES: All proposals should be submitted to the Corporation for National and Community Service, 1100 Vermont Avenue, NW., Washington, DC., 20525.

FOR FURTHER INFORMATION CONTACT: Ruby Anderson, senior program officer, at the Corporation for National and Community Service, (202) 606–5000.

SUPPLEMENTARY INFORMATION:

Background

On September 21, 1993 the President signed into law the National and Community Service Trust Act (the Act), which created the Corporation for National and Community Service (the Corporation). The Corporation's mission is to engage Americans of all ages and backgrounds in service that addresses the nation's educational, public safety, health, and environmental needs to achieve direct and demonstrable results. In doing so, the Corporation will foster civic responsibility, strengthen the ties that bind us together as a people, and provide educational opportunity for those who make a substantial commitment to service.

The Corporation is a new federal agency that encompasses the work and staff of two existing independent agencies, the Commission on National and Community Service and ACTION. The Corporation will fund a new national service initiative called AmeriCorps, service-learning initiatives for elementary and secondary schools and institutions of higher education called Learn and Serve America, and the new National Civilian Community Corps. The Corporation will also engage in efforts to improve the quality of service programs and continue to support the Volunteers in Service to America (VISTA) program and the senior volunteer programs previously sponsored by ACTION.

The Act authorizes the Corporation to support summer service programs directly (such as the Summer of Safety) and indirectly, in conjunction with the States. Programs that operate during the summer offer an excellent opportunity to experiment with new approaches to solving community problems and to bring new resources and participants into community service efforts.

Objectives of the Summer of Safety Program

"Summer of Safety," the Corporation's 1994 summer service program, is being launched in response to growing concern and frustration over the levels of crime and violence across the country. The 1994 Summer of Safety program will demonstrate the potential of service as a means of addressing these community problems by tapping the talents and energies of Americans of all ages and backgrounds.

The Learn and Serve America component of Summer of Safety will support community-based initiatives that provide youth with opportunities to learn and develop their own capabilities through service-learning. Service-learning is an educational method which engages young people in service to their communities as a means of enriching their academic learning, promoting personal growth, and helping them to develop the skills needed for productive citizenship. Summer of Safety will promote youth development and address the public safety needs of communities by achieving the following objectives:

—Supporting community-based organizations to create, develop, and offer public safety-related service-learning opportunities for youth between the ages of five and 17 inclusive;
—Building new partnerships and collaborations for safety that capitalize on a broad range of community resources;
—Demonstrating that young people can play a role in making communities safer; and
—Stimulating public interest in national service as a means to respond to America's problems.

Program Overview

The Learn and Serve America Summer of Safety Program is designed to engage young people in meeting the public safety needs of their communities. In doing so, these projects can build positive community relationships, with young people involved; provide hands-on education in crime prevention that will be shared with parents, siblings and other youth; increase crime reporting by youth; help prevent crimes against and by youth; and help young people play a role in making their neighborhoods safer.

The Corporation will fund up to eight exceptionally innovative summer programs that will operate for eight to ten weeks during the summer months. Selected programs will be officially launched on June 21, and should end by August 24. Grants will be made to programs recruiting a minimum of 100 participants between the ages of five and 17 inclusive and will range from approximately $50,000 to $75,000.

Eligible applicants must be public or private nonprofit organizations experienced in working with school-age youth. In addition, a nonprofit must have been in existence for at least one year. Summer of Safety programs should be carried out by community-based organizations, including law enforcement, in partnership with one or more local education agencies or other organizations. Programs must be based on the creative and innovative application of service-learning opportunities that address community public safety needs. In addition, the Corporation encourages programs that encompass multiple sites.

Summer of Safety will support community-based programs that engage youth of different ages, races, genders, ethnic groups, disabilities, or economic backgrounds in a variety of service-learning activities. These service-learning activities must promote personal growth and, at the same time, address the community's public safety needs. Possible program activities could include:

—Training youth in conflict resolution strategies to function as peer mediators to reduce violent conflicts among other youth. Participants would gain self-esteem, develop problem-solving, communication and critical thinking skills, and a better understanding of how to resolve differences effectively without violence.
—Youth researching public safety issues in their community through contacts with local law enforcement officials, residents and crime prevention organizations in order to develop service projects that address specific needs like a neighborhood playground cleanup with a recycling component

and then a public awareness campaign aimed at keeping playgrounds clean, safe and hazard-free.

—Older youth leading younger children in creating posters and brochures that cover first aid, crime prevention, reporting crime, substance abuse prevention or other topics. Development of the materials might involve youths working with representatives of law enforcement, crime prevention and substance abuse prevention organizations, local emergency health care employees, local residents or other youth. Participants might also present their material and ideas to local officials and residents at community meetings.

—Middle school and high school age youth teaching young children about violence prevention, substance abuse prevention, vandalism prevention, self-esteem, and peer pressure. The older youth research issues and design the presentations developing their research, organizational and public speaking skills.

—Young people of all ages designing and coordinating a crime prevention or public safety fair with exhibit booths and workshops. Youth participants can use art and vocational skills and improve their organizational and communication skills through presentations. They will build self-confidence and awareness of the community's resources through soliciting community groups and businesses for their input and support.

—Plays, skits and puppet shows with crime, violence, drug prevention, or self-protection themes that are written and organized by teens and presented to younger children. This project requires participants to utilize writing skills and creativity and increases their knowledge of substantive public safety issues.

—Young people tackling the issue of substance abuse in their community by conducting a survey of their peers, analyzing the responses, and developing strategies for combating the identified problems. This project will incorporate peer counseling and peer involvement leading to improved interpersonal skills.

—Participants creating a peer court system where youth are trained by local justice experts to be the judges, lawyers, jurors, bailiffs, and court clerks. They hear and try cases involving peers, make real judgments and pass actual sentences. Young people would learn how the legal system works and gain excellent analytical and communications skills.

Funding Guidelines

The Corporation expects to make grants ranging from $50,000 to $75,000. There are four basic requirements concerning program funding for Learn and Serve America Summer of Safety grants:

—The Corporation share of the total cost to carry out a funded project may not exceed 90 percent.

—A qualified organization must spend no more than five percent of the grant funds on administrative costs for any fiscal year.

—A qualified organization may spend between 10 and 15 percent of the grant to build capacity through training, technical assistance, curriculum development, and coordination activities.

—Stipends, allowances, or other financial support may not be paid to any program participant except as reimbursement for transportation, meals, and other reasonable out-of-pocket expenses directly related to program participation.

Restrictions Governing the Use of Corporation Assistance

Corporation assistance may not be used:

—To provide religious instruction, conduct worship services or engage in any form of proselytization;

—To assist, promote, or deter union organizing;

—To finance, directly or indirectly, any activity designed to influence the outcome of an election to any public office;

—To impair existing contracts for services or collective bargaining agreements; or

—To make up for any budget cuts in State or local public funds in this or the preceding fiscal year.

Selection Criteria

Applications for Learn and Serve America Summer of Safety programs will be evaluated based on the following criteria which are listed in order of importance with maximum points for each item listed:

(1) Quality (70)

(a) Concept and Design (40)

—The plan meets community needs and involves individuals from diverse backgrounds (including economically disadvantaged youth and disabled individuals) who will serve together and explore the underlying causes of public safety problems.

—The goals and objectives of the plan are appropriate for promoting community-based service-learning.

—The plan provides for productive, meaningful, educational experiences that incorporate service-learning methods.

—The extent to which service projects will be carried out in areas that are economically or environmentally distressed (such as empowerment zones, redevelopment areas, or other areas with high concentrations of low-income people).

—The extent to which the program will recruit participants from among residents of the communities in which service projects would be conducted.

—The extent to which the program will involve participants and community residents in the design, leadership, and operation of the program.

—The extent and quality of the program's partnership, including the ongoing involvement of partners and the applicant's plan for partnership maintenance.

(b) Organizational Capacity (30)

—The plan describes a sound process for training, technical assistance, supervision, quality control, evaluation, administration, and other key activities.

—The principal leaders who will implement the plan are well qualified for their responsibilities.

—The plan describes the experience in operating public safety and/or community service initiatives.

—The plan describes the track record demonstrating capacity to organize and facilitate partnership of participating agencies and organizations.

—The plan describes ability to conduct fiscal affairs of program.

(2) Innovation and Replicability (15)

—The plan is unique and innovative in its approach to applying service-learning strategies to promote public safety.

—The applicant demonstrates the ability to assist others in replicating the program concept.

—The plan advances knowledge about how to do effective and innovative community service-learning aimed at addressing public safety needs.

(3) Sustainability (15)

—The plan fosters collaborative efforts among community-based organizations, local educational agencies, and local government agencies, and/or businesses.

—The plan has strong, broad-based partnerships and has community support.

—The program shows evidence of a cost-effective approach in using Corporation and other Federal funds and non-Federal resources (cash or in-kind).

—There is evidence that financial resources will be available to continue the Learn and Serve America effort after the expiration of the grant.

Proposal Guidelines

The application consists of, among other things, the submission of a proposal that describes how the qualified organization will promote, manage, and evaluate a community-based service-learning project which addresses public safety needs.

The application must contain the following components in this order:

(1) Title page
(2) Abstract
(3) Program narrative
(4) Institutional and personnel information
(5) Budget information
(6) Assurances signature form
(7(Certification signature form
(8) Appendices

The following information describes requirements for each component listed above.

I. Title Page

Please complete the attached form.

II. Abstract

Attach a one-page, double-spaced summary following the title page. It should describe the proposal's.

—goals and objectives;
—proposed activities; and
—expected outcomes.

III. Program Narrative

This portion of the proposal, not to exceed 20 typed, double-spaced pages, should cover a period of eight to ten weeks. The program narrative must include the following items (the questions under each section are not prescriptive but illustrative).

(A) Needs

—What specific unmet public safety need(s) will the applicant seek to address through service-learning strategies?
—What process will be, or has been, used to determine the need(s)?
—Who will be, or has been, involved in making the determination?
—How will youth participants be involved?

(B) Demographics

—How will the applicant ensure broad-based community involvement in identifying service-learning projects and diverse participant mix (different ages, grade levels, races, genders, ethnic groups, disabilities, or economic backgrounds)?
—How will community input be encouraged?
—What will be the geographic breakdown (rural, suburban, urban, etc.)?
—What will be the socio-economic and ethnic breakdown of the participants?

(C) Goals and Objectives

Describe the goals and objectives of the proposal.

—What are the desired, time-phased, and demonstrable outcomes?
—How will the program be innovative?
—How many youth will be involved in the program?
—How will service-learning be integrated into community-based program curricula?
—Who are potential local partners?
—What is your expected participant impact? For example, what knowledge, skills, and attitudes will participants achieve as a result of service-learning?
—What is the expected community impact? For example, how many local organizations will benefit, how many people will be served, how many hours of service will be provided, and what improvements will result from student service-learning?
—How will your goals and objectives build on the existing service-learning activities in the local community? For example, what current service-learning programs exist, and what will be their relationship to the program?

(D) Design and Activities

(1) Participant Recruitment

—How will the applicant recruit the minimum of 100 program participants between the ages of five and 17 inclusive?
—Will the program focus on a particular age group?
—What will be the criteria for participant selection?
—How will the applicant ensure diversity among participants?

(2) Training and Building Capacity for Service-Learning

—What training will be provided?
—Who will provide the training?
—Who will receive the training, (e.g. teachers, staff, participants organizations and agencies, community members, and other adults)?
—What technical assistance will be provided to other communities who would like to implement successfully-tested local models?
—What partnerships will be developed?
—What outreach to other community-based organizations, local education agencies, or local government agencies will be conducted?

(3) Types of Service Activities Offered

—How will you ensure age-appropriate public safety-related service-learning activities?
—Who will determine what service activities are offered?
—How will participants be oriented or prepared for their service-learning experiences?
—What opportunities will be provided to participants to reflect on their service-learning experiences?
—How will professionals in the service-learning field be involved?
—Who will be responsible for coordinating this effort?
—How will student input be obtained?
—How will service opportunities for economically and educationally disadvantaged youth and individuals with disabilities be assured?

(4) Coordination

—What are the roles and responsibilities of program partners?
—If the program involves multiple sites, how will they be coordinated? What will be the common elements?
—How will information be disseminated and outreach efforts be conducted to ensure the involvement of a wide range of organizations?
—Will service-learning activities be coordinated with federally and non-federally assisted education and training programs?
—How will the plan promote public awareness of service-learning and recognize exemplary service?

(E) Quality Control and Evaluation

—How will the applicant conduct program management?
—How will the achievement of goals and objectives and timely implementation be monitored?
—How will the qualified organization provide on-going self-evaluation (e.g. data collection, measuring outcomes, and assessing the process to make improvement as needed)?
—At the end of the summer, what difference will the program have made?

(F) Sustainability of the Program

—How will the applicant replicate or sustain its efforts after the Corporation funding is completed?
—Will potential funding sources be identified?
—Is there a commitment to support service-learning activities after Summer of Safety funding expires?
—Will the program be linked to other State, Federal or local initiatives?

(G) Institutional and Personnel Information

This portion addresses the applicant's, its staff's, and its partners'

capability to manage a local service-learning program. The applicant should describe its:

—Experience in administering service-learning programming;
—Capacity to operate service-learning programs, including information on experience of key staff members or plans to recruit for that expertise;
—Capacity to evaluate service-learning programming, including information on the staff person responsible for this component or plans to recruit for that expertise.

(H) Budget Information

Complete the budget form provided on page xx. Applicants may request between $50,000 and $75,000. Also provide a budget narrative that explains both federal and non-federal resources which include:

—The basis used to estimate the total cost for each line item; and
—How each line item relates to the proposed program.

The budget should be sufficient to perform the task described in the proposal narrative. It should not contain unexplained amounts for miscellaneous or contingency costs or unallowable line items such as stipends.

(I) Assurances Signature Form

Programs that are funded will be required to sign a form certifying that they will agree to perform all actions and support all intentions stated in the assurances.

(J) Certification Signature Form

Because grants from the Corporation are federal grants, potential grantees will be required to execute federal certifications, including drug-free workplace, buy America, prohibition on lobbying activities, and debarment, suspension and other responsibility matters.

(K) Appendices

This portion of the proposal is limited to five pages. Items could include:

—Partnership information;
—Letters of support with details on cooperation;
—Brochures, pamphlets, and publicity items.

Video and cassette tapes should not be submitted.

Term of Grants

Programs should consider June 21 as the official date to launch their efforts, and programs should end by August 24.

Review Process

The Corporation will review these applications in a multi-stage assessment process, including a peer review and staff review and approval. Additionally, the Corporation may conduct discussions and/or site visits with some or all applicants. Applicants should be prepared to participate if requested.

Submission Procedure

Applicants must mail or hand-deliver an unbound original and seven unbound copies of the complete application to the address listed at the beginning of this notice.

Appendix: Definitions

Administrative costs. Administrative costs are costs associated with the overall administration of a Corporation program. Such costs include the following: (1) Indirect costs (e.g., costs identified with two or more cost objectives but not identified with a particular cost objective) as described in applicable provisions of Office of Management and Budget Circulars that relate to indirect costs; (2) costs for financial, accounting, or contracting functions; (3) costs for insurance that protects the entity that operates the program; and (4) costs for salaries and benefits of the director and any other administrative staff of the program. Administrative costs do not include allowable costs directly related to program operations, such as the following: (1) Costs for living allowances and training of participants; (2) costs for staff training; (3) costs for travel; (4) costs related to the evaluation of the program; (5) costs for salaries and benefits of staff who recruit, train, place, or supervise participants. Particular costs such as those associated with staff who perform both administrative and program functions may be prorated between administrative costs and costs directly related to program operations.

Community-based agency. A community-based agency is a private nonprofit organization (including a church or religious entity) that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public safety community needs.

Grantmaking entity. A grantmaking entity for school-based programs is a public or private nonprofit organization experienced in service-learning that submits an application to make grants for school-based service-learning programs and was in existence at least one year before the date on which the organization submitted the application.

Local Educational Agency (LEA). Local Educational Agency has the same meaning given such term in section 1471(12) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 2891(12)).

Partnership. A partnership is an organization comprised of two or more entities that entered into a written agreement specifying the responsibilities of each partner with respect to a service-learning program.

Qualified organization. A qualified organization is a public or private nonprofit organization, other than a grantmaking entity, that has experience in working with school-age youth, and that was in existence at least one year before the date on which the organization submitted an application for a service-learning program.

School-age youth. School-age youth are individuals between the ages of 5 and 17, inclusive; and children with disabilities as defined in section 602(a)(1)) of the Individuals with Disabilities Education Act (20 U.S.C. 1401(a)(1)), who receive services under part B of such Act.

Service-learning. Service-learning is a method whereby participants or participants learn and develop through active participation in thoughtfully-organized service that is conducted in and meets the needs of a community; is coordinated with an elementary school, secondary school, institution of higher education, or community service program, and with the community; helps foster civic responsibility; is integrated into and enhances the academic curriculum of the participants, or the educational components of the community service program in which the participants are enrolled; and provides structured time for the participants or participants to reflect on the service experience.

Dated: February 4, 1994.

Catherine Milton,

Vice President and Director of National and Community Service Programs.

BILLING CODE 6820–BA–M

Title Page
Learn and Serve America – Summer of Safety

1. **Proposal Title:** _____

2. **Legal Applicant:** _____

   Contact Person's Name: _____

   Address: _____

   _____

   City, State, Zip: _____

   Phone/Fax: _____

3. **Employer ID Number:** _____

   IRS Tax Number: _____

4. **Project Director:** _____

   Organization's Name: _____

   Address: _____

   _____

   City, State, Zip: _____

   Phone/Fax: _____

5. **Budget:**

   Corporation Funds Requested: _____

   Total Budget Amount: _____

6. **Duration of Project:**

   Start Date: _____

   End Date: _____

7. **Anticipated Number of Participants:** _____

8. **Certification:**

   The applicant certifies to the best of his/her knowledge and belief that the data in this application are true and correct and that the filing of the application has been duly authorized by the governing body of the applicant and that the applicant will comply with the assurances required of applicants if the assistance is approved.

Name: _____ Signature: _____

Title: _____ Phone: _____ Date: _____

Learn and Serve America – Summer of Safety – Budget Form

Please attach the Budget Narrative to this page.
Instructions for this form are on the following page.

		Corporation Funds Requested from the Corporation	+	Match Other Federal/ State/Local/ Private Funds	=	Total Total Program Funding
A.	Community-Based Service-Learning	_____		_____		_____
B.	Planning and Capacity Building (e.g. training/technical assistance/ evaluation; not less than 10% and not more than 15% of Corporation funds.)	_____		_____		_____
C	Administration (not to exceed 5% of Corporation funds)	_____		_____		_____
D	Other (please specify in Budget Narrative)	_____				
TOTAL		_____ (not to exceed 90% of total program cost)	+	_____	=	_____

Reader Aids

Federal Register

Vol. 59, No. 27

Wednesday, February 9, 1994

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	202–523–5227
Public inspection desk	523–5215
Corrections to published documents	523–5237
Document drafting information	523–3187
Machine readable documents	523–3447

Code of Federal Regulations

Index, finding aids & general information	523–5227
Printing schedules	523–3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523–6641
Additional information	523–5230

Presidential Documents

Executive orders and proclamations	523–5230
Public Papers of the Presidents	523–5230
Weekly Compilation of Presidential Documents	523–5230

The United States Government Manual

General information	523–5230

Other Services

Data base and machine readable specifications	523–3447
Guide to Record Retention Requirements	523–3187
Legal staff	523–4534
Privacy Act Compilation	523–3187
Public Laws Update Service (PLUS)	523–6641
TDD for the hearing impaired	523–5229

ELECTRONIC BULLETIN BOARD

Free **Electronic Bulletin Board** service for Public Law numbers, and Federal Register finding aids.	202–275–1538, or 275–0920

FEDERAL REGISTER PAGES AND DATES, FEBRUARY

4547–4778 1
4779–5070 2
5071–5312 3
5313–5514 4
5515–5696 7
5697–5928 8
5929–6212 9

CFR PARTS AFFECTED DURING FEBRUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
12896 5515
12897 5517

Proclamations:
6648 5591
6649 5593

Administrative Orders:

Presidential Determinations:
94–14 of February 1, 1994 5931

Memorandums:
January 8, 1994 5071
January 29, 1994 5929

5 CFR

293 5223
351 5223
430 5223
432 5223
451 5223
511 5223
530 5223
531 5223
536 5223
540 5223
575 5223
591 5223
595 5223
733 5313
771 5223
2635 4779

7 CFR

58 5933
271 5697
272 5697
273 5697
911 5073
915 5073

Proposed Rules:
1007 5132
1093 5132
1094 5132
1096 5132
1099 5132
1108 5132
1945 5737

8 CFR

Proposed Rules:
103 5740
214 5533
74a 5533

10 CFR

1 5519
21 5519
30 5519
32 5519
50 5519
55 5934

Proposed Rules:
19 5132
20 ..... 4868, 5132
474 5336

12 CFR

231 4780
567 4785
1627 5939

Proposed Rules:
25 5138
228 5138
230 5536
261a 5548
345 5138
563e 5138
630 5341

13 CFR

122 5940

Proposed Rules:
107 5552

14 CFR

39 ..... 4789, 5074, 5078
71 ..... 5080, 5520, 5521
95 5080
97 ..... 5522, 5523

Proposed Rules:
Ch. I 5554
33 5356
39 ..... 4869, 4870, 4873, 4875, 5139, 5359, 5361, 5554, 5964, 5965, 5966, 5968
71 ..... 4978, 5556, 5740
121 5741
129 5741
135 5741

16 CFR

305 5699

17 CFR

1 ..... 5082, 5525, 5700
3 5315
4 5082
5 5315
7 5316
9 5701
10 ..... 5700, 5701
11 5701
19 5702
21 5702
30 5702
31 5703
32 5703
33 5526
100 5526
140 5527
143 5527
145 5527

148....5528
150....5528
155....5528
156....5703
166....5529
180....5529
190....5704
200....5942
202....5942
203....5942
230....5942
239....5942
240....5942
249....5942
249b....5942
259....5942
269....5942
274....5942
275....5942
279....5942

18 CFR

157....5946

Proposed Rules:

11....5142
381....5142

19 CFR

12....5082
102....5082
134....5082
206....5087
207....5087

Proposed Rules:

4....5362

20 CFR

621....5484
655....5484, 5486

21 CFR

5....5316, 5317
172....53170
177....5947
178....5704
331....5060
343....5068
520....5705
524....5104, 5705

Proposed Rules:

73....5363
74....5363
164....5153
168....5363
172....5363
173....5363
182....5363
184....5363
351....5226
356....6084

22 CFR

503....5706

24 CFR

87....5320
905....5321
970....5321

Proposed Rules:

232....5157
247....5155
880....5155
881....5155
883....5155

26 CFR

1....4791, 4799, 4831
602....4799, 4831

Proposed Rules:

1....4876, 4878, 5370
52....5161

28 CFR

511....5924
551....5514
600....5321
603....5321

Proposed Rules:

551....5926

29 CFR

504....5484, 5486
1601....5708
1910....6126
1915....6126
1917....6126
1918....6126
1926....6126
1928....6126

30 CFR

913....4832
915....5709

31 CFR

348....5723
500....5696
550....5105

32 CFR

228....5948

33 CFR

100....5322, 5950
110....5951
117....5953
161....117, 5323
165....5324, 5950, 5951, 5954

Proposed Rules:

117....5970

34 CFR

Proposed Rules:

Ch. VI....5560

36 CFR

Proposed Rules:

223....4879

38 CFR

3....5106

Proposed Rules:

3....5161

39 CFR

233....5326

40 CFR

52....5327, 5330, 5332, 5724, 5955
60....5107, 5955
81....5332
180....4834
185....5108
186....4834, 5108
261....5725
300....5109
712....5956
716....5956
763....5236

Proposed Rules:

50....5164
52....5370, 5371, 5374, 5742
55....5745
61....5674
63....4879, 5868
81....5374
156....5971
180....5972
430....4879

41 CFR

101–38....5962

Proposed Rules:

201–1....4978
201–3....4978
201–20....4978
201–39....4978

42 CFR

Proposed Rules:

433....4880

44 CFR

64....5726
65....5727, 5728, 5730
67....5731, 5732

Proposed Rules:

67....5747, 5748

45 CFR

233....4835

46 CFR

15....4839

Proposed Rules:

514....4885, 5974
580....5974
581....4885, 5974

47 CFR

Proposed Rules:

2....5166
68....5166

48 CFR

225....5335
252....5335
525....5484
552....5484
970....5529

Proposed Rules:

15....5750
31....5750
42....5750
46....5750
52....5750
516....5561
552....5561
912....5751
952....5751
970....5751
1819....5974
1852....5974

49 CFR

350....5262
1002....4843
1207....5110
1249....5110
1312....4843

Proposed Rules:

192....5168
391....5376

50 CFR

17....4845, 5306, 5494, 5499, 5820
228....5111
642....5963
651....5128
672....5736

Proposed Rules:

17....4887, 4888, 5311, 5377
625....5384
644....5978
646....5562
651....5563
661....4895
676....5979
685....4898

LIST OF PUBLIC LAWS

Note: The list of Public Laws for the first session of the 103d Congress has been completed and will resume when bills are enacted into law during the second session of the 103d Congress, which convenes on January 25, 1994.

A cumulative list of Public Laws for the first session of the 103d Congress was published in Part IV of the **Federal Register** on January 3, 1994.

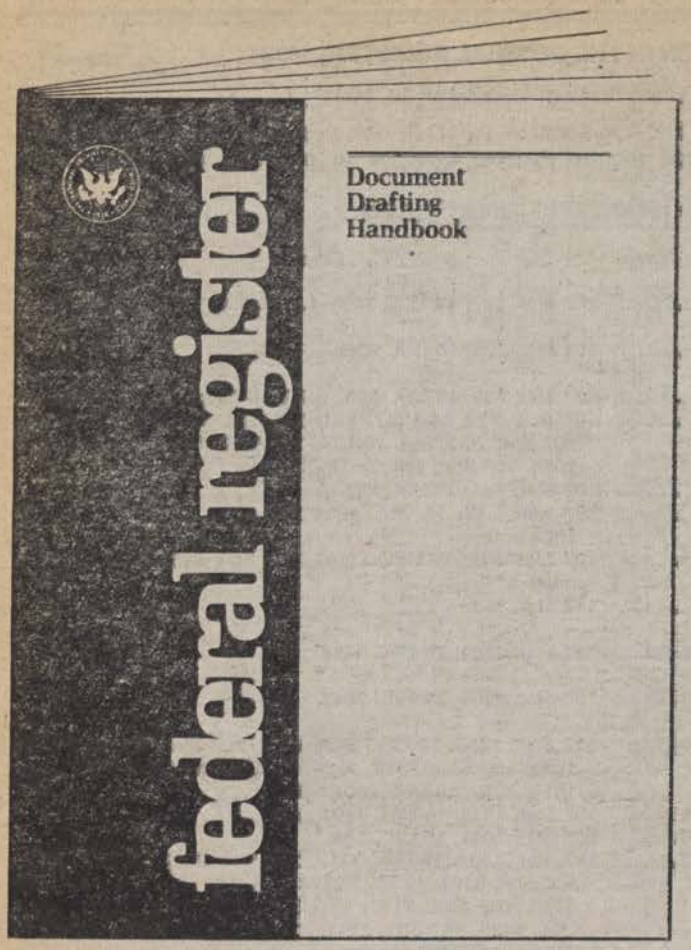
LIST OF ACTS REQUIRING PUBLICATION IN THE FEDERAL REGISTER, 1993

Additions to Table II, January 15, 1993, through December 20, 1993

This table lists the subject matter, public law number, and citations to the U.S. Statutes at Large and U.S. Code for those acts of the first session of the 103d Congress that require Federal agencies to publish documents in the **Federal Register**.

Table II appears in the CFR Index and Finding Aids volume revised as of January 1, 1994.

Description of Act	*Public Law*	*Citation*
National Institutes of Health Revitalization Act of 1993	103–43	107 Stat. 127; 42 USC 289a–1. 107 Stat. 135; 42 USC 289a–2.
Forest Resources Conservation and Shortage Relief Amendments Act of 1993.	103–45	107 Stat. 225; 16 USC 620c.
Big Thicket National Preserve Addition Act of 1993	103–46	107 Stat. 229; 16 USC 698. 107 Stat. 230; 16 USC 698 note.
Omnibus Budget Reconciliation Act of 1993	103–66	107 Stat. 339; 12 USC 1721. 107 Stat. 344; 20 USC 1087c. 107 Stat. 352, 353; 20 USC 1087g. 107 Stat. 355; 20 USC 1078. 107 Stat. 364; 20 USC 1077a.
Rehabilitation Act Amendments of 1993	103–73	107 Stat. 725; 29 USC 753.
Depository Institutions Disaster Relief Act of 1993	103–76	107 Stat. 752; 12 USC 4008 note. 107 Stat. 754; 12 USC 1828 note.
National and Community Service Trust Act of 1993	103–82	107 Stat. 819; 42 USC 12602. 107 Stat. 895; 42 USC 12651 note.
Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1994.	103–87	107 Stat. 953.
Catawba Indian Tribe of South Carolina Land Claims Settlement Act of 1993.	103–116	107 Stat. 1124; 25 USC 941e.
Treasury, Postal Service, and General Government Appropriations Act, 1994.	103–123	107 Stat. 1269; 39 USC 3642.
National Defense Authorization Act for Fiscal Year 1994	103–160	107 Stat. 1715; 10 USC 2430 note. 107 Stat. 1747; 33 USC 1902. 107 Stat. 1818, 1819; 10 USC 2501 note. 107 Stat. 1917, 1919; 10 USC 2687 note.
Lechuguilla Cave Protection Act of 1993	103–169	107 Stat. 1983; 16 USC 4301 note.
Patent and Trademark Office Authorization Act of 1993	103–179	107 Stat. 2041; 35 USC 156.
North American Free Trade Agreement Implementation Act	103–182	107 Stat. 2064; 19 USC 3313. 107 Stat. 2102; 19 USC 3353. 107 Stat. 2104; 19 USC 2112 note. 107 Stat. 2105; 19 USC 3358. 107 Stat. 2115; 17 USC 104A. 107 Stat. 2138; 19 USC 3435. 107 Stat. 2141, 2144; 19 USC 1516a. 107 Stat. 2148; 19 USC 3431 note.
Copyright Royalty Tribunal Reform Act of 1993	103–198	107 Stat. 2305, 2306; 17 USC 802. 107 Stat. 2309; 17 USC 118.
Resolution Trust Corporation Completion Act	103–204	107 Stat. 2412; 12 USC 1441a.
Coast Guard Authorization Act of 1993	103–206	107 Stat. 2425; 46 USC 3703 note.



Federal Register Document Drafting Handbook

A Handbook for Regulation Drafters

This handbook is designed to help Federal agencies prepare documents for publication in the Federal Register. The updated requirements in the handbook reflect recent changes in regulatory development procedures, document format, and printing technology.

Price $5.50

Superintendent of Documents Publication Order Form

Order processing code: *6133

Charge your order. It's easy! MasterCard VISA

To fax your orders and inquiries—(202) 512-2250

☐ **YES,** please send me the following indicated publications:

_____ copies of **DOCUMENT DRAFTING HANDBOOK at $5.50 each.** S/N 069–000–00037–1

1. The total cost of my order is $_____ Foreign orders please add an additional 25%.
All prices include regular domestic postage and handling and are subject to change.

Please Type or Print

2. _____
(Company or personal name)

_____
(Additional address/attention line)

_____
(Street address)

_____
(City, State, ZIP Code)

(_____) _____
(Daytime phone including area code)

3. Please choose method of payment:

☐ Check payable to the Superintendent of Documents

☐ GPO Deposit Account ☐☐☐☐☐☐☐–☐

☐ VISA or MasterCard Account

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

_____
(Credit card expiration date)

Thank you for your order!

_____
(Signature)

(Rev 12/91)

4. **Mail To:** New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954

Printed on recycled paper